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SOP: Definitions

1 PURPOSE

1.1 This policy establishes the definitions followed by the human research protection program. This is a non-exhaustive list and regulatory agencies should be referenced for complete definitions where applicable.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Summary of Changes:

2.1.1 Added the definition of Artificial Intelligence, including a corresponding endnote referencing 15 USC 9401(3).

2.1.2 Expanded the definition of Non-Committee Review to include detemination re: engagement.

2.1.3 Added the definition of Staff Reviewer (to differentiate Staff Reviewers from Designated Reviewers), including the types of determinations that Staff Reviewers are permitted to make.

2.2 Reason for Change: HRP Toolkit version 5.4 released December 2025.

2.3 Prior Version: 09/01/2025

3 POLICY

3.1 Adverse Event (AE): For Veterans Administration (VA) human subjects research any untoward physical or psychological occurrence in a human subject participating in research, whether or not considered related to the subject's participation in research.

3.1.1 Adverse events are untoward diagnostic or therapeutic incidents, iatrogenic injuries, or other occurrences of harm or potential harm directly associated with care or services delivered by VA providers.

3.2 Allegation of Non-Compliance: An unproved assertion of Non-Compliance.

Artificial Intelligence: A machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments.[i]

3.3 Assurance of Compliance (Human Subjects) or Federalwide Assurance: An assurance is a written commitment to protect human research subjects and comply with the requirements of the Common Rule.

3.4 Authorization Agreement: Also called a Reliance Agreement, is the agreement that documents respective authorities, roles, responsibilities, and communication between an institution/organization providing the ethical review and a participating institution relying on the ethical review.

3.5 Certificate of Confidentiality: A Certificate of Confidentiality is a document issued by a component of HHS pursuant to The Public Health Service Act Section 301(d), 42 U.S.C. 241(d) amended by Section 2012 of the 21st Century Cures Act, Public Law 114-255, to protect the privacy of individuals who are subjects of certain specified research activities by authorizing investigators to withhold from all persons not connected with the conduct of such research the names or other identifying characteristics of such subjects. Persons so authorized to protect the privacy of such individuals may not disclose information in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.

3.6 Certification: The official notification by the institution to the supporting Federal department or agency component that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

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3.7 Children: persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

3.7.1 See HRP-013 - SOP - LARs, Children, and Guardians for applicable law at this institution.

3.8 Clinical Investigation: Any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the FDA under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, or is not subject to requirements for prior submission to the FDA under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.

3.9 Clinical Trial: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

3.10 Coded Information/Data: For the purposes of this policy, identifying information that would enable the Investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof and a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

3.11 Collaborating Individual Investigator: The Office for Human Research Protections notes that some human subjects research conducted by an assured institution may involve the following two types of collaborating individual investigators:

3.11.1 Collaborating independent investigator: not otherwise an employee or agent of the assured institution; conducting collaborative research activities outside the facilities of the assured institution; and not acting as an employee of any institution with respect to his or her involvement in the research being conducted by the assured institution.

3.11.2 Collaborating institutional investigator: not otherwise an employee or agent of the assured institution; conducting collaborative research activities outside the facilities of the assured institution; acting as an employee or agent of a non-assured institution with respect to his or her involvement in the research being conducted by the assured institution; and employed by, or acting as an agent of, a non-assured institution that does not routinely conduct human subjects research.

3.12 Collaborative Study: A study in which two or more institutions coordinate, with each institution completing a portion of the research activities outlined in a specific protocol.

3.12.1 For Veterans Administration (VA) research, Collaborative (Study) Research involves human subjects research activities involving investigators from VA and at least one non-VA institution. Collaborative Research includes VA and non-VA institutions.

3.13 Conflicting Interest: An individual involved in research review is automatically considered to have a conflicting interest when the individual or the individual's spouse, domestic partner, children, and/or dependents have any of the following interests in the sponsor, product or service being tested, or competitor of the sponsor held by the individual or the individual's immediate family:

3.13.1 Involvement in the design, conduct, or reporting of the research.

3.13.2 Ownership interest, stock options, or other ownership interest of any value exclusive of interests in publicly-traded, diversified mutual funds.

3.13.3 Compensation of any amount in the past year or of any amount expected in the next year, excluding compensation for costs directly related to conducting research.

3.13.4 Proprietary interest including, but not limited to, a patent, trademark, copyright or licensing agreement.

3.13.5 Board or executive relationship, regardless of compensation.

3.13.6 Reimbursed or sponsored travel by an entity other than a federal, state, or local government agency, higher education institution or affiliated research institute, academic teaching hospital, or medical center.

3.13.7 Any other reason for which the individual believes that he or she cannot be independent.

3.14 Continuing Non-Compliance: A pattern of Non-Compliance that indicates an inability or unwillingness to comply with applicable laws, regulations, or institutional policies pertaining to the protection of human subjects and / or with the requirements or determinations of an IRB.

3.14.1 For Veterans Administration (VA) research Continuing Non-Compliance means repeated instances of same or similar noncompliance with applicable laws, regulations, policies, agreements, or determinations of a research review committee or the prolonged persistence of noncompliance occurring after its identification, awareness, or implementation of a corrective action intended to effectively resolve the noncompliance.

3.15 Continuing Review**:** Periodic review of research activities necessary to determine whether the risk/benefit ratio has changed, whether there are unanticipated findings involving risks to participants or others, whether any new information regarding the risks and benefits should be provided to participants, and to ensure that the protocol remains in compliance with all federal regulations, state laws and UC/UCI policies and procedures.

3.16 Cooperative Research: Cooperative research projects are non-exempt/clinical investigations that involve more than one institution. See Collaborative Study and Multi-Site Study.

3.17 De-Identified Health Information: Health information that has been stripped of all 18 identifiers as defined by HIPAA (*See* Appendix A), so that the information could not be traced back to an individual. De-identified data also pertains to health information that has been assigned and retains a code or other means of identification provided that:

3.17.1 The code is not derived from or related to the information about the individual;

3.17.2 The code could not be translated to identify the individual; and

3.17.3 The covered entity (as described above) does not use or disclose the code for other purposes or disclose the mechanism for re-identification.

3.18 Designated Reviewer: The IRB chair, an Experienced IRB Member as designated by the IRB chair to conduct Non-Committee Reviews.

3.19 Deviation: Accidental or unintentional change to the research protocol that does not increase risk or decrease benefit or have a significant effect on the participant's rights, safety or welfare, or on the integrity of the data. Deviations may result from the action of the participant, researcher, or staff. *This definition may not match the Principal Investigator's or Sponsor's definition.* Examples: a rescheduled study visit, an omitted routine safety lab for a participant with previously normal values; or failure to collect an ancillary self-report questionnaire data (e.g., quality of life).

3.20 Experienced IRB Member: An IRB member is considered experienced if the IRB chair considers the IRB member to have sufficient experience in and knowledge of conducting IRB reviews.

3.21 Experimental Subject: For Department of Defense (DOD) research, research involving an "experimental subject" is an activity, for research purposes, where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction. Research involving "experimental subjects" is a subset of research involving human participants.

3.22 Expiration Date: The first date that the protocol is no longer approved. The date after the end date of the approval period.

3.23 Finding of Non-Compliance: Non-Compliance in fact.

3.24 Guardian: an individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care.

3.24.1 See HRP-013 - SOP - LARs, Children, and Guardians for applicable law at this institution.

3.25 HIPAA Authorization: A customized document, usually as a part of the informed consent document, that gives UCI permission to use specified protected health information (PHI) for a specific purpose, or to disclose PHI to a third party specified by the individual other than for treatment, payment or healthcare operations.

Human Research: Any activity that either:[ii]

3.25.1 Is Research as Defined by DHHS and involves Human Subjects as Defined by DHHS; or

3.25.2 Is Research as Defined by FDA and involves Human Subjects as Defined by FDA.

3.26 Human Subject as Defined by DHHS: A living individual about whom an investigator (whether professional or student) conducting research (1) obtains information or biospecimens through Intervention or Interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. For the purpose of this definition:

3.26.1 Intervention: Physical procedures by which information or biospecimens are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

3.26.2 Interaction: Communication or interpersonal contact between investigator and subject.

3.26.3 Private Information: Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record).

Identifiable Private Information[iii]: Private Information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

3.26.4 Identifiable Biospecimen[ii]: A biospecimen for which the identity of the subject is or may be readily ascertained by the investigator or associated with the biospecimen.

3.27 Human Subject as Defined by FDA: An individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whose specimen a medical device is used.

3.28 Immediate Family: Spouse, domestic partner; and dependent children.

3.29 Individual Investigator Agreement: a permissible mechanism under which an institution holding an Office for Human Research Protections (OHRP)-approved Federalwide Assurance (FWA) may extend – for one or more research protocols – the applicability of its FWA to cover two types of collaborating individual investigators: collaborating independent investigators and collaborating institutional investigators employed by a non-assured institution.

3.30 Institutional Review Board (IRB): A specifically constituted review body established or designated by an entity to protect the rights and welfare of human subjects recruited to participate in biomedical or social science/behavioral research.

3.31 Institutional Official/ Organizational Official (IO/OO):

Institutional Official (IO): Term utilized by DHHS. The Institutional Official (IO) is the individual who is legally authorized to act for the institution and, on behalf of the institution, obligates the institution to the Terms of the Assurance. The IO is responsible for ensuring that the Human Research Protection Program (HRPP) functions effectively and that the institution provides the resources and support necessary to comply with all requirements applicable to research involving human subjects. The IO represents the institution named in the Federalwide Assurance (FWA)[iv]. The IO is the Vice Chancellor for Research.

3.31.1 For Veteran's Administration (VA) research, the Institutional Official (IO) is the individual legally authorized as Signatory Official to commit an institution to an FWA. The Signatory Official assures that human subjects research to which the FWA applies is conducted in accordance with the terms of the assurance (see VHA Handbook 1058). The Principal Deputy Under Secretary for Health or designee is the IO for VHA Central Office, and VA facility Directors are the IOs for local VA facilities.

3.32 Institutional Profile: A record of information an institution keeps about another collaborating institution/organization for one or more Collaborative Studies or Multi-Site Studies.

3.33 Investigation: A searching inquiry for facts; detailed or careful examination.

3.34 Legally Authorized Representative (LAR): An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedures(s) involved in the research.

3.34.1 If there is no applicable law addressing this issue, then this individual is recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

3.34.2 See HRP-013 - SOP - LARs, Children, and Guardians for who may serve as a Legally Authorized Representative at this institution.

3.35 Limited Data Set: Protected health information that excludes direct identifiers of the individual or of relatives, employers, or household members of the individual, with the exception of city, state, ZIP Code, elements of dates, and other numbers, characteristics, or codes not listed as direct identifiers.

Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.[v]

3.35.1 For research involving prisoners Minimal Risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

3.35.2 When following Department of Defense regulations, the definition of minimal risk in 32 CFR 219 does not include the inherent occupational risks that certain participants face in their everyday life, such as those:

3.35.2.1 Encountered by Service members, law enforcement, or first responders while on duty.

3.35.2.2 Resulting from or associated with high-risk behaviors or pursuits.

3.35.2.3 Experienced by individuals whose medical conditions involve frequent tests or constant pain.

3.36 Multi-Site Study: A study in which two or more institutions coordinate, with each institution completing all research activities outlined in a specific protocol.

3.37 Non-Committee Review: Any of the following:

3.37.1 Determination of whether an activity is Human Research.

3.37.2 Determination of engagement in Human Research.

3.37.3 Determination of whether Human Research is exempt from regulation.

3.37.4 Reviews of non-exempt research using the expedited procedure.

3.37.5 Determinations of which subjects can continue in expired research.

3.37.6 Concurrence of IRB Chair or designee for non-emergency individual patient/small group expanded access for an unapproved medical device (commonly known as Compassionate Use) or non-emergency individual patient expanded access IND with request for authorization to use alternative IRB review procedures.

3.38 Non-Compliance: Failure to comply with applicable laws, regulations, or institutional policies pertaining to the protection of human subjects, and/or with the requirements or determinations of an IRB.

3.38.1 In the case of research funded or conducted by the Department of Defense (DOD), Non-Compliance includes failure of a person, group, or institution to act in accordance with Department of Defense (DOD) instruction 3216.02, its references, or applicable requirements

3.38.2 In the case of Veterans Administration (VA) research, Non-Compliance is any failure to adhere to the requirements for overseeing, reviewing, approving, or conducting VA research set forth in law, regulation, policy, or study agreements (such as reliance agreements, memoranda of understanding, data use agreements), including any failure to conduct research in accordance with a VA study protocol approved by a research review committee.

3.39 Nonviable: An expelled or delivered fetus which, although it is living, cannot possibly survive to the point of sustaining life independently, even with the support of available medical therapy [45 CFR 46.203 (d) and (e)]. Although it may be presumed that an expelled or delivered fetus is nonviable at a

gestational age less than 20 weeks and weight less than 500 grams [Federal Register 40 (August 8, 1975): 33552], a specific determination as to viability must be made by a physician in each instance.

3.40 Participating Site (pSite): An institution that participates in a Single IRB (sIRB) Study.

3.41 Prisoner: Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

3.41.1 For Department of Defense (DOD) research the term includes military personnel in either civilian or military custody.

3.42 Protected Health Information (PHI): Individually identifiable health information that is or has been collected or maintained by the covered entity in the course of providing healthcare that can be linked back to the individual participant.

3.43 Protocol Exception: a one-time, intentional action or process that departs from the approved protocol. Protocol Exceptions are generally for a single subject (e.g., the subject does not meet eligibility criteria or is allergic to one of the medications provided as supportive care). IRB approval of the Protocol Exception is required prior to implementation by the study team.

3.44 Related to the Research: A financial interest is Related to the Research when the interest is in:

3.44.1 Related financial interests occur when the Researcher, their spouse/registered domestic partner and/or dependent children have a disclosable financial interest that would reasonably appear to be affected by the research or when the entity in which the financial interests are held would reasonably appear to be affected by the research.

3.44.2 The following are examples (which are not all inclusive) of related financial interests:

3.44.2.1 The project results could be relevant to the development, manufacturing, or improvement of products or services of the entity in which the Researcher has a financial interest.

3.44.2.2 The Researcher has a financial interest in an entity that might license (for commercial purposes) an invention, technology, drug, device, procedure or any other product used in the project or that will predictably result from the project.

3.44.2.3 The Researcher received compensation from activities in his/her professional field during the prior twelve months, where the financial interest of the entity or the investigator would reasonably appear to be affected by the project.

3.44.2.4 The Researcher has a financial interest in an entity, and the project proposes to subcontract a portion of the work, or lease property, or refer participants to, or make purchases from the entity.

3.44.2.5 The Researcher has a financial interest in an entity that will participate in the project, including as part of a consortium.

3.45 Research as Defined by DHHS: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

3.45.1 The following activities are not considered Research as Defined by DHHS:

3.45.1.1 Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

3.45.1.2 Public health surveillance activities conducted by a public health authority, limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance.

3.45.1.2.1 Including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.

3.45.1.2.2 Including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products.

3.45.1.2.3 Including those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

3.45.1.3 Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

3.45.1.4 Authorized operational activities (as determined by the relevant federal agency) in support of intelligence, homeland security, defense, or other national security missions.

3.45.1.5 Secondary research involving non-identifiable newborn screening blood spots.

3.46 Research as Defined by FDA: Any experiment that involves a test article and one or more Human Subjects, and that meets any one of the following:

3.46.1 Must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act meaning any use of a drug other than the use of an approved drug in the course of medical practice;

3.46.2 Must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act meaning any activity that evaluates the safety or effectiveness of a device; OR

3.46.3 Any activity the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.

3.47 Restricted: Applies to investigators who are delinquent in meeting IRB requirements.

3.48 Research (Scientific) Misconduct: Fabrication, falsification, plagiarism or other practices that seriously deviate from those that are commonly accepted within the academic community for proposing, performing, or reviewing research, or reporting research results. Misconduct does not include honest error or honest differences in interpretations or judgments of data

3.49 Right to Try: In May 2018, the Federal Right to Try (RTT) Act was signed into law, creating a federal framework for patients to access investigational new drugs and biologics outside of clinical trials and outside of the U.S. Food and Drug Administration's (FDA) expanded access program. The federal law enables manufacturers and physicians to provide investigational drugs to eligible patients without risk of liability. It follows California's passage of the State's Right to Try Act, signed into law in 2016. Similar to the federal law, the California law enables manufacturers and physicians to provide investigational products to eligible patients without risk of liability under state law.

3.50 Serious Adverse Event (SAE): An untoward occurrence, whether or not considered related to a subject's participation in Human Research, that results in death, a life-threatening experience, inpatient hospitalization, prolongation of hospitalization, persistent or significant disability or incapacity, congenital anomaly or birth defect, or that requires medical, surgical, behavioral, social or other intervention to prevent such an outcome.

3.51 Serious Non-Compliance: Non-Compliance such that the failure to comply could adversely affect the rights, safety, or welfare of a human subject; place a human subject at increased risk of harm; cause harm to a human subject; affect a human subject's willingness to participate in research; or damage or compromise the scientific integrity of research data.

3.51.1 For Department of Defense (DOD) research Serious Non-Compliance includes failure of a person, group, or institution to act in accordance with Department of Defense (DOD) Instruction 3216.02 and its references such that the failure could adversely affect the rights, safety, or welfare of a human subject; place a human subject at increased risk of harm; cause harm to a human subject; affect a human subject's willingness to participate in research; or damage or compromise the scientific integrity of research data.

3.51.2 For Veterans Administration (VA) research Serious Non-Compliance is any failure to adhere to requirements for conducting Human Research that may reasonably be regarded as:

3.51.2.1 Presenting a genuine risk of substantive harm, to the safety, rights, or welfare of human research subjects, or others, including their rights to privacy and confidentiality of identifiable private information;

3.51.2.2 Presenting a genuine risk of substantive harm to the safety, rights, or welfare of research personnel who conduct research;

3.51.2.3 Presenting a genuine risk of substantive reputational harm to the Veterans Administration (VA); or

3.51.2.4 Substantively compromising a VA medical facility's human research protection programs (HRPP).

3.52 Single IRB (sIRB) Study: A study in which two or more institutions (participating sites, or pSites) coordinate to complete the research activities, but all institutions rely on a single institution's/organization's IRB for ethical review. The reviewing IRB may or may not be affiliated with any of the pSites.

3.53 Staff Reviewer: IRB staff that are not identified as a Designated Reviewer on the IRB Roster but, in the opinion of the IRB manager, can conduct Non-Committee Reviews limited only to the following:

3.53.1 Determination of whether an activity is Human Research.

3.53.2 Determination of whether the organization is engaged in Human Research.

3.53.3 Determination of whether Human Research is exempt from regulation, when limited IRB review is not required.

3.54 Suspension of IRB Approval: An action of the IRB, IRB designee, Institutional Official/Organizational Official, or designee of the Institutional Official/Organizational Official to temporarily or permanently withdraw IRB approval of some or all research procedures short of a Termination of IRB Approval. Suspended studies remain open and are subject to continuing review.

3.55 Systematic: Having or involving a system, method, or plan.

3.56 Termination of IRB Approval: An action of the IRB, IRB designee, Institutional Official/Organizational Official, or designee of the Institutional Official/Organizational Official to permanently withdraw IRB approval of all research procedures. Terminated studies are permanently closed and no longer require continuing review.

3.57 UCI Facilities: Facilities owned, operated, or leased by UCI including UCI campus, UCIMC, and any space rented to the University.

3.58 UCI Personnel: UCI students, staff, and faculty (including part-time, emeritus, and volunteer faculty), or any other agents of UCI.

3.59 UCI Resources: Funds, facilities, employee time, equipment, supplies, services, and non-public information.

3.60 Unanticipated: An event is "unanticipated" when it was unforeseeable at the time of its occurrence. Unanticipated and unexpected are not synonymous. A research protocol can monitor for an unexpected event but cannot monitor for an unforeseen event. All unanticipated events are unexpected, but not vice versa.

Unanticipated Problem Involving Risks to Participants or Others: Any event, experience, or problem that is: (1) unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the IRB-approved documents, such as the protocol and informed consent document, and (b) the characteristics of the subject population being studied; (2) related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or problem may have been caused by the procedures involved in the research); and (3) suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.[vi]

3.60.1 For Department of Defense (DOD) research the term Unanticipated Problem Involving Risks to Subjects or Others includes any incident, experience, or outcome that meets ALL three of the following conditions:

3.60.1.1 Is unexpected (in terms of nature, severity, or frequency) given the procedures described in the research protocol documents (e.g., the IRB-approved research

protocol and informed consent document) and the characteristics of the human subject population being studied.

3.60.1.2 Is related or possibly related to participation in the research (in this Instruction, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research).

3.60.1.3 Suggests that the research places human subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized, even if no harm has actually occurred.

3.60.2 For Veterans Administration (VA) research:

3.60.2.1 Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO) is an incident, experience or outcome that is: unexpected; related or possibly related to participation in the research; and indicative of the research placing subjects or others at substantively greater risk of harm (including physical, psychological, economic or social harm) than was previously known or recognized.

3.60.2.2 The term "unexpected" refers to an incident, experience, or outcome that is new or greater than previously known in terms of nature, severity, or frequency, given the procedures described in protocol-related documents and the characteristics of the study population.

3.60.2.3 The phrase "related to participation in the research" means a logical sequence of cause and effect shows that the study procedures were the reason for the incident, experience, or outcome. The phrase "possibly related to participation in the research" implies a lesser degree of certainty about causality and refers to an incident, experience, or outcome for which there is some evidence to reasonably suggest a causal relationship between study procedures and the incident, experience, or outcome.

3.60.2.4 An unexpected SAE that is related or possibly related to participation in human subjects research constitutes a UPIRTSO.

4 RESPONSIBILITIES

4.1 Individuals writing policies and procedures are to indicate terms defined in this policy with a double underline.

4.2 Individuals using policies and procedures are to consult this policy for the definitions of double underlined terms.

5 PROCEDURE

5.1 None

6 MATERIALS

6.1 HRP-013 - SOP - LARs, Children, and Guardians

7 REFERENCES

7.1 UCI Administrative Policies and Procedures Section 481-3: Conflicts of Interest in Human Subjects Research

7.2 45 CFR §46.102

7.3 21 CFR §50.3, 21 CFR §56.102, 21 CFR §312.3, 21 CFR §812.2(a), 21 CFR §812.3(p)

7.4 VHA Directive 1058 dated November 8, 2024; VHA Directive 1004.08 dated October 31, 2018; VHA Directive 1200.05(3) dated January 7, 2019, amended July 13, 2023

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[i] 15 U.S.C. 9401(3)

[ii] The terms "Human Subject Research," "Research Involving Human Subjects," "Clinical Research," "Clinical Investigation," "Clinical Study" and similar phrases are considered to be synonyms for the term Human Research.

[iii] Definitions of “identifiable private information” and “identifiable biospecimen” are included in FDA’s proposed rule to amend part 50, Protection of Human Subjects, and part 56, Institutional Review Boards (87 FR 58733, September 28, 2022). In that rule, the proposed definitions of “identifiable private information” and “identifiable biospecimen” harmonize with the revised Common Rule’s definitions of these terms (45 CFR 46.102(e)(5) and (6)).

[iv] https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2008-september-18-letter-attachment/index.html

[v] The phrase “ordinarily encountered in daily life or during the performance of routine physical or physiological examinations or tests” should not be interpreted to include the inherent risks certain categories of subjects face in their everyday life. For example, the risks imposed in research involving human subjects focused on a special population should not be evaluated against the inherent risks encountered in their environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).

[vi] See OHRP guidance “Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events: OHRP Guidance (2007)” at https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html

SOP: Observation of Consent Process

1 PURPOSE

1.1 This procedure establishes the process to observe the consent process.

1.2 The process begins when the IRB determines that the consent process should be observed.

1.3 The process ends when the consent observation is complete.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Summary of Changes: Updated SOP to add additional details regarding the observation process and ensure observation findings are reported back to the IRB.

2.2 Reason for Change: HRP Toolkit version 5.4 released December 2025.

2.3 Prior Version: 09/01/2025.

3 POLICY

3.1 The IRB may consider requiring observation of the consent process when:

3.1.1 The IRB wants verification from sources other than the investigator that consent processes adhere to the current version of the IRB-approved study protocol and applicable regulatory requirements.

3.1.2 There are Allegations or Findings of Non-Compliance.

3.1.3 The nature of the research or reportable new information indicates that the consent process can be improved through observation.

3.2 The IRB, Institutional Official/ Organizational Official (IO/OO), or designee determines who conducts the observation. The individual conducting the observation should have sufficient experience to appropriately evaluate the consent process. This may include, but is not limited to:

3.2.1 IRB staff.

3.2.2 IRB members.

3.2.3 A person recommended by the investigator.

3.2.4 An independent person hired by the IRB but paid for by the investigator's funds.

4 RESPONSIBILITIES

4.1 The person designated to conduct the observation of the consent process carries out these procedures.

5 PROCEDURE

5.1 Notify the subject or the subject's Legally Authorized Representative (LAR) of the intent to observe the consent process, including the purpose of the observation, and obtain their agreement to observe the process.

5.1.1 If the subject objects to the observation, document that the observation could not take place and work with the study team to re-schedule the observation.

5.2 Observe the consent process and determine whether consent was obtained in a manner consistent with:

5.2.1 Section 1 ("Consent Process") of HRP-314a - WORKSHEET - Criteria for Consent; and

5.2.2 The current version of the IRB-approved study protocol.

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5.2.3 If these requirements are not met, indicate that consent is not legally effective and the prospective subject may not be entered into the research.

5.3 If these requirements are met, when applicable, verify consent was documented in a manner consistent with Section 2 (“Long Form of Consent Documentation”), of HRP-314a - WORKSHEET - Criteria for Consent and the current version of the IRB-approved study protocol.

5.3.1 Document in writing that the consent process was observed, including whether informed consent was freely given by the subject or LAR and the requirements identified above were met. Report this information back to the IRB, submitting the information as Reportable New Information (RNI), when necessary.

6 MATERIALS

6.1 HRP-314a - WORKSHEET - Criteria for Consent

7 REFERENCES

7.1 45 CFR §46.109
21 CFR §56.109

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SOP: LARs, Children, and Guardians

1. PURPOSE

1.1. This policy establishes how to determine which individuals meet the following DHHS and FDA definitions:

1.1.1. Legally Authorized Representative (LAR)

1.1.2. Children

1.1.3. Guardian

2. REVISIONS FROM PREVIOUS VERSION

2.1. None

3. POLICY

3.1. Unless the IRB has waived the requirement to obtain consent, when research involves adults unable to consent, permission must be obtained from a LAR.

3.1.1. When research is conducted in California the following individuals meet this definition:

3.1.1.1. A “legally authorized representative” means "an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research."

3.1.1.2. In California, individuals under the age of 18 years old are considered minors. Because in California some people under 18 years of age can consent for themselves to some research procedures, not all “minors” meet the federal criteria for being “children.”

3.1.1.3. California Health & Safety Code § 24178 identifies the individuals who are legally authorized in California to provide surrogate consent for research.

3.1.1.4. For purposes of obtaining informed consent required for medical experiments i*n a non-emergency room environment,* if a person is unable to consent and does not express dissent or resistance to participation, surrogate informed consent may be obtained from a SDM with reasonable knowledge of the subject, who shall include any of the following persons, in the following descending order of priority:

3.1.1.4.1. The agent named in the potential research participant’s advance health care directive. The conservator or guardian of the potential research participant, with authority to make healthcare decisions for the potential participant.

3.1.1.4.2. The spouse of the potential research participant.

3.1.1.4.3. The registered domestic partner of the potential research participant as defined in Section 297 of the Family Code.

3.1.1.4.4. An adult child of the potential research participant.

3.1.1.4.5. A custodial parent of the potential research participant.

3.1.1.4.6. An adult sibling of the potential research participant.

3.1.1.4.7. An adult grandchild of the potential research participant.

3.1.1.4.8. An available adult relative with the closest degree of kinship to the potential research participant, whose relationship to the potential participant does not fall within one of the above listed categories (e.g., aunt; uncle; cousin; etc.).

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3.1.1.4.9. The investigator is responsible for making a reasonable effort to determine if that individual is available to serve as surrogate. Potential surrogates must be advised that if a higher-ranking surrogate is identified at any time, the investigator will defer to the higher-ranking surrogate's decision regarding the subject's participation in the research. When there are two or more available persons who may provide surrogate consent and who are in the same order of priority (e.g., an adult son and daughter of the potential participant), if any of those persons in the same order of priority expresses dissent as to the participation of the person in the medical experiment, consent shall not be considered as having been given.

3.1.1.5. For purposes of obtaining informed consent required for medical experiments *in an emergency room environment,* if a person is unable to consent and does not express dissent or resistance to participation, surrogate informed consent may be obtained from a SDM who is any of the following persons:

3.1.1.5.1. The agent named in the potential research participant's advance health care directive.

3.1.1.5.2. The conservator or guardian of the potential research participant, with authority to make health care decisions for the potential participant.

3.1.1.5.3. The spouse of the potential research participant.

3.1.1.5.4. The registered domestic partner of the potential research participant as defined in Section 297 of the Family Code.

3.1.1.5.5. The adult child of the potential research participant.

3.1.1.5.6. A custodial parent of the potential research participant.

3.1.1.5.7. An adult sibling of the potential research participant.

3.1.1.5.8. In emergency room research settings, no surrogate consent may be utilized if there is a disagreement whether to consent among any available surrogates.

3.1.1.5.9. SDMs described in this section shall exercise substituted judgment, and base decisions about participation in accordance with the person's individual health care instructions, if any, and other wishes, to the extent known to the SDM. Otherwise, the SDMs shall make the decision in accordance with the person's best interests. In determining the person's best interests, the SDM shall consider the person's personal values and his or her best estimation of what the person would have chosen if he or she were capable of making a decision per Cal. Health & Safety Code § 24178(g).

3.1.1.5.10. A surrogate decision-maker is prohibited from receiving financial compensation for providing consent per Cal. Health & Safety Code § 24178(i).

3.1.1.5.11. Section 3.1.1.4. and 3.1.1.5. above do not apply to any of the following persons, except as otherwise provided by law:

3.1.1.5.11.1. Persons who lack the capacity to give informed consent and who are involuntarily committed pursuant the California Welfare and Institutions Code § 5000 *et seq*; or

3.1.1.5.11.2. Persons who lack the capacity to give informed consent and who have been voluntarily admitted or have been admitted upon the request of a conservator pursuant to Chapter 1 (commencing with Section 6000) of Part 1 of Division 6 of the California Welfare and Institutions Code.

3.1.1.6. Required Documentation. In all cases involving adult patients who are incompetent or lacks decision-making capacity for healthcare decisions and consent of a Surrogate Decision-Maker is utilized, the Principal Investigator, shall document in the medical record:

3.1.1.6.1. The basis for their determination that the individual lacks decision-making capacity;

3.1.1.6.2. The investigator must detail a decision-making capacity assessment which the IRB reviews and approves.

3.1.1.6.3. If the determination that the prospective participant lacks decision making capacity is based on a diagnosis of mental illness, the researcher obtains consultation with a psychiatrist or licensed psychologist.

3.1.1.6.4. The identity of the SDM and the rationale for the selection of the individual as SDM, which shall be documented on the Investigator Certification of Surrogate Decision Makers for Potential Subject's Participation in University of California Research form. A copy of the form should be provided to the SDM. In addition, the researcher must keep the original, signed form in the research records with the signed informed consent document.

3.2. For research outside California, a determination of who is a LAR is to be made with consultation from legal counsel.

3.3. DHHS and FDA's Subpart D applies to all research involving children.

3.3.1. When research is conducted in California all individuals under the age of 18 years are children. Exceptions exist for minors as follows.

3.3.2. Minors may consent for themselves to medical care related to the prevention or treatment of pregnancy, but not necessarily to sterilization or abortion [California Family Code Section 6925; Health and Safety Code Section 123450 for abortion]. [1]

3.3.2.1. Minors 12 years of age or older have the legal right to consent on their own behalf, for:

3.3.2.1.1. Mental health treatment or counseling on an outpatient basis or residential shelter services (in limited circumstances) [California Family Code Section 6924].

3.3.2.1.2. Medical care related to the diagnosis or treatment of infectious, contagious, or communicable diseases that are required to be reported to the local health officer or a related sexually transmitted disease [California Family Code Section 6926].

3.3.2.1.3. Medical care related to the diagnosis or treatment of the condition and collection of medical evidence about alleged rape or sexual assault [California Family Code Section 6927].

3.3.2.1.4. Medical care and counseling related to the diagnosis and treatment of an alcohol or drug-related problem [California Family Code Section 6929].

3.3.2.2. Self-sufficient minors who are:

3.3.2.2.1. 15 years of age or older;

3.3.2.2.2. living separately from their parents/guardians; and

[1] American Academy of Pediatrics v. Lungren (1997) 16 Cal.4th 307. **A minor may consent to an abortion without parental consent and without court permission.** California Health and Safety Code remains unchanged.

3.3.2.2.3. managing their own financial affairs have the legal right to consent on their own behalf to medical or dental care [California Family Code 6922].

3.3.2.3. Emancipated minors, those who are:

3.3.2.3.1. married or divorced

3.3.2.3.2. on active duty in the U.S. armed forces *or* emancipated by the court; and

3.3.2.3.3. have the legal right to consent on their own behalf to medical, dental, or mental health treatment. They also have extensive other rights to enter into legal and business arrangements, and so can consent to be included in other research (e.g., interviews, surveys) [California Family Code 7000-7143].

3.3.2.4. Capacity to consent depends upon:

3.3.2.4.1. The age, ability, experience, education, training, and degree of maturity and judgment of the minor. A minor between the ages of fourteen (14) and eighteen (18) may have such capacity, but a minor under the age of fourteen (14) would rarely have such capacity;

3.3.2.4.2. The conduct and demeanor at the time consent is to be given;

3.3.2.4.3. The totality of the circumstances;

3.3.2.4.4. The nature of the proposed research procedures and their risks, probable consequences, benefits, and alternatives to the treatment; and

3.3.2.4.5. The minor's ability to appreciate the nature, risks, consequences, benefits, and alternatives of the proposed research procedures.

3.3.3. Contact legal counsel for more information.

3.3.4. For research outside California, a determination of who is a child is to be made with consultation from legal counsel.

3.4. Unless the IRB has waived the requirement to obtain consent, when research involves children consent may only be obtained from biologic or adoptive parents, guardian, an individual legally authorized to consent on behalf of the child to general medical care[i]. Before obtaining permission from an individual who is not a parent, contact legal counsel.

4. RESPONSIBILITIES

4.1. Investigators are to follow this policy when obtaining permission for adults unable to consent or children to take part in research.

5. PROCEDURE

5.1. None

6. MATERIALS

6.1. None

7. REFERENCES

7.1. 45 CFR §46.102, 45 CFR §46.402

7.2. 21 CFR §50.3

[i] DHHS and FDA definition of “guardian.”

SOP: Incoming Items

1 PURPOSE

1.1 This procedure establishes the process to triage information submitted to the IRB.

1.2 The process begins when any communication is received by the IRB.

1.3 The process ends when an IRB staff member determines the appropriate action for the received information.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Summary of Changes:

2.1.1 Added missing system text in the Procedures section to assign the submissions to IRB staff prior to the Designated Review for submissions involving emergency use of a test article and requests to continue subjects in expired research, consistent with ZOT IRB.

2.1.2 Added HRP-024 - SOP - New Information in Materials section, consistent with the content in the Procedure section.

2.2 Reason for Change: HRP Toolkit version 5.4 released December 2025.

2.3 Prior Version: 11/24/2025.

3 POLICY

3.1 Assign items to IRB staff for pre-review within 1 business day.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 If the item is a request either for this IRB to review for another Participating Site (pSite) or for this institution to rely on an external IRB, follow HRP-021 - SOP - Pre-Review.

5.2 If the item is a request for an approval or determination[i] by this institution's IRB that does not include other pSites, follow HRP-021 - SOP - Pre-Review.

5.3 If the item is an update to a study for which an external IRB is the IRB of record, follow HRP-805 - SOP - External IRB Updates.

5.3.1 If there are financial disclosures, follow HRP-055 - SOP - Financial Conflicts of Interests.

5.4 If the item is a notification of an emergency use of a test article in a life-threatening situation assign to IRB staff and then have a Designated Reviewer follow HRP-023 - SOP - Emergency Use, Compassionate Use, Indiv Patient Expanded Access.

5.5 If the item is an investigator's request to continue subjects in expired research assign to IRB staff and then have a Designated Reviewer follow HRP-063 - SOP - Expiration of IRB Approval.

5.6 If the item does not fit into the above categories:

5.6.1 If the item is a question, concern, or complaint involving research or human subjects:

5.6.1.1 Document the following:

5.6.1.1.1 Nature of the question, concern, or complaint and date of incident,

5.6.1.1.2 Contact information of the person contacting the IRB and whether the person's name can be disclosed,

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5.6.1.1.3 IRB study number, PI name, and name of research personnel with whom the person had contact.

5.6.1.2 Respond to any questions or concerns. When appropriate, tell the person that you will call/email him/her once you have been able to find additional information. If necessary, consult with your supervisor.

5.6.1.3 Create and submit a “Report New Information” with the information gathered. Once submitted, assign to the Administrator of the appropriate team.

5.6.2 Follow HRP-024 - SOP - New Information.

5.7 Self-determination of either non-human subject research or exemption will remain in Pre-Submission status. They are not to be submitted for IRB review.

5.8 Assign items to IRB staff for pre-review no later than 2 business days.

6 MATERIALS

6.1 HRP-021 - SOP - Pre-Review

6.2 HRP-023 - SOP - Emergency Use, Compassionate Use, Indiv Patient Expanded Access

6.3 HRP-024 - SOP - New Information

6.4 HRP-055 - SOP - Financial Conflicts of Interests

6.5 HRP-063 - SOP - Expiration of IRB Approval

6.6 HRP-805 - SOP - External IRB Updates

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[i] A “request for an approval or determination” includes approval of new research, response to modifications required to secure approval, continuing review of research, modification to previously approved research, request for study closure, or a determination whether an activity is exempt Human Research or is not Human Research.

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SOP: Pre-Review

1 PURPOSE

1.1 This procedure establishes the process to pre-review a request for approval (approval of new research, approval to rely on an external IRB, humanitarian use device (HUD), continuing review of research, or modification to previously approved research) or a determination whether an activity is exempt Human Research, self-exempt Human Research or is not Human Research.

1.2 The process begins when the IRB receives a request for local IRB approval, including requests from other institutions when this institution is the IRB of record, e.g., for a Collaborative Study or Multi-Site Study, or a request to rely on an external IRB.

1.3 The process ends when the information has been placed on the agenda for an IRB meeting or will be handled by Non-Committee Review, or the information is sent to the Reliance Coordinator or IRB staff to review the request to rely on an external IRB.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Summary of Changes:

2.1.1 Modified the Procedures under 5.1 regarding the review of modifications to secure approval to be consistent with the ZOT IRB "Review Required Modifications" action/activity.

2.1.2 Revised the Procedures section, under 5.1, to clarify that submissions should be sent for convened board review, when the investigator refuses to make the modifications required to secure approval.

2.1.3 Updated the name of HRP-801 - SOP - Establishing Reliance Agreements in the Procedures section, consistent with revisions to HRP-801. Added HRP-801 to the Materials section.

2.1.4 Added steps to the Procedure section at 5.4 re: the review of submissions involving a Collaborating Independent Investigator or Collaborating Institutional Investigator, with instructions to follow HRP-311 and HRP-801 to determine engagement and, if engaged, to determine whether to establish an Individual Investigator Agreement.

2.2 Reason for Change: HRP Toolkit version 5.4 released December 2025.

2.3 Prior Version: 09/01/2025.

3 POLICY

3.1 The addition of a participating site to a previously approved protocol for which the IRB will serve as the IRB of record for that participating site is considered a modification to previously approved research.

3.2 Single subject protocol exceptions are reviewed as modifications to previously approved research.[i]

3.3 A new HUD protocol submission must be reviewed at a convened IRB meeting. Continuing review of a HUD can be handled by Non-Committee Review.

3.4 Pre-Review is conducted by IRB staff within 5 business days.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

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5.1 If the submission is a response to modifications required to secure approval received within 30 days of the IRB review date:

5.1.1 Evaluate whether the investigator made the required modifications.

5.1.2 Execute the “Review Required Modifications” activity and indicate whether the modifications were completed as required.

5.1.2.1 If the investigator made the required modifications, follow HRP-052 - SOP - Post-Review.

5.1.2.2 If the investigator did not make the required modifications add additional direction in “Notes”, if needed, and indicate that the required modifications were not completed. The submission will be returned to the investigator.

5.1.3 If the investigator refuses to make the changes required for approval, schedule the submission for convened IRB review.

5.2 If the request is for this institution to rely on an external IRB:

5.2.1 Refer to HRP-806 - SOP - Review Request to Rely on External IRB

5.3 If the request includes review of a pSite submission:

5.3.1 Determine if the pSite is engaged in the non-exempt human subjects research using HRP-311- WORKSHEET - Engagement Determination.

5.3.1.1 If the pSite is not engaged in the non-exempt human subjects research, execute the “Submit Invitation Decision” activity to notify the lead investigator using HRP-850 - LETTER - Decline to Serve that this IRB will not serve as the IRB of Record for the pSite.

5.3.2 If the pSite is engaged, click on the Institutional Profile area in the IRB system and:

5.3.2.1 Confirm that the pSite has an active profile. If not, see 5.3.2.2.1.

5.3.2.2 Determine whether an existing Authorization Agreement covers the study activities for the pSite.

5.3.2.2.1 If not, follow HRP-801 - SOP - Establishing Reliance Agreements to collect the information needed to confirm reliance and create a new or updated Institutional Profile in the IRB system.

5.3.3 Execute the “Submit Invitation Decision” activity to notify the pSite using HRP-851 - LETTER - Invitation Decision or HRP-850 - LETTER - Decline to Serve that this IRB will or will not serve as the IRB of Record for their participation in the study.

5.3.4 If the IRB will serve as the sIRB for the pSite, after all site materials are submitted, proceed to Section 5.5.

5.4 If the request includes review of a Collaborating Independent Investigator or Collaborating Institutional Investigator:

5.4.1 Determine if the Collaborating Independent Investigator or Collaborating Institutional Investigator is engaged in the non-exempt human subjects research using HRP-311 - WORKSHEET - Engagement Determination.

5.4.1.1 If the Collaborating Independent Investigator or Collaborating Institutional Investigator is not engaged in the non-exempt human subjects research, notify the PI that the activities of the Collaborating Independent Investigator or Collaborating Institutional Investigator do not engage them in human subjects research.

5.4.2 If the Collaborating Independent Investigator or Collaborating Institutional Investigator is engaged in the non-exempt human subjects research, follow HRP-801 - SOP - Establishing Reliance Agreements to consider whether to establish an Individual Investigator Agreement.

5.5 For all other submissions, complete Pre-Review Activity or review the previously completed Pre-Review Activity and revise as needed, considering the items on HRP-308 - WORKSHEET - Pre-Review and note all remaining contingencies in the “Notes” section.

5.6 If the information is not complete, contact the investigator by selecting the “Request Pre-Review Clarifications” Activity. Offer the investigator the opportunity to provide additional information.

5.6.1 Continue processing once the investigator responds to the request for additional information.

5.7 If the request is for an initial approval and principal investigator is Restricted, contact the investigator. Explain that the investigator is Restricted, give the reasons, and indicate that if a new protocol goes to the IRB, the IRB policy is to disapprove the research. Offer the investigator the opportunity to withdraw the submission pending removal of the Restricted status.

5.7.1 If the investigator withdraws the submission, stop processing the current submission.

5.7.2 If the investigator will not withdraw the submission, discuss whether you may continue to process the submission with the IRB Manager.

5.8 Evaluate the most likely level of review using HRP-310 - WORKSHEET - Human Research Determination, HRP-311 - WORKSHEET - Engagement Determination, HRP-312 - WORKSHEET - Exemption Determination, HRP-313 - WORKSHEET - Expedited Review, and/or HRP-323 - PI WORKSHEET - Criteria for Approval HUD as references:

5.8.1 If the request can be handled as a Non-Committee Review and the principal investigator is not Restricted, Follow HRP-031 - SOP - Non-Committee Review Preparation.

5.8.2 If the request cannot be handled as a Non-Committee Review, place the protocol on the agenda for a convened IRB meeting in an IRB with appropriate scope using the “Assign Meeting” activity. Follow HRP-040 - SOP - IRB Meeting Preparation. (Do not assign a Veterans Administration (VA) protocol to a commercial IRB unless it has been specifically designated by the VA Office of Research and Development to serve as an IRB for cooperative research.[ii]) If the request is a non-emergency individual patient expanded access use of an investigational drug for which an IRB waiver is requested or device compassionate use, follow HRP-031 - SOP - Non-Committee Review Preparation and HRP-023 - SOP - Emergency Use, Compassionate Use, Indiv Patient Expanded Access.

6 MATERIALS

6.1 HRP-023 - SOP - Emergency Use, Compassionate Use, Indiv Patient Expanded Access
6.2 HRP-024 - SOP - New Information
6.3 HRP-031 - SOP - Non-Committee Review Preparation
6.4 HRP-040 - SOP - IRB Meeting Preparation
6.5 HRP-052 - SOP - Post-Review
6.6 HRP-308 - WORKSHEET - Pre-Review
6.7 HRP-310 - WORKSHEET - Human Research Determination
6.8 HRP-311 - WORKSHEET - Engagement Determination
6.9 HRP-312 - WORKSHEET - Exemption Determination
6.10 HRP-313 - WORKSHEET - Expedited Review
6.11 HRP-323 - PI WORKSHEET - Criteria for Approval HUD
6.12 HRP-801 - SOP - Establishing Reliance Agreements
6.13 HRP-806 - SOP - Review Request to Rely on External IRB
6.14 HRP-850 - LETTER - Decline to Serve
6.15 HRP-851 - LETTER - Invitation Decision

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[i] Per OHRP correspondence dated 07/22/2011, protocol exceptions are considered changes to previously approved research and eligible for review via expedited procedure.

[ii] Refer to the VA application process for the use of a commercial IRB approved by ORD: https://www.research.va.gov/programs/epros/irb_relationships.cfm

SOP: All Emergency Use, Compassionate Use (Device Only) and IRB Waiver for Individual Patient Expanded Access (Drug Only) Review

1 PURPOSE

1.1 This procedure establishes the process to review notifications of:

1.1.1 Emergency use of a drug, biologic, or device in a life-threatening situation.

1.1.2 Non-emergency individual patient/small group expanded access for an unapproved medical device (commonly known as Compassionate Use).

1.1.3 Non-emergency individual patient expanded access use of an investigational drug for which an IRB waiver is requested.

1.1.4 The use of an investigational drug, agent, or biologic as part of the Right to Try (RTT) Act.

1.2 The process begins when the Designated Reviewer receives a notification of a proposed or actual use.

1.3 The process ends when a Designated Reviewer (Physician Scientist) has:

1.3.1 Determined whether the proposed or actual use will follow or has followed FDA-regulation and guidance; and

1.3.2 Notified the physician and IRB staff of the determination.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Summary of Changes:

2.1.1 Revised "IRB" to "Designated Reviewer" in 1.2 to clarify when the process starts (consistent with the content of HRP-020 - SOP - Incoming Items).

2.1.2 Updated 5.1.1.1 to clarify that 5d reporting is not required when sufficient information is provided in advance to the IRB, consistent with FDA correspondence, and added an endnote to reference the correspondence.

2.1.3 Updated the ZOT IRB language to select IRB Chair concurrence for compassionate use of devices and non-emergency individual patient expanded access, consistent with ZOT IRB updates (v10.5.8).

2.1.4 Removed duplicative system step of documenting chair concurrence in the "Notes" section for determinations related to compassionate use of devices in 5.1.2.2.

2.1.5 Added 21 CFR §312.305 to Reference section (consistent with activities identified in Items 14 & 15 in HRP-105 - OHRP FDA Written Procedure Crosswalk).

2.1.6 Updated the link to FDA guidance on Form FDA 3926.

2.2 Reason for Change: HRP Toolkit version 5.4 released December 2025.

2.3 Prior Version: 09/01/2025.

3 POLICY

3.1 Whenever possible physicians are to notify the IRB of a proposed emergency use of a drug, biologic, or device in a life-threatening situation in advance of the use.

3.2 Physicians are to notify the IRB of a proposed compassionate use of an unapproved device, for the purpose of obtaining concurrence from an IRB Chair.

3.3 Emergency uses and device compassionate uses cannot be claimed as research.

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3.4 Investigators are to notify the IRB of a non-emergency individual patient expanded access use of an investigational drug "Request for Authorization to Use Alternative IRB Review Procedures" identified on FDA Form 3926 (field 10.b.) or a separate waiver request included with FDA Form 1571 for the purpose of obtaining concurrence from an IRB Chair or designee.

3.5 Involving Right to Try, committee review is required.

4 RESPONSIBILITIES

4.1 A Designated Reviewer carries out these procedures.

5 PROCEDURE

5.1 Determine if the notification/request is one of the following:

5.1.1 Emergency use of a drug, biologic, or device in a life-threatening situation. If so, use the HRP-322 - PI WORKSHEET - Emergency Use to determine whether the circumstances will meet, or if the use described in the 5-day report have met, the regulatory and guidance criteria for emergency use, and indicate the results of this determination to the IRB staff (or directly to the physician if time sensitive).

5.1.1.1 If the notice is in advance of the use, inform the IRB staff (or physician if time sensitive) that the physician can proceed with the use or work with the physician to identify what additional information/procedures the physician needs to follow. If the information provided is sufficient to confirm the circumstance meets the criteria for emergency use, no further reporting is required.[i] If further reporting is necessary, inform the IRB staff to request the 5-day report.

5.1.1.2 If the actual emergency use described in the 5-day report did not follow FDA requirements, manage as Non-Compliance using the Submit RNI activity.

5.1.2 Compassionate use of a device. If so, use HRP-325 - PI WORKSHEET - Expanded Access. Compassionate Use to determine whether the circumstances will meet the regulatory and guidance criteria and indicate the results of this determination to the physician.

5.1.2.1 Execute the "Submit Designated Review" activity. For the Review Level, choose Expedited Review and choose "IRB Chair concurrence" and "Non-emergency individual/small group compassionate use of a device" for the category. Choose that continuing review is not required.

5.1.3 Non-emergency individual patient expanded access use of an investigational drug for which an IRB waiver is requested. If so, use HRP-314 - WORKSHEET - Criteria for Approval to determine whether the proposed use meets the requirements under 21 CFR 50 and 56.111[ii] and indicate the results of this determination to the IRB staff.

5.1.3.1 Execute the "Submit Designated Review" activity. For the Review Level, choose Expedited Review and choose "IRB Chair concurrence" and "Non-emergency individual patient drug expanded access" for the category. Choose that continuing review is required.

5.1.3.2 In the "Notes" section document that the decision to concur (or not) is in lieu of review and approval at a convened IRB meeting at which a majority of the members are present per the request for a waiver under 21 CFR § 56.105 of the requirements in § 56.108(c).

5.1.4 If none of the above, stop processing the request and inform the physician or submitter.

5.2 Inform IRB staff of the results of the evaluation.

6 MATERIALS

6.1 HRP-024 - SOP - New Information
6.2 HRP-314 - WORKSHEET - Criteria for Approval
6.3 HRP-322 - WORKSHEET - Emergency Use
6.4 HRP-325 - WORKSHEET - Expanded Access

7 REFERENCES

7.1 21 CFR § 50.23; 21 CFR § 50.24; 21 CFR § 56.102(d); 21 CFR § 56.104(c)
7.2 21 CFR § 312.305
7.3 21 CFR § 812.36; 21 CFR § 812.47
7.4 21 CFR § 56.105; 21 CFR § 56.108(c)
7.5 FDA Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors Frequently Asked Questions About Medical Devices: http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf.
7.6 Individual Patient Expanded Access Applications: Form FDA 3926 Guidance for Industry: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/individual-patient-expanded-access-applications-form-fda-3926
California Right to Try: https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201520160AB1668
https://research.uci.edu/human-research-protections/clinical-research/drugs-and-biologics-used-in-clinical-research/right-to-try-drugs-biologics/

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[i] Per FDA correspondence dated 5/6/2025, "21 CFR 50.23(a) (3) requires that the documentation required in 21 CFR 50.23(a) or (b) be submitted to the IRB within 5 working days after the use of the test article. However, if there is time for this information to be provided to the IRB before the administration of the test article, and the information was sufficient for the IRB's needs, then there would be no expectation that the information would need to be subsequently submitted to the IRB again."

[ii] "The IRB chairperson (or designated IRB member) would consider the same information that the full IRB would consider to determine whether to approve the treatment when reviewing and concurring for individual patient expanded access use." Per FDA correspondence dated 10/10/17.

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SOP: New Information

1 PURPOSE

1.1 This procedure establishes the process to manage information reported to the IRB to ensure that information that represents Non-Compliance, Unanticipated Problems Involving Risks to Subjects or Others, Suspensions of IRB Approval, and Terminations of IRB Approval are managed to protect the rights and welfare of subjects.

1.2 The process begins when the IRB receives an information item.

1.3 The process ends when the information item is determined not to represent a problem that requires management, is managed administratively, or referred to the convened IRB for review.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Summary of Changes:

2.1.1 Revised 5.1 to include system steps for executing "Request Pre-Review Clarifications" or complete the "Submit RNI Pre-Review" and added references to HRP-031 - SOP - Non-Committee Review Preparation & HRP-040 - SOP - IRB Meeting Preparation. Added HRP-031 & HRP-040 to Materials section.

2.1.2 Simplified "IRB chair or IRB manager" to "IRB" in 5.3 re: referencing HRP-025 - SOP - Investigations and added "if needed" to the statement in 5.4.4.2 re: confirming with the IRB chair or IRB manager.

2.1.3 Revised the Procedure section at 5.9 re: information that does not involve serious non-compliance, etc. to clarify ZOT IRB steps and remove reference to HRP-052. Removed reference to HRP-052 in the Materials section.

2.2 Reason for Change: HRP Toolkit version 5.4 released December 2025.

2.3 Prior Version: 09/01/2025.

3 POLICY

3.1 Allegations of Serious or Continuing Non-Compliance on the part of IRB staff or IRB members will be referred to the Institutional Official (IO)/Organizational Official (OO) for further action.

3.2 All incidents of serious and/or continuing noncompliance that occur either at a UCI site, or at a non-UCI site where the UCI IRB is the IRB of record, must be reported to the IRB in ZOT IRB within 5 business days of the occurrence or within 5 business days from the date in which the Principal Investigator (PI) learned of the occurrence.

3.3 Such reports may come from any source including, but not limited to, an IRB Committee Member, an Investigator, a participant or their family members, institutional personnel, other institutional Committees, UC Irvine Whistleblower Office, UCI Health Affairs Compliance Officer, the media, anonymous sources, or the public.

3.4 By investigating and managing issues of potential noncompliance, the IRB seeks to:

3.5 Assure the safety of human research participants;

3.6 Develop action plans to prevent reoccurrence, and promote future compliance;

3.7 Educate research staff to assure their understanding of Food and Drug Administration (FDA) and Office for Human Research Protections (OHRP) guidelines and regulations, and UCI IRB Policy; and

3.7 Fulfill its obligation and responsibility to report Serious Non-Compliance and/or Continuing Non-Compliance to applicable government oversight agencies.

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3.8 If the non-compliance appears to meet the definition of research misconduct, forward to the Vice Chancellor for Research.

3.9 The organization will promptly notify the federal department or agency funding the research of any for cause investigation of that research by another federal department or agency.

3.9.1 For Department of Defense (DOD) research the report is sent to the DOD human research protection officer.

3.10 The organization will promptly notify the Department of Defense (DOD) if the IRB of record changes.

3.11 Substantiated allegations related to classified Department of Defense (DOD) Human Subjects Research must be reported immediately.

3.12 For Veterans Administration (VA) research:

3.12.1 The following events involving exempt or nonexempt VA human subjects research must be reported to the local VA medical facility per the facility's required reporting timelines:

3.12.1.1 Deaths of a human subject participating in VA human subjects research that is believed to be both unexpected and related or possibly related to participation in a VA human subjects research study (applies to the death of a human subject enrolled in the study under the auspices of the VA medical facility).

3.12.1.1.1 The VA medical facility Director must notify ORO within 1 business day after VA medical facility personnel first become aware of the death of a human subject enrolled in a study approved by the VA medical facility.

3.12.1.2 Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO) in VA human subjects research.

3.12.1.2.1 The VA medical facility Director must notify ORO promptly, but no later than 60 calendar days after VA medical facility personnel first become aware of the occurrence of an unanticipated problem involving risks to subjects or others (UPIRTSO).

3.12.1.3 Occurrence of serious or continuing noncompliance with applicable laws, regulations, policies, and agreements pertaining to VA human subjects research.

3.12.1.3.1 The VA medical facility Director must notify ORO promptly, but no later than 60 calendar days after VA medical facility personnel first become aware of the serious or continuing noncompliance.

3.12.1.4 The suspension or early termination of a VA human research study by the IRB, R&DC, or IO due to the study not being conducted in accordance with applicable regulations, policies, agreements, or IRB requirements or due to concerns about the safety, rights, or welfare of human subjects or others.

3.12.1.5 A change in the status (e.g., expiration, restriction, suspension, or termination) of the VA medical facility's human subjects research FWA.

3.12.1.6 The termination or non-renewal of the HHS-OHRP registration of any IRB relied upon by the VA medical facility for review and oversight of VA research.

3.12.1.7 A failure of the VA medical facility to achieve or maintain full accreditation of its HRPP if such accreditation is sought by the VA medical facility.

3.12.1.8 The issuance of a research-related citation or determination of noncompliance by a state or Federal entity (including the VA Office of Inspector General) or an accrediting organization, pertaining to the VA medical facility's HRPP and human subjects research portfolio.

3.12.1.8.1 The VA medical facility Director must notify ORO promptly, but no later than 5 business days after VA medical facility personnel first become aware of any of the items above from suspension or early termination through issuance of a research-related citation.

3.13 IRB members or staff who believe they are being or have been subject to undue influence must report this to the Associate Vice Chancellor for Research Administration, the Senior Director, Human Research Protections, or utilize the University of California Whistleblower Policy.

3.14 Attempts to unduly influence an IRB committee member or IRB staff will be investigated in accordance with Sec. 480-7, Resolving Regulatory Non-compliance.

3.15 A modification is required in order to lift a suspension of IRB approval and must be reviewed by the convened IRB to determine whether all corrective actions are met.

3.16 If IRB staff become aware of an information item that has not been submitted in the IRB system, they will enter the new information using the “Report New Information” activity and associate the information item with the appropriate study as applicable.

3.17 Information items are reviewed within 1 business day of submission.

4 RESPONSIBILITIES

4.1 The IRB staff members carry out this procedure.

5 PROCEDURE

5.1 Answer the following questions and complete the Submit RNI Pre-Review Activity: (See attached flowchart for a diagram of the flow of this procedure.)

5.1.1 Is this an Allegation of Non-Compliance?

5.1.2 Is this a Finding of Non-Compliance?

5.1.3 Is this an Unanticipated Problem Involving Risks to Subjects or Others?

5.1.4 Is this a Suspension of IRB Approval or Termination of IRB Approval?

5.2 If you are unable to answer a question, consult the IRB chair or IRB Compliance manager. After consultation, execute “Request Pre-Review Clarifications” or complete “Submit RNI Pre-Review” and indicate “Additional review required”.

5.2.1 If assigning to a Designated Reviewer, follow HRP-031 - SOP - Non-Committee Review Preparation.

5.2.2 If assigning to an IRB meeting, follow HRP-040 - SOP - IRB Meeting Preparation.

5.3 The IRB may request that additional information be obtained by the IRB Education and Quality Improvement (EQUIP) team.

5.4 If the IRB is unable to answer a question, follow HRP-025 - SOP - Investigations.

5.5 If the answer is “yes” to one or more questions, then follow the corresponding sections below.

5.5.1 Allegations of Non-Compliance: Determine whether each Allegation of Non-Compliance has any basis in fact.

5.5.1.1 If yes, follow the procedures under Findings of Non-Compliance.

5.5.1.2 If no, follow any other corresponding sections.

5.5.2 Findings of Non-Compliance: Determine whether each Finding of Non-Compliance is Serious Non-Compliance or Continuing Non-Compliance.

5.5.2.1 If no, follow the procedures under Non-Serious/Non-Continuing Non-Compliance.

5.5.2.2 If yes, follow the procedures under Serious or Continuing Non-Compliance.

5.5.3 Non-Serious/Non-Continuing Non-Compliance

5.5.3.1 Determine whether the individual or group responsible for the Non-Compliance has developed and implemented a suitable corrective action plan.

5.5.3.2 If the individual or group responsible for the Non-Compliance is unwilling or unable to develop and implement a suitable corrective action plan, consider the Non-Compliance to be Continuing Non-Compliance and follow the procedures for Serious or Continuing Non-Compliance.

5.5.4 Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others

5.5.4.1 If the notification involves enrollment of a Prisoner in a study not approved to enroll Prisoners, please see below for additional considerations to aid in decision-making.

5.5.4.2 Confirm your decision with the IRB chair or IRB manager, if needed.

5.5.4.3 Place on the agenda for the next available convened IRB meeting in an IRB with appropriate scope as an item of Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others.

5.6 If in your opinion the rights and welfare of subjects might be adversely affected before the convened IRB can review the information, contact the IRB chair or IRB manager to consider a Suspension of IRB Approval following the HRP-026 - SOP - Suspension or Termination Issued Outside of Convened IRB.

5.7 If the notification involves a subject becoming a Prisoner in a study not approved by the IRB to involve Prisoners:

5.7.1 Confirm that the subject is currently a Prisoner.

5.7.1.1 If the subject is currently not a Prisoner no other action is required.

5.7.2 Consider whether stopping all research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated subject until the regulatory requirements for research involving Prisoners are met or until the subject is no longer a Prisoner would present risks to the subject.

5.7.2.1 If the subject's involvement in the research cannot be stopped for health or safety reasons, do one of the following:

5.7.2.1.1 Keep the subject enrolled in the study and review the research for involvement of Prisoners. If the research is subject to DHHS oversight, notify OHRP.

5.7.2.1.2 Remove the subject from the study and provide the study intervention as clinical care or compassionate use.

5.7.2.2 If the subject's involvement in the research can be stopped, inform the investigator that all research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated subject must be stopped immediately until the regulatory requirements for research involving Prisoners are met or until the subject is no longer a Prisoner.

5.7.3 For Department of Defense (DOD) research, have the convened IRB promptly (within 30 days) re-review the research protocol to ensure that the rights and well-being of the human subject, now a prisoner, are not in jeopardy.

5.7.3.1 Promptly report all decisions to the Department of Defense (DOD).

5.7.3.2 The Department of Defense (DOD) must concur with the IRB before the subject can continue to participate while a Prisoner.

5.8 Take any additional actions required to resolve any concerns or complaints associated with the information.

5.9 If the information does not involve a Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others complete the "Submit RNI Prereview and prepare and send letter per HRP-052 - SOP - Post-Review" activity.

5.9.1 As applicable, select “Non-compliance that is neither serious nor continuing”, “Allegation of non-compliance with no basis in fact”, or “None of the above” as the determination(s). The RNI state will move to “Acknowledged” and an automated e-mail notification will be sent.

6 MATERIALS

6.1 HRP-025 - SOP - Investigations

6.2 HRP-026 - SOP - Suspension or Termination Issued Outside of Convened IRB

6.3 HRP-031 - SOP - Non - Committee Review Preparation

6.4 HRP-040 - SOP - IRB Member

7 REFERENCES

7.1 21 CFR §56.108(b)

7.2 45 CFR §46.103(b)(5), 45 CFR §46.108(a)

7.3 VHA Directive 1200.05(3), Amended July 13, 2023

7.4 VHA Directive 1058, November 8, 2024

7.5 DoDI 3216.02

7.6 University of California Whistleblower Protection Policy

7.7 Sec. 480-7, Resolving Regulatory Non-compliance

7.8 Flowchart



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SOP: Investigations

1 PURPOSE

1.1 This procedure establishes the process to conduct investigations.

1.2 The process begins when the IRB staff members and chair cannot answer a question required by HRP-024 - SOP - New Information.

1.3 The process ends when the investigation is complete and the answer has been provided to the Institutional Official/Organizational Official (IO/OO) or designee.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 None

4 RESPONSIBILITIES

4.1 The IO/OO or designee:

4.1.1 Appoints the members of the investigative committee based on the expertise and background needed to answer the question.

4.2 Appoints a chair of the investigative committee.

4.2.1 Charges the investigative committee with the question to be answered.

4.3 The investigative committee carries out these procedures within 60 days.

4.4 Investigative committee members make their decisions based on a preponderance of the evidence.

4.5 Investigative committee decisions are made by majority vote.

4.6 Individuals being interviewed may have counsel present. However, counsel cannot address the investigative committee. The investigative committee by a vote of the majority may exclude counsel when in the opinion of the investigative committee that person’s presence is disruptive.

5 PROCEDURE

5.1 Notify the investigator that an investigation is being conducted, the question to be answered, and the time frame for completion.

5.2 Determine what information to gather and what individuals to interview.

5.3 Gather information and interview individuals.

5.4 If the investigative committee believes that a transcription of the interviews will be required to make a proper decision, the investigative committee may record the interviews and obtain a transcript.

5.5 Repeat information gathering and interviews until a decision can be made.

5.6 The investigative committee provides a written report of the investigative committee’s decision to the IO/OO or designee.

6 MATERIALS

6.1 HRP-024 - SOP - New Information

7 REFERENCES

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SOP: Suspension or Termination Issued Outside of Convened IRB

1 PURPOSE

1.1 This procedure establishes the process for someone other than the convened IRB to institute a Suspension of IRB Approval or a Termination of IRB Approval.

1.2 The process begins when the IRB Chair, Organizational Official / Institutional Official (IO/OO) or designee institutes a Suspension of IRB Approval or a Termination of IRB Approval.

1.3 The process ends when the Suspension of IRB Approval or a Termination of IRB Approval has been placed on the agenda for review by the convened IRB.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Summary of Changes:

2.1.1 Added ZOT IRB steps for suspension and termination.

2.1.2 Added 'and relevant agencies' to 5.4.5 re: reporting adverse events/outcomes.

2.1.3 Updated 5.7 re: sending HRP-515 - LETTER - Suspension to include reference HRP-515b - LETTER - Termination. Updated the Materials section to include HRP-515b.

2.1.4 Added 5.8 re: Sponsor-initiated suspension.

2.2 Reason for Change: HRP Toolkit version 5.4 released December 2025.

2.3 Prior Version: 09/01/2025.

3 POLICY

3.1 The IRB chair may institute a Suspension of IRB Approval when in the opinion of the IRB chair subjects may be at risk of adverse effects on their rights and welfare before action may be considered by the convened IRB.

3.2 The IO/OO or designee may institute a Suspension of IRB Approval or Termination of IRB Approval for any reason.

3.2.1 For Veterans Administration (VA) research, this authority may be delegated by the IO to the Chief of Staff (COS). ORD has authority to suspend or terminate any research activity it is funding.

3.3 Whenever possible the individual following these procedures communicates with investigators orally and in writing.

3.4 Suspension of IRB Approval or Termination of IRB Approval must be reported to the local VA medical facility per the facility's required reporting timelines.

4 RESPONSIBILITIES

4.1 The individual instituting a Suspension of IRB Approval or Termination of IRB Approval follows these procedures.

5 PROCEDURE

5.1 Notify the investigator of the Suspension of IRB Approval or Termination of IRB Approval along with the reasons for the decision.

5.1.1 If the determination was Suspension of IRB Approval:

5.1.1.1 Execute the "Suspend" activity in the study workspace.

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5.1.1.2 Execute the “Prepare Letter” activity in the study workspace and modify the letter as needed.

5.1.1.3 Execute the “Send Letter” activity.

5.1.2 If the determination was Termination of IRB Approval:

5.1.2.1 Execute the “Terminate” activity in the study workspace.

5.1.2.2 Execute the “Prepare Letter” activity in the study workspace and modify the letter as needed.

5.1.2.3 Execute the “Send Letter” activity.

5.2 Ask the investigator to provide for the status of all Human Subjects currently involved in the research (e.g., actively receiving investigational treatment, follow-up only).

5.3 Ask the investigator whether any actions are required to protect those subjects’ rights and welfare or to eliminate an apparent immediate hazard.

5.4 Consider whether any of the following additional actions are required to protect those or other subjects’ rights and welfare or to eliminate an apparent immediate hazard:

5.4.1 Transferring subjects to another investigator.

5.4.2 Making arrangements for clinical care outside the research.

5.4.3 Allowing continuation of some research activities under the supervision of an independent monitor.

5.4.4 Requiring or permitting follow-up of subjects for safety reasons.

5.4.5 Requiring adverse events or outcomes to be reported to the IRB, the sponsor, and relevant agencies.

5.4.6 Notification to current Human Subjects.

5.4.7 Notification to former Human Subjects.

5.5 For Veterans Administration (VA) research, the VA medical facility Director must report the Suspension of IRB Approval or Termination of IRB Approval to ORO within 5 business days of becoming aware of the determination(s). The notification must include a statement of the reason for the action.

5.6 Refer to the IRB staff to place on the agenda for a convened IRB meeting in an IRB with appropriate scope as an item of Suspension of IRB Approval or Termination of IRB Approval. Follow HRP-041 - SOP - IRB Meeting Conduct for convened IRB review of the item.

5.7 Complete and send to the investigator HRP-515 - LETTER - Suspension or HRP-515b - LETTER - Termination.

5.8 Regarding reporting: A sponsor-initiated suspension does not independently trigger reporting of events described in 56.108(b)(1), as the IRB has an obligation to evaluate the reasons behind the suspension to determine whether those reasons meet the criteria for reporting of events described in 56.108(b)(1). The reporting obligation is triggered by an action taken by the IRB itself, i.e., a formal suspension or termination of the IRB's own approval of the research. A sponsor-initiated hold on enrollment or procedures will be considered an operational action taken by the sponsor under its own authority (e.g., pursuant to its investigational plan, a clinical hold response, or safety monitoring findings). It does not, on its own, alter the status of IRB approval.

6 MATERIALS

6.1 HRP-041 - SOP - IRB Meeting Conduct

6.2 HRP-515 - LETTER - Suspension

6.3 HRP-515b - LETTER - Termination

7 REFERENCES

7.1 21 CFR §56.108(b)(3), 21 CFR §56.113

7.2 45 CFR §46.103(b)(5)(ii), 45 CFR §46.108(a), 45 CFR §46.113

7.3 VHA Directive 1058, November 8, 2024

7.4 VHA Directive 1200.05(3), January 7, 2019, Amended July 13, 2023

SOP: All Emergency Use, Compassionate Use (Device Only) and IRB Waiver for Individual Patient Expanded Access (Drug Only) Post-Review

1 PURPOSE

1.1 This procedure establishes the process to communicate the review of:

1.1.1 Emergency use of a drug, biologic, or device in a life-threatening situation.

1.1.2 Non-emergency individual patient/small group expanded access for an unapproved medical device (commonly known as Compassionate Use).

1.1.3 Non-emergency individual patient expanded access use of an investigational drug for which an IRB waiver is requested.

1.2 The process begins when the Designated Reviewer has notified IRB staff of whether an actual or proposed use has followed or will follow FDA regulations and guidance.

1.3 The process ends when the IRB staff has communicated the results to the physician and if necessary initiated the non-compliance process.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Summary of Changes:

2.1.1 Updated 5.1.1.2 consistent with revisions to HRP-023 - SOP - Emerg and Device Comp Use Review re: 5d reporting requirements, revising to state "If a 5-day report is required…".

2.1.2 Added 21 CFR §312.305 to Reference section (consistent with activities identified in Items 14 & 15 in HRP-105 - OHRP FDA Written Procedure Crosswalk).

2.2 Reason for Change: HRP Toolkit version 5.4 released December 2025.

2.3 Prior Version: 09/01/2025.

3 POLICY

3.1 None

4 RESPONSIBILITIES

4.1 IRB staff carry out these procedures.

5 PROCEDURE

5.1 For emergency use of a drug, biologic, or device in a life-threatening situation:

5.1.1 If the Designated Reviewer has indicated that the proposed use will follow FDA regulations:

5.1.1.1 Manually complete HRP-570 - LETTER - Pre-Rev EU - Crit Met and send to the physician.

5.1.1.2 If a 5-day report is required, set a 5-day deadline for receipt of the 5-day report.

5.1.2 If the Designated Reviewer has indicated that the proposed use will NOT follow FDA regulations, manually complete HRP-571 - LETTER - Pre-Rev EU - Crit Not Met and send to the physician.

5.1.3 If the Designated Reviewer has indicated that the actual use described in the 5-day report followed FDA regulations, complete HRP-572 - LETTER - Review of EU - Crit Met and send to the physician.

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5.1.4 If the Designated Reviewer has indicated that the actual use did NOT follow FDA regulations:

5.1.4.1 Complete HRP-573 - LETTER - Review of EU - Crit Not Met and send to the physician.

5.1.4.2 Manage under HRP-024 - SOP - New Information as Non-Compliance.

5.2 For compassionate use of a device, complete HRP-574 - LETTER - Device Compassionate Use.

5.3 For non-emergency individual patient expanded access use of an investigational drug for which an IRB waiver is requested, complete HRP-575 - LETTER - Rev of IRB Waiver for Indiv Pt Drug Exp Access.

6 MATERIALS

6.1 HRP-024 - SOP - New Information

6.2 HRP-570 - LETTER - Pre-Rev EU - Crit Met

6.3 HRP-571 - LETTER - Pre-Rev EU - Crit Not Met

6.4 HRP-572 - LETTER - Review of EU - Crit Met

6.5 HRP-573 - LETTER - Review of EU - Crit Not Met

6.6 HRP-574 - LETTER - Device Compassionate Use

6.7 HRP-575 - LETTER - Rev of IRB Waiver for Indiv Pt Drug Exp Access

7 REFERENCES

7.1 21 CFR §50.23; 21 CFR §50.24; 21 CFR §56.102(d); 21 CFR §56.104(c)

7.2 21 CFR §312.305

7.3 21 CFR §812.36; 21 CFR §812.47

7.4 FDA Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors Frequently Asked Questions About Medical Devices: http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf.

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SOP: Designated & Staff Reviewers

1 PURPOSE

1.1 This procedure establishes the process for documenting who can conduct Non-Committee Reviews.

1.2 The process begins when the IRB chair designates an Experienced IRB Member or the IRB manager determines an IRB staff member can act as a Staff Reviewer, to conduct Non-Committee Reviews.

1.3 The process ends when the Experienced IRB Member or Staff Reviewer has been noted in the corresponding roster to conduct Non-Committee Reviews.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Summary of Changes:

2.1.1 Modified the SOP to define the process for identifying and documenting Staff Reviewers; including:

2.1.1.1 Updating the SOP title;

2.1.1.2 Modifying the Purpose statements to be inclusive of Staff Reviewers;

2.1.1.3 Identifying the use of HRP-602 - DATABASE - Staff Reviewer Roster in the Policy section;

2.1.1.4 Adding instruction in the Procedure section to add Staff Reviewers to the corresponding roster, as identified by the IRB manager; and

2.1.1.5 Adding HRP-602 to the Materials section.

2.1.1.6 Modified the Procedure section to clarify how Designated Reviewers are identified in the ZOT IRB.

2.2 Reason for Change: HRP Toolkit version 5.4 released December 2025.

2.3 Prior Version: 09/01/2025.

3 POLICY

3.1 IRB rosters are maintained using HRP-601 - DATABASE - IRB Roster.

3.2 Staff Reviewer rosters are maintained using HRP-602 - DATABASE - Staff Reviewer Roster.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 Obtain from the IRB chair the name of the IRB member designated to conduct Non-Committee Reviews.

5.1.1 Verify that the IRB member is an Experienced IRB Member.

5.1.2 Update HRP-601 - DATABASE - IRB Roster to indicate that the IRB member is a Designated Reviewer.

5.1.3 Navigate to the Meetings menu. In the “Committees tab”, click on the applicable IRB Committee. Execute the “Update Eligible Designated Reviewers” activity to indicate that the IRB member is a Designated Reviewer.

5.2 Obtain from the IRB manager the name of the IRB staff member eligible to act as a Staff Reviewer to conduct certain Non-Committee Reviews.

5.2.1 Update HRP-602-DATABASE-Staff Reviewer to indicate that the IRB staff member is a Staff Reviewer.

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6 MATERIALS

6.1 HRP-601 - DATABASE - IRB Roster

6.2 HRP-602 - DATABASE- Staff Reviewer

7 REFERENCES

7.1 21 CFR §56.110(b).

7.2 45 CFR §46.110(b).

SOP: Non-Committee Review Preparation

1 PURPOSE

1.1 This procedure establishes the process to prepare for a Non-Committee Review.

1.2 The process begins when an IRB staff member identifies an application as being possibly eligible for Non-Committee Review.

1.3 The process ends when the IRB staff member provides the materials to a Designated Reviewer or Staff Reviewer for Non-Committee Review.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Summary of Changes:

2.1.1 Modified the SOP to accommodate revisions related to the role of Staff Reviewers, including:

2.1.1.1 Modifying Section 1.3 to include Staff Reviewers;

2.1.1.2 Adding a Policy statement to indicate that Staff Reviewers are maintained via HRP-602 - DATABASE - Staff Reviewer Roster (consistent with revisions to HRP-030 - SOP);

2.1.1.3 Adding reference to HRP-601 (for ZOT IRB only) and HRP-602 in the Procedure section and clarified the types of Non-Committee reviews that can be conducted by reviewer role (Designated vs. Staff Reviewer);

2.1.1.4 Adding reference to HRP-001 and HRP-602 in the Materials section; and

2.1.1.5 Adding 45 CFR 46.164.512(i) to the References section.

2.1.1.6 Added a statement in the Policy section to specify that only Designated Reviewers and Privacy Board designees can issue waivers/alterations of HIPAA authorization reviewed via Non-Committee Review (for ZOT IRB v12, the existing statement was modified to include reference to Privacy Board designees).

2.2 Reason for Change: HRP Toolkit version 5.4 released December 2025.

2.3 Prior Version: 09/01/2025.

3 POLICY

3.1 IRB rosters are maintained using HRP-601 - DATABASE - IRB Roster.

3.2 Staff Reviewer rosters are maintained using HRP-602 - DATABASE - Staff Reviewer Roster.

3.3 For individuals who access materials through an electronic system or are provided all submitted materials, those individuals are expected to review the materials listed in HRP-301 - WORKSHEET - Review Materials according to their role: “Documents Provided to All IRB Members and Alternate IRB Members,” “Additional Items Provided to Primary Reviewer,” and “Additional Items Provided to Scientific/Scholarly Reviewer.”

3.4 Waiver or alterations of HIPAA authorization reviewed via Non-Committee Review must be completed by a Designated Reviewer.

3.5 A reviewer is assigned to a submission within 3 business days of receipt of a complete submission.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

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5.1 Refer to HRP-601 - DATABASE - IRB Roster and/or HRP-602 - DATABASE - Staff Reviewer Roster to identify an appropriate reviewer, based on the review level and/or required determination.

5.1.1 All Non-Committee Reviews can be performed by Designated Reviewers.

5.1.1.1 If no Designated Reviewer is available, or if available Designated Reviewers are unable to perform a Non-Committee Review in a timely manner such that review by the convened IRB would result in a timelier review, schedule the protocol to be reviewed by the convened IRB.

5.1.2 Staff Reviewers are not Designated Reviewers and therefore are limited to making the determinations identified in the definition of Staff Reviewer in HRP-001 - SOP - Definitions.

5.2 Execute the “Assign Designated Reviewer” activity to select a reviewer.

5.3 Protocols eligible for a self-determination of exemption or a self-determination of non-human subject research are not assigned a Designated Reviewer. They remain in “Pre-Review” status as part of the self-determination process.

6 MATERIALS

6.1 HRP-001-SOP - Definitions

6.2 HRP-301 - WORKSHEET - Review Materials

6.3 HRP-601 - DATABASE - IRB Roster

6.4 HRP-602 - DATABASE - Staff Reviewer Roster

7 REFERENCES

7.1 21 CFR §56.110(b)

7.2 45 CFR §46.110(b)

7.3 45 CFR §164.512(i)

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SOP: Non-Committee Review Conduct

1 PURPOSE

1.1 This procedure establishes the process for conducting a Non-Committee Review.

1.2 The process begins when the Designated Reviewer or Staff Reviewer receives the review materials.

1.3 The process ends when the Designated Reviewer or Staff Reviewer completes the review and returns the completed materials to an IRB staff member.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Summary of Changes:

2.1.1 Modified the SOP to accommodate revisions related to the role of Staff Reviewers, including:

2.1.1.1 Revising purpose statement at 1.1 to generically refer to Non-Committee reviews (removing "Designated Reviewers");

2.1.1.2 Revising "Designated Reviewer" to "Designated Reviewer or Staff Reviewer" throughout the document; and

2.1.1.3 Adding new content in the Procedure section to clarify when re-assignment, based on role, may be necessary.

2.1.2 Added statement in the Policy section to reference HRP-301 - WORKSHEET - Review Materials to clarify what documents are used to conduct the review (consistent with activities identified in Items 2 & 20 in HRP-105).

2.1.3 Added "Modifications required to secure approval..." as potential determination in the Procedures section, consistent with federal regulations (and activities identified in Item 2 of HRP-105).

2.1.4 Added HRP-301 to the Materials section. Added HHS & FDA criteria for approval citations in the References section (consistent with Item 3 of HRP-105).

2.1.5 Removed "for approval" from Section 3.5 regarding exemption determinations.

2.1.6 Added language to the Procedure section to clarify appropriate selection of review categories for follow-on submissions.

2.2 Reason for Change: HRP Toolkit version 5.4 released December 2025.

2.3 Prior Version: 09/01/2025.

3 POLICY

3.1 The Designated Reviewer may not disapprove research.

3.2 The Designated Reviewer and Staff Reviewer utilize all applicable worksheets in the review of research.

3.3 The documents, worksheets, and checklists described HRP-301 - WORKSHEET - Review Materials are provided to the reviewer to conduct their review and meet regulatory requirements.

3.4 All applicable criteria for approval in HRP-314 - WORKSHEET - Criteria for Approval must be satisfied in order for the research to be approved using the expedited procedure.

3.5 All applicable criteria in HRP-312 - WORKSHEET - Exemption Determination must be satisfied for research to be determined to be exempt (including applicable criteria for Limited IRB Review in HRP-319 - WORKSHEET - Limited IRB Review when appropriate).

3.6 Reviews are completed and returned to the IRB staff within 5 business days of receipt.

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4 RESPONSIBILITIES

4.1 The HRP staff and/or a Designated Reviewer or Staff Reviewer carries out these procedures.

5 PROCEDURE

5.1 Review all materials.

5.2 If the information is not complete, contact the investigator by selecting the “Request Designated Review Clarifications” activity. Offer the investigator the opportunity to provide additional information.

5.2.1 Continue processing once the investigator responds to the request for additional information.

5.2.2 If the investigator will not correct the submission, have the investigator execute the “Submit Response” activity to resubmit and continue processing.

5.3 Make the appropriate determination:

5.3.1 Not Human Research,

5.3.2 Human Research not Engaged,

5.3.3 Exempt Research Self-Determination

5.3.4 Exempt Human Research that requires IRB review (including exempt Human Research that requires Limited IRB Review),

5.3.5 Modifications required to secure approval of Human Research using the expedited procedure,

5.3.6 Human Research approved using the expedited procedure, or

5.3.7 Human Research that requires review by a convened IRB.

5.4 Notify IRB staff to re-assign the submission if:

5.4.1 The submission is assigned to a Staff Reviewer and requires review using the expedited procedure.

5.4.2 The submission is assigned to a Designated Reviewer and requires review by a convened IRB.

5.5 If consultation is needed follow HRP-051 - SOP - Consultation.

5.6 If the review is complete, execute the “Submit Designated Review” activity.

5.6.1 The risk level determination should reflect the entirety of the research, not components of individual follow-on submissions. For follow-on submission, update the risk level only when modifications to study procedures prompt a change in risk level of the research.

5.6.2 For follow-on submissions to Minimal Risk research, confirm that the review categories selected are still applicable.

5.6.2.1 Update the review category(ies) only when study procedures are modified and impact the category(ies).

5.6.2.2 For research initially reviewed by the convened IRB and determined to be Minimal Risk (via Category 9), leave the review category identified as Category 9.

5.6.3 For follow-on submission to research involving greater than Minimal Risk:

5.6.3.1 For modifications, select minor modification.

5.6.3.2 For continuing reviews, confirm that greater than Minimal Risk activities have not occurred during the review period and select the applicable expedited review category (8a – long-term follow-up; 8b – no subjects enrolled; 8c – data analysis).

5.6.4 For non-emergency individual patient expanded access use of a drug and non-emergency individual/small group compassionate use of a device, select ‘IRB chair concurrence’ and the corresponding sub-category.

5.6.5 For continuing reviews involving Humanitarian Use Devices (HUD), select “Other”.

6 MATERIALS

6.1 HRP-051 - SOP - Consultation

6.2 HRP-301 - WORKSHEET - Review Materials

6.3 HRP-312 - WORKSHEET - Exemption Determination

6.4 HRP-314 - WORKSHEET - Criteria for Approval

6.5 HRP-319 - WORKSHEET - Limited IRB Review and Broad Consent

7 REFERENCES

7.1 21 CFR §56.110(b), 21 CFR 56.111

7.2 45 CFR §46.110(b), 21 CFR §46.111

SOP: IRB Meeting Preparation

1 PURPOSE

1.1 This procedure establishes the process to prepare for a convened IRB meeting.

1.2 The process begins when the agenda is closed, approximately 10 business days before a meeting date.

1.3 The process ends when IRB meeting agenda materials have been sent or made available to IRB members.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Summary of Changes:

2.1.1 Added a statement in the Policy section re: HRP-301 - WORKSHEET - Review Materials consistent with HRP-031 - SOP - Non-Committee Review Preparation (also consistent with activities identified in Item 1 in HRP-105).

2.1.2 Added a statement in the Procedures section re: preparing the expedited report (consistent with activities identified Item 2 in HRP-105).

2.1.3 Corrected FDA citation in references from 21 CFR §56.108(b) to 21 CFR §56.108(c) (consistent with activities identified in Item 1 in HRP-105).

2.2 Reason for Change: HRP Toolkit version 5.4 released December 2025.

2.3 Prior Version: 09/01/2025.

3 POLICY

3.1 At least one IRB member or consultant is responsible for scientific/scholarly review of research.

3.2 Protocols are reviewed by IRB members and consultants with sufficient expertise.

3.3 When IRB members review research that involves vulnerable subjects, at least one individual who is knowledgeable about or experienced in working with such subjects will be present at the meeting.

3.4 IRB members are provided sufficient information so that each member can provide an opinion on whether the regulatory criteria for approval are met.

3.5 Alternate IRB members serve the same function as other IRB members, except that if the alternate IRB member and the regular IRB member for whom the alternate member is substituting are both present only one member may vote.

3.6 For individuals who access materials through an electronic system or are provided all submitted materials, those individuals are expected to review the materials listed in HRP-301 - WORKSHEET - Review Materials according to their role: “Documents Provided to All IRB Members and Alternate IRB Members”, “Additional Items Provided to Primary Reviewer”, and “Additional Items Provided to Scientific/Scholarly Reviewer”.

3.7 Review materials are provided to all IRB members at least 7 business days before convened meetings.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 Confirm which IRB members (regular, alternate, and chairs) will be present at the meeting.

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5.2 Consult HRP-601 - DATABASE - IRB Roster to be aware of the experience, expertise, and representational capacity of the IRB.

5.3 Review all submissions placed on the agenda for a convened IRB meeting.

5.4 Education. As necessary, education will be placed on the agenda for IRB Committee members, which may include; federal regulations, local policies and procedures, any changes in federal regulations, any changes in local policies and procedures, or other items as requested by the IRB.

5.5 Prepare an agenda for the meeting.

5.5.1 Execute the “Assign Reviewers” activity in the meeting workspace to assign a primary reviewer to each agenda item.

5.5.2 Execute the “Assign Reviewers” activity in the meeting workspace to assign a scientific/scholarly reviewer to each agenda item who has scientific/scholarly expertise in the area of research. The primary reviewer and scientific/scholarly reviewer may be the same individual.

5.5.3 If the scientific/scholarly reviewer is not an IRB member, determine whether the scientific/scholarly reviewer has a Conflicting Interest as defined in HRP-001 - SOP - Definitions. If so, assign another scientific/scholarly reviewer.

5.5.4 Execute the “Prepare Agenda” activity in the meeting workspace to generate the agenda and modify as needed.

5.5.5 **For social, behavioral, and educational research:** An appropriate scientific statistical review takes place at the school or departmental level. The Department Chair or Institute Director signs the IRB application attesting that the research is appropriate in design (i.e., the research uses procedures consistent with sound research design, the study design can be reasonably expected to answer the proposed question, and the importance of the knowledge expected to result from the research is known). The IRB reserves the right to require statistical review on a study-by study basis.

5.6 Use HRP-305 - WORKSHEET - Quorum and Expertise to ensure that the meeting will be appropriately convened and to ensure the IRB will have the appropriate expertise for each protocol.

5.6.1 If the meeting will not meet the quorum and expertise requirements, take steps to obtain the required attendance of members and consultants or cancel the meeting.

5.6.2 Follow the procedures in HRP-051 - SOP - Consultation to obtain consultants. Note any consultants on the agenda.

5.7 Ensure the report of protocols approved using the expedited procedure is available in the meeting workspace.

5.8 For individuals who are provided materials (IRB members, scientific/scholarly reviewers, consultants):

5.8.1 Execute the “Send Agenda” activity in the meeting workspace to deliver review materials to reviewers.

6 MATERIALS

6.1 HRP-001 - SOP - Definitions

6.2 HRP-051 - SOP - Consultation

6.3 HRP-301 - WORKSHEET - Review Materials

6.4 HRP-305 - WORKSHEET - Quorum and Expertise

6.5 HRP-601 - DATABASE - IRB Roster

7 REFERENCES

7.1 45 CFR §46.108(b)
7.2 21 CFR §56.108(c)

SOP: IRB Meeting Conduct

1 PURPOSE

1.1 This procedure establishes the process to conduct convened meetings.

1.2 The process begins when the IRB members gather for a convened meeting.

1.3 The process ends when the meeting is adjourned.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Summary of Changes:

2.1.1 Modified the statement in the Policy section re: HRP-301 - WORKSHEET - Review Materials to add the word 'documents' and remove 'and listed below in Section 6: Materials' to make HRP-301 the single source for identifying the documents, worksheets, and worksheets provided to IRB members for the purpose of conducting the review (consistent with revisions to HRP-032 - SOP - Non-Committee Review Conduct).

2.1.2 Similarly, removed all worksheets and worksheets in the Materials sections that are not directly referenced in this SOP (but instead, are listed in HRP-301).

2.1.3 Moved the statement in the Procedures section at 5.5.6.1 re: the approval period and level of risk to a separate bullet (5.5.7). The statement was further revised to clarify that the approval period and risk should also be made with motions of "Modification Required to Secure Approval" (in addition to approval) and to address considerations to take into account re: the approval interval (consistent with activities identified in Items 12 & 17 in HRP-105).

2.1.4 Added HHS criteria for approval citation in References section (consistent with Item 3 in HRP-105).

2.2 Reason for Change: HRP Toolkit version 5.4 released December 2025.

2.3 Prior Version: 09/01/2025.

3 POLICY

3.1 The IRB reviews research in accordance with the applicable regulatory criteria for approval.

3.2 The IRB chair (and vice chair, where applicable), votes as a regular member.

3.3 Meetings are conducted in person or via teleconference.

3.4 IRB attendance is captured by documenting in the IRB meeting minutes the IRB members and alternates in attendance, replacement of a voting member by an alternate, attendance of IRB members who participate through teleconference, and IRB members who are recused due to a conflicting interest. Members are absent when recused and do not count towards quorum while recused.

3.5 If quorum is lost during a meeting, the IRB cannot take votes until the quorum is restored, even if more than half of the members are still present.

3.6 Substantive changes or requirements, requests for more information for IRB consideration, and other issues related to the criteria for approval require review and approval by the convened IRB.

3.7 Minor or prescriptive changes or requirements (modifications required to secure approval) may be reviewed for approval by the IRB chair or a designated individual.

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3.8 The documents and worksheets described in HRP-301 - WORKSHEET - Review Materials are provided to IRB members in advance of meetings per HRP-040 - SOP - IRB Meeting Preparation to conduct meetings and meet regulatory requirements.

3.9 For Veterans Administration (VA) Research “Substantive Changes” are defined as those ineligible for “Modifications Required to Secure Approval” as defined in this SOP.

4 RESPONSIBILITIES

4.1 The IRB chair carries out these procedures, unless otherwise noted.

4.2 Primary reviewers lead IRB members through consideration of the regulatory criteria for approval.

5 PROCEDURE

5.1 Call the meeting to order.

5.2 Ask IRB members whether anyone has a Conflicting Interest in any item on the agenda and note the responses.

5.3 Ask IRB members if there are any questions about the report of completed non-committee reviews that was made available to the IRB prior to the meeting.

5.4 For each agenda item:

5.4.1 Table the item when notified by IRB staff that requirements for review of a specific item as defined in HRP-305 - WORKSHEET - Quorum and Expertise are not met.[i]

5.4.2 If there are IRB members with a Conflicting Interest, invite the IRB to ask questions of those members and then ask those members to leave for discussion and voting or if present by teleconference, be placed on hold or disconnect for discussion and voting.

5.4.2.1 For Veterans Administration (VA) research, members with a Conflicting Interest present by teleconference are to disconnect for discussion and voting.

5.5 For each agenda item involving the initial review, modification or continuing review of a protocol:

5.5.1 If there is a consultant present, ask the consultant to present his or her review to the IRB.

5.5.2 If a consultant provided written information to the IRB, ask the primary reviewer to present that information to the IRB.

5.5.3 Ask the scientific or scholarly reviewer or primary reviewer to present the scientific or scholarly review to the IRB.

5.5.4 Ask the primary reviewer to lead the IRB through a discussion of the criteria in HRP-314 - WORKSHEET - Criteria for Approval and all referenced worksheets (listed below) to have the convened IRB determine which regulatory criteria are met (or continue to be met), which are not met (or no longer met), and which would be met if the investigator modified the protocol as requested by the IRB.

5.5.5 Restate the IRB’s consensus regarding any protocol specific findings justifying a determination when required by a worksheet and not previously determined and documented.

5.5.6 Make a motion for one of the following actions:

5.5.6.1 Approve (with a specific continuing review interval for initial or continuing review when applicable): Made when all criteria for approval are met.

5.5.6.2 Modifications Required to Secure Approval (with a specific continuing review interval for initial or continuing review when applicable): Made when IRB members require specific modifications such that an IRB staff member can determine whether an investigator has made the required changes without judging whether a change meets the regulatory criteria for approval. When making this motion, the

assigned primary reviewer restates the modifications required by the IRB members and the IRB member's reasons for those changes.

5.5.6.3 Defer: Made when the research does not qualify for Approval or Modifications Required to Secure Approval and the IRB has recommendations that might make the protocol approvable. When making this motion, the assigned primary reviewer describes the IRB member's reasons for the decision and describes recommendation to make the research approvable.

5.5.6.4 Disapprove: Made when the research does not qualify for Approval or Modifications Required to Secure Approval and the IRB has no recommendations that might make the protocol approvable. When making this motion, the assigned primary reviewer describes the IRB member's reasons for the decision.

5.5.6.4.1 PI should be invited to the convened meeting for a discussion of the protocol, prior to issuing a disapproval.

5.5.6.5 Suspension or Termination of IRB Approval: Made when current approved research does not qualify for Approval or Modifications Required to Secure Approval. When making this motion, have the primary reviewer use HRP-321 - WORKSHEET - Review of Information Items to lead the convened IRB through a discussion of what actions are needed, if any, to protect subjects. The assigned primary reviewer describes the IRB member's reasons for the decision.

5.5.7 For motions of "Approval" or "Modifications Required to Secure Approval", for initial and continuing reviews, include the risk level if minimal risk and approval period when less than one year. Confirm whether the continuing review interval should be annual, or more frequently than annual based on considerations such as the nature and level of risks, the degree of uncertainty regarding the risks, subject vulnerability, investigator experience, the IRB's experience with the investigator or sponsor, the projected rate of subject enrollment, or whether the study involves novel procedures.

5.5.8 For modifications in response to a previous Suspension of IRB approval:

5.5.8.1 Have the primary reviewer summarize any corrective actions taken by the Principal Investigator.

5.5.8.2 Based on this new information, determine whether the corrective actions are sufficient to address the issues that prompted the suspension.

5.5.8.2.1 If so, make a motion for the IRB to approve the modification, which will lift the suspension of IRB approval.

5.5.8.2.2 If not, make an appropriate motion and identify the additional action items are required to protect subjects.

5.5.9 Review any modifications required to secure approval to ensure that the IRB staff has recorded them.

5.5.9.1 Ensure that the required modifications include all final contingencies listed in the "Notes" section of the Pre-Review activity.

5.5.9.2 For a pending financial interest review indicate that a determination that the financial interest is not a conflict of interest or has been eliminated can be verified by the IRB staff, but if there is a management plan, it must return to the convened IRB for review.

5.6 For each agenda item that is new information (Unanticipated Problem Involving Risks to Subjects or Others, Serious Non-Compliance, Continuing Non-Compliance, Suspension of IRB Approval, or Terminations of IRB Approval):

5.6.1 Have the primary reviewer use HRP-321 - WORKSHEET - Review of Information Items to lead the convened IRB through a discussion of what actions are needed, if any, to protect subjects.

5.6.2 Restate the IRB's consensus regarding any actions that need to be taken to protect subjects.

5.6.3 Make a motion for the IRB's determination(s) regarding the action items (e.g., the motion is for the Principal Investigator to provide the IRB additional information regarding the status of currently enrolled subjects).

5.7 Open the floor for additional discussion.

5.8 Call for a vote.

5.9 Only IRB members may vote.

5.9.1 If a member and an alternate are both present, only one may vote.

5.9.1.1 Consultants may not vote.

5.9.1.2 For a motion to be approved, it needs the approval of more than half of the members present at the meeting. (If there are 10 or 11 members present at the meeting, 6 votes are required for approval, which is greater than 5 and 5.5, respectively.)

5.10 Re-invite IRB members with a Conflicting Interest back into the meeting.

5.11 Provide any written information provided by a member or consultant to the IRB staff.

5.12 Adjourn the meeting when notified by IRB staff that quorum has been lost or when there is no further business.

6 MATERIALS

6.1 HRP-040 - SOP - IRB Meeting Preparation

6.2 HRP-301 - WORKSHEET - Review Materials

6.3 HRP-305 - WORKSHEET - Quorum and Expertise

6.4 HRP-314 - WORKSHEET - Criteria for Approval

6.5 HRP-321 - WORKSHEET - Review of Information Items

7 REFERENCES

7.1 21 CFR §50.20, §50.25, §50.27, §56.109, §56.111.

7.2 45 CFR §46.109, §46.111, §46.116, §46.117.

[i] "Tabled" is not an action of the IRB, but is a status based on the inability of the IRB to take an action because of reasons of quorum.

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SOP: IRB Meeting Attendance Monitoring

1 PURPOSE

1.1 This procedure establishes the process to monitor quorum at convened IRB meetings.

1.2 The process begins when the IRB staff member responsible for monitoring quorum notifies the IRB chair that quorum has been attained.

1.3 The process ends when the meeting is adjourned.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 None

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 At meetings consult HRP-305 - WORKSHEET - Quorum and Expertise to determine that the meeting is appropriately convened by meeting the “QUORUM REQUIREMENTS” and notify the IRB chair when the meeting is appropriately convened.

5.2 Before each protocol consult HRP-305 - WORKSHEET - Quorum and Expertise to determine that the meeting is appropriately convened by meeting the “EXPERTISE REQUIREMENTS” and notify the IRB chair when the meeting is not appropriately constituted for the review of that protocol.

5.3 When a member leaves the meeting room for any reason (including a Conflicting Interest) consult HRP-305 - WORKSHEET - Quorum and Expertise to determine that the meeting continues to be appropriately convened by meeting the “QUORUM REQUIREMENTS” and notify the IRB chair when the meeting is not appropriately convened.

6 MATERIALS

6.1 HRP-305 - WORKSHEET - Quorum and Expertise

7 REFERENCES

7.1 45 CFR §46.108(b)

7.2 21 CFR §56.108(c)

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SOP: IRB Meeting Minutes

1 PURPOSE

1.1 This procedure establishes the process to record minutes for convened meetings.

1.2 The process begins when the meeting is called to order.

1.3 The process ends when the minutes are approved by the IRB chair or IRB Manager.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Summary of Changes: Modified section 3.3 to include turnaround times and removed turnaround times defined in the Procedure section.

2.2 Reason for Change: HRP Toolkit version 5.4 released December 2025.

2.3 Prior Version: 09/01/2025.

3 POLICY

3.1 Minutes are to comply with regulatory and guidance requirements.

3.2 Minutes are to record separate deliberations for each action.

3.3 Minutes are provided to the IRB chair or IRB manager prior to the next meeting for approval.

3.4 IRB members may make corrections to minutes.

3.5 The IRB writes minutes and makes them available for review by the committee by the next IRB meeting. Minutes are made available to the Institutional Official/ Organizational Official (IO/OO).

3.6 Minutes may not be altered by anyone including a higher authority once accepted by the convened IRB. Any updates to an already accepted version of the IRB minutes must be re-accepted by the convened IRB.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 Execute the “Convene Meeting” activity

5.2 Record each voting member (regular members and alternates) present at the meeting at any time. (Do not record non-voting members under “Attendance Table”)

5.2.1 Name.

5.2.2 Status: E.g., chair, vice chair, scientific member, non-scientific member, unaffiliated member, representative of vulnerable population (specify), prisoner representative, Veterans Administration (VA) representative, or alternate member.

5.2.3 For alternate members who are substituting for a regular member, indicate the name of the regular member for whom the alternate member is substituting.

5.2.4 Whether the member was present by teleconference.

5.2.5 Identify any member who has a conflicting interest in the research and was recused from participation in the review and deliberation process.

5.3 Record the total number of members in HRP-601 - DATABASE - IRB Roster. Exclude alternate members in this count.

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5.4 Record the number of members required for quorum. Divide the number of members by two and select the next whole number. For example, if there are 10 IRB members on the HRP-601 - DATABASE - IRB Roster, then 10/2 = 5 and the next whole number is 6. If there 11 IRB members on the HRP-601 - DATABASE - IRB Roster, then 11/2=5.5 and the next whole number is 6.

5.5 Indicate whether members present by teleconference received all pertinent material before the meeting and were able to actively and equally participate in all discussions. Delete if no members were present by teleconference.

5.6 Record the meeting start time.

5.7 For each submission reviewed record in the “Submit Committee Review” activity or “Submit RNI Committee Review” activity, as appropriate:

- 5.7.1 Motion: Approved, Modifications Required to Secure Approval, Deferred, Disapproved, Suspended, or Terminated. For initial or continuing review add the period of approval to the motion.
- 5.7.2 Risk Level: Minimal Risk or more than Minimal Risk.
- 5.7.3 Refer to HRP-302 - WORKSHEET - Approval Intervals to calculate approval intervals (if applicable).
- 5.7.4 Last Day of Approval Period: Record the study expiration date.
- 5.7.5 Recommended Changes and Reasons: If the motion is Modifications Required to Secure Approval or Deferral/Disapproval, complete the table with the required changes and corresponding reasons. If no recommended changes, indicate “None.”
- 5.7.6 Controverted Issues and their Resolutions: Summarize the issues where IRB members expressed a difference of opinion. For each issue indicate the resolution or indicate that there was none. If no controverted issues, indicate “None.”
- 5.7.7 Determinations and findings that require documentation: If the research involves waiver or alteration of consent, waiver of written documentation of consent, children, pregnant women, neonates, Prisoners, or adults with impaired decision-making capacity, enter “See attached Supporting Documents” and ensure that the corresponding completed checklist is uploaded as a supporting document. If no determinations that require documentation, indicate “None.”
- 5.7.8 RNI Determinations: Record the determination of Unanticipated Problem Involving Risks to Subjects or Others, suspension or termination of IRB approval, serious non-compliance, continuing non-compliance, non-compliance that is neither serious nor continuing, allegation of non-compliance with no basis in fact, or none of the above.
- 5.7.9 RNI Considerations: Record requirements determined by the IRB, for example modification to the protocol or ask subjects to re-consent.
- 5.7.10 Additional Information and Notes: Summarize issues useful to understand the agenda item. For example, a brief history of recent IRB actions
- 5.7.11 Supporting documents: For any determinations that require documentation, upload the appropriate worksheet(s), or any other appropriate supporting documents.
- 5.7.12 Vote: Record as the number of members for, against, abstaining, absent, or recused. List the names of IRB members who were absent or recused. Do not count votes of consultants. If both a regular IRB member and the alternate IRB member are present at the meeting record the vote of just one.
  - 5.7.12.1 For: Voting for the motion.
  - 5.7.12.2 Against: Voting against the motion.
  - 5.7.12.3 Abstain: Present for the vote, but not voting “For” or “Against.”
  - 5.7.12.4 Absent: Listed under “Members Present” but not present for the discussion and vote on this protocol for reasons other than a Conflicting Interest. List the names of absent members in the vote. For example: “For: 7 Against: 3 Abstain: 2 Absent: 2 (Alice Baker, Charlie Delta) Recused: 0 Substitutions: 0.”
  - 5.7.12.5 Recused: Listed under “Members Present” but not present for the discussion and vote on this protocol for because of a Conflicting Interest. List the names of

recused members in the vote. For example: “For: 7 Against: 3 Abstain: 2 Absent: 0 Recused: 2 (Evelyn Foxtrot, George India) Substitutions: 0.”

5.7.12.6 Substitutions: Listed under “Members Present” When regular members and their alternate(s) are listed under “Members Present” and an alternate member substitutes for the regulator member, identify the name of the alternate to indicate which individual is serving as the voting member for this vote. May be deleted if there are no substitutions. For example: “For: 7 Against: 3 Abstain: 2 Absent: 0 Recused: 0 Substitutions: 1 (Evelyn Foxtrot substituted for George India).”

5.8 Record the meeting end time.

5.9 Execute the “Prepare Minutes” activity and combine the attendee information with the generated submission-specific determinations.

5.10 Revise minutes for accuracy and provide them to the IRB chair or IRB manager for review and approval.

5.11. The Administrator develops a draft of the IRB Committee meeting minutes and includes the draft in the full Committee materials for the next convened meeting.

5.12. The IRB Committee members review and communicate to the Administrator any necessary revisions. The final version of the meeting minutes is maintained electronically.

5.11 The Institutional Official has access to all final versions of minutes.

5.12 Once approved by the IRB chair or IRB manager, execute the “Close Meeting” activity.

5.13 Email minutes to:

5.13.1 Veterans Administration (VA) Research and Development Committee

5.13.2 When an affiliate IRB is the IRB of Record, the affiliate may either:

5.13.2.1 Provide VA with unredacted copies of meeting minutes, or

5.13.2.2 Provide VA with redacted copies of meeting minutes and permit relevant VA personnel (including, but not limited to, ORO staff, local VA Research Office staff, local RCOs, and R&D Committee members) to review the unredacted meeting minutes within two business days of a written request from VA. Such review may occur at the affiliate site during normal business hours, or as otherwise mutually acceptable to VA and the affiliate.

5.14 The minutes will show on the next agenda for that IRB committee under “Previous meetings with minutes for approval” for the IRB members at the next convened meeting to review and accept.

5.15 Once accepted, execute the “Approve Minutes” activity to finalize the minutes.

6 MATERIALS

6.1 HRP-501 - TEMPLATE MINUTES

7 REFERENCES

7.1 21 CFR §56.115(a)(2)

7.2 45 CFR §46.115(a)(2)

7.3 VHA Directive 1200.05(3) Amended July 13, 2023

SOP: Not Otherwise Approvable Research

1 PURPOSE

1.1 This procedure establishes the process for the organization to review research that is not otherwise approvable.

1.2 This process begins when the IRB determines that research involving children, pregnant women, fetuses or neonates as subjects is not otherwise approvable, but presents a reasonable opportunity to understand, prevent, or alleviate a serious problem affecting those subjects' health or welfare.

1.3 The process ends when the federal agency or the Institutional Official/ Organizational Official (IO/OO) or designee communicates a decision to the IRB.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 For HHS-funded or conducted research and FDA-regulated research involving children, the research may proceed only if the HHS Secretary or his or her designee/Commissioner of Food and Drugs, after consulting with a panel of experts in pertinent disciplines (e.g., science, medicine, education, ethics, law) and following an opportunity for public review and comment, makes a determination as indicated in the applicable regulation.

3.2 When research is not otherwise approvable, but because the research is not subject to regulatory approval no government agency will conduct a review of this research to determine whether it can be approved, this organization will conduct its own review that parallels the regulatory process.

3.3 The criteria used to make a determination are:

3.3.1 That the research in fact satisfies the conditions of IRB approvable research in HRP-413 - PI WORKSHEET - Non-Viable Neonates, HRP-414 - PI WORKSHEET - Neonates of Uncertain Viability, or HRP-416 - PI WORKSHEET - Children, or HRP-412 - PI WORKSHEET - Pregnant Women.

3.3.2 All of the following criteria are met:

3.3.2.1 The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children or pregnant women, fetuses or neonates.

3.3.2.2 The research will be conducted in accordance with sound ethical principles;

3.3.2.3 Adequate provisions are made for soliciting the assent of children, the permission of their parents or guardians, and the consent of subjects as required by HRP-314 - WORKSHEET - Criteria for Approval, HRP-413 - PI WORKSHEET - Non-Viable Neonates, HRP-414 - PI WORKSHEET - Neonates of Uncertain Viability, or HRP-416 - PI WORKSHEET – Children.

4 RESPONSIBILITIES

4.1 IRB staff members carry out the procedures in Sections 5.1 and 5.2.

4.2 The IO/OO or designee carries out these procedures in Section 5.3.

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5 PROCEDURE

5.1 For research involving children, when using HRP-416 - PI WORKSHEET – Children and the IRB determines the research meets the criteria for category 21 CFR §50.54/45 CFR §46.407 "*Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children*," proceed as follows:

5.1.1 For DHHS, the research may proceed only after OHRP has reviewed and approved the research. Refer to DRAFT guidance Research Involving Children as Subjects and Not Otherwise Approvable by an IRB: Process for Referrals to FDA and OHRP for appropriate next steps. Contact OHRP OHRP@hhs.gov for additional information and the appropriate next steps.

5.1.2 For FDA-regulated research, the research may proceed only after the FDA has reviewed and approved the research. Refer to Process for Handling Referrals to FDA Under 21 CFR 50.54 - Additional Safeguards for Children in Clinical Investigations for appropriate next steps. Contact the FDA opt@fda.gov for additional information and the appropriate next steps.

5.1.3 For research conducted or funded by the Department of Defense (DOD), the research may proceed when the DoD institutions demonstrate to the Senior Designated Official (SDO) that the IRB has fulfilled its duties in accordance with Part 407 of Subpart D of Part 46 of Title 45, CFR, and Section 50.54 of Title 21, CFR. Work with the study investigator to contact the institution's assigned DOD point of contact (e.g. HRPO/HPA/EDO) for the study to determine next steps.

5.1.4 For all other research, refer to Section 5.3.

5.2 For research involving pregnant women, fetuses, or neonates, when using HRP-412 - PI WORKSHEET - Pregnant Women, HRP-413 - PI WORKSHEET - Non-Viable Neonates, and/or HRP-414 - PI WORKSHEET - Neonates of Uncertain Viability and the IRB determines the research meets the criteria for category §46.207 "*Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates*," proceed as follows:

5.2.1 For DHHS-regulated research, the research may proceed only after the Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in the FEDERAL REGISTER, has reviewed and approved the research. Contact OHRP OHRP@hhs.gov for additional information and the appropriate next steps.

5.2.2 For research conducted or funded by the Department of Defense (DOD), the research may proceed when the DoD institutions demonstrate to the Senior Designated Official (SDO) that the IRB has fulfilled its duties in accordance with Subpart B of 45 CFR §46 and the SDO must receive explicit written approval from the DoD Office of Human Research Protections (DOHRP). Work with the study investigator to contact the institution's DOD assigned point of contact (e.g. HRPO/HPA/EDO) for the study to determine next steps.

5.2.3 For all other research, refer to Section 5.3.

5.3 For research that is not otherwise approvable and not subject to regulatory approval by a government agency, proceed as follows:

5.3.1 Identify a panel of five or more experts in pertinent disciplines (e.g., science, medicine, education, ethics, and law) and relevant subject advocates to review the protocol.

5.3.2 Screen for Conflicting Interests of panel members and do not use panel members with a Conflicting Interest.

5.3.3 Inform potential experts that they will be asked to provide individual written recommendations and that their reports, as well as their identities, will be publicly available during the public review and comment period.

5.3.4 Publish in a form accessible to the public:

5.3.4.1 A request for written comments, including an Internet link to the protocol, relevant sections of grant applications, parental permission and assent documents, and relevant excerpts from the IRB minutes and correspondence.

5.3.4.2 The date and location of the expert panel meeting (to be held a minimum of 30 days after the notice is posted).

5.3.4.3 Indicate that the panel meeting will be open to the public and that the public will be given an opportunity to comment at the panel meeting.

5.3.4.4 Note that written comments on posted materials must be submitted at least 7 days before the day of the panel meeting to be considered by the panelists (which will allow the public 21 days to comment on posted materials);

5.3.4.5 Indication that the panelists' reports/recommendations (see below) will be posted 14 days after the panel meets.

5.3.4.6 Invite comments for up to 30 days after the meeting of the convened panel for review and consideration by the panel.

5.3.5 Open the meeting to the public.

5.3.6 After the convened panel discussion occurs and public comments are received, have each panel member write an independent recommendation as to whether the protocol should proceed, proceed with modifications, or not proceed.

5.3.7 Post panel reports on the organization's website for informational purposes for 30 days after the panel meeting.

5.3.8 Review the panel deliberations, reports, public comments, and make one of the following recommendations within 90 days of the convened panel meeting:

5.3.8.1 The organization approves support of the research as submitted;

5.3.8.2 The organization approves support of the research, but with required and/or recommended modifications; or

5.3.8.3 The organization disapproves support of the research.

5.3.9 Inform the IRB and the investigator.

5.3.10 Post the decision on the organization's Website.

6 MATERIALS

6.1 HRP-314 - WORKSHEET - Criteria for Approval

6.2 HRP-412 - PI WORKSHEET - Pregnant Women

6.3 HRP-413 - PI WORKSHEET - Non-Viable Neonates

6.4 HRP-414 - PI WORKSHEET - Neonates of Uncertain Viability

6.5 HRP-416 - PI WORKSHEET - Children

7 REFERENCES

7.1 45 CFR §46.207, 45 CFR §46.407

7.2 21 CFR §50.24(e), 21 CFR §50.54(b), 21 CFR §812.6

SOP: Conflicting Interests of IRB Members

1 PURPOSE

1.1 This procedure establishes the process to identify and manage Conflicting Interest of IRB members.

1.2 The process begins when an IRB member is asked to review an IRB submission.

1.3 The process ends when an IRB member has either identified a Conflicting Interest and notified IRB staff, or when an IRB member has determined that he or she does not have a Conflicting Interest.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 IRB members are responsible to know the definition of Conflicting Interest and self-identify when they have a Conflicting Interest.

4 RESPONSIBILITIES

4.1 IRB members (regular and alternate) follow these procedures.

5 PROCEDURE

5.1 Before reviewing research, IRB members are to determine whether they have a Conflicting Interest with research.

5.2 If an IRB member has a Conflicting Interest for review outside a meeting (e.g., the expedited procedure), he or she is to notify the IRB staff and return all materials.

5.3 If an IRB member has a Conflicting Interest for review of a submission for which he or she has been assigned as a primary or scientific reviewer, he or she is to notify the IRB staff so the submission can be re-assigned.

5.4 If an IRB member has a Conflicting Interest for review of research at a meeting, he or she is to notify the meeting chair, stay in the meeting room only to answer questions about the research, and to leave the meeting room for discussion and voting regarding that research.

6 MATERIALS

6.1 None

7 REFERENCES

7.1 21 CFR §56.107(e)

7.2 45 CFR §46.107(e)

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SOP: Consultation

1 PURPOSE

1.1 This procedure establishes the process for the IRB to obtain consultants.

1.2 The process begins when the IRB staff or IRB member has identified the need for consultation.

1.3 The process ends when the consultant has provided additional expertise to the IRB.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Summary of Changes:

2.1.1 Added reference to Staff Reviewer in 4.2.

2.1.2 Added reference to Director or Designee responsibility in 4.3.

2.2 Reason for Change: HRP Toolkit version 5.4 released December 2025.

2.3 Prior Version: 09/01/2025.

3 POLICY

3.1 The IRB invites consultants with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB.

3.2 Consultants with a Conflicting Interest may not provide information to the IRB.

4 RESPONSIBILITIES

4.1 For review by a convened IRB, IRB staff members carry out these procedures.

4.2 For Non-Committee Review, the Designated Reviewer or Staff Reviewer carries out these procedures.

4.3 For external consultants, the IRB Director or designee will be responsible for the onboarding procedures 5.2 and 5.3.

5 PROCEDURE

5.1 Identify a consultant with the required expertise who can provide a review. Identify individuals as follows:

5.1.1 IRB members from other committees

5.1.2 Other employees of the organization

5.1.3 External consultants

5.2 Contact the consultant and determine availability for review.

5.3 Determine whether the consultant has a Conflicting Interest as defined in HRP-001 - SOP – Definitions. If so, obtain another consultant.

5.4 Use HRP-301 - WORKSHEET - Review Materials to determine which documents to make available to the consultant so the IRB can obtain the additional expertise needed, and make these documents available to the consultant. If the additional expertise needed does not require review of any materials, no materials need be provided.

5.5 For review by the convened IRB:

5.5.1 Make the consultant's written comments, if any, available to the IRB members attending the meeting.

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5.5.2 If the consultant did not provide a written report or if requested by an IRB member, invite the consultant to the IRB meeting.

5.6 For Non-Committee Review:

5.6.1 Directly obtain the information (oral or written) from the consultant.

5.6.2 Document information received with the name of the consultant.

6 MATERIALS

6.1 HRP-001 - SOP - Definitions

6.2 HRP-301 - WORKSHEET - Review Materials

7 REFERENCES

7.1 21 CFR §56.107(f)

7.2 45 CFR §46.107(e)

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SOP: Post-Review

1 PURPOSE

1.1 This procedure establishes the process for communications after a protocol is reviewed.

1.2 The process begins when:

1.2.1 A Designated Reviewer has completed a Non-Committee Review and provided completed materials to the IRB staff; OR

1.2.2 An IRB meeting has adjourned, and the IRB chair or IRB manager has approved the minutes; OR

1.2.3 An IRB staff member has verified that modifications required to secure approval have been made.

1.3 The process ends when all correspondence related to IRB determinations and actions have been sent and additional tasks have been completed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Summary of Changes:

2.1.1 Added steps in the Procedures section to execute the NIJ Privacy Certificate.

2.1.2 Added 45 CFR §46.109(d) and 21 CFR §56.109(e) re: notifications to the References section (consistent with activities identified in Item 13 in HRP-105).

2.1.3 Updated OHRP incident reporting form link in endnotes.

2.2 Reason for Change: HRP Toolkit version 5.4 released December 2025.

2.3 Prior Version: 09/01/2025.

3 POLICY

3.1 The IRB reports its findings and actions to the investigator.

3.2 The IRB reports its findings and actions to the institution through IRB minutes, accessible to the Institutional Official.

3.3 When the IRB disapproves research, it provides the investigator with a statement of the reasons for the decision and gives the investigator an opportunity to respond in person or in writing.

3.4 Communication of review results to investigators are to be completed within 10 business days of the IRB meeting or 10 business days following the receipt of the completed Non-Committee Review materials.

3.5 When a modification is reviewed to lift a suspension for a previous Suspension of IRB Approval, the state of the study will change from “Suspended” to “Approved” when the modification is approved.

3.6 Reporting of Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; and Unanticipated Problem Involving Risks to Subjects or Others to outside agencies is to take place within 30 business days from the determination of a reportable problem.

3.6.1 Reporting to OHRP only occurs for non-exempt Human Research that:

3.6.1.1 Is HHS-supported or conducted;

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3.6.1.2 Is conducted or supported by a Federal Agency that has adopted the Common Rule and has not approved a separate assurance, other than the FWA, for the research; OR

3.6.1.3 The institution has chosen to apply the Common Rule on its FWA to all its non-exempt Human Research regardless of the source of support.

3.6.2 Reporting to the FDA only occurs for FDA-regulated Human Research.

3.6.3 Reporting to OHRP or the FDA should not occur if any of the above criteria are not met.

3.7 If the report is determined to be an unanticipated problem involving risk to subjects or others for a multi-site study AND did not occur locally (meaning at any site under this IRB's purview) (e.g. the sponsor submits a protocol modification that includes a newly identified risk), reporting to OHRP and the FDA is not required.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 If the Non-Committee Review indicated a Conflicting Interest or a lack of expertise, follow HRP-031 - SOP - Non-Committee Review Preparation.

5.2 For initial reviews, continuing reviews, or modifications:

5.2.1 If the communication is an IRB determination of Approved:

5.2.1.1 For DHHS-regulated research involving prisoners, if HRP-415 – PI WORKSHEET – Prisoners reflects prisoners as a class or prisoners as controls, await OHRP approval before proceeding.

5.2.1.2 For NIJ-supported research, send the IRB approved Privacy Certificate to the IRB Chair or authorized institutional representative for signature.

5.2.1.2.1 Execute "Add Comment" and upload the signed Privacy Certificate to Supporting Documents; send notification to the PI/PI Proxy/Primary Contact.

5.2.1.3 Execute the "Finalize Documents" to stamp and accept all changes for attached documents.

5.2.1.4 Execute the "Prepare Letter" activity and modify the letter as needed.

5.2.1.5 Execute the "Send Letter" activity.

5.2.2 If the communication is an IRB determination other than Approved:

5.2.2.1 Execute the "Prepare Letter" activity and modify the letter as needed.

5.2.2.2 Execute the "Send Letter" activity.

5.3 Refer to HRP-303 - WORKSHEET - Communication of Review Results to determine if any paper-based letters need to be sent.

5.3.1 Have letter signed by the signatory in the template letter.

5.3.2 Send the letter to the inside addresses and cc list as directed by the letter.

5.4 For continuing reviews or modifications to studies where enrollment is suspended and the submission does not change the enrollment suspension status, execute the "Suspend" activity in the study workspace, and document that the enrollment to the study remains suspended.

5.5 For determinations of Serious Non-Compliance; Continuing Non-Compliance; Suspension of IRB Approval; Termination of IRB Approval; or Unanticipated Problem Involving Risks to Subjects or Others:

5.5.1 If the determination was Serious Non-Compliance; Continuing Non-Compliance; or Unanticipated Problem Involving Risks to Subjects or Others:

5.5.1.1 Execute the "Prepare Letter" activity and modify the appropriate letter as needed.

5.5.1.2 Execute the "Send Letter" activity.

5.5.2 If the determination was Suspension of IRB Approval:

5.5.2.1 Execute the “Suspend” activity in the study workspace.

5.5.2.2 Execute the “Prepare Letter” activity in the study workspace and modify the letter as needed.

5.5.2.3 Execute the “Send Letter” activity.

5.5.3 If the determination was Termination of IRB Approval:

5.5.3.1 Execute the “Terminate” activity in the study workspace.

5.5.3.2 Execute the “Prepare Letter” activity in the study workspace and modify the letter as needed.

5.5.3.3 Execute the “Send Letter” activity.

5.5.4 When reporting to OHRP only, complete the *OHRP Incident Report Form*[i].

5.5.5 If reporting to both OHRP and any other outside agency concurrently, utilize the OHRP Incident Report Form email confirmation and HRP-520a - LETTER - External Report – OHRP and Other Agencies.

5.5.6 If reporting to other outside agencies NOT including OHRP, complete HRP-520 - LETTER - External Report NOT Including OHRP.

6 MATERIALS

6.1 HRP-031 - SOP - Non-Committee Review Preparation

6.2 HRP-303 - WORKSHEET - Communication of Review Results

6.3 HRP-520 - LETTER - External Report NOT Including OHRP

6.4 HRP-520a - LETTER - External Report OHRP and Other Agencies

7 REFERENCES

7.1 45 CFR §46.103(b)(4)(i), 45 CFR §46.109(d), 45 CFR §46.207, 45 CFR §46.305(c), 45 CFR §46.306(a)(1), 45 CFR §46.407, Informed Consent Requirements in Emergency Research (OPRR Letter, 1996)

7.2 21 CFR §56.108(a)(1), 21 CFR §109(e), 21 CFR §50.24(e), 21 CFR §50.54(b), 21 CFR §812.66

7.3 VHA Directive 1058.01 October 22, 2020

[i] https://oashsps.my.site.com/ohrpwebforms/s/incident-web-form

SOP: Institutional Conflicts of Interest

1 PURPOSE

1.1 This procedure establishes the process to identify institutional financial interests that may cause an institutional conflict of interests.

1.2 The process begins when the Organizational Official/ Institutional Official (IO/OO) or designee is informed of a change in the institution's financial holdings outside of standard investments.

1.3 The process ends when the IRB staff are provided an updated list of the institution's financial holdings.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 An institutional financial conflict of interests exists when any of the following might affect the design, conduct, or reporting of research:

- 3.1.1 Licensing, technology transfer, patents
- 3.1.2 Investments of the organization
- 3.1.3 Gifts to the organization when the donor has an interest in the research
- 3.1.4 Financial interests of senior administrative officials
- 3.1.5 Other financial interests

3.2 Senior administrative officials are required to disclose their financial interests to the Conflict of Interests Officer:

- 3.2.1 Upon joining the organization
- 3.2.2 Every year
- 3.2.3 When there are changes to financial interests

3.3 The Technology Transfer Office, Sponsored Projects, legal counsel, and the Conflict of Interests Officer are to notify the IO/OO or designee of any change in the institution's financial holdings not controlled by the institution's investment managers related to:

- 3.3.1 Licensing (e.g., licensing or technology transfer agreements)
- 3.3.2 Investments of the organization
- 3.3.3 Gifts to the organization when the donor has an interest in the research
- 3.3.4 Financial interests of senior administrative officials
- 3.3.5 Other financial interests

3.4 The fiduciary responsibility of the institution's investment managers is to maintain a diversified portfolio of holdings that that meets the institution's goals in terms of capital appreciation, income, and risk. IO/OO may not influence the decisions of the institution's investment managers. This institution considers such investments to be similar to diversified mutual funds and not subject to disclosure under this policy.

3.5 The evaluation and management of an institutional conflict of interest may not vary by funding or regulatory oversight.

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3.6 If an institutional financial holding related to prospective or ongoing Human Research is identified, it will be managed according to HRP-055 - SOP - Financial Conflicts of Interests.

4 RESPONSIBILITIES

4.1 The IO/OO or designee carries out these responsibilities.

5 PROCEDURE

5.1 Upon receipt of information of a change in financial interest update the list of investments that are not controlled by the institution’s investment managers. Include information about the name of the company, the names of related companies, and affected products or services.

5.2 Provide a copy of the updated list to the IRB staff.

6 MATERIALS

6.1 HRP-055 - SOP - Financial Conflicts of Interests

7 REFERENCES

None.

SOP: Financial Conflicts of Interest

1 PURPOSE

1.1 This procedure establishes the process to evaluate a report of an individual financial interest of an investigator or research staff Related to the Research.

1.2 The process begins when COI Office determines that an investigator or research staff has reported a financial interest Related to the Research.

1.2.1 IRB staff may detect an institutional conflict of interest. This will be handled outside of the COI Office. IRB staff may request a non-UCI COI Office or non-UCI IRB assist in the review of the reported interest and impact on the research.

1.3 The process ends when the UCI Conflict of Interest Oversight Committee (COIOC) has evaluated the reported interest and communicated the results of this evaluation to the IRB.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 Individuals engaged in human subjects research by doing one or more of the following in a human subjects research project:

3.1.1 Intervenes with subjects by performing research procedures, or by manipulating the environment for research purposes;

3.1.2 Participates in the recruitment and/or selection of subjects;

3.1.3 Participates in the informed consent process;

3.1.4 Collects or reports subject identifiable data; and/or

3.1.5 Have access to subject identifiable study data or identifiable specimens.

3.2 Individuals subject to this policy are required to disclosable their financial interests Related to the Research:

3.2.1 On submission of an initial review.

3.2.2 When adding new research personnel, only the new Researchers must disclose.

3.2.3 When a Researcher has acquired or discovered a new disclosable financial interest (e.g., through purchase, marriage, or inheritance) that relates to an active IRB protocol(s).

3.3 Disclosable financial interest: An outside financial interest that needs to be disclosed and reviewed by the COIOC includes one or more of the following for the researcher, their spouse/registered domestic partner and/or dependent children:

3.3.1 Income greater than $10,000 received from a single entity (excluding UC Regents) over the twelve months prior to disclosure. Income includes salary, consultant payments, honoraria, royalty payments, dividends, or any other payments or consideration with value, including payments made to the University of California Health Sciences Compensation Plans.

3.3.2 Equity in a publicly-traded entity greater than $10,000 (current market value) or greater than a 5% ownership interest. Equity includes stock or stock options, real estate, or any other investment or ownership interest. Equity does not include investments in a mutual fund,

pension fund or other investment fund over which the Researcher or his/her immediate family member do not exercise any control.

3.3.3 Any equity in a non-publicly-traded entity, including stock or stock options, or any other investment or ownership interest.

3.3.4 Any management position, such as Board of Directors, director, officer, partner or trustee.

3.3.5 Intellectual property interest in a patent, patent application, or a copyright of software assigned or to be assigned to a party other than the UC Regents held by the Researcher, their spouse/registered domestic partner and/or dependent children

3.4 For Veterans Administration (VA) research:

3.4.1 Veterans Administration (VA) facilities are not required to follow PHS requirements, even when research is funded by a PHS agency (e.g., NIH).

3.4.2 When serving as the IRB of record for a VA facility, the VA financial conflict of interest form must be used, and the form may not be created, re-drafted, or changed.

4 PROCEDURE

4.1 COIOC will review the disclosures and provide a recommendation for disclosure including language for the consent.

4.2 COIOC will provide the IRB staff of the reviewing IRB with recommendation so the IRB can either accept the recommendation as is or make further modifications to ensure the rights and welfare of the participants are adequately protected.

4.3 The IRB will have final authority to decide whether an investigator's financial interest and the COIOC management plan, if any, allow the research to be approved.

4.4 When required provide the final determination to the funding or regulatory agencies.

4.5 Maintain a copy of determinations and management plans in the records.

5 MATERIALS

5.1 None

6 REFERENCES

6.1 42 CFR §50

6.2 45 CFR §94

6.3 UCI Administrative Policies and Procedures Policy Section 481-3 Conflicts of Interest in Human Subjects Research

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SOP: Annual Evaluations of the HRPP

1 PURPOSE

1.1 This procedure establishes the process to conduct annual evaluations of the Human Research Protection Program (HRPP).

1.2 The process begins the first business day of each June.

1.3 The process ends when all evaluations have been completed and communicated to those evaluated.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Summary of Changes:

2.1.1 Updated Section 5.2 to directly reference HRP-065 - SOP - Continuity Planning for HRPP Disruptions. Added HRP-065 to the Materials section.

2.1.2 Revised 'IRB staff' to 'IRB Manager or designee' in the Responsibilities section.

2.1.3 Modified statements re: IRB registration and FWA status to reference HRP-080 - SOP - IRB Formation and Registration.

2.1.4 Added statements to verify the IRB roster is up-to-date and assess outstanding toolkit updates. Added HRP-071 and HRP-601 to the Materials section.

2.2 Reason for Change: HRP Toolkit version 5.4 released December 2025.

2.3 Prior Version: 09/01/2025.

3 POLICY

3.1 The human research protection program is evaluated annually.

3.2 The subject outreach program for enhancing the understanding of subjects, prospective subjects, and communities is accomplished through this HRP webpage.

4 RESPONSIBILITIES

4.1 The IRB Manager or their designee ensures completion of these procedures.

5 PROCEDURE

5.1 Have the Institutional Official/ Organizational Official (IO/OO) or designee evaluate the following resources provided to the human research protection program and make adjustments as part of the budgeting process.

5.1.1 Space

5.1.2 HRPP educational program

5.1.3 Legal counsel

5.1.4 Conflicts of interests

5.1.5 Quality improvement plan

5.2 Have the IO/OO or designee evaluate HRP-065 - SOP - Continuity Planning for HRPP Disruptions and make changes when appropriate.

5.2.1 When updates to HRP-065 - SOP - Continuity Planning for HRPP Disruptions are made, the IRB Director will designate appropriate IRB staff to make changes to associated educational materials for the HRPP research community.

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5.3 Have the IO/OO or their designee establish the annual compliance, quality, efficiency and effectiveness goals of the HRPP using HRP-603 - DATABASE - Quality and Compliance Improvement Tracker.

5.3.1 Review progress made towards the previous year's program goals.

5.3.2 Revise existing goals and/or create new goals.

5.4 Evaluate whether the number of IRBs is appropriate to the volume and types of research reviewed.

5.4.1 Provide a copy of the evaluation to the IO/OO or designee.

5.4.2 If the number of IRBs is not appropriate to the volume and types of research reviewed, work with the IO/OO or designee to modify the IRB structure.

5.5 Have the IO/OO or designee evaluate the knowledge, skills, and performance of each IRB chair using HRP-326 - WORKSHEET - Performance Evaluation for IRB Chairs.

5.5.1 Communicate the results of the evaluation to each IRB chair and the IO/OO or designee.

5.5.2 If needed, work with each IRB chair to develop a plan to improve the individual's knowledge, skills, and performance.

5.6 Have the IRB chair or IRB manager evaluate the knowledge, skills, and performance of each regular and alternate IRB member using HRP-327 - WORKSHEET - Performance Evaluation for IRB Members.

5.6.1 Have the IRB Chair or IRB Manager utilize HRP-327 - WORKSHEET - Performance Evaluation for IRB Members to complete the evaluation. Communicate the results of the evaluation to each IRB member and the IO/OO or designee.

5.6.2 Send a copy of HRP-562 - LETTER - IRB Member Appreciation to the IRB member's supervisor.

5.6.3 If needed, work with each IRB member to develop a plan to improve the individual's knowledge, skills, and performance.

5.7 Follow the Human Resources annual employee evaluation process to evaluate the knowledge, skills, and performance of IRB staff. Use HRP-328 - WORKSHEET - Performance Evaluation for IRB Staff as part of the evaluation.

5.7.1 If needed, work with each IRB staff person to develop a plan to improve the individual's knowledge, skills, and performance.

5.8 Verify IRB registrations are current, consistent with HRP-080 - SOP - IRB Formation and Registration.

5.9 Verify the federalwide assurance (FWA) is current, consistent with HRP-080 - SOP - IRB Formation and Registration.

5.10 Verify HRP-601 - WORKSHEET - IRB Roster is current and use HRP-304 - WORKSHEET - IRB Composition to evaluate whether the composition of the IRB meets regulatory and organizational requirements.

5.10.1 Provide a copy of the evaluation to the IO/OO or designee.

5.10.2 If the composition of an IRB does not meet regulatory and organizational requirements, work with the IO/OO or designee to modify the IRB composition.

5.11 Check whether each member of a Veteran's Administration (VA) IRB or VA representative has been a member longer than 2 years, and if so, send the member HRP-560 - LETTER - IRB Member Appointment.

5.12 Evaluate whether there are outstanding updates that need to be made to standard operating procedures and associate checklists and worksheets.

5.12.1 If needed, work with IRB staff to develop a plan to implement necessary updates consistent with HRP-071-SOP-Toolkit Management.

5.13 Evaluate the subject outreach plan.

5.13.1 Consider the following areas when evaluating the outreach plan:

5.13.1.1 Whether the existing scope and content of HRPP outreach materials, including the HRP webpage;

5.13.1.2 Whether modifications to existing outreach materials are necessary;

5.13.1.3 Whether or not the HRPP's existing materials are being regularly utilized by the IRB Office or by members of the research community in their own interaction with the communities in which they conduct research;

5.13.1.4 Whether there are new opportunities to provide outreach activities to the community, and;

5.13.1.5 Whether additional information is needed from the research community to assess the extent to which outreach materials are used and outreach activities take place.

5.13.2 Provide a copy of the evaluation to the IO/OO or designee.

5.13.3 If the subject outreach program is not meeting organizational goals, work with the IO/OO or designee to modify the plan. Modifications may include, but are not limited to:

5.13.3.1 Modifying existing outreach materials;

5.13.3.2 Developing new materials;

5.13.3.3 Surveying the research community to identify and participate in additional outreach opportunities, and;

5.13.3.4 Working directly with community organizations to identify and participate in additional outreach opportunities.

6 MATERIALS

6.1 HRP-065 - SOP - Continuity Planning for HRPP Disruptions

6.2 HRP-071 - SOP - Toolkit Management

6.3 HRP-080 - SOP - IRB Formation and Registration

6.4 HRP-304 - WORKSHEET - IRB Composition

6.5 HRP-326 - WORKSHEET- Performance Evaluation for IRB Chairs

6.6 HRP-327 - WORKSHEET - Performance Evaluation for IRB Members

6.7 HRP-328 - WORKSHEET - Performance Evaluation Criteria for IRB Staff

6.8 HRP-560 - LETTER - IRB Member Appointment

6.9 HRP-562 - LETTER - IRB Member Appreciation

6.10 HRP-601 - DATABASE - IRB Roster

6.11 HRP-603 - DATABASE - Quality and Compliance Improvement Tracker

SOP: Quarterly Evaluations of the HRPP

1 PURPOSE

1.1 This procedure establishes the process to conduct quality improvement of the Human Research Protection Program (HRPP).

1.2 The process begins the first business day of each quarter.

1.3 The process ends when all evaluations have been completed and if needed, acted upon.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Summary of Changes:

2.1.1 Revised 'IRB staff' to 'IRB Manager or designee' in the Responsibilities section.

2.1.2 Modified the Procedures section to combine statements at re: reviewing results/examining for trends identified via HRP-430 - WORKSHEET - Investigator Quality Improvement and HRP-431 - WORKSHEET - Minutes Quality Improvement into one statement, thereby removing duplicative content.

2.1.3 Additional editorial corrections.

2.2 Reason for Change: HRP Toolkit version 5.4 released December 2025.

2.3 Prior Version: 09/01/2025.

3 POLICY

3.1 The goal of the quality improvement plan is to achieve and maintain compliance and to achieving targeted levels of quality, efficiency, and effectiveness of the HRPP.

3.2 Objectives of the quality improvement program are to:

3.2.1 Improve compliance of investigators with their responsibilities.

3.2.2 Improve compliance of minutes with regulatory compliance.

3.2.3 Increase efficiency of recording and finalizing minutes.

3.3 The measures of the quality improvement program are defined in:

3.3.1 HRP-430 - WORKSHEET - Investigator Quality Improvement Assessment

3.3.2 HRP-431 - WORKSHEET - Minutes Quality Improvement Assessment

4 RESPONSIBILITIES

4.1 The IRB Manager or their designee ensures completion of these procedures.

5 PROCEDURE

5.1 Conduct Investigator QI Assessment:

5.1.1 At least quarterly, complete HRP-534 - LETTER - Investigator QI Assessment and send HRP-430 - WORKSHEET - Investigator Quality Improvement Assessment to 10 investigators.

5.2 Complete HRP-431 - WORKSHEET - Minutes Quality Improvement Assessment on the minutes of the previous quarter. Track compliance and the days required to complete minutes.

5.3 Review the results of HRP-430 - WORKSHEET - Investigator Quality Improvement Assessment and HRP-431 - WORKSHEET - Minutes Quality Improvement Assessment to track results and examine for significant trends.

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5.4 Send the results to the IRB manager and Institutional Official/ Organizational Official (IO/OO) or designee.

5.4.1 If the results of any evaluations demonstrate inconsistency, recurring noncompliance or misinterpretation of HRPP requirements, high variability, or are outside performance targets, work with the IRB manager and IO/OO to implement an intervention.

5.4.2 Interventions may include policy and procedure modifications, education and training efforts, system modifications, and/or other corrective actions.

5.4.3 Document and track the intervention using HRP-603 - DATABASE - Quality and Compliance Improvement Tracker.

6 MATERIALS

6.1 HRP-430 - WORKSHEET - Investigator Quality Improvement Assessment

6.2 HRP-431 - WORKSHEET - Minutes Quality Improvement Assessment

6.3 HRP-534 - LETTER - Investigator QI Assessment

6.4 HRP-603 - DATABASE - Quality and Compliance Improvement Tracker

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SOP: Expiration of IRB Approval

1 PURPOSE

1.1 This procedure establishes the process for a Designated Reviewer to determine whether current subjects may continue in expired research.

1.1.1 The expiration date (the last day the research is approved) is the last day of the approval period. Research may be conducted on the expiration date but may not be conducted after the expiration date without re-approval. For example, if the approval period is April 27, 2025-April 11, 2026, the expiration date is April 11, 2026. Research must stop at 11:59PM on April 11, 2026 unless IRB re-approval has been received.

1.2 The process begins when the Designated Reviewer is notified of a request by an investigator of a request for current subjects to continue in expired research.

1.3 The process ends when the Designated Reviewer has communicated a decision and documented the decision in writing.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 If research is granted “Modifications Required to Secure Approval” and expires before responsive materials are reviewed and approved, these procedures are to be followed.

4 RESPONSIBILITIES

4.1 A Designated Reviewer is responsible to follow these procedures.

5 PROCEDURE

5.1 Do not allow new subjects to be enrolled under any circumstances.

5.2 Determine from the investigator which subjects need to continue in the expired research, what procedures are being requested to continue, and why. The IRB Chair or IRB Vice-Chair or their designee(s) will review the request. Use the ‘Comment’ feature within the study workspace to obtain the information needed. Use text from HRP-532-Letter and paste within the Comment box.

5.3 Determine which subjects can continue in the research based on these principles:

5.3.1 In general, research procedures should be safely discontinued.

5.3.2 In general, the only research procedures that should continue are those that are not available outside of the research context and it is in the subject’s best interest to continue these procedures. If the required procedures can be provided as standard of care, these should be provided as such.

5.3.3 In general, research procedures conducted to collect data with no direct benefit to the subject should not continue.

5.3.4 In some cases, an ethical issue may be raised where the above general principles may not be followed.

5.4 In the case of Veterans Administration (VA) research, have the IRB chair determine within 2 business days whether participants may continue participating in the research interventions or interactions.

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5.5 Communicate with the investigator using template text contained within HRP-532 - LETTER - Conti Subj Expired Research.

6 MATERIALS

6.1 HRP-532 - LETTER - Conti Subj Expired Research

7 REFERENCES

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SOP: NIH Genomic Data Sharing (GDS) Institutional Certification

1 PURPOSE

1.1 This procedure establishes the process to certify approval for investigator submission of large-scale human genomic data to an NIH-designated data repository.

1.2 The process begins when an investigator contacts IRB staff for certification of the genomic data sharing plan.

1.3 The process ends when the Institutional Official/ Organizational Official (IO/OO) or designee has certified and communicated to the investigator.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Summary of Changes: Updated NIH hyperlinks in References re: Institutional Certification.

2.2 Reason for Change: HRP Toolkit version 5.4 released December 2025.

2.3 Prior Version: 09/01/2025.

3 POLICY

3.1 Investigators must request certification from IRB staff prior to investigator submission of large-scale human genomic data or approval of funding.

4 RESPONSIBILITIES

4.1 The IRB Director or designee verifies for the IO/OO that all data meet criteria for submission to the data repository.

5 PROCEDURE

5.1 Use HRP-332 - WORKSHEET - NIH GDS Institutional Certification to evaluate and document whether the investigator's genomic data sharing plan meets the criteria for submission to a NIH-designated data repository.

5.2 Populate the applicable NIH Extramural Institutional Certification form. Pass the letter to the IO/OO or designee for review and certification.

5.2.1 Provide NIH Provisional Institutional Certification when required by investigators prior to IRB review of the data sharing plan.

5.3 Save a copy of the signed form in IRB Office records.

5.4 Communicate certification approval to the investigator and provide a copy of the signed GDS Institutional Certification form for the investigator to forward to the NIH.

6 MATERIALS

6.1 HRP-332 - WORKSHEET - NIH GDS Institutional Certification

7 REFERENCES

7.1 National Institutes of Health Final Genomic Data Sharing Policy (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html)

7.2 NIH Institutional Certifications (https://grants.nih.gov/policy-and-compliance/policy-topics/sharing-policies/gds/institutional-certifications)

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SOP: Continuity Planning for HRPP Disruptions

1 PURPOSE

1.1 This SOP establishes the process for initiating a response to an emergency, disaster, or other disruptive event impacting the HRPP or essential HRPP operations. Challenges to HRPP operations or the conduct of Human Research may arise, for example, from:

1.1.1 Extreme weather events.

1.1.2 Natural disasters.

1.1.3 Man-made disasters.

1.1.4 Infectious disease outbreaks.

1.1.5 Loss or failure of facilities, equipment and/or information security standards.

1.1.6 Significant and unexpected loss of institutional funding and/or workforce.

1.2 The process starts when an emergency/disaster situation or other significant disruption impacting the HRPP has occurred, or in preparation for scenarios where a potential emergency situation or significant disruption is imminent and HRPP operations and/or the ability of investigators to conduct Human Research is, or is likely to be, adversely impacted.

1.3 The process ends when the impact to the HRPP and the conduct of Human Research is assessed, and appropriate guidance is provided to HRPP personnel and the broader Human Research community.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Summary of Changes: Revised SOP to more broadly address business continuity (i.e., include scenarios such as mass funding cuts and/or loss of facilities). Specific updates include:

2.1.1 Updated SOP title;

2.1.2 Expanded list of disruptive event examples in 1.1;

2.1.3 Additional content in 5.1.2 re: circumstances that may warrant postponing study activities by the IO/OO;

2.1.4 Clarification in 5.2.2.1 re: prioritization of IRB reviews;

2.1.5 Clarifications and editorial revisions throughout to accommodate the broadened scope; and

2.1.6 Updated the Materials section consistent with remainder of the document, as well as updates to other related Toolkit documents.

2.2 Reason for Change: HRP Toolkit version 5.4 released December 2025.

2.3 Prior Version: 09/01/2025.

3 POLICY

3.1 HRPP leadership defers to designated institutional leadership and institution-wide emergency response planning and limits HRPP-specific emergency response planning only to those areas of operations or human research protections not otherwise covered by institution-level plans.

3.2 The HRPP evaluates its emergency response plans at least annually in accordance with the HRP-101 - Human Research Protection Program Plan and HRP-060 - SOP - Annual Evaluations of the HRPP.

4 RESPONSIBILITIES

4.1 The IRB Director or designee is responsible for carrying out these procedures.

5 PROCEDURE

5.1 If an emergency/disruption has occurred, or there is an imminent possibility of an upcoming emergency/disruption, assess the nature of the event and the appropriate response.

5.1.1 Consult HRP-101 - Human Research Protection Program Plan to reference existing HRPP specific or institution specific emergency preparedness plans or information already in place.

5.1.2 Contact the IO/OO and/or designated institutional personnel responsible for institutional level emergency preparedness, where applicable, and determine whether there are (or will be) institution level emergency preparedness plans relevant to the current or anticipated emergency.

5.1.2.1 If yes, proceed in accordance with those plans and determine whether further actions and/or notification specific to the human research community is necessary.

5.1.2.2 Based on the nature of the emergency/disruption, further action may include determining the types of studies for which study initiation should be postponed, the types of studies for which recruitment should be halted but research activities continued with existing subjects, and the types of studies that can continue via alternate mechanisms. In making this determination, consider whether the study:

5.1.2.2.1 Presents a likelihood of direct benefit to subjects;

5.1.2.2.2 Does not involve interaction or intervention that creates increased risk;

5.1.2.2.3 Involves direct interaction or intervention but can manage risks by conducting study procedures via alternate mechanisms;

5.1.2.2.4 Will have an adverse impact on resources required to address the emergency/disruption.

5.2 Assess whether the emergency/disruption has or could impact IRB operations:

5.2.1 If the current or anticipated emergency/disruption will prevent any upcoming IRB meetings from properly convening in-person, and an in-person meeting was planned, determine whether the meeting can be conducted virtually or via teleconference.

5.2.1.1 If yes, work with IRB members and staff to arrange for a virtual meeting. Follow HRP-040 - SOP - IRB Meeting Preparation to confirm quorum and availability of IRB members.

5.2.1.2 If a virtual meeting is also not feasible under the circumstances caused by the emergency/disruption, determine whether to cancel or reschedule the meeting(s).

5.2.1.3 If currently approved Human Research has or will expire prior to IRB review due to the IRB meeting cancelation/rescheduling, follow HRP-063 - SOP - Expiration of IRB Approval.

5.2.2 If IRB staff will be unable to complete their protocol processing and review responsibilities during the emergency/disruption, or if capacity will be limited for a period of time:

5.2.2.1 Work with the staff to use any available capacity to prioritize processing submissions related to assuring the safety of research subjects. E.g., continuing review submissions and submissions (new studies, modifications, and reportable new information) related to responding to and/or mitigating risks resulting from the emergency/disruption.

5.2.2.2 If currently approved Human Research has or will expire prior to IRB review due to IRB office capacity limitations follow HRP-063 - SOP - Expiration of IRB Approval.

5.2.2.3 Work with the IO/OO to notify the research community of the IRB Office's limited capacity to process and review submissions.

5.2.2.4 When the emergency/disruption no longer presents a limitation to IRB Office functions, work with the IO/OO to notify IRB members and staff and the research community that normal business operations have resumed.

5.2.3 If the impact to local IRB operations will be extensive or long-lasting, determine whether reliance on an external IRB(s) is required.

5.2.3.1 If reliance on one or more external IRBs is required and the necessary reliance agreements are not currently in place, work with the IO/OO to identify appropriate candidates for external IRB reliance and follow HRP-801 - SOP - Establishing Reliance Agreements.

5.2.4 If data or records (paper or electronic) are unavailable during the current or anticipated emergency/disruption, implement alternative procedures to access and back up data/records. Consult with local IT support and/or electronic system vendors, when appropriate.

5.3 Assess whether the emergency/disruption necessitates additional flexibility in IRB review processes. If yes:

5.3.1 Review HRP-352 - WORKSHEET - Additional Emergency-Disruption Review Considerations with the IRB Chair(s) and staff in advance of upcoming IRB meetings.

5.3.2 Communicate to IRB Members (including Designated Reviewers performing non-committee reviews) that the additional considerations in the worksheet may be incorporated into IRB reviews where appropriate to maximize regulatory flexibility while continuing to ensure research subject safety during the emergency/disruption.

5.3.3 Determine whether additional communications to the research community are necessary to inform investigators of any additional measures the IRB will take to maximize regulatory flexibility during the emergency.

5.4 Assess whether the emergency/disruption has or could impact some or all investigators' ability to conduct Human Research. If yes:

5.4.1 Notify the research community of the need for protocol-specific emergency/disruption risk mitigation planning. Use HRP-542 - LETTER - Implementation of HRPP Emergency-Disruption Response Plan.

5.4.2 Provide investigators with copies of (or links to) HRP-108 - FLOWCHART - Study-Specific Emergency-Disruption Risk Mitigation Planning.

5.4.3 Provide investigators with copies of (or links to) HRP-351 - WORKSHEET - Protocol-Specific Emergency-Disruption Risk Mitigation Planning.

5.4.4 If the emergency/disruption has or could impact clinical care standards which could in turn impact research, develop guidance for researchers that clarifies what does and does not require IRB review (e.g., screening procedures mandated by the health care system in which a clinical trial is being conducted).

5.4.5 When the emergency/disruption no longer presents a limitation to Human Research activities, work with the IO/OO to notify the research community that normal business operations have resumed.

5.5 Evaluate whether the nature of the emergency/disruption has or could pose additional threats or risks to specific aspects of the broader HRPP. For example, man-made disasters, industrial accidents, or terrorist threats could potentially impact some chemical, biological, or radiologic facilities to a greater

extent than other facilities; cybersecurity attacks could broadly impact institutional data/records, and unanticipated cuts/freezes in funding and/or workforce could impact the ability to carry out HRPP responsibilities.

5.5.1 If yes, and if broader institution-level emergency preparedness measures do not already address these specific threats, work with the IO/OO and appropriate institutional leadership (e.g., Grants and Contracts Office, Billing Compliance, Facilities/Environmental Services, Information Technology) to escalate and address any additional threats or risks.

6 MATERIALS

6.1 HRP-040 - SOP - IRB Meeting Preparation
6.2 HRP-060 - SOP - Annual Evaluations of the HRPP
6.3 HRP-063 - SOP - Expiration of IRB Approval
6.4 HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN
6.5 HRP-108 - FLOWCHART - Study-Specific Emergency-Disruption Risk Mitigation Planning
6.6 HRP-351 - WORKSHEET - Protocol-Specific Emergency-Disruption Risk Mitigation Planning
6.7 HRP-352 - WORKSHEET - Additional Emergency-Disruption Review
6.8 HRP-542 - LETTER - Implementation of HRPP Emergency-Disruption Response Plan
6.9 HRP-801 - SOP - Establishing Reliance Agreements

SOP: Institutional Review Board Federal Inspections

1 PURPOSE

1.1 This procedure establishes the process to manage federal regulatory inspections of the IRB.

1.2 The process begins when the IRB is notified of an upcoming inspection.

1.3 The process ends when the regulatory agency notifies the IRB the inspection has concluded, based on the agency's procedures and the findings observed. E.g., the inspection process may conclude at the exit interview if no findings are observed, or additional determination letters/reports and further follow-up from the IRB may be required.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None - New SOP to support IRB inspections conducted by a federal agency.

3 POLICY

3.1 IRB records subject to oversight by the agency conducting the inspection are made accessible for inspection in accordance with HRP-072 - SOP - IRB Records Retention.

4 RESPONSIBILITIES

4.1 The Institutional Official/Organizational Official (IO/OO) is responsible for the acknowledgement and oversight of the IRB inspection. Additionally, is it the responsibility of the IO/OO to review any written response to findings raised during the inspection.

4.2 The IRB Manager or designee is responsible for carrying out these procedures.

5 PROCEDURE

5.1 If notification of the inspection is provided in advance, ask the inspector for the following details (if not provided):

5.1.1 Inspector's name and contact information.

5.1.2 Date and time the inspection will start.

5.1.3 Anticipated duration of the inspection.

5.1.4 In person or virtual.

5.1.5 Scope of the inspection and inspection type (i.e., surveillance/not-for-cause vs. directed/for-cause).

5.1.6 Any specific areas of concern, materials or files to have available for review, and/or individuals they will interview.

5.2 Notify the IO/OO, IRB chair(s), IRB members, IRB staff, and all other pertinent parties of the inspection.

5.2.1 If applicable, notify IT the inspector will need read-only access to applicable studies within the electronic system, based on the agency conducting the inspection.

5.2.2 Notify Huron Consulting Group of the inspection.

5.3 Communicate expectations and responsibilities of IO/OO, IRB chair(s) and IRB staff during, and in preparation of, the inspection.

5.3.1 The IO/OO, IRB chair(s), and IRB Manager should be available for interview (including the entrance and exit interviews) and/or consultation during the inspection.

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5.3.2 Designate at least one senior level staff member to be the inspector's point of contact, responsible for:
- 5.3.2.1 Participating in the entrance briefing.
- 5.3.2.2 Answering questions on behalf of the institution.
- 5.3.2.3 Always being available to the inspector during the inspection.
- 5.3.2.4 Locating all requested information and/or individuals the inspector requests interviews with.
- 5.3.2.5 Preparing documents.
- 5.3.2.6 Making copies.
- 5.3.2.7 Debriefing with the inspector.
- 5.3.2.8 When necessary, assigning additional staff members the responsibility of supporting the point of contact (e.g., in locating information, making copies, and/or providing IT expertise when inspections are conducted remotely).

5.4 Prepare to provide the following to the inspector:

5.4.1 HRPP Toolkit documents including all SOPs, general documents, forms, worksheets, and checklists.
- 5.4.1.1 Review HRP-105 - OHRP FDA Written Procedure Crosswalk to ensure all information is correct and includes up-to-date document versions.

5.4.2 Recent updates to the IRB registration and federalwide assurance (FWA) in accordance with HRP-080 - SOP - IRB Formation and Registration and HRP-081 - SOP - IRB Removal.

5.4.3 A list of active protocols subject to oversight by the agency conducting the inspection.
- 5.4.3.1 Include/identify any protocols meeting criteria specifically requested by the inspector (e.g. studies involving children).

5.4.4 IRB membership records, including HRP-601 - DATABASE - IRB Roster.

5.4.5 IRB meeting minutes.
- 5.4.5.1 Minutes that have not yet been finalized should be identified as drafts.

5.4.6 Organizational (or personnel) charts identifying:
- 5.4.6.1 The IRB office within the institutional reporting structure.
- 5.4.6.2 IRB staff within the IRB's reporting structure.

5.4.7 IRB records, as identified in HRP-070 - SOP - IRB Records.
- 5.4.7.1 If an electronic submission system is utilized, determine whether the inspector will be provided read-only access or hard copy files.

5.4.8 If the inspection is occurring on-site:
- 5.4.8.1 A private office or conference room for the inspector to work in that, when possible, is not located directly in the IRB office but in the vicinity and is spacious enough to accommodate meetings with multiple individuals.
- 5.4.8.2 Access to the building, as well as a copy machine and internet.

5.5 At the start of the inspection:

5.5.1 Ask the inspector to present their credentials (if not already provided). Ensure the individual conducting the inspection has the authority to do so.
- 5.5.1.1 Confirm the center (e.g., CDER, CDRH) that has requested the inspection.
- 5.5.1.2 Questions or concerns regarding the legitimacy of the credentials should be directed to the agency conducting the interview.

5.5.2 For inspections conducted by the Food & Drug Administration (FDA), ask the inspector for FDA Form 482 "Notice of Inspection" (if not provided).

5.5.3 If on-site, provide an orientation to the facility to the inspector and escort them to their workspace.

5.5.4 During the entrance briefing:
- 5.5.4.1 Provide the inspector with a copy of HRP-105 - OHRP FDA Written Procedure Crosswalk.

5.5.4.2 Request a daily debrief at the end of each day. The inspector may not be required to provide this service, but if willing, provides an opportunity to clarify questions.

5.6 Document all activities that take place during the inspection to facilitate addressing any findings and/or responding to questions following the inspection. Documentation should replicate records the inspector maintains. This includes (but is not limited to) maintaining:

5.6.1 A list of all individuals who attend the entrance briefing, all debrief meetings, and the exit interview, as well as minutes of these meetings.

5.6.2 All documents provided by the inspector to the IRB.

5.6.3 A list of all materials provided to the inspector.

5.6.4 Questions asked by the inspector and corresponding responses.

5.6.5 A list of all staff interviewed by the inspector and notes on any post-interview debriefs.

5.6.6 A list of all attendees and notes on any convened board meetings the inspector observes.

5.6.6.1 IRB meeting minutes should document the presence of the inspector.

5.6.6.2 Questions should only be directed to the inspector at the start and/or close of the meeting; they should not participate in the review/discussion of materials on the agenda.

5.6.7 Copies of all documents the inspector copies.

5.7 During the exit interview, request clarification as necessary on the following:

5.7.1 Any discrepancies or findings identified, either verbally or in writing by the inspector and their rationale.

5.7.2 Next steps, including if and when a formal inspection report or evaluation will be provided to the IRB and how and when to respond to the report.

5.7.3 Any other anticipated actions that may be taken by the regulatory agency.

5.8 Following the inspection:

5.8.1 Debrief with the IO/OO and IRB chair(s) to review findings and determine appropriate corrective actions measures. Respond, in writing, as directed by the regulatory agency to all written reports/evaluations.

5.8.1.1 If the inspection was conducted by the FDA and a Form 483 “Inspectional Observations” was issued, respond within 15 business days.[i]

5.8.2 Ensure all corrective actions are specific, measurable, designed to address the root cause of the non-compliance, and include a timeline for implementation.

5.8.2.1 Following implementation, at an appropriate time based on the action, evaluate all corrective actions to confirm the non-compliance has been appropriately addressed.

5.8.3 Promptly implement all corrective actions and, if applicable, all actions required by the regulatory agency.

6 MATERIALS

6.1 HRP-024 - SOP - New Information

6.2 HRP-070 - SOP - IRB Records

6.3 HRP-072 - SOP - IRB Records Retention

6.4 HRP-080 - SOP - IRB Formation and Registration

6.5 HRP-081 - SOP - IRB Removal

6.6 HRP-105 - OHRP FDA Written Procedure Crosswalk

6.7 HRP-601 - DATABASE - IRB Roster

7 REFERENCES

7.1 FDA Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors “FDA Institutional Review Board Inspections”, January 2006.

7.2 Office for Human Research Protection's Compliance Oversight Assessments, January 2024.
7.3 Public Responsibility in Medicine & Research (PRIM&R) & Bankert, E.A. (2005, 2021). *Institutional Review Board: Management and Function* (2nd & 3rd ed.). Jones & Bartlett Publishers.

[i] FDA Bioresearch Monitoring Program (BIMO) Compliance Program Manual – Institutional Review Boards

SOP: IRB Records

1 PURPOSE

1.1 This procedure establishes the process to maintain paper-based and electronic IRB records.

1.2 The process begins when records are received or created.

1.3 The process ends when records have been filed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 IRB records are to include:

- 3.1.1 Protocol files.
- 3.1.2 Minutes of IRB meetings.
- 3.1.3 Copies of all correspondence between the IRB and the investigators.
- 3.1.4 Current and all previous IRB member rosters.
- 3.1.5 Current and all previous IRB member files.
- 3.1.6 Current and all previous policies and procedures.

3.2 Protocol files are to include, as applicable:

- 3.2.1 All submitted materials.
- 3.2.2 Protocols (e.g., sponsored master protocol).
- 3.2.3 Investigator brochures.
- 3.2.4 Scientific evaluations.
- 3.2.5 Recruitment materials.
- 3.2.6 Consent and assent documents.
- 3.2.7 DHHS-approved sample consent document and protocol, when they exist.
- 3.2.8 Progress reports submitted by investigators.
- 3.2.9 Reports of injuries to subjects.
- 3.2.10 Records of continuing review activities, including the rationale for requiring continuing review of research that otherwise would not require continuing review when applicable under the 2018 Rule.
- 3.2.11 Data and safety monitoring board reports.
- 3.2.12 Amendments.
- 3.2.13 Reports of unanticipated problems involving risks to subjects or others.
- 3.2.14 Documentation of non-compliance.
- 3.2.15 Correspondence between the IRB and investigator related to the protocol.
- 3.2.16 Significant new findings and statements about them provided to subjects.
- 3.2.17 For initial and continuing review of research by the expedited procedure:
  - 3.2.17.1 The specific permissible category.
  - 3.2.17.2 Description of action taken by the reviewer.

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3.2.17.3 Any findings required under the regulations.

3.2.17.4 The rationale for a determination that research that otherwise meets a category for expedited review is greater than Minimal Risk.

3.2.18 For exemption determinations the specific category of exemption.

3.2.19 Unless documented in the IRB minutes determinations required by the regulations and protocol-specific findings supporting those determinations for.

3.2.19.1 Waiver or alteration of the consent process.

3.2.19.2 Research involving pregnant women, fetuses, and neonates.

3.2.19.3 Research involving Prisoners.

3.2.19.4 Research involving children including wards of the state.

3.2.19.5 Research involving adults unable to consent.

3.2.19.6 Significant/non-significant device determinations.

3.2.20 For each protocol's initial and continuing review, the frequency for the next continuing review, including the rationale for requiring continuing review for protocols approved by expedited review that otherwise would not require continuing review.

3.2.21 The institution will maintain record of all research conducted by the organization reviewed by an external IRB. Records will include all materials identified in section 3.2

3.2.22 For Veterans Administration (VA) research:

3.2.22.1 Correspondence between the IRB and the Veterans Administration (VA) Research and Development Committee.

3.2.22.2 Internal or local serious adverse events.

3.2.22.3 Documentation of protocol deviations.

3.2.22.4 Reports of complaints from subjects

3.2.22.5 Records of expedited review activities

3.2.22.6 HIPAA Authorization documents

3.2.22.7 Audit results and documentation of compliance with remediation requirements

3.3 Policies and procedures include:

3.3.1 Worksheets.

3.3.2 Forms.

3.3.3 SOPs.

3.3.4 Template letters.

3.3.5 Template minutes.

3.4 IRB member files include a resume for each IRB member.

4 RESPONSIBILITIES

4.1 IRB staff members are responsible to carry out these procedures.

5 PROCEDURE

5.1 Minutes of IRB meetings: File in the electronic system.

5.2 Store all protocol-specific information (communications, documents, determinations) in the electronic system.

5.3 IRB member rosters: File in IRB member roster e-folder.

5.4 IRB membership records (e.g., curricula vita and resumes): File in IRB member e-folder.

5.5 Policies and procedures:

5.5.1 File current policies and procedures in the IRB Library in the electronic system.

5.5.2 File replaced policies and procedures in the policies and procedures history e-file.

5.5.3 IRB paper files for currently active or archived studies are stored off-site at an Iron Mountain Storage Facility.

5.5.4 IRB paper minutes and rosters are stored off-site at an Iron Mountain Storage Facility.

5.5.5 Beginning in 2019, IRB records are stored in UCI's electronic IRB databases.

6 MATERIALS

6.1 None

7 REFERENCES

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SOP: Toolkit Management

1 PURPOSE

1.1 This procedure establishes the process to create and update standard operating procedures and associated worksheets.

1.2 The process begins when the IRB manager or Institutional Official/ Organizational Official (IO/OO) or designee determines that a standard operating procedure needs to be created or modified.

1.3 The process ends when the new or revised standard operating procedure has been approved and filed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Summary of Changes:

2.1.1 Added instructions to update HRP-100 - Huron HRPP Toolkit Table of Contents, HRP-105 - OHRP FDA Written Procedure Crosswalk and all other applicable documents at 5.3.3, when necessary (consistent with Item 26 in HRP-105).

2.1.2 Added HRP-100 and HRP-105 to Materials section.

2.2 Reason for Change: HRP Toolkit version 5.4 released December 2025.

2.3 Prior Version: 09/01/2025.

3 POLICY

3.1 For all new or revised standard operating procedures, review is conducted of all associated Toolkit documents and if additional changes are warranted, each document is updated per the procedures below.

4 RESPONSIBILITIES

4.1 The IRB manager carries out these procedures.

5 PROCEDURE

5.1 For a new Toolkit document:

5.1.1 Assign a number.

5.1.2 Assign an author and approver.

5.1.3 Have the author create the standard operating procedure following HRP-505 - TEMPLATE SOP.

5.1.4 Have the approver review and approve the document.

5.2 For a revision to a previously approved Toolkit documents:

5.2.1 Edit the current document using the tracked changes feature in MS Word.

5.2.2 Update Section 2 (Revisions from Previous Version) and include:

5.2.2.1 A short summary of changes,

5.2.2.2 Indicate origin of the change eg. HRP administrative change or HRP toolkit version change

5.2.2.3 The date of the most recent previous approval.

5.2.3 Have the approver review and approve the document.

5.3 Once approved by the approver:

5.3.1 Update the approval/effective date.

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5.3.2 File and maintain the approved revised document in the standard operating procedure files.

5.3.3 When necessary, update HRP-100 - HRPP Toolkit Table of Contents, HRP-105 - OHRP FDA Written Procedure Crosswalk, and all other applicable Toolkit documents to reflect the new/revised document.

5.3.4 Post the approved procedure on the Human Research Protection Program Web site.

5.3.5 File and retain the previous version in the standard operating procedure files.

5.3.6 Send an email to affected individuals informing them of the change.

6 MATERIALS

6.1 HRP-100 - HRPP Toolkit Table of Contents

6.2 HRP-105 - OHRP FDA Written Procedure Crosswalk

6.3 HRP-505 - TEMPLATE SOP

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SOP: IRB Records Retention

1 PURPOSE

1.1 This procedure establishes the process to retain IRB records.

1.2 The process begins each year in June.

1.3 The process ends when records that no longer need to be retained are destroyed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 In accordance with UC Office of the President policy, research records must be retained for 10 years after the end of the calendar year in which the research is completed unless otherwise specified in the award agreement. RB records are stored for 10 years beyond the end of the calendar year in which the study is closed in both onsite and off-site locations. Records are stored electronically and on paper.

3.1.1 IRB paper files for currently active or archived studies are stored offsite at an Iron Mountain Storage Facility.

3.1.2 IRB minutes and rosters are stored off-site at an Iron Mountain Storage Facility with the more recent documents (post-2019) being stored in UCI's electronic IRB database.

3.2 Completion of a study occurs when the Lead Researcher submits a closing report or 30 days after IRB approval of the study expires, whichever comes first.

3.3 If a study is canceled without participant enrollment, records also are still maintained for 10 years beyond the end of the calendar year in which the study is closed.

3.4 All records not in protocol files are retained indefinitely.

3.5 Records may be maintained in printed form or electronically.

3.6 Protocols in which there was no subject enrollment or no research was conducted are to be retained the same as protocols where research was conducted.

3.7 All records for research conducted or funded by a Common Rule department or agency are to be accessible for inspection and copying by authorized representatives of that agency at reasonable times and in a reasonable manner.

3.8 Records maintained that document compliance or non-compliance with Department of Defense DOD) regulations shall be made accessible for inspection and copying by representatives of the DOD at reasonable times and in a reasonable manner as determined by the supporting DOD component.

3.9 All records for research subject to FDA regulations are to be accessible for inspection and copying by authorized representatives of FDA at reasonable times and in a reasonable manner.

3.10 Administrative records (e.g., minutes, member lists, and budgets) are maintained indefinitely.

3.11 Access to UCI's electronic IRB database is limited to Office of Research, OR staff and UCI partners as needed for business purposes (e.g., School of Medicine). Electronic systems are frequently backed up and have a data recovery and disaster management plan.

3.12 All records are to be accessible for inspection and copying by the Veterans Administration (VA) Research and Development Committee at reasonable times and in a reasonable manner.

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3.13 Veterans Administration (VA) IRB records are retained in accordance with VHA's Records Control Schedule.

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

5.1 Destroy protocol files for Veterans Administration (VA) research per Records Control Schedule 10-1 (VHA RCS 10-1).

5.2 Destroy protocol files for the Department of Defense (DOD) research when approved by the Department of Defense. The agency may require submitting records to the Department of Defense for archiving.

6 MATERIALS

6.1 None

7 REFERENCES

7.1 VHA Directive 1200.05 dated January 7, 2019

7.2 DoDI 3216.02

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SOP: IRB Formation and Registration

1 PURPOSE

1.1 This procedure establishes the process to form a new IRB or update the OHRP IRB registration of an existing IRB.

1.2 The process begins when the Institutional Official/ Organizational Official (IO/OO) or designee determines the need for a new IRB or updated OHRP IRB registration.

1.3 The process ends when the IRB is registered, the federalwide assurance (FWA) is updated (if needed).

2 REVISIONS FROM PREVIOUS VERSION

2.1 Summary of Changes: Replaced IRB Staff with IRB Director or designee in 4.1.

2.2 Reason for Change: For accuracy.

2.3 Prior Version: 08/01/2026.

3 POLICY

3.1 IRB rosters are maintained using HRP-601 - DATABASE - IRB Roster.

3.2 A FWA will be submitted or updated as follows:

3.2.1 To engage in human subjects research that is not exempt from the regulations, and is conducted or supported by any HHS agency.

3.2.2 To list the institution's legal components that operate under different names that will be covered by the FWA and the city and state or country where the component is located.

3.2.3 To designate all internal IRBs (or external IRBs that review the largest percentage of research if the institution does not have an internal IRB) that will review research covered by the FWA.

3.2.4 Within 90 days after changes regarding the legal name of the institution, the Human Protections Administrator, or the Signatory Official.

3.3 FWAs are renewed every 5 years, even if no changes occur. Any renewal or update approved by OHRP begins a new 5-year effective period.

3.4 IRB registrations on file with OHRP will be made or updated as follows:

3.4.1 To register any additional IRB before it is designated under an FWA and reviews research conducted or supported by HHS.

3.4.2 Within 90 days after changes regarding the contact person who provided the IRB registration information, the IRB chairperson, or changes to the IRB membership roster.

3.4.3 Within 30 days of the change if an FDA-regulated IRB decides to review additional types of FDA-regulated products (e.g., to review device studies if it only reviewed drug studies previously) or to discontinue reviewing clinical investigations regulated by FDA.

3.4.4 Within 30 days of permanent cessation of the IRB's review of HHS-conducted or supported research when an institution disbands a registered IRB that it is operating.

3.4.5 IRB registration must be renewed every 3 years, even if no changes occur. Any renewal or update accepted by OHRP begins a new 3-year effective period.

3.5 Prior to seeking an FWA, VA medical facilities must secure approval from the VHA Office of Research & Development (ORD) to establish a Human Research Protection Program (HRPP).

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3.6 Prior to registering an IRB that will be internally operated by a VA medical facility, VA facilities must secure approval from the VHA ORD.

4 RESPONSIBILITIES

4.1 IRB Director or designee carry out these procedures.

4.2 The IO/OO or designee appoints IRB members, alternate members, IRB chairs, and if used, other officers (e.g., vice chairs.)

5 PROCEDURE

5.1 For new IRBs:

5.1.1 Determine from the IO/OO or designee whether the IRB will conduct all reviews without limitation or will be limited to certain types of reviews. Indicate this on the "IRB Scope" tab of HRP-601 - DATABASE - IRB Roster.

5.1.1.1 Select:

5.1.1.1.1 At least five individuals to serve as IRB members.

5.1.1.1.2 Additional individuals to serve as alternate IRB members, if needed.

5.1.1.1.3 At least one of the individuals to be the IRB chair.

5.1.1.2 Follow HRP-082 - SOP - IRB Membership Addition for each IRB member.

5.1.1.3 Use HRP-304 - WORKSHEET - IRB Composition and revise the selected individuals as needed to ensure that the IRB is appropriately constituted.

5.1.1.4 The biomedical IRB Committees are primarily made up of School of Medicine and UCI Medical Center faculty and staff with sufficient scientific expertise and scholarship to review each protocol to determine the study meets the criteria for IRB approval.

5.1.1.5 The social/behavioral/ educational IRB Committee is made up of faculty and staff from the School of Social Sciences, School of Social Ecology, School of Humanities; the Donald Bren School of Information and Computer Sciences; School of Medicine, School of Education; and School of Business with sufficient scientific expertise and scholarship to determine that each study meets criteria 45 CFR 46.111 and if applicable, 21 CFR 56.111.

5.1.1.6 To support American Nurses Credentialing Center Magnet designation each biomedical IRB includes at least one UCI nurse as a voting member.

5.1.1.7 Using the "Create Committee" SmartForm, create the new committee in the system.

5.1.1.8 Once training is completed, add committee members to the system with the Committee Member role.

5.1.1.9 Assign any designees eligible to conduct non-committee reviews using the "Update Eligible Designated Reviewers" activity.

5.2 File a new FWA, or update an existing, by following the instructions available at the OHRP website: https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/index.html

5.2.1 If the new FWA is for a VA medical facility, secure approval from the VHA ORD prior to filing and then notify the VHA Office of Research Oversight (ORO).

5.3 Register the new IRB, or update an existing IRB's OHRP registration as required by this policy, by following the instructions available at the OHRP website: https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/irb-registration/new-irb-registration/index.html.

5.3.1 If the New IRB will be operated by a VA medical facility, secure approval from the VHA ORD prior to registration.

6 MATERIALS

6.1 HRP-082 - SOP - IRB Membership Addition

6.2 HRP-202 - FORM - IRB Member Information

6.3 HRP-304 - WORKSHEET - IRB Composition

6.4 HRP-601 - DATABASE - IRB Roster

7 REFERENCES

7.1 45 CFR §46.103, 45 CFR §46.107, 45 CFR §46.108, 45 CFR §46.115(a)(5).

7.2 21 CFR §56.107, 21 CFR §56.115(a)(5).

7.3 VHA Directive 1058.03 September 17, 2020

SOP: IRB Removal

1 PURPOSE

1.1 This procedure establishes the process to remove an IRB.

1.2 The process begins when the Institutional Official/Organizational Official (IO/OO) or designee determines that an IRB is no longer needed.

1.3 The process ends when the IRB is unregistered with OHRP and the Federalwide Assurance (FWA) is updated.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Summary of Changes:

2.1.1 Clarified system steps for removing a Committee in the system.

2.1.2 Replaced IRB Staff with IRB Director or designee in 4.1.

2.2 Reason for Change: HRP Toolkit version 5.4 released December 2025. Revised responsible party for accuracy.

2.3 Prior Version: 09/01/2025.

3 POLICY

3.1 IRB rosters are maintained using HRP-601 - DATABASE - IRB Roster.

3.2 Any termination or non-renewal of OHRP IRB registration of any IRB relied on by a VA medical facility for review and oversight of VA research must be reported to the local VA medical facility per the facility's required reporting timelines.

3.2.1 The VA medical facility Director must report this to ORO promptly, but no later than 5 business days after VA medical facility personnel first become aware.

4 RESPONSIBILITIES

4.1 IRB Director or designee carry out these procedures.

5 PROCEDURE

5.1 For internal IRBs:

5.1.1 For each IRB member who will no longer serve as an IRB member prepare HRP-561 - LETTER - IRB Member Thank You, have them signed by the IO/OO or designee and send to the former IRB members.

5.1.2 Unregister the IRB with OHRP.[i]

5.1.3 Remove the IRB from the FWA.[ii]

5.1.4 Remove members from HRP-601 - DATABASE - IRB Roster.

5.1.5 Remove the individual's Committee Member role in the system by executing the "Edit Members" activity, updating the individual's record to include the IRB Membership End Date and deleting them from the list of IRB Committee Members.

5.1.6 Execute "Edit Committee Info" and note in the description that the IRB has been removed, including the date of removal.

5.1.7 File:

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5.1.7.1 DATABASE: IRB Roster (HRP-601)

5.1.7.2 FWA

5.1.7.3 HRP-561 - LETTER - IRB Member Thank You

5.2 For external IRBs follow the requirements of the inter-institutional agreement or contract.

6 MATERIALS

6.1 HRP-561 - LETTER - IRB Member Thank You

6.2 HRP-601 - DATABASE - IRB Roster

7 REFERENCES

7.1 45 CFR §46.107, 45 CFR §46.103(b)(3), 45 CFR §46.115(a)(5).

7.2 21 CFR §56.107, 21 CFR §56.115(a)(5).

7.3 VHA Directive 1200.05(3), Amended July 13, 2023

7.4 VHA Directive 1058, November 8, 2024

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[i] See http://www.hhs.gov/ohrp/assurances/. Use the Web site: http://ohrp.cit.nih.gov/efile/.

[ii] See http://www.hhs.gov/ohrp/assurances/. Use the Web site: http://ohrp.cit.nih.gov/efile/.

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SOP: IRB Membership Appointment

1 PURPOSE

1.1 This procedure establishes the process to appoint and re-appoint an IRB member.

1.2 The process begins when an individual expresses interest, is nominated or applies to join the IRB in consultation with the Institutional Official/ Organizational Official (IO/OO) (this may be a completely new IRB member, or re-appointment of a previous member).

1.3 The process ends when the IRB roster is updated and the new member has completed training.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Summary of Changes:

2.1.1 Added endnote at 5.4 to reference OHRP and FDA guidance re: scientific vs. non-scientific reviewers (consistent with activities identified in Items 34 & 35 in HRP-105).

2.1.2 Replaced IRB staff with IRB Director or designee in 4.1.

2.1.3 Specified IRB staff is responsible for new member training in 5.12.2.

2.2 Reason for Change: HRP Toolkit version 5.4 released December 2025. Revised responsibilities for accuracy.

2.3 Prior Version: 09/01/2025.

3 POLICY

3.1 IRB rosters are maintained using HRP-601 - DATABASE - IRB Roster.

3.2 IRB members /alternates are appointed for a three-year term. Members/alternates are eligible for re-appointment at the end of their term. In general, IRB Chairs and Vice Chairs are appointed for a two-year term.

3.3 The following individuals may not be appointed as IRB members or be involved in the day-to-day operations of the IRB:

3.3.1 Those responsible for business development for the organization (e.g., director of grants and contracting, the vice president for research, deans of research who are responsible for raising funds or garnering support for research, senior officers).

3.3.2 Those who own equity in the organization.

4 RESPONSIBILITIES

4.1 IRB Director or designee carry out these procedures.

4.2 IRB staff members carry out the training in 5.12.2.

4.3 The IO/OO or designee appoints/re-appoints IRB members, alternate members, IRB chairs, and if used, other officers (e.g., vice chairs.).

5 PROCEDURE

5.1 Have the individual complete HRP-202 - FORM - IRB Member Information.

5.2 Have the individual complete the IRB Member Conflict of Interest Disclosure.

5.3 Obtain a copy of the individual’s résumé or curriculum vita.

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5.4 Use the information in the completed HRP-202 - FORM - IRB Member Information and the individual's résumé or curriculum vita to determine if the individual qualifies as a scientist or nonscientist, and if they are affiliated or unaffiliated[i].

5.5 Interview the individual to assess suitability and availability.

5.5.1 Determine from the IO/OO or designee whether the individual will be a regular IRB member, alternate IRB member, or IRB chair.

5.5.2 In any instance for which the scientific or non-scientific status or affiliation status of a newly appointed or re-appointed IRB member may be questionable, the IO/OO or designee will be consulted before proceeding with the appointment.

5.5.3 For Veterans Administration (VA) representatives, communicate with the Veterans Administration (VA) Medical Center Director in writing to obtain confirmation of the appointment.

5.6 Schedule a time for the applicant to attend and observe an IRB meeting, as applicable.

5.7 Add the individual to HRP-601 - DATABASE - IRB Roster.

5.8 Complete HRP-304 - WORKSHEET - IRB Composition and revise the membership as needed to ensure that the IRB is appropriately constituted.

5.9 Prepare HRP-560 - LETTER - IRB Member Appointment for the individual.

5.10 Provide to the IO/OO or designee for review and approval:

5.10.1 HRP-202 - FORM - IRB Member Information.

5.10.2 Résumé or curriculum vita.

5.10.3 Completed HRP-560 - LETTER - IRB Member Appointment.

5.11 If not approved, select another individual and restart at 5.1.

5.12 Once the appointment letter is signed:

5.12.1 Send the signed HRP-560 - LETTER - IRB Member Appointment to the individual.

5.12.2 If the individual requires training, schedule the individual for training.

5.12.2.1 Forward information on the Collaborative IRB Training Initiative (CITI) Basic Human Research Protections Course for IRB Members: All IRB members are required to complete this tutorial within 3 months of their appointment.

5.12.2.2 A refresher course is required every five years for members to maintain their knowledge of ethical considerations and regulations regarding human research protections.

5.12.2.3 Health Insurance Portability and Accountability Act (HIPAA) Research Tutorial: The internet-based tutorial developed by the UC is designed specifically for researchers involved with Protected (Personal) Health Information (PHI). All IRB members are required to complete the HIPAA Research tutorial within 3 months of their appointment.

5.12.3 Update the registration of all affected IRBs.[ii]

5.13 File:

5.13.1 HRP-601 - DATABASE - IRB Roster.

5.13.2 Signed IRB appointment/re-appointment letter.

5.13.3 HRP-202 - FORM - IRB Member Information.

5.13.4 Résumé or curriculum vita.

5.13.5 Any other signed agreements.

5.14 Notify the IRB manager when the individual has completed training.

5.15 Assign individual the "Committee Member" role in the system.

5.16 If the individual is designated to conduct non-committee reviews, update the “Update Eligible Designated Reviewers” activity.

6 MATERIALS

6.1 HRP-202 - FORM - IRB Member Information

6.2 HRP-304 - WORKSHEET - IRB Composition

6.3 HRP-560 - LETTER - IRB Member Appointment

6.4 HRP-601 - DATABASE - IRB Roster

7 REFERENCES

7.1 45 CFR §46.107, 45 CFR §46.108(a)(2), 45 CFR §46.115(a)(5).

7.2 21 CFR §56.107, 21 CFR §56.115(a)(5).

7.3 VHA Directive 1200.05 January 7, 2019

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[i] See OHRP’s IRB Registration Process FAQ “How do I determine the various categories of members for the IRB roster?” and FDA’s IRB FAQs on IRB Membership for additional guidance.

[ii] See http://www.hhs.gov/ohrp/assurances/. Use Web site: http://ohrp.cit.nih.gov/efile/.

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SOP: IRB Membership Removal

1 PURPOSE

1.1 This procedure establishes the process to remove an IRB member.

1.2 The process begins when an IRB member resigns or is removed from one or more IRBs. This procedure applies if an individual is a member of more than one IRB and is being removed from some but not all IRBs.

1.3 The process ends when the IRB registration is updated.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Summary of Changes:

2.1.1 Clarified system steps for removing Committee Members in the system.

2.1.2 Replaced IRB staff with IRB Director or designee in 4.1.

2.2 Reason for Change: HRP Toolkit version 5.4 released December 2025. Revised responsibilities for accuracy.

2.3 Prior Version: 09/01/2025.

3 POLICY

3.1 The Institutional Official/ Organizational Official (IO/OO) or designee may remove IRB members, alternate members, IRB chairs, and if used, other officers (e.g., vice chairs) with consultation from the IRB manager and IRB chair(s).

3.2 IRB rosters are maintained using HRP-601 - DATABASE - IRB Roster.

4 RESPONSIBILITIES

4.1 IRB Director or designee carry out these procedures.

5 PROCEDURE

5.1 Remove the individual from HRP-601 - DATABASE - IRB Roster.

5.2 Complete HRP-304 - WORKSHEET - IRB Composition to ensure that the IRB is appropriately constituted.

5.2.1 If not, identify one or more replacement members and follow HRP-082 - SOP - IRB Membership Addition.

5.3 Prepare HRP-561 - LETTER - IRB Member Thank You, have it signed by the IO/OO or designee and send to the individual.

5.4 Update the registration of all affected IRBs.[i]

5.5 File:

5.5.1 HRP-601 - DATABASE - IRB Roster.

5.5.2 HRP-561 - LETTER - IRB Member Thank You.

5.6 Remove individual's "Committee Member" role in the system by executing the "Edit Members" activity, updating the individual's record to include the IRB Membership End Date and deleting them from the list of IRB Committee Members.

6 MATERIALS

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6.1 HRP-082 - SOP - IRB Membership Addition
6.2 HRP-304 - WORKSHEET - IRB Composition
6.3 HRP-561 - LETTER - IRB Member Thank You
6.4 HRP-601 - DATABASE - IRB Roster

7 REFERENCES

7.1 45 CFR §46.107, 45 CFR §46.103(b)(3), 45 CFR §46.115(a)(5)
7.2 21 CFR §56.107, 21 CFR §56.115(a)(5)

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[i] See http://www.hhs.gov/ohrp/assurances/. Use the Web site: http://ohrp.cit.nih.gov/efile/.

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SOP: IRB Meeting Scheduling and Notification

1 PURPOSE

1.1 This procedure establishes the process to schedule and notify individuals of convened meetings.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 Scheduled meetings are to occur at intervals appropriate for the quantity, complexity, and frequency of required actions, and to permit adequate oversight of the progress of approved research.

3.2 Additional meetings may be scheduled on an ad hoc basis.

4 RESPONSIBILITIES

4.1 The IRB manager or designee carries out these procedures.

5 PROCEDURE

5.1 Create a schedule of meetings for each IRB.

5.1.1 Execute the “Create Meeting” SmartForm in the system for each scheduled meeting.

5.2 Post the schedule on the organization’s Web site.

5.3 Notify the following individuals of the updated schedule with an email providing a link to the IRB Web page with the schedule information:

5.3.1 IRB members.

5.3.2 Investigators and research staff on the IRB email list.

5.3.3 Institutional Official / Organizational Official (IO/OO) or designee.

6 MATERIALS

6.1 None

7 REFERENCES

7.1 ICH-GCP E6 1.4.2

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SOP: Informed Consent Process for Research

1 PURPOSE

1.1 This procedure establishes the process to obtain informed consent from subjects, the Legally Authorized Representative (LAR) of adults unable to consent, or the parents or guardians of children.

1.2 The process begins when an individual identifies a subject as a potential candidate for a research study.

1.3 The process ends when a subject or the subject's LAR provides legally effective informed consent or declines to do so.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 In this procedure "investigator" means a principal investigator or an individual authorized by the principal investigator (PI) and approved by the IRB to obtain consent for the specific protocol, such as a co-investigator, research assistant, or coordinator.

3.2 In this procedure "subject/representative" means:

3.2.1 The subject when the subject is an adult capable of providing consent.

3.2.2 LAR when the subject is an adult unable to give consent.

3.2.3 One or both biologic or adoptive parents when the subject is a child or in the absence of a parent a person other than a parent authorized under applicable law to consent on behalf of the child to general medical care.

3.2.4 In this procedure "finalize" means those authorized to obtain the final verbal or written consent from participants.

3.2.5 Investigators must provide details that demonstrate their education, training, and expertise to finalize the consent process. This includes being capable of answering questions or concerns the subject may have about the study. In the case of a clinical investigation, the investigator must be able to address questions about alternative procedures, if any.[1]

3.2.6 When considering which investigators names should be included on the informed consent document as those who can finalize the consent process the following guidelines apply:

3.2.6.1 For minimal risk research, the PI must list their name on the consent document.

3.2.6.2 For greater than minimal risk research all investigators who are approved by the IRB to finalize consent must be listed on the consent document.

3.2.6.3 For greater than minimal risk research that involves the application of an investigational drug, device, or surgical procedure, the protocol must include an individual authorized by the institution to independently prescribe the drug, device or perform the surgical procedure on the protocol. This individual, as approved by the IRB, must also be listed on the consent form and available to finalize consent.

[1] U.S. HHS and FDA's Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023) https://www.fda.gov/media/88915/download

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3.2.6.4 When UCI is the IRB of record for multisite, investigator-initiated trials (IITs), the UCI IRB may require a cover sheet specific to each relying site, listing the UCI PI, site-specific lead collaborating investigators and site-specific investigators approved to finalize consent. This cover sheet may be appended to the top of the single, IRB approved, consent document. This efficiency allows necessary investigator changes at study sites to be handled at the respective site only (along with verification of human research subject trainings).

3.2.6.5 When UCI is the relying IRB for multisite research conducted under the auspices of the Lead Clinical Trial Units, the UCI PI may utilize a cover sheet to list the UCI PI and UCI Co-Is approved to finalize consent. This cover sheet may be appended to the top of the single IRB approved, consent document. This efficiency allows necessary Co-I changes at UCI to be handled by the study team (along with verification of human research subjects trainings).

3.2.6.6 Departments may have specific policies related to consent that may be more restrictive. Researchers should be aware of these policies and adhere accordingly.

3.3 If the subject/representative understands more than one language, whenever possible, conduct the consent process in the preferred language of the subject/representative.

3.4 If the subject is an adult unable to consent:

3.4.1 The IRB must have specifically approved the protocol to allow the enrollment of adults unable to consent.

3.4.2 Permission is obtained from a LAR.

3.4.3 A LAR must be in the class or persons approved by institutional policy or the IRB. See HRP-013 - SOP - LARs, Children, and Guardians.

3.5 If the subject is a child:

3.5.1 The IRB must have specifically approved the protocol to allow the enrollment of children.

3.5.2 Permission is obtained from both parents unless:

3.5.2.1 One parent is deceased, unknown, incompetent, not reasonably available;

3.5.2.2 Only one parent has legal responsibility for the care and custody of the child; or

3.5.2.3 The IRB has specifically approved the protocol to allow the permission of one parent regardless of the status of a second parent.

3.5.3 In the absence of a parent permission may be obtained from an individual authorized to consent under applicable law on behalf of a child to general medical care.

3.5.4 Refer to HRP-103 - SOP - Investigator's Manual

3.6 If the subject/representative cannot speak English:

3.6.1 The IRB must have specifically approved the protocol to allow the enrollment of non-English speaking subjects.

3.7 Conduct all discussions in a private and quiet setting.

3.8 Any knowledgeable individual may:

3.8.1 Review the study with subject/representative to determine preliminary interest.

3.8.2 If the subject/representative is interested, notify an investigator.

3.8.3 If the subject/representative is not interested, take no further steps regarding recruitment or enrollment.

3.9 UCI does not utilize broad consent. UCI's interpretation of broad consent is that it is a system-wide program that allows institutions to track via a central system biospecimens and data for which individuals provide their broad consent, or decline, as well as the terms of the broad consent to

determine which future research uses remain within scope. This interpretation aligns with the Health and Human Services (HHS) Secretary's Advisory Committee on Human Research Protections (SACHRP) interpretation.

3.10 Involving a Participant Advocate in the consent process: The IRB Committee may require, at their discretion, that the Investigator use a participant advocate or provide an advocacy group as a contact to the participants. The role of a participant advocate is to assure that the participant receives equitable and ethical treatment during the informed consent process and/or throughout the course of the research study. The advocate could be a single person with an interest in the population studied or a group of people interested in the safety of human research participants, usually within a certain population (e.g., breast cancer patients, patients with schizophrenia, etc.).

3.11 When the research protocol requires creation, use or disclosure of PHI, Researchers must indicate whether subjects will sign a written HIPAA research authorization for release of PHI for research, formally titled, "UC Permission to Use Personal Health Information for Research" form, or request a waiver of authorization from the IRB. In addition, if a study involves PHI, all members of the research protocol team engaged in human subject research must complete the HIPAA Research tutorial.

3.12 The Protection of Human Subjects in Medical Experimentation Act (California Health and Safety Code Sections 24170-24179.5) requires that individuals be provided the Subject's Bill of Rights as part of the informed consent process prior to participation in a medical experiment.

3.12.1 When meeting the requirement to attest that informed consent to the California Medical Experiment Act have been satisfied, the consent form is signed and dated by any person other than the subject or the subject's guardian or legally authorized representative who can attest that the requirements for informed consent has been met, as specified in Section 24175 of the California Health and Safety Code. At UCI, the investigator's signature serves this purpose and an impartial witness is not required.

4 RESPONSIBILITIES

4.1 The principal investigator is responsible to ensure these procedures are carried out.

5 PROCEDURE

5.1 **If the consent process will be documented electronically:**

5.1.1 For FDA-Regulated Studies using an electronic process to document consent, the PI must use DocuSign Part 11 for obtaining signatures on the Informed Consent Form.

5.2 **If the consent process will be documented in writing with the long form of consent documentation:**

5.2.1 Verify that you are using the most current IRB-approved version of the study specific consent form and that the consent form is in a language understandable to the subject/representative.

5.2.1.1 Use only the IRB-stamped version of the consent. For UCI IRB approved consent documents, the expiration date is not specified. The most recent IRB approval dates, including the date of study expiration are stated on the UCI IRB approval letter.

5.2.2 Provide a copy of the consent form to the subject/representative. Whenever possible provide the consent form to the subject/representative in advance of the consent discussion.

5.2.3 If the subject/representative cannot read, or is physically unable to talk or write, obtain an impartial witness to be present during the entire consent discussion to attest that the information in the consent form and any other information provided was accurately explained to, and apparently understood by, the subject/representative, and that consent was freely given.

5.2.4 The role of the witness may be served by a member of the IRB or may be an impartial third party. A witness must be an adult who is not a member of the study team and who is not a family member of the subject.

5.2.5 If the subject/representative cannot speak English, obtain the services of an interpreter fluent in both English and the language understood by the subject/representative. The interpreter may be a member of the research team, a family member, or friend of the subject/representative.

5.2.6 Read the consent document (or have an interpreter read the translated consent document) with the subject/representative. Begin with a concise and focused presentation of key information that is most likely to assist the subject/representative to understand the reasons why one might or might not want to participate in the research. Explain the details in such a way that the subject/representative understands what it would be like to take part in the research study.

5.3 **If the consent process will be documented in writing with the short form of consent documentation:**

5.3.1 In general, for studies that involve greater than minimal risk a request for Short Forms will require full committee review. The IRB Chair or Vice Chair's has discretion on a protocol-by-protocol basis however and may decide that review of a request for Short Forms can occur at a subcommittee level. The reason for the level of review (full committee or subcommittee) should be appropriately documented in the IRB Worksheet.

5.3.2 In the instance that the UCI IRB has approved Short Form use but the specific foreign language translation of the English Short Form is not immediately available on the UCI HRP webpage, UCI researchers may use the appropriate language translation of the Short Form as found on the following websites; WCG IRB, Advarra IRB, Central IRB for the National Cancer Institute (CIRB) or any UC HRP that has the needed translation available.

5.3.3 Obtain the current IRB approved short consent form and summary (same as the English consent form used for long form of consent documentation).

5.3.4 Verify that you are using the most current IRB-approved version of the study specific short consent form and summary and that the short consent form is in a language understandable to the subject/representative.

5.3.5 Provide copies to the subject/representative. Whenever possible provide the short consent form and summary to the subject/representative in advance of the consent discussion.

5.3.6 Obtain the services of an interpreter fluent in both English and the language understood by the subject/representative. The interpreter may be a member of the research team, family member, or friend of the subject/representative.

5.3.7 Obtain the services of an impartial witness who is fluent in both English and the language spoken by the subject/representative to be present during the entire consent discussion to attest that the information in the short consent form, summary, and any other information provided was accurately explained to, and apparently understood by, the subject/representative, and that consent was freely given. The witness and the interpreter may be the same person. If possible, it is recommended that the witness should not be related to the subject[i]. The witness may not be a person involved in the design, conduct, or reporting of the research study.

5.3.7.1 In cases where the interpreter or translator is an impartial third party to an oral / IRB approved short form consent process but is not physically present (e.g., a virtual consent process), the family member of the participant may be allowed to serve as a witness. The family member serving as a witness must be fluent in both English and the language of the participant. The witness must sign and date both

the short form written informed consent document and a copy of the IRB approved English version of the consent document.

5.3.8 Have the interpreter translate the summary (not the short consent form) to the subject/representative. Begin with a concise and focused presentation of the key information that is most likely to assist the subject/representative to understand the reasons why one might or might not want to participate in the research.

5.3.9 Through the interpreter explain the details in such a way that the subject/representative understand what it would be like to take part in the research study. When necessary, provide a different or simpler explanation to make the information understandable.

5.3.10 Have the subject/representative read the short consent form or have the interpreter read the short consent form to the subject/representative.

5.3.11 The translated consent form must be provided to the participant within one month from the date that eligibility is confirmed.

5.3.11.1 Translation Requirements:

5.3.11.1.1 Greater than minimal risk studies: professional or certified translation of the consent form and recruitment materials is required for studies that pose more than minimal risk to participants. For a professional translation the PI must provide the qualifications of the individual who translated the informed consent documents and recruitment materials. Include any credentials, certifications, education, native language fluency, etc. For a certified translation, a copy of the certification from the translator or translation service should be attached to the translation of any informed consent documents and recruitment materials.

5.3.11.1.2 Minimal risk studies: Studies that are eligible for expedited review also require translation of the consent form and recruitment materials; however, certified translation is not required. The IRB will accept documents translated by an individual fluent (i.e., can speak, read, and write) in a given language. The qualifications of the individual performing the translation will be assessed by the IRB. A letter or statement from the translator describing their qualifications must be provided with the translation documents.

5.3.11.2 The translated consent form must be provided to the participant within one month from the date that eligibility is confirmed.

5.4 **If the requirement for written documentation of the consent process has been waived by the IRB:**

5.4.1 Obtain the current IRB approved script.

5.4.2 Verify that you are using the most current IRB-approved version of the study specific script and that the script language is understandable to the subject/representative.

5.4.3 When possible, provide a copy of the script to the subject/representative.

5.4.4 If the subject/representative cannot speak English, obtain the services of an interpreter fluent in both English and the language understood by the subject/representative. The interpreter may be a member of the research team, a family member, or friend of the subject/representative.

5.4.5 Read the script (or have an interpreter translated the script) with the subject/representative. Begin with a concise and focused presentation of the key information that is most likely to assist the subject/representative to understand the reasons why one might or might not want

to participate in the research. Explain the details in such a way that the subject/representative understands what it would be like to take part in the research study.

5.5 Invite and answer the subject/representative's questions.

5.6 Give the subject/representative time to discuss taking part in the research study with family members, friends and other care providers as appropriate.

5.7 Invite and encourage the subject/representative to take the written information home to consider the information and discuss the decision with family members and others before making a decision.

5.8 Ask the subject/representative questions to determine whether all of the following are true, and if not, either continue the explanation or determine that the subject/representative is incapable of consent:

- 5.8.1 The subject/representative understands the information provided.
- 5.8.2 The subject/representative does not feel pressured by time or other factors to make a decision.
- 5.8.3 The subject/representative understands that there is a voluntary choice to make.
- 5.8.4 The subject/representative is capable of making and communicating an informed choice.

5.9 If the subject/representative has questions about treatments or compensation for injury, provide factual information and avoid statements that imply that compensation or treatment is never available.

5.10 Once a subject/representative indicates that he or she does not want to take part in the research study, this process stops.

5.11 If the subject/representative agrees to take part in the research study:

- 5.11.1 If the subject is a child:
  - 5.11.1.1 Whenever possible explain the research to the extent compatible with the child's understanding.
  - 5.11.1.2 Request the assent (affirmative agreement) of the child unless:
    - 5.11.1.2.1 The capability of the child is so limited that the child cannot reasonably be consulted.
    - 5.11.1.2.2 The IRB determined that assent was not a requirement.
  - 5.11.1.3 Once a child indicates that he or she does not want to take part in the research study, this process stops.
- 5.11.2 If the subject is an adult unable to consent:
  - 5.11.2.1 Whenever possible explain the research to the extent compatible with the adult's understanding.
  - 5.11.2.2 Request the assent (affirmative agreement) of the adult unless:
    - 5.11.2.2.1 The capability of the adult is so limited that the adult cannot reasonably be consulted.
    - 5.11.2.2.2 The IRB determined that assent was not a requirement.
  - 5.11.2.3 Once an adult unable to consent indicates that he or she does not want to take part in the research study, this process stops.
- 5.11.3 Obtain written documentation of the consent process according to HRP-091 - SOP - Written Documentation of Consent. *Note any exceptions are reflected in HRP-90 – SOP – Informed Consent Process for Research.*

5.12 Clinical trials conducted or supported by a Common Rule department or agency initially approved by the IRB on or after January 21, 2019, must post one (1) IRB-approved clinical trial consent form at a publicly available federal website. The consent form must be posted after recruitment closes, and no

later than 60 days after the last study visit. For additional guidance, refer to the OHRP FAQs on Informed Consent.

6 MATERIALS

6.1 Long form of consent documentation:

6.1.1 Consent form

6.2 Short form of consent documentation:

6.2.1 Short consent form

6.2.2 Summary (same information as the English consent form used for long form of consent documentation)

6.3 Requirement for written documentation of the consent process has been waived by the IRB:

6.3.1 Consent script (same as consent form used for long form of consent documentation except that signature block is optional)

6.4 HRP-013 - SOP - LARs, Children, and Guardians

6.5 HRP-091 - SOP - Written Documentation of Consent

7 REFERENCES

7.1 21 CFR §50.20, 50.25

7.2 45 CFR §46.116

7.3 UCI Health Office of Information Technology

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[i] FDA's Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023) https://www.fda.gov/media/88915/download

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SOP: Written Documentation of Consent

1 PURPOSE

This procedure establishes the process to document the informed consent process in writing.

The process begins when a subject agrees to take part in a research study.

The process ends when the consent process is documented in writing, including in an electronic format, to the extent required by this procedure.

2 REVISIONS FROM PREVIOUS VERSION

None

3 POLICY

In this procedure “investigator” means a principal investigator or an individual authorized by the principal

investigator and approved by the IRB to obtain consent for the specific protocol, such as a co-investigator,

research assistant, or coordinator.

In this procedure “subject/representative” means:

3.1. The subject when the subject is an adult capable of providing consent.

3.2. The Legally Authorized Representative (LAR) when the subject is an adult unable to give consent.

3.3. One or both biologic or adoptive parents when the subject is a child or in the absence of a parent, a person authorized under applicable law to consent on behalf of the child to the child’s general medical care.

4 RESPONSIBILITIES

The principal investigator is responsible to ensure these procedures are carried out.

5 PROCEDURE

If the consent process will be documented in writing with the long form of consent documentation:

5.1. Verify that the consent form is in language understandable to the subject/representative.

5.2. Print the name of the following individuals on the consent document:

5.2.1. Subject/Representative

5.2.2. Person obtaining consent

5.3. Have the following individuals personally sign and date (or otherwise "make their mark” on) the consent document:

5.4. Subject/Representative

5.4.1. If the subject/representative can only “make their mark,” document in a note to the subject’s file: the method used for communication with the prospective subject/representative, the reason for the lack of a signature and date, and the date consent was obtained[i].

5.4.2. If the subject/representative is physically unable to sign the consent form, note this on the consent form and document in a note to the subject’s file: the method used for communication with the prospective subject/representative, and the specific means by which their agreement was communicated[i].

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5.5. Person obtaining consent

5.5.1. If the IRB required written documentation of assent, note on the signature block one of the following:

5.5.1.1. Assent of the child was obtained.

5.5.1.2. Assent of the child was not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.

5.6. If an impartial witness was part of the consent process:

5.6.1. Print the name of the impartial witness on the consent document.

5.6.2. Have the impartial witness personally sign and date the consent document to attest that the information in the consent document and any other information provided was accurately explained to, and apparently understood by, the subject, and that consent was freely given.

5.7. Provide copies of the signed and dated consent document to the subject/representative. This may be accomplished either by making a photocopy or by having the above individuals sign and date two copies of the consent document.

5.8. If the consent process will be documented in writing with the short form of consent documentation:

5.8.1. Verify that the short consent form is in language understandable to the subject/representative.

5.8.2. Print the name of the following individuals on the short form consent document and the summary:

5.8.2.1. Subject/Representative

5.8.2.2. Person obtaining consent

5.8.2.3. Impartial witness

5.8.3. Have the following individuals personally sign and date the short form consent document and/or the summary:

5.8.3.1. Subject/Representative sign short form consent document

5.8.3.2. Person obtaining consent sign summary

5.8.3.3. Impartial witness signs both short form consent document and summary

5.9. If the IRB required written documentation of assent, note on the signature block on the short consent document one of the following:

5.9.1. Assent of the child was obtained.

5.9.2. Assent of the child was not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.

5.10. Provide a copy of the signed and dated short consent document and a copy of the signed and dated summary to the subject/representative. This may be accomplished either by making photocopies or by having the above individuals sign and date two copies of the short consent document and summary.

5.11. If non-English languages are anticipated[i], obtain a translated copy of the IRB-approved English version of the long form consent promptly and submit to the IRB for review.

5.11.1. After IRB approval of the translated version, provide it to the subject or LAR as soon as possible.

5.12. When the research protocol requires creation, use or disclosure of PHI, Researchers must indicate whether subjects will sign a written HIPAA research authorization for release of PHI for research, formally titled, "UC Permission to Use Personal Health Information for Research" form, or request a waiver of authorization from the IRB. In addition, if a study involves PHI, all members

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of the research protocol team engaged in human subject research must complete the HIPAA Research tutorial.

5.13. The Protection of Human Subjects in Medical Experimentation Act (California Health and Safety Code Sections 24170-24179.5) requires that individuals be provided the Subject's Bill of Rights as part of the informed consent process prior to participation in a medical experiment. When meeting the requirement to attest that informed consent to the California Medical Experiment Act have been satisfied, the consent form is signed and dated by any person other than the subject or the subject's guardian or legally authorized representative who can attest that the requirements for informed consent has been met, as specified in Section 24175 of the California Health and Safety Code. At UCI, the investigator's signature serves this purpose and an impartial witness is not required.

5.14. If the requirement for written documentation of the consent process has been waived by the IRB and the IRB determined that the subject/representative had to be offered the opportunity to document his or her consent in writing, offer the subject/representative the option to document his or her consent in writing.

5.14.1. If the subject/representative declines, take no further action.

5.14.2. If the subject/representative accepts, follow the process to document consent in writing with the long or short form of consent documentation.

5.15. Place the signed and dated documents in the subject's binder.

6. MATERIALS

6.1. If the consent process will be documented in writing with the long form of consent documentation:

6.1.1. Consent document

6.2. If the consent process will be documented in writing with the short form of consent documentation:

6.2.1. Short consent document

6.3. Summary (same content as the long form of consent documentation).

7. REFERENCES

7.1. HRP-090 - SOP – Informed Consent Process for Research

7.2. 21 CFR §50.27

7.3. 45 CFR §46.117

7.4. https://www.fda.gov/media/88915/download

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[i] FDA's Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023) https://www.fda.gov/media/88915/download

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SOP: Veterans Affairs Research

1 PURPOSE

1.1 Within the Department of Veterans Affairs (VA) is the Veterans Health Administration (VHA). The VHA is America's largest integrated health system, providing care at over 1,300 health facilities. The VHA is also the only organizational component of the VA that can conduct human subject research. The VHA Office of Research and Development (ORD) is responsible for the creation of human research policies. This policy addresses the human subject research protections considerations when the UCI IRB reviews a human subject research protocol supported by the VHA.

2 REVISIONS FROM PREVIOUS VERSION

1.1 None

3 POLICY

3.1.1 The VHA has the ability to fund veteran-centric research led by VA investigators. To serve as a VA investigator, one must be a VA employee.

3.1.2 The VHA Directive 1200.05(3): Provides the requirements for the protection of human research subjects. This is generally aligned with Office for Human Research Protections (OHRP) guidance.

3.1.3 The VA also aligns with the 2018 Common Rule at 38 CFR 16. The 2018 Common Rule applies to VA research regardless of funding.

3.1.4 The VA follows the Privacy Rule (Health Insurance Portability and Accountability Act of 1996)

3.1.5 The VA Long Beach Healthcare System (VALBHS) Medical Center Director is the individual legally authorized as a Signatory Official to commit VCALBHS to an Assurance.

4 RESPONSIBILITIES

4.1 If the UCI-IRB determines a given VALBHS project does not constitute research, does not constitute human subjects research, or that a particular site is not engaged in human subjects research pertaining to that project, the UCI PI will provide written correspondence concerning its decision to the VALBHS Principal Investigator (PI) via the IRB electronic submission system.

4.2 The UCI-IRB Research Office will seek feedback from the VALBHS PIs, and VALBHS on the efficiency and effectiveness of UCI-IRB operations as part of a continuous quality improvement process.

4.3 If UCI obtains accreditation of the Human Research Protection Program (HRPP) from an accrediting body but fails to maintain accreditation, UCI will notify the VALBHS and ORD in writing within ten (10) business days.

4.4 The UCI-IRB Research Office and UCI-IRB will maintain all VALBHS project documentation, membership documents, and other relevant records in accordance with UCI-IRB SOPs, and all VA and other Local, State, and Federal requirements.

4.5 The VA facility is responsible for ancillary reviews, including Conflict of Interest, and an assessment of the Principal Investigator and Study Team (e.g., expertise, training, including human subject training, credentialed, etc.) not the reviewing IRB.

5 PROCEDURE

5.1 Initial Submission

5.1.1 The VA requires both an initial privacy and information security review, prior to IRB review. A final privacy and information security review occurs prior to VA Research and Development Committee (R&D) review.

5.2 Single IRB

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5.2.1 The VA is agreeable to single IRB; Prior to the 2018 Common Rule, the VA created a central IRB for ORD-funded multi-site studies.

5.2.2 Exceptions from single IRB may be requested from the ORD by VA facility research leadership (i.e., not the investigator).

5.2.3 The VA IRB cannot serve as the IRB of record for any non-VA site.

5.2.4 Collaborative research involving non-VA institutions may not be undertaken without a signed written agreement (e.g., a Cooperative Research and Development Agreement [CRADA] or a Data Use Agreement) that addresses such issues as the responsibilities of each party, the ownership of the data, and the reuse of the data for other research. Any use or reuse of data must be consistent with the protocol, the informed consent document, and the Health Insurance Portability and Accountability Act (HIPAA) authorization.

5.3 **Greater than Minimal Risk Research**

5.3.1 Human research protocols involving greater than minimal risk must include a Data Safety Monitoring Board or Committee. The meeting frequency, as well as the scope of the Board or Committee must be described in the protocol.

5.3.2 Any minutes, reports or records related to the Data Safety Monitoring Board or Committee will be accessible to the VA.

5.4 **Informed Consent Considerations**

5.4.1 Informed consent documents must be both signed and dated by the subject or the subject's legally authorized representative.

5.4.2 Electronic consent is allowable should the process confirm to VA requirements for use of electronic signatures. The VA requirements for use of electronic signatures must meet governmental requirements for authenticity and identification.

5.4.3 Broad consent can only be used when identifiable data or biospecimens are collected solely for *research* purposes in accordance with the requirements in section 17.f of the VHA Directive 1200.05.[1]

5.4.4 Use of the VA ICF template is highly recommended to ensure all the VA mandate elements and boiler plate language is in place.

5.5 **Required Consent Language**

5.5.1 ORD Policy mandates the following consent language, as applicable:

5.5.2 A statement that the VA will provide treatment for research related injury.

5.5.3 A statement that informs VA research subjects that their insurance will not be charged for any costs related to the research. Note: co-payments for standard medical care or services not part of the research procedures may still apply.

5.5.4 When photos, video and/ or audio recordings are taken or obtained exclusively for research purposes:

5.5.4.1 A description of any photographs, video, and / or audio recordings to be taken or obtained for research purposes;

5.5.4.2 How the photographs, video, and / or audio recordings will be used for the research; and

5.5.4.3 Whether the photographs, video, and / or audio recordings will be disclosed outside of the VA

5.6. **When the VA conducts a study protected by a Certificate of Confidentiality (CoC):**

5.6.1. When information about the subject's participation will be included in the VHA medical record, information must be given to the prospective subjects as part of the informed consent process that informs them of this research component.

5.6.2. For studies that mandate informed consent, the consent document approved by the IRB must include the statement that a study has a CoC.

5.7. **Recruitment:**

[1] The VA Long Beach does not allow for the use of Broad Consent.

5.7.1. If prospective participants are being contacted by telephone, the study team must make initial contact in person or by letter prior to any telephone contact and refer to those prior contacts when phoning the participant unless there is written documentation that the subject is willing to be contacted by telephone about the study in question or a specific kind of research.
5.7.2. The initial contact must provide a telephone number or other means that the potential participant can use to verify the study constitutes VA research.
5.7.3. Later Contact – the research team may use telephone calls to the participant by referring to previous contacts and when applicable, the information provided in the informed consent form.
5.7.4. The scope of telephone contacts with the participant is limited to topics outlined in IRB-approved protocols and informed consent forms.

5.8. **HIPAA**

5.8.1. The VHA is a covered entity under HIPAA.
5.8.2. The VA will handle the review of any HIPPA human subject research considerations.
5.8.3. VA Form 10-0493 must be used; a standalone HIPAA authorization document is required. The HIPAA authorization must not be combined with the consent document.
5.8.4. The VA facility must ensure the HIPAA authorization language is valid.
5.8.5. For collaborative research that involves both UCI and the VA, the VA will serve as the privacy board for the VA site. The VALBHS Privacy Officer (PO) and Information System Security Officer (ISSO) Representatives will perform the required privacy and information security reviews and provide these reviews to the IRB with submissions.

5.9. **Reportable Events**

5.9.1. Reviewing serious adverse events, unanticipated problems involving risks to subjects or others, protocol deviations, complaints, Research Compliance Officer (RCO) audit reports, and any audit reports from sponsors, VA oversight bodies or other oversight agencies, regarding projects for which the UCI-IRB is serving as the IRB of record, in accordance with VHA Directive 1058.01 and VHA Directive 1200.05.
5.9.2. Reportable events must be reported to OHRP even if not supported by an agency signed onto the Common Rule. Due to their Federalwide Assurance (FWA), reportable events that occur on non-exempt human subject research mandate reporting.
5.9.3. UCI Principal Investigator (PI) will provide timely written notice, usually within seven (7) calendar days, to VALBHS PI of UCI-IRB determinations involving the conduct of a research project at VALBHS. This includes contingent approvals and requested amendments, etc.
5.9.4. The VA has specific reporting requirements as follows:
5.9.4.1. Death/s at local site/s, both unanticipated and related to the research must be reported to the IRB “immediately.”
5.9.4.2. All local reportable events and unanticipated serious adverse device effects must be reported to the IRB within 5 business days.
5.9.4.3. Protocol deviations and other non-reportable events must be noted in the research file.
5.9.4.4. Local breaches of confidentiality and security must be reported to the IRB within 1 hour, as well as to the necessary privacy offices at the VA.
5.9.5. It is noted that UCI IRB however requires the submission of those events that appear reportable per federal regulations (e.g., unanticipated problems, serious and continuing noncompliance, suspension and terminations of research).

5.10. **Application Supplement Forms:**

5.10.1. **General DoD:** Researchers conducting DoD supported research must complete and submit to the IRB the DoD Supplement Form in addition to the protocol materials submitted to the IRB for initial review. The DoD Supplement Form can be found on the Office of Research (OR), Human Research Protection (HRP) Website at: https://research.uci.edu/human-research-protections/irb-forms/ https://research.uci.edu/wp-content/uploads/WCG-405-Worksheet-Addl-Criteria-DOD.pdf
5.10.2. **Investigational Drugs:** VA Form10-9012, Investigational Drug Information Record is to be provided at initial application when investigational drugs are involved.

6 MATERIALS

None

7 REFERENCES

A special thank you to Karen Jeans, Director for Regulatory Affairs for the Office of Research Protections, Policy and Education, Department of Veteran Affairs, whose Smart IRB presentation from March 2024 has been heavily referenced in the creation of this policy.

38 CFR 16
38 CFR 17.85
VHA Directive 1200.05(3) Requirement for the Protection of Human Subjects in Research: https://www.va.gov/vhapublications/
VHA Directive 1200.05(3), Paragraph 17.d.(10)
VHA Directive 1200.05(3), Paragraph 17.e.(10)
VHA Directive 1200.05(3), Paragraph 17.k.(10)
VHA Directive 1200-01(1) R&D Committee: https://www.va.gov/vhapublications/
https://grants.nih.gov/faqs
https://www.research.va.gov/programs/orppe/irb_relationships.cfm
https://www.research.va.gov/programs/orppe/Checklist-for-VA-Facilities-Using-Independent-Commercial-IRBs-ICDs-and-Combined-ICD-HIPAA-Authorization.docx
https://www.research.va.gov/programs/orppe/VA-HIPAA-Authorization-Requirements-When-Using-an-Independent-Commercial-IRB.docx
https://www.research.va.gov/programs/orppe/VA-Specific-and-Selected-2018-Common-Rule-Informed-Consent-Requirements-When-Using-an-Independent-Commercial-IRB.docx
https://www.research.va.gov/programs/orppe/ORD-IRB-Reliance-Request-Form.docx

Investigator Manual

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Scope

Throughout this document “institution” refers to University of California, Irvine.

What is the purpose of this manual?

This document, Human Research Protections (HRP)-103 - INVESTIGATOR MANUAL, is designed to guide you through policies and procedures related to the conduct of Human Research that are specific to this institution.

General information regarding Human Research protections and relevant federal regulations and guidance is incorporated into the required human protections training. For additional information see below: “What training does my staff and I need in order to conduct Human Research?”

What is Human Research?

HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN defines the activities that this institution considers to be “Human Research.” An algorithm for determining whether an activity is Human Research can be found in HRP-310 - WORKSHEET - Human Research Determination, located in the Institutional Review Board (IRB) Policies & Procedures section of the IRB Web site. Use this document for guidance as to whether an activity meets either the DHHS or FDA definition of Human Research, keeping in mind that the IRB makes the ultimate determination in questionable cases as to whether an activity constitutes Human Research subject to IRB oversight.

An IRB is a specifically constituted review body established or designated by an entity to protect the rights and welfare of human subjects recruited to participate in biomedical or social science/behavioral research.

You are responsible not to conduct Human Research without prior IRB review and approval (or an institutional review and determination of exempt Human Research, including self-determinations of non-human subject research and exemption). If you have questions about whether an activity is Human Research, contact the IRB Office.

The implications of engaging in activities that qualify as human subjects research therefore requiring IRB review and approval without obtaining such approval are significant. Results from such studies may not be published or presented unless IRB approval had been obtained prior to collecting the data. The IRB will determine whether the data may be used to satisfy thesis or dissertation requirements.

The IRB may not approve applications where the Investigator has attempted to circumvent IRB policies and procedures regarding human subjects research by collecting data as non-research and then applying to use it as existing data. It is therefore in the Investigator’s best interest to carefully consider the likelihood that they will want to use the data for research purposes in the future, and to err on the side of inclusion and seek IRB approval prior to commencing the work.

Investigators who request approval to continue human subjects research under 45 CFR 46 and/or under 21 CFR 50 and 56 that was not previously reviewed, or request approval to use data that was collected without IRB approval, face the possibility that the IRB will recommend withdrawal or request that the Investigator administratively withdraw their application, as the IRB cannot give post-hoc (retroactive) approval.

What is the Human Research Protection Program?

HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN describes this institution’s overall plan to protect subjects in Human Research.

1) The mission of the Human Research Protection Program.
2) The ethical principles that the institution follows governing the conduct of Human Research.
3) The applicable laws that govern Human Research.

4) When the institution becomes “engaged in Human Research” and when someone is acting as an agent of the institution conducting Human Research.
5) The types of Human Research that may not be conducted.
6) The roles and responsibilities of individuals within the institution.

What training does my staff, and I need to conduct Human Research?

This section describes the training requirements imposed by the IRB. You may have additional training imposed by other federal, state, or institutional policies.

Investigators and staff conducting research must complete the Collaborative Institutional Training Initiative (CITI) human subjects online training program. Refer to the CITI site for more information. Training is valid for a 5-year period, after which time the training must be repeated. The type of research proposed dictates the type of training necessary. For instance, research that involves Protected Health Information (PHI) requires the completion of the UCI Health Insurance Portability and Accountability Act of 1996 (HIPAA) module.

Where individuals may not have access to the internet for the purpose of completing the CITI training, (e.g., UCI LIFTED) use of Office of Human Research Protections (OHRP) educational training material is acceptable in meeting the human subject education requirement.

All members of the research team involved in the design, conduct, or reporting of the research must complete training. Members of the research team who have not completed human research protections training may not take part in aspects of the research that involve human subjects.

Who may serve as a Lead Researcher or Principal Investigator?

There are requirements for those who may serve as a Lead Researcher or Principal Investigator at UCI. If an individual meets the criteria for Principal Investigator by virtue of their university appointment status, they may also serve as Principal Investigator on a research protocol. If an individual does not meet the criteria for Principal Investigator, they may only serve as Principal Investigator if they obtain a faculty sponsor for the activity. Refer to this webpage for more information.

What financial interests do my staff, and I need to disclose to conduct Human Research?

Individuals involved in the design, conduct, or reporting of research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards are considered to have an institution responsibility.

All individuals involved in the design, conduct, or reporting of research are required to disclose the financial interests in the New Study SmartForm in the electronic IRB system.

Any changes in the financial relationship between the study sponsor and any of the investigators on the study and/or any new potential conflicts of interest must be reported immediately to the UCI Conflict of Interest Oversight Committee (COIOC). If these changes affect the conduct of the study or result in a change in the text of the approved informed consent document, these changes must also be reported to the UCI IRB via a modification.

Disclosable Financial Interests are:

An outside financial interest that needs to be disclosed and reviewed by the COIOC includes one or more of the following for the researcher, their spouse/registered domestic partner and/or dependent children:

- Income greater than $10,000 received from a single entity (excluding UC Regents) over the twelve months prior to disclosure. Income includes salary, consultant payments, honoraria, royalty payments, dividends, or any other payments or consideration with value, including payments made to the University of California Health Sciences Compensation Plans.

- Equity in a publicly traded entity greater than $10,000 (current market value) or greater than a 5% ownership interest. Equity includes stock or stock options, real estate, or any other investment or ownership interest. Equity does not include investments in a mutual fund, pension fund or other investment fund over which the Researcher or his/her immediate family member do not exercise any control.
- Any equity in a non-publicly traded entity, including stock or stock options, or any other investment or ownership interest.
- Any management position, such as Board of Directors, director, officer, partner or trustee.
- Intellectual property interest in a patent, patent application, or a copyright of software assigned or to be assigned to a party other than the UC Regents held by the Researcher, their spouse/registered domestic partner and/or dependent children

Additional details can be found in HRP-055 - SOP - Financial Conflicts of Interests. In addition, refer to this webpage.

How do I submit new Human Research to the IRB?

All IRB submissions must include a protocol. When applicable, the submission must also include:

- Written materials that will be provided to or meant to be seen or heard by subjects including (but not limited to) evaluation instructions and surveys, recruitment materials, and consent documents.
- Details pertaining to study funding, research locations, and participating (external) sites.
- Study staff information, including any Conflicting Interests that are Related to the Research.
- Information related to drugs, biologics, supplements, food and/or devices that are under study.

To submit to the IRB, complete the New Study SmartForm in the electronic IRB system and attach all requested supplements. Have the SmartForm submitted by the PI by clicking the “Submit” activity. Maintain electronic copies of all information submitted to the IRB in case revisions are required. Before submitting the research for initial review, you must:

1) Obtain the financial interest status (“yes” or “no”) of each research staff.
2) Obtain the agreement of research staff to his/her role in the research.
3) In general, the Principal Investigator’s primary school, department, or program determines whether a protocol is reviewed by a biomedical committee or by the social/behavioral/educational committee.
    i. For example, School of Medicine protocols will be reviewed by one of the biomedical committees, while School of Social Sciences protocols will be reviewed by the social/behavioral/educational committee.
    ii. The social/behavioral/educational committee may review research that involves prospective collection of biological specimens (e.g., blood, saliva, deciduous teeth) and/or collection of data via non-invasive measures (e.g., magnetic resonance imaging, tests of sensory acuity, electrocardiography) that customarily may be considered clinical in nature, as long as the procedures involve no more than minimal risk.
4) Identify whether any IRB fees will be charged for this study and address any budget considerations. Refer to this webpage for more information about IRB fees.
5) For studies that involve greater than minimal risk, unless waived by the IRB, all participants must be provided with an explanation in the consent form as to whether any medical treatments are available if injury occurs and, if so, what they consist of and where further information may be obtained.
6) For commercially sponsored studies, compensation or payment of immediate necessary care for injury related to participation in research activities shall be provided according to the contractual agreement between the sponsor and UC Irvine. In general, if a participant is injured as a direct result of

participation in this study, the sponsor is required to reimburse the University for reasonable and necessary medical care to treat the injury. Contractual agreements are negotiated through Sponsored Projects in the Office of Research Administration.

7) HRP conducts a pre-review of the IRB submission, allowing the study to be ready for IRB review. If there remains no response to pre-review after 3 months, the submission will be closed. A new transaction will be required to reinitiate the protocol or modification.

What is the Principal Investigator (PI) Proxy?

The UCI PI may enable the PI Proxy ability for each protocol, allowing a member of their current study team to submit protocols and responses on their behalf. The PI will continue to receive email confirmation when transactions are submitted to the IRB. Further, the PI will have access to the History tab on their protocol page, for transparency of all study communications and formal transactions.

How do I submit a request to use a Humanitarian Use Device (HUD) for clinical use?

This Institution utilizes the IRB to review and approve the use of a HUD before it can be used at a facility for clinical care. The clinical use of a HUD is not considered Human Research but must still be submitted for review and approval by the IRB prior to clinical use (with the exception of emergency use).

Complete the New Study SmartForm in the electronic IRB system and attach all requested supplements. Have the SmartForm submitted by the PI by clicking the “Submit” activity.
Maintain electronic copies of all information submitted to the IRB in case revisions are required. Before submitting the research for initial review, you must:

1) Obtain the financial interest status (“yes” or “no”) of each research staff.
2) Obtain the agreement of research staff to his/her role in the research.

The PI must complete HRP-323 - PI WORKSHEET - Criteria for Approval HUD to provide additional info on the use of the HUD, for IRB review. Use HRP-499 - TEMPLATE CONSENT DOCUMENT for the HUD consent template. While not required by the IRB for HUD use, it is routine practice at UCI to provide informed consent. All versions of the PI WORKSHEETS AND CONSENT FORMS are available on the HRP Toolkit page.

The Protection of Human Subjects in Medical Experimentation Act (California Health and Safety Code Sections 24170-24179.5) requires that individuals be provided the Subject’s Bill of Rights as part of the informed consent process prior to participation in a medical experiment. Since the use of a HUD according to its label is not considered a medical experiment the Bill of Rights is not required.

Regarding the Health Insurance Portability and Accountability Act (HIPAA), a signed HIPAA Research Authorization Form is not needed unless required by the IRB.

When is single IRB review required?

Any cooperative nonexempt human subjects research subject to the Common Rule requires use of single IRB. This requirement applies to that portion of the research that is conducted in the United States. See Appendix A-10.

When will the UCI IRB serve as the IRB of record (sIRB) or rely on an external IRB?

An IRB is considered the IRB of record when it assumes IRB responsibilities for another institution and is designated to do so through an approved Assurance with the Office for Human Research Protections (OHRP).

A Memorandum of Understanding is required, designating the relationship, for UCI to serve as the IRB of Record.

For criteria used to determine whether this institution will serve as the sIRB, refer to HRP-833-PI WORKSHEET - Considerations for Serving as the Reviewing IRB. For criteria used to determine whether this institution will rely on an external IRB, refer to HRP-832 - PI WORKSHEET- Considerations for Relying on an External IRB. An Authorization Agreement(s) must be in place before this IRB can serve as the reviewing IRB or rely on an external IRB.

When should I submit a request to rely on an External IRB?

For studies where this institution is a participating site (pSite), requests to rely on an external IRB should be submitted after the reviewing IRB (sIRB) has approved the study (e.g., lead site protocol), including consent templates and other document templates.

How do I request to rely on an external IRB?

Complete the New Study SmartForm in the electronic IRB system, indicate that an External IRB will serve as the IRB of Record and attach all requested supplements. Have the SmartForm submitted by the PI by clicking the “Submit” activity. Maintain electronic copies of all information submitted to the IRB in case revisions are required.

When should I consult with this IRB when planning a study for which this IRB will be asked to serve as the IRB of record (sIRB)?

If you will request this IRB to serve as the reviewing IRB (sIRB) for cooperative research, contact the IRB Office prior to submitting grant or other funding applications to determine whether this IRB will agree to serve as the sIRB for the study.

How do I request that this IRB serve as the IRB of record (sIRB) for my collaborative or multi-site research study?

On the New Study SmartForm in the electronic IRB system, indicate if the study is a multi-site or collaborative research study, then select “Yes” to the question “Will your IRB act as the single IRB of record for other participating sites?” Complete the rest of the New Study SmartForm and attach all available supplements. Participating sites are added by executing the “Add Participating Site” activity. Have the SmartForm submitted by the PI by clicking the “Submit” activity.

If your research involves sending or receiving data, including protected health information (PHI), you may need a Data Use Agreement. This is an agreement between UCI and the recipient of the PHI. This agreement establishes who is permitted to use or receive the limited data set; and provides that the limited data set recipient will:

1) Not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law;
2) Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the data use agreement;
3) Report to the covered entity any use or disclosure of the information not provided for by its data use agreement of which it becomes aware;
4) Ensure that any agents, including a subcontractor, to whom it provides the limited data set agrees to the same restrictions and conditions that apply to the limited data set recipient with respect to such information; and
5) Not identify the information or contact the individuals.

How do I write a Protocol? What is the Protocol Narrative?

Use the applicable version of HRP-503 – TEMPLATE PROTOCOL NARRATIVE to provide further study details. Follow the prompts throughout the Protocol Narrative, answering each question. Incomplete Protocol Narratives will result in back-and-forth correspondence with the IRB staff and / or IRB and will ultimately delay the IRB review process.

You may not involve any individuals who are members of the following populations as subjects in your research unless you indicate this in your inclusion criteria as the inclusion of subjects in these populations has regulatory implications:

1) Adults with Impaired Decision-Making Capacity
2) Children
3) Pregnant People, Fetuses, and Neonates
4) Prisoners

What are the PI Worksheets?

As referenced above, PI Worksheets are to be completed when special populations or topics are part of the protocol submission. The PI Worksheets collect additional context from the PI to be used during the IRB review process. The PI Worksheets also include information used to document specific regulatory determinations. All versions PI Worksheets are available on the HRP Toolkit page.

How do I create a consent document?

Refer to HRP-502(a-e) CONSENT or HRP-506 CONSENT to create a consent document.

Note that all long form consent documents and all summaries for short form consent documents must contain all of the required and all additional appropriate elements of informed consent disclosure.

Review the “Long Form of Consent Documentation” section in HRP-314a - WORKSHEET - Criteria for Consent, to ensure that these elements are addressed. When using the short form of consent documentation, the appropriate signature block from CONSENT TEMPLATE should be used on the short form. All CONSENT FORMS are available on the HRP Toolkit page.

If your research study meets the requirements for an exemption and there are interactions with subjects, you may use an abbreviated process for obtaining consent. Consent can be verbal, but you must provide the following information to participants through an information sheet or written script:

1) The subject is being asked to participate in a research study;
2) A description of the procedure(s) the participant will be asked to complete;
3) Participation is voluntary; and
4) The investigator’s name and contact information.

We recommend that you date the revisions of your consent documents to ensure that you use the most recent version approved by the IRB.

Unless a waiver of informed consent is granted by the IRB, the consent documents (consent form; information sheet) with the UCI IRB approval stamp must be used for consenting all human subjects enrolled in this study. Only the current approved version of the consent documents may be used to consent subjects. **Approved consent documents are not to be used beyond the expiration date provided on the IRB approval letter.** All CONSENT FORMS are available on the HRP Toolkit page.

Posting of the Informed Consent Document

Clinical trials conducted or supported by a Common Rule department or agency initially approved by the IRB on or after January 21, 2019, must post one (1) IRB-approved clinical trial consent form at a publicly available

federal website. The consent form must be posted after recruitment closes, and no later than 60 days after the last study visit. For additional guidance, refer to the OHRP FAQs on Informed Consent.

Do I need to obtain informed consent in order to screen, recruit, or determine the eligibility of prospective subjects?

The IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:

1) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, OR
2) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

The research protocol should include information about how potential subjects will be identified and recruited in order for the IRB to be able to determine whether informed consent for these activities is required.

Review the HRP Website or contact the IRB Office with additional questions or for further guidance regarding the requirement to obtain HIPAA Research authorization or a waiver to obtain HIPAA Research authorization for recruitment purposes.

What are the different regulatory classifications that research activities may fall under and who may review my protocol?

Submitted activities may fall under one of the following four regulatory classifications:

1) Not "Human Research": Activities must meet the institutional definition of "Human Research" to fall under IRB oversight. Activities that do not meet this definition of are not subject to IRB oversight or review. Review the IRB Office's HRP-310 - WORKSHEET - Human Research Determination for reference. Use the self-determination of non-human subject research process to obtain documentation of non-human subject research. Contact the IRB Office in cases where it is unclear whether an activity is Human Research.
2) Exempt: Certain categories of Human Research may be exempt from regulation but require IRB review. There are also categories of exempt research that may be self-determined by faculty. More information may be found on this HRP webpage. Review the IRB Office's HRP-312 - WORKSHEET - Exemption Determination for reference on the categories of research that may be exempt.
3) Review Using the Expedited Procedure: Certain categories of non-exempt Human Research may qualify for review using the expedited procedure, meaning that the project may be approved by a single designated IRB reviewer, rather than the convened board. Review the IRB Administration's HRP-313 - WORKSHEET - Expedited Review for reference on the categories of research that may be reviewed using the expedited procedure.
4) Review by the Convened IRB: Non-Exempt Human Research that does not qualify for review using the expedited procedure must be reviewed by the convened IRB. This is also referred to as Committee Review.
5) IRB Reviewers include the following: IRB Chairs, IRB Vice Chairs, and single designated reviewers, including IRB Staff colleagues.

What are the decisions the IRB can make when reviewing proposed research?

The IRB may approve research, require modifications to the research to secure approval, table research, defer research or disapprove research:

1) Approval: Made when all criteria for approval are met. See "How does the IRB decide whether to approve Human Research?" below.
2) Modifications Required to Secure Approval: Made when IRB members require specific modifications to the research before approval can be finalized.
3) Tabled: Made when the IRB cannot approve the research at a meeting for reasons unrelated to the research, such as loss of quorum. When taking this action, the IRB automatically schedules the research for review at the next meeting.
4) Deferred: Made when the IRB determines that the board is unable to approve research, and the IRB suggests modifications that might make the research approvable. When making this motion, the IRB describes its reasons for this decision, describes modifications that might make the research approvable, and gives the investigator an opportunity to respond to the IRB in person or in writing.
5) Disapproval: Made when the IRB determines that it is unable to approve research and the IRB cannot describe modifications that might make the research approvable. When making this motion, the IRB describes its reasons for this decision and gives the investigator an opportunity to respond to the IRB in person or in writing.

How does the IRB decide whether to approve Human Research?

The criteria for IRB approval can be found in HRP-312 - WORKSHEET - Exemption Determination for exempt Human Research and HRP-314 - WORKSHEET - Criteria for Approval for non-exempt Human Research. The latter worksheet references other checklists that might be relevant. All checklists and worksheets can be found on the IRB Web site.

These checklists are used for initial review, continuing review, and review of modifications to previously approved Human Research.

You are encouraged to use the worksheets to write your Protocol Narrative and the PI Worksheets, along with other attachments, as applicable, in a way that addresses the criteria for approval.

What will happen after IRB review?

The IRB will provide you with a written decision indicating that the IRB has approved the Human Research, requires modifications to secure approval, or has disapproved the Human Research.

1) If the IRB has approved the Human Research: The Human Research may commence once all other institutional approvals have been met. IRB approval is usually good for a limited period of time which is noted in the approval letter.
2) If the IRB requires modifications to secure approval and you accept the modifications: Make the requested modifications and submit them to the IRB. If all requested modifications are made, the IRB will issue a final approval. Research cannot commence until this final approval is received. If you do not accept the modifications, write up your response and submit it to the IRB. If a response is not received within 3 months the transaction will be administratively closed. A new transaction will be required to reinitiate the protocol or modification.
3) If the IRB tables or defers the Human Research: The IRB will provide a statement of the reasons for deferral and suggestions to make the study approvable and give you an opportunity to respond in writing. In most cases if the IRB's reasons for the deferral are addressed in a modification, the Human Research can be approved. If a response is not received within 3 months the transaction will be administratively closed. A new transaction will be required to reinitiate the protocol or modification.
4) If the IRB disapproves the Human Research: The IRB will provide a statement of the reasons for disapproval and give you an opportunity to respond in writing.

5) If a response is not received within 90 days of the IRB written decision, the transaction may be administratively withdrawn by the HRP.

In all cases, you have the right to address your concerns to the IRB directly at an IRB meeting. Refer to Sec. 480-7 Resolving Regulatory Noncompliance which allows for the appeal of a suspension or termination of IRB approval.

What are my obligations after IRB approval?

1) **Do not start Human Research activities until you have the final IRB approval letter.**
   i. Note: General Counsel of the Regents of the UC has stated that: "If a principal investigator conducts an activity involving human subjects but does not obtain the approval of the campus Human Subjects committee or designated IRB, the Regents would not be obligated to defend or indemnify the principal investigator if legal action were instituted by the subject."
2) **Do not start Human Research activities until you have obtained all other required institutional approvals, including approvals of departments or divisions that require approval prior to commencing research that involves their resources.** Determine which institutional requirements apply to your study and ensure all are met. Refer to HRP-309 - WORKSHEET - Ancillary Review Matrix.
   i. As an example, research undertaken in conjunction with outside entities, such as drug or device companies are typically contractual in nature and require an agreement with the University and the entity. These agreements must be executed by an institutional official in Sponsored Projects, a division of the Office of Research. The University is not obligated to legally defend or indemnify an employee who individually enters into these agreements; Investigators are personally liable for the contracts they sign.
   ii. All individuals engaged in human-subjects research are responsible for compliance with all federal, state and applicable UCI Research Policies. The PI / Faculty Sponsor of the study is ultimately responsible for assuring all study team members adhere to applicable policies for the conduct of human-subjects research.
   iii. Together with your Department Chair, ensure that there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space. Ideally, this is done prior to or as part of the initial IRB submission.
   iv. Ensure that Research Staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials, protocol requirements and, when relevant, privileges) to perform procedures and duties assigned to them during the study.
   v. Update the IRB office with any changes to the list of study personnel, as necessary. Use the Research Team Table and the Research Team Tracking Log as appropriate to maximize study conduct efficiencies.
   vi. Personally conduct or supervise the Human Research. Recognize that the investigator is accountable for the failures of any study team member.
      a. Conduct the Human Research in accordance with the relevant current protocol as approved by the IRB, and in accordance with applicable federal regulations and local laws.
      b. When required by the IRB ensure that consent or permission is obtained in accordance with the relevant current protocol as approved by the IRB.
      c. Do not modify the Human Research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects.
      d. Protect the rights, safety, and welfare of subjects involved in the research.
      e. When research includes locations outside of California, the investigator is responsible for identifying and following relevant policies.
3) Submit to the IRB:
   i. Proposed modifications as described in this manual. (See "How do I submit a modification?").
   ii. No changes are permissible (unless to avoid an immediate, apparent hazard to a subject) to the approved protocol or the approved, IRB stamped consent form without the prior review and approval by the IRB.

iii. In addition, if this human subject research is funded by a Federal agency, the Principal Investigator is responsible to ensure that the IRB protocol continues to be identical in principle and congruent with the scope of work outlined in the grant proposal application.
iv. Protocol exceptions should be submitted via the reportable new information application. Specify that this exception should be for no more than 3 subjects. Upload the protocol exception template.
v. A continuing review application as requested in the approval letter. (See "How do I submit continuing review?")
vi. A continuing review application when the Human Research is closed. (See "How Do I Close Out a Study?")

4) Complete the Report New Information SmartForm within 5 days of becoming aware of any information that meet the definition/s of Serious and/or Continuing Noncompliance or Unanticipated Problems as found on this HRP webpage. The following are examples that may meet these definitions:
   i. Information that indicates a new or increased risk, or a new safety issue. For example:
      a) New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor report, or investigator finding) indicates an increase in the frequency or magnitude of a previously known risk or uncovers a new risk. This may include an FDA, Data Safety Monitoring Board (DSMB) or Sponsor hold/ suspension.
      b) An investigator brochure, package insert, or device labeling is revised to indicate an increase in the frequency or magnitude of a previously known risk, or describe a new risk
      c) Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol
      d) Protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm
      e) Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm
      f) Any changes significantly affecting the conduct of the research
   ii. Harm experienced by a subject or other individual, which in the opinion of the investigator are **unexpected** and **probably related** to the research procedures.
      a) A harm is "unexpected" when its specificity or severity are inconsistent with risk information previously reviewed and approved by the IRB in terms of nature, severity, frequency, and characteristics of the study population.
      b) A harm is "probably related" to the research procedures if in the opinion of the investigator, the research procedures more likely than not caused the harm.
   iii. Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such non-compliance.
   iv. Audit, inspection, or inquiry by a federal agency and any resulting reports (e.g. FDA Form 483.)
   v. Written reports of study monitors.
   vi. Failure to follow the protocol due to the action or inaction of the investigator or research staff.
   vii. Breach of confidentiality.
   viii. Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject.
   ix. Incarceration of a subject in a study not approved by the IRB to involve prisoners.
   x. Complaint of a subject that cannot be resolved by the research team.
   xi. Premature suspension or termination of the protocol by the sponsor, investigator, or institution.
   xii. Unanticipated adverse device effect (any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects).
5) If the incident does not meet the definition of serious and / or continuing noncompliance or an unanticipated problem, do not submit the event to the IRB.
6) Any changes in the financial relationship between the study sponsor and any of the investigators on the study and/or any new potential conflicts of interest must be reported immediately to the UCI Conflict of

Interest Oversight Committee (COIOC). If these changes affect the conduct of the study or result in a change in the text of the approved informed consent document, these changes must also be reported to the UCI IRB via a modification.

7) Do not accept or provide payments to professionals in exchange for referrals of potential subjects ("finder's fees."). Compensation of any type (cash, office or medical supplies, educational stipends, gift certificates, priority in authorship listings, travel reimbursement, or anything else of value) to an individual made in exchange for referral or recruitment of a participant to a research study. Such payments, generally, are made to residents, physicians, nurses, or others in a position to identify potential participants that might qualify for enrollment into a study. The fee is paid only for participants who are actually enrolled into the study.
8) Do not accept payments designed to accelerate recruitment that were tied to the rate or timing of enrollment ("bonus payments").
   i. Examples of bonus payments include but are not limited to the following:
      a) The sponsor announces that the highest enrolling site in the nation will receive a $10,000 bonus;
      b) The sponsor offers to pay an additional $10,000 to any site that enrolls five participants within a week;
      c) The sponsor offers to pay an additional $10,000 to any site that fulfills its recruitment target by the end of the month;
      d) The sponsor offers to pay an additional $1,000 for any subject who agrees within one day of initial contact.
   ii. See additional requirements of various federal agencies in Appendix A. These represent additional requirements and do no override the baseline requirements of this section.
9) As noted above, if the study is a clinical trial and supported by a Common Rule agency, one IRB-approved version of a consent form that has been used to enroll participants must be posted on a public federal website designated for posting such consent forms. The form must be posted after recruitment closes, and no later than 60 days after the last study visit. Please contact the study sponsor with any questions.
   i. If certain information should not be made publicly available on a federal website (e.g. confidential commercial information), the supporting Federal department or agency may permit or require redactions to the information posted. Contact the Federal department or agency supporting the clinical trial for a formal determination.
   ii. Contact the supporting Federal department or agency sponsor with any other questions regarding consent form posting obligations.
10) In accordance with Federal regulations and HRP policies, there are PI responsibilities during the conduct, as well as after completion, of your research. Use HRP-430 to ensure adherence with your post-approval regulatory responsibilities.
11) In accordance with UC Office of the President policy, research records must be retained for 10 years after the end of the calendar year in which the research is completed unless otherwise specified in the award agreement. If research involves the investigation of FDA regulated products: Information/biospecimens must be retained for two years after an approved marketing application. If approval is not received, the information/biospecimens will be kept for 2 years after the investigation is discontinued and the FDA is notified per FDA sponsor requirements.

What are my obligations as the overall study PI for an sIRB study?

1) Coordinate with HRPP personnel to determine whether this institution's IRB can act as the single IRB for all or some institutions participating in the study or if an external IRB will assume oversight.
2) Identify whether any IRB fees will be charged for this study and address any budget considerations.
3) Identify all sites that will be engaged in the human research and requiring oversight by the IRB.
4) Ensure that all sites receive a request to rely on the reviewing IRB and that all institutional requirements are satisfied before a study is activated at a relying site.
5) Collaborate with the reviewing IRB to document roles and responsibilities for communicating and coordinating key information from study teams and the IRB or HRPP at relying on sites.

6) Respond to questions or information requests from study teams or the IRB or HRPP staff at relying on sites.
7) Provide relying on site investigators with the policies of the reviewing IRB.
8) Provide relying on site investigators with the IRB-approved versions of all study documents, including an approved consent template.
9) Help prepare and submit IRB applications on behalf of all sites. This includes initial review, modifications, personnel updates, reportable new information and continuing review information for all sites.
10) Establish a process for obtaining and collating information from all sites and submitting this information to the reviewing IRB. This includes site-specific variations in study conduct, such as the local consent process and language, subject identification and recruitment processes and local variations in study conduct.
11) Provide pSites with HRP-103p – pSite Manual.
12) Fulfill any communication responsibilities as outlined in HRP-830 - WORKSHEET - Communication and Responsibilities.
13) Use HRP-811- FORM - Basic Site Information, HRP-812 - FORM - Site Continuing Review, HRP-813 - FORM - Site Modification, and 814 - FORM - Site Reportable New Information to collect information from participating sites.
14) Ensure that consent forms used by pSites follow the consent template approved by the reviewing IRB and include required language as specified by the pSites.
15) Provide site investigators with all determinations and communications from the reviewing IRB.
16) Submit reportable new information from pSites to the reviewing IRB in accordance with the terms outlined in the authorization agreement or communication plan. Note that the UCI IRB will be involved in assessing reportable events, even if not the IRB of record.
17) Report the absence of continuing review information from pSites if they do not provide the required information prior to submission of the continuing review materials to the reviewing IRB. Notifying the pSite of their lapse in approval and applicable corrective actions.
18) Provide study records to the relying institution, reviewing IRB or regulatory agencies upon request.

What are my obligations as investigator when relying on an external IRB?

1) Obtain appropriate approvals from this institution prior to seeking review by another IRB.
2) Comply with determinations and requirements of the reviewing IRB.
3) Prepare consent and other study documents that are consistent with those approved by the sIRB (e.g., use the approved consent template to create site-specific documents).
4) Provide the reviewing IRB with requested information about local requirements or local research context issues relevant to the IRB's determination prior to IRB review.
5) Notify the reviewing IRB when local policies that impact IRB review are updated.
6) Cooperate in the reviewing IRB's responsibility for initial and continuing review, record keeping and reporting and providing all information requested by the reviewing IRB in a timely manner.
7) Disclose conflicts of interest as required by the reviewing IRB and complying with management plans that may result.
8) Promptly report to the reviewing IRB any proposed changes to the research and not implementing those changes to the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to the participants.
9) When enrolling participants, obtain, document and maintain records of consent for each participant or each participant's legally authorized representative.
10) Promptly report to the reviewing IRB any unanticipated problems involving risks to participants or others according to the requirements specified in the reliance agreement.
11) Provide the reviewing IRB with data safety monitoring reports in accordance with the reviewing IRB's reporting policy.
    a) Additional information on data safety monitoring:
        i) Data and Safety Monitor (DSM): An individual assigned to conduct interim monitoring of accumulating data from research activities to assure the continuing safety of research participants, relevance of the study question, appropriateness of the study, and integrity of the accumulating

data. The individual should have expertise in the relevant medical, ethical, safety and scientific issues.

ii) Data and Safety Monitoring: A plan to oversee the implementation of a study protocol for compliance monitoring.

iii) Data and Safety Monitoring Board/Committee (DSMB or DSMC): A formally appointed independent group consisting of at least three members assigned to conduct interim monitoring of accumulating data from research activities to assure the continuing safety of research participants, relevance of the study question, appropriateness of the study, and integrity of the accumulating data. Membership should include expertise in the relevant field of study, statistics, and research study design.

iv) Data and Safety Monitoring Plan (DSMP): A DSMP describes how the LR plans to oversee the research participant's safety and welfare and how adverse events will be characterized and reported. The intensity and frequency of monitoring should be tailored to fit the expected risk level, complexity, and size of the particular study.

12) Report non-compliance, participant complaints, protocol deviations or other events according to the requirements specified in the reliance agreement.
13) Specify the contact person and providing contact information for researchers and research staff to obtain answers to questions, express concerns, and convey suggestions regarding the use of the reviewing IRB.
14) Fulfill any communication responsibilities as outlined in HRP-830 - WORKSHEET - Communication and Responsibilities.
15) Determine which institutional requirements apply to your study and ensure all are met. Refer to HRP-309 - WORKSHEET - Ancillary Review Matrix.
16) Report to the local IRB any changes to the study required by this institution. Report updates to the overall study using the "Update Study Details" activity. Report modifications to this site (e.g., personnel changes) using the "Create Site Modification" activity.

How do I document consent?

Use the signature block approved by the IRB. Complete all items in the signature block, including dates and applicable checklists.

The following are the requirements for long form consent documents:

1) The subject or representative signs and dates the consent document.
2) If the subject/representative is physically unable to sign the consent form, note this on the consent form and document the method used for communication with the prospective subject/representative and the specific means by which their agreement was communicated.
3) The individual obtaining consent signs and dates the consent document.
4) Whenever the IRB or the sponsor requires a witness to the oral presentation, the witness signs and dates the consent document.
5) For subjects or read who cannot read and whenever required by the IRB or the sponsor, a witness to the oral presentation signs and dates the consent document.
6) A copy of the signed and dated consent document is to be provided to the subject.
7) The Protection of Human Subjects in Medical Experimentation Act (California Health and Safety Code Sections 24170-24179.5) requires that individuals be provided the Subject's Bill of Rights as part of the informed consent process prior to participation in a medical experiment.

The following are the requirements for short form consent documents:

1) The subject or representative signs and dates the short form consent document.
2) The person obtaining consent signs and dates the summary.
   a) The impartial witness (fluent in both English and the language spoken by the subject/representative) to the oral presentation signs and dates the short form consent document and the summary. The witness and the interpreter may be the same person.

b) In cases where the interpreter or translator is an impartial third party to an oral / IRB approved short form consent process but is not physically present (e.g., a virtual consent process), the family member of the participant may be allowed to serve as a witness. The family member serving as a witness must be fluent in both English and the language of the participant.

3) The witness must sign and date both the short form written informed consent document and a copy of the IRB approved English version of the consent document.
4) Copies of the signed and dated consent document and summary are provided to the subject/ or representative.

In general, for studies that involve greater than minimal risk a request for Short Forms will require full committee review. The IRB Chair or Vice Chair's has discretion on a protocol-by-protocol basis however and may decide that review of a request for Short Forms can occur at a subcommittee level. The reason for the level of review should be appropriately documented with the IRB application.

In the instance that the UCI IRB has approved Short Form use but the specific foreign language translation of the English Short Form is not immediately available on the UCI HRP webpage, UCI researchers may use the appropriate language translation of the Short Form as found on the following websites; WCG IRB, Advarra IRB, Central IRB for the National Cancer Institute (CIRB) or any UC HRP that has the needed translation available.

Once eligibility is confirmed, obtain a translated copy of the IRB-approved English version of the long form consent promptly and submit to the IRB for review. After IRB approval of the translated version, provide it to the subject or LAR as soon as possible and within one month from the date that eligibility is confirmed.

Translation Requirements

Greater than minimal risk studies: professional or certified translation of the long form and recruitment materials is required for studies that pose more than minimal risk to participants. For a professional translation the PI must provide the qualifications of the individual who translated the informed consent documents and recruitment materials. Include any credentials, certifications, education, native language fluency, etc. For a certified translation, a copy of the certification from the translator or translation service should be attached to the translation of any informed consent documents and recruitment materials.

Minimal risk studies: Studies that are eligible for expedited review also require translation of the long form or verbal consent document and recruitment materials; however, certified translation is not required. The IRB will accept documents translated by an individual fluent (i.e., can speak, read, and write) in a given language. The qualifications of the individual performing the translation will be assessed by the IRB. A letter or statement from the translator describing their qualifications must be provided with the translation documents.

How do I submit a modification?

The UCI HRP does not require the submission of a modification for minor changes to exempt research. For those studies in which a PI (and faculty sponsor (FS), if applicable) has submitted to and received UCI IRB confirmation of exemption, minor changes may be made without notifying the UCI IRB. For more information about this including what constitutes a minor change versus a change that must be prospectively submitted for review and approval by the UCI IRB via a formal modification, visit: Post-Review Responsibilities.

Complete the Modification SmartForm in the electronic IRB system and attach all requested supplements, have the SmartForm submitted by the PI (or PI Proxy) by clicking the "Submit" activity. Maintain electronic copies of all information submitted to the IRB in case revisions are required. Please note that research must continue to be conducted without inclusion of the modification until IRB approval is received.

Note that there are two types of modifications (scope) that can be submitted: "Updates to study team member information" and "Other parts of the study." There can only be one type of modification in process at any given time (i.e., you can only have one study team member modification reviewed at a time), but you may have

modifications of both types being processed at any given time (i.e., you can have a study member update and other parts of the study modification in process at the same time).

How do I submit continuing review?

Complete the Continuing Review SmartForm in the electronic IRB system and attach all requested supplements and have the SmartForm submitted by the PI (or PI Proxy) by clicking the "Submit" activity. Maintain electronic copies of all information submitted to the IRB in case revisions are required.

If the continuing review involves modifications to previously approved research, submit those modifications either as a combined Modification and Continuing Review or as a separate request for modification using the Modification SmartForm the electronic system.

If the continuing review application is not received by the date requested in the approval letter, you may be restricted from submitting new Human Research until the completed application has been received.

If the approval of Human Research expires all Human Research procedures related to the protocol under review must cease, including recruitment, advertisement, screening, enrollment, consent, interventions, interactions, and collection or analysis of private identifiable information. Continuing Human Research procedures is a violation of institutional policy. If current subjects will be harmed by stopping Human Research procedures that are available outside the Human Research context, provide these on a clinical basis as needed to protect current subjects. If current subjects will be harmed by stopping Human Research procedures that are not available outside the Human Research context, immediately contact the IRB chair and provide a written list of the currently enrolled subjects and why they will be harmed by stopping Human Research procedures.

Additional reminder about continuing review: In all cases the expiration date (the last day the research is approved) is the last day of the approval period. Research may be conducted on the expiration date but may not be conducted after the expiration date without re-approval. For example, if the approval period is April 27, 2005 - April 11, 2006, the expiration date is April 11, 2006. Research must stop at midnight April 11, 2006 unless the Investigator received re-approval of the research. When a protocol lapses, the study will be administratively closed out after 1 year. Thereafter, to reinitiate the research, a new study submission will be required. IRB fees will apply for new clinical research supported by industry.

How do I close out a study?

The UCI IRB approval letter references the protocol expiration date under the IRB Chair's signature authorization. A courtesy email will be sent prior to expiration reminding the PI to apply for renewal**. It is the PI's responsibility to apply for renewal to ensure continuous approval throughout the conduct of the study. Lapses in approval must be avoided to protect the safety and welfare of enrolled subjects.**

Complete the Continuing Review SmartForm in the electronic IRB system and attach all requested supplements and have the SmartForm submitted by the PI (or PI Proxy) by clicking the "Submit" activity. Maintain electronic copies of all information submitted to the IRB in case revisions are required.

If you fail to submit a continuing review form to close out Human Research, you will be restricted from submitting new Human Research until the completed application has been received.

How long do I keep records?

You are responsible for the retention of protocol–related records. For more information about the LR's recordkeeping responsibilities for the preparation and maintenance of research files, visit: Post-Review Responsibilities.

What if I need to use an unapproved drug, biologic, or device and there is no time for IRB review?

Consider contacting the IRB Office or IRB chair immediately to discuss the situation. Then utilize the Report of New Information. Complete HRP-322 - PI WORKSHEET - Emergency Use for the regulatory criteria allowing such a use for both the initial notification (not required by the FDA however some PIs may prefer this route) and the follow up report (mandated by the FDA). Make sure that all criteria are followed.

Include in the report a description of how the use meets the criteria outlined in HRP-322 - PI WORKSHEET - Emergency Use, a summary of the patient's diagnosis and treatment history, and date and time of the use. Attach to the report the consent document templates used (if applicable), approval of the use from the FDA (drugs and biologics), or concurrence letter from an independent physician that the use of the device is warranted and no other alternative treatments are/were available (devices).

Remember: you MUST submit a report of the use to the IRB within five working days of the use. This is a requirement of the FDA. All versions of PI Worksheets and Consent Forms are available on the HRP Toolkit page.

If you fail to submit the report within five working days, you will be restricted from submitting new Human Research until the report has been received.

Emergency use of an unapproved drug or biologic in a life-threatening situation without prior IRB review is "research" as defined by FDA, the individual getting the test article is a "subject" as defined by FDA and therefore is governed by FDA regulations for IRB review and informed consent. Emergency use of an unapproved device without prior IRB review is not "research" as defined by FDA and the individual getting the test article is not a "subject" as defined by FDA. However, FDA guidance recommends following similar rules as for emergency use of an unapproved drug or biologic.

Individuals getting an unapproved drug, biologic, or device without prior IRB review cannot be considered a "subject" as defined by DHHS and their results cannot be included in prospective "research" as that term is defined by DHHS.

FDA regulations require that any subsequent use of a test article at the institution have prospective IRB review and approval. If it is anticipated that this test article may be used again (for the same patient, a different patient, or for any indication), submit a protocol and consent document(s) to the IRB for review so that an approved protocol will be in place when the next need arises.

How do I submit a non-emergency expanded access request for an unapproved drug, biologic, or device to the IRB?

There are five different types of non-emergency use expanded access:

1) Individual patient expanded access use of an investigational drug

Individual patient drug expanded access requests should be submitted to the IRB as a new study. If the study team checked "Request for Authorization to Use Alternative IRB Review Procedures" on FDA Form 3926 (field 10.b.) or has a separate waiver request included with FDA Form 1571 for the purpose of obtaining concurrence from an IRB Chair or designee, this information should be included in the application. At minimum, the submission should include the following:

1) A thorough patient history and treatment plan, included in the Form FDA 3926 or in a separate document that includes:
    a. The proposed daily dose, route, and frequency of administration of planned treatment; duration of planned treatment; criteria for discontinuation of treatment; and planned dose modifications for adverse events;

b. The planned monitoring for adverse events, response to treatment, and changes in clinical status, as well as proposed modifications to the treatment plan to mitigate risks to the patient if appropriate;
c. The key details of the patient's history, including diagnosis and summary of prior therapy (including response to such therapy); the reason for request, including an explanation of why the patient lacks other therapeutic options; and information regarding a patient's relevant clinical characteristics (such as comorbid conditions and concomitant medications) that is necessary to assess the potential for increased risks of the drug; and
d. A summary of known risks of the drug

Complete the applicable version of HRP-325 - PI WORKSHEET - Expanded Access to provide the above details. The PI WORKSHEET must be attached to the SmartForm. All versions of PI Worksheets and Consent Forms are available on the HRP Toolkit page. Refer to the Expanded Access version of the consent template. A Continuing Review application must be submitted to the IRB at least annually, and any modifications or new information should be reported accordingly.

2) Compassionate Use (Individual patient/small group access) of a device

Requests for compassionate use of a device should be submitted to the IRB as a new study. Complete HRP-325 - PI WORKSHEET - Expanded Access to address the regulatory criteria allowing such a use and make sure these are followed. The FDA does not consider the compassionate use of an unapproved device to be a clinical investigation; however, it is expected that informed consent be obtained.

The submission should include a summary of the conditions constituting the compassionate use, other relevant details of the case, approval from the device manufacturer, device/product manual, FDA authorization, and any other relevant information (i.e., patient-facing materials, etc..).

The HRP-325 - PI WORKSHEET - Expanded Access must be attached to the SmartForm. All versions of PI Worksheets and Consent Forms are available on the HRP Toolkit page. A Continuing Review application must be submitted to the IRB at least annually, and any modifications or new information should be reported accordingly.

3) Intermediate-size patient population access of a drug
4) Expanded access for widespread use of a drug
5) Treatment use of a device

Requests for any of these types of expanded access use should be submitted to the IRB as a new study. Submissions should include the protocol, consent form, and other pertinent information (i.e., Investigator's Brochure, device/product manual, patient-facing materials, etc.).

Complete HRP-325 - PI WORKSHEET - Expanded Access to address the regulatory criteria allowing such a use and make sure these are followed. All versions of PI Worksheets and Consent Forms are available on the HRP Toolkit page. A Continuing Review application must be submitted to the IRB at least annually, and any modifications or new information should be reported accordingly.

How do I transfer responsibility to a new principal investigator?

Changes of PI often prompt changes to other parts of the study. Review all consent/assent forms, recruitment materials and other documents to make certain they have been updated to reflect the change. The current PI may transfer responsibility to a new PI by submitting a modification (See "How do I submit a modification?").

If the current PI is leaving the institution but will remain a study team member, please contact the IRB Office to determine if a reliance agreement is appropriate. If the current PI is leaving the institution and plans to take

research data or specimens with them, there are contractual agreements that may be needed in order to share individual level human subjects research data/specimens.

If a PI goes on an unanticipated leave or there is an abrupt departure from the institution, a modification should be submitted by a current member of the study team as soon as possible to update the PI. Create and submit the Report New Information SmartForm. Select the category “Failure to follow the protocol due to the action or inaction of the investigator or research staff.” The submission should include an explanation as to why a modification will not be submitted, whether the unanticipated leave is temporary (and for how long) or permanent, and who will be responsible for the conduct of the study during this time.

Access and use of IRB data

Trial Quest is a tool used by the 5 clinical and translational science institutes (Davis, Irvine, Los Angeles, San Diego, and San Francisco) to assist contracting officers and other campus administrators in speeding contract negotiations and administrative reviews. This database contains information about IRB-approved or pending studies. It is accessed by contracting officers and other research administrators to expedite their processes by alerting them to contracts and studies that may already be in place at other UC campuses.

Trial Quest includes the following information:

- Submission Date (entered into the IRB system)
- Campus & ID #
- Status (generally pending or active)
- Study Title
- Sponsor name
- PI name (with link to PI Profiles page)
- ClinicalTrials.gov ID# (with link)

The database is hosted at UCSF and is supported by its Research Technology team and UC BRAID staff. Please contact David Grady, UC BRAID Program Manager at david.grady@ucbraid.org, if you have any questions

Additional UC Irvine partners access the IRB database to support daily operations ancillary yet related to the IRB process. Such processes include committees (e.g., Radiation Safety Committee, Conflict of Interest Committee), Departments including Pharmacy and the Compliance and Privacy Office. All individuals accessing the IRB database must complete a Huron Authorized User Agreement prior to use. This agreement specifies the terms of access and precludes sharing of data to a third party, except other authorized users, without prior written permission from the data provider.

How do I get additional information and answers to questions?

This document and the policies and procedures for the Human Research Protection Program are available on the IRB Web Site at https://research.uci.edu/human-research-protections/

The IRB Office wants your questions, information, and feedback. Contact and location information for the IRB Office is:

Beverley Alberola, CIP
Senior Director, Human Research Protections
Human Research Protections
Office of Research, University of California - Irvine
Irvine, CA 92697
Email: beverley.alberola@uci.edu

949-824-5746
(she/her)

Jessica Sheldon, CIP
Director, Human Research Protections
Human Research Protections
Office of Research, University of California - Irvine
Irvine, CA 92697
Email: jessica.sheldon@uci.edu
949-824-3831
(she/her)

If you have questions, concerns, complaints, allegations of undue influence, allegations or findings of non-compliance, or input regarding the Human Research Protection Program that cannot be addressed by contact the IRB Office, follow the directions in HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN under “Reporting and Management of Concerns.”

Appendix A-1 ***Additional Requirements for DHHS-Regulated Research***[i]

1) When a subject decides to withdraw from a clinical trial, the investigator conducting the clinical trial should ask the subject to clarify whether the subject wishes to withdraw from all components of the trial or only from the primary interventional component of the trial. If the latter, research activities involving other components of the clinical trial, such as follow-up data collection activities, for which the subject previously gave consent may continue. The investigator should explain to the subject who wishes to withdraw the importance of obtaining follow-up safety data about the subject.
2) Investigators are allowed to retain and analyze already collected data relating to any subject who chooses to withdraw from a research study or whose participation is terminated by an investigator without regard to the subject's consent, provided such analysis falls within the scope of the analysis described in the IRB-approved protocol. This is the case even if that data includes identifiable private information about the subject.
3) For research not subject to regulation and review by FDA, investigators, in consultation with the funding agency, can choose to honor a research subject's request that the investigator destroy the subject's data or that the investigator exclude the subject's data from any analysis.
4) When seeking the informed consent of subjects, investigators should explain whether already collected data about the subjects will be retained and analyzed even if the subjects choose to withdraw from the research.
5) When research is covered by a certificate of confidentiality, researchers:
    a. May not disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or
    b. May not disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.
    c. May not utilize third parties or entities to collect or store information (e.g., contractors, online platform vendors) that cannot or will not protect against the compelled disclosure of the personally identifiable information.
    d. May disclose information only when:
        i. Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding.
        ii. Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;
        iii. Made with the consent of the individual to whom the information, document, or biospecimen pertains; or
        iv. Made for the purposes of other scientific research that follows applicable Federal regulations governing the protection of human participants in research.
    e. Researchers must inform participants of the protections and limitations of certificates of confidentiality. Consent templates are available on the HRP Toolkit page.
        i. For studies that were previously issued a Certificate and notified participants of the protections provided by that Certificate, NIH does not expect participants to be notified that the protections afforded by the Certificate have changed, although IRBs may determine whether it is appropriate to inform participants.
        ii. If part of the study cohort was recruited prior to issuance of the Certificate, but are no longer activity participating in the study, NIH does not expect participants consented prior to the change in authority, or prior to the issuance of a Certificate, to be notified that the protections afforded by the Certificate have changed, or that participants who were

previously consented to be re-contacted to be informed of the Certificate, although the IRB may determine whether it is appropriate to inform participants.

f. Researchers conducting research covered by a certificate of confidentiality, even if the research is not federally funded, must ensure that if identifiable, sensitive information is provided to other researchers or organizations, the other researcher or organization must comply with applicable requirements when research is covered by a certificate of confidentiality.

Appendix A-2 ***Additional Requirements for FDA-Regulated Research***

1) When a subject withdraws from a study:[ii]
    a. The data collected on the subject to the point of withdrawal remains part of the study database and may not be removed.
    b. An investigator may ask a subject who is withdrawing whether the subject wishes to provide continued follow-up and further data collection subsequent to their withdrawal from the interventional portion of the study. Under this circumstance, the discussion with the subject would distinguish between study-related interventions and continued follow-up of associated clinical outcome information, such as medical course or laboratory results obtained through non-invasive chart review and address the maintenance of privacy and confidentiality of the subject's information.
    c. If a subject withdraws from the interventional portion of the study but agrees to continued follow-up of associated clinical outcome information as described in the previous bullet, the investigator must obtain the subject's informed consent for this limited participation in the study (assuming such a situation was not described in the original informed consent form). IRB approval of informed consent documents is required.
    d. If a subject withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the investigator must not access for purposes related to the study the subject's medical record or other confidential records requiring the subject's consent.
    e. An investigator may review study data related to the subject collected prior to the subject's withdrawal from the study, and may consult public records, such as those establishing survival status.
2) For FDA-regulated research involving investigational drugs:
    a. The IDS is a division of the UCIMC Pharmacy Department that must be consulted in advance of study initiation concerning the storage, handling, and dispensing of investigational drugs, agents, and biologics to assure compliance with all IDS policies and procedures, institutional, State, Federal (FDA) and Joint Commission on Accreditation of Hospital Organizations (JCAHO) requirements.
    b. Investigators must abide by FDA restrictions on promotion of investigational drugs:[iii]
        i. An investigator, or any person acting on behalf of an investigator, must not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug.
        ii. This provision is not intended to restrict the full exchange of scientific information concerning the drug, including dissemination of scientific findings in scientific or lay media. Rather, its intent is to restrict promotional claims of safety or effectiveness of the drug for a use for which it is under investigation and to preclude commercialization of the drug before it is approved for commercial distribution.
        iii. An investigator must not commercially distribute or test market an investigational new drug.
    c. Follow FDA requirements for general responsibilities of investigators[iv]
        i. An investigator is responsible for ensuring that an investigation is conducted according to the signed investigator statement, the investigational plan, and applicable regulations; for protecting the rights, safety, and welfare of subjects under the investigator's care; and for the control of drugs under investigation.
        ii. An investigator must, in accordance with the provisions of 21 CFR §50, obtain the informed consent of each human subject to whom the drug is administered, except as provided in 21 CFR §50.23 or §50.24 of this chapter.
        iii. Additional specific responsibilities of clinical investigators are set forth in this part and in 21 CFR §50 and 21 CFR §56.
    d. Follow FDA requirements for control of the investigational drug[v]

i. An investigator must administer the drug only to subjects under the investigator's personal supervision or under the supervision of a sub-investigator responsible to the investigator.
ii. The investigator must not supply the investigational drug to any person not authorized under this part to receive it.

e. Follow FDA requirements for investigator recordkeeping and record retention[vi]
i. Disposition of drug:
1. An investigator is required to maintain adequate records of the disposition of the drug, including dates, quantity, and use by subjects.
2. If the investigation is terminated, suspended, discontinued, or completed, the investigator must return the unused supplies of the drug to the sponsor, or otherwise provide for disposition of the unused supplies of the drug under 21 CFR §312.59.
ii. Case histories.
1. An investigator is required to prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation.
2. Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital charts, and the nurses' notes. The case history for each individual must document that informed consent was obtained prior to participation in the study.

3) Record retention: In accordance with UC Office of the President policy, research records must be retained for 10 years after the end of the calendar year in which the research is completed unless otherwise specified in the award agreement. If research involves the investigation of FDA regulated products: Information/biospecimens must be retained for two years after an approved marketing application. If approval is not received, the information/biospecimens will be kept for 2 years after the investigation is discontinued and the FDA is notified per FDA sponsor requirements.
a. Follow FDA requirements for investigator reports[vii]
i. Progress reports: The investigator must furnish all reports to the sponsor of the drug who is responsible for collecting and evaluating the results obtained.
ii. Safety reports: An investigator must promptly report to the sponsor any adverse effect that may reasonably be regarded as caused by, or probably caused by, the drug. If the adverse effect is alarming, the investigator must report the adverse effect immediately.
iii. Final report: An investigator must provide the sponsor with an adequate report shortly after completion of the investigator's participation in the investigation.
iv. Financial disclosure reports:
1. The clinical investigator must provide the sponsor with sufficient accurate financial information to allow an applicant to submit complete and accurate certification or disclosure statements as required under 21 CFR §54.
2. The clinical investigator must promptly update this information if any relevant changes occur during the course of the investigation and for 1 year following the completion of the study.

b. Follow FDA requirements for assurance of IRB review[viii]
i. An investigator must assure that an IRB that complies with the requirements set forth in 21 CFR §56 will be responsible for the initial and continuing review and approval of the proposed clinical study.
ii. The investigator must also assure that he or she will promptly report to the IRB all changes in the research activity and all unanticipated problems involving risk to human subjects or others, and that he or she will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

c. Follow FDA requirements for inspection of investigator's records and reports[ix]
    i. An investigator must upon request from any properly authorized officer or employee of FDA, at reasonable times, permit such officer or employee to have access to, and copy and verify any records or reports made by the investigator pursuant to 312.62.
    ii. The investigator is not required to divulge subject names unless the records of particular individuals require a more detailed study of the cases, or unless there is reason to believe that the records do not represent actual case studies, or do not represent actual results obtained.
d. Follow FDA requirements for handling of controlled substances[x]
    i. If the investigational drug is subject to the Controlled Substances Act, the investigator must take adequate precautions, including storage of the investigational drug in a securely locked, substantially constructed cabinet, or other securely locked, substantially constructed enclosure, access to which is limited, to prevent theft or diversion of the substance into illegal channels of distribution.

4) For FDA-regulated research involving investigational devices:
a. General responsibilities of investigators.[xi]
    i. An investigator is responsible for ensuring that an investigation is conducted according to the signed agreement, the investigational plan and applicable FDA regulations, for protecting the rights, safety, and welfare of subjects under the investigator's care, and for the control of devices under investigation. An investigator also is responsible for ensuring that informed consent is obtained in accordance with 21 CFR §50.
b. Specific responsibilities of investigators[xii]
    i. Awaiting approval: An investigator may determine whether potential subjects would be interested in participating in an investigation but must not request the written informed consent of any subject to participate and must not allow any subject to participate before obtaining IRB and FDA approval.
    ii. Compliance: An investigator must investigate in accordance with the signed agreement with the sponsor, the investigational plan, and other applicable FDA regulations, and any conditions of approval imposed by an IRB or FDA.
    iii. Supervising device use: An investigator must permit an investigational device to be used only with subjects under the investigator's supervision. An investigator must not supply an investigational device to any person not authorized to receive it.
    iv. Financial disclosure:
        1. A clinical investigator must disclose to the sponsor sufficient accurate financial information to allow the applicant to submit complete and accurate certification or disclosure statements required under 21 CFR §54.
        2. The investigator must promptly update this information if any relevant changes occur during the course of the investigation and for 1 year following completion of the study.
    v. Disposing of device: Upon completion or termination of a clinical investigation or the investigator's part of an investigation, or at the sponsor's request, an investigator must return to the sponsor any remaining supply of the device or otherwise dispose of the device as the sponsor directs.
c. Maintain the following accurate, complete, and current records relating to the investigator's participation in an investigation:[xiii]
    i. All correspondence with another investigator, an IRB, the sponsor, a monitor, or FDA, including required reports.
    ii. Records of receipt, use or disposition of a device that relate to:
        1. The type and quantity of the device, the dates of its receipt, and the batch number or code mark.
        2. The names of all persons who received, used, or disposed of each device.
        3. Why and how many units of the device have been returned to the sponsor, repaired, or otherwise disposed of.

iii. Records of each subject's case history and exposure to the device. Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital charts, and the nurses' notes. Such records must include:
    1. Documents evidencing informed consent and, for any use of a device by the investigator without informed consent, any written concurrence of a licensed physician and a brief description of the circumstances justifying the failure to obtain informed consent.
    2. Documentation that informed consent was obtained prior to participation in the study.
    3. All relevant observations, including records concerning adverse device effects (whether anticipated or unanticipated), information and data on the condition of each subject upon entering, and during the course of, the investigation, including information about relevant previous medical history and the results of all diagnostic tests.
    4. A record of the exposure of each subject to the investigational device, including the date and time of each use, and any other therapy.
iv. The protocol, with documents showing the dates of and reasons for each deviation from the protocol.
v. Any other records that FDA requires to be maintained by regulation or by specific requirement for a category of investigations or a particular investigation.

d. Inspections[xiv]
    i. Entry and inspection: A sponsor or an investigator who has authority to grant access must permit authorized FDA employees, at reasonable times and in a reasonable manner, to enter and inspect any establishment where devices are held (including any establishment where devices are manufactured, processed, packed, installed, used, or implanted or where records of results from use of devices are kept).
    ii. Records inspection: A sponsor, IRB, or investigator, or any other person acting on behalf of such a person with respect to an investigation, must permit authorized FDA employees, at reasonable times and in a reasonable manner, to inspect and copy all records relating to an investigation.
    iii. Records identifying subjects: An investigator must permit authorized FDA employees to inspect and copy records that identify subjects, upon notice that FDA has reason to suspect that adequate informed consent was not obtained, or that reports required to be submitted by the investigator to the sponsor or IRB have not been submitted or are incomplete, inaccurate, false, or misleading.
e. Prepare and submit the following complete, accurate, and timely reports[xv]
    i. Unanticipated adverse device effects. An investigator must submit to the sponsor and to the reviewing IRB a report of any unanticipated adverse device effect occurring during an investigation as soon as possible, but in no event later than 10 working days after the investigator first learns of the effect.
    ii. Withdrawal of IRB approval. An investigator must report to the sponsor, within 5 working days, a withdrawal of approval by the reviewing IRB of the investigator's part of an investigation.
    iii. Progress. An investigator must submit progress reports on the investigation to the sponsor, the monitor, and the reviewing IRB at regular intervals, but in no event less often than yearly.
    iv. Deviations from the investigational plan:
        1. An investigator must notify the sponsor and the reviewing IRB of any deviation from the investigational plan to protect the life or physical well-being of a subject in an emergency.

2. Such notice must be given as soon as possible, but in no event later than 5 working days after the emergency occurred.
3. Except in such an emergency, prior approval by the sponsor is required for changes in or deviations from a plan, and if these changes or deviations may affect the scientific soundness of the plan or the rights, safety, or welfare of human subjects, FDA and IRB also are required.

v. Informed consent. If an investigator uses a device without obtaining informed consent, the investigator must report such use to the sponsor and the reviewing IRB within 5 working days after the use occurs.
vi. Final report. An investigator must, within 3 months after termination or completion of the investigation or the investigator's part of the investigation, submit a final report to the sponsor and the reviewing IRB.
vii. Other. An investigator must, upon request by a reviewing IRB or FDA, provide accurate, complete, and current information about any aspect of the investigation.

Appendix A-3 ***Additional Requirements for Clinical Trials (ICH-GCP)***

1) The clinical trial should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with good clinical practice (GCP) and the applicable regulatory requirements. Clinical trials should be designed and conducted in ways that ensure the rights, safety, and well-being of participants.
    a. The rights, safety and well-being of the participants are the most important considerations and should prevail over interests of science and society.
    b. When designing a clinical trial, the scientific goal and purpose should be carefully considered so as not to unnecessarily exclude particular participant populations. The participant selection process should be representative of the population groups that the investigational product is intended to benefit, once authorized, to allow for generalizing the results across the broader population. Certain trials (e.g., early phase, proof of concept trials, bioequivalence studies) may not require such heterogeneous populations.
    c. A qualified physician, or when appropriate, a qualified dentist (or other qualified healthcare professionals in accordance with local regulatory requirements) should have the overall responsibility for the trial-related medical care given to and medical decisions made on behalf of participants; however, the practical interactions and the delivery of medical care and decisions can be carried out by appropriately qualified healthcare professionals in accordance with applicable regulatory requirements.
2) Clinical trials should be scientifically sound for their intended purpose and based on adequate and current scientific knowledge and approaches.
    a. The available nonclinical and clinical information on an investigational product(s) should be adequate to support the proposed clinical trial.
    b. Clinical trials should be scientifically sound and reflect the state of knowledge and experience with the investigational product(s), including, if applicable, the condition being treated, diagnosed or prevented; the current understanding of the underlying biological mechanism (of both the condition and the investigational product); and the population for which the investigational product is intended.
    c. There should be periodic review of current scientific knowledge and approaches to determine whether modifications to the trial are needed, since new or unanticipated information may arise once the trial has begun.
3) Investigator's Qualifications and Training
    The investigator should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial, should meet all the qualifications specified by the applicable regulatory requirements, and should provide evidence of such qualifications.
    a. The investigator should be thoroughly familiar with the appropriate use of the investigational product(s) as described in the protocol, in the current Investigator's Brochure, in the product information and/or in other information sources provided by the sponsor.
    b. Resources
    c. The investigator should be able to demonstrate (e.g., based on retrospective data) a potential for recruiting the required number of eligible participants within the recruitment period as agreed with the sponsor.

The investigator should have sufficient time, an adequate number of available and qualified staff, and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely.

4) Responsibilities
    a. The investigator may delegate trial-specific activities to other persons or parties. The investigator may be supported by the sponsor in the identification of a suitable service provider(s); however, the investigator retains the final decision on whether the service provider intended to support the investigator is appropriate based on information provided to the

sponsor. The investigator retains the ultimate responsibility and should maintain appropriate oversight of the persons or parties undertaking the activities delegated to ensure the rights, safety and well-being of the trial participants and reliability of the data. The level of investigator oversight of the delegated activities should depend on the nature of the delegated activities and be proportionate to the importance of the data being protected and the risks to trial participant safety and data reliability.

b. The investigator should ensure that all persons or parties to whom the investigator has delegated trial-related activities are appropriately qualified and are adequately informed about the relevant aspects of the protocol, the investigational product(s), and their assigned trial activities (including activities conducted by staff provided by other parties in accordance with local regulatory requirements). Trial-related training to persons assisting in the trial should correspond to what is necessary to enable them to fulfill their delegated trial activities that go beyond their usual training and experience.
c. The investigator should ensure a record is maintained of the persons and parties to whom the investigator has delegated trial-related activities. Documentation of delegation should be proportionate to the significance of the trial-related activities. In situations where the activities are performed as part of clinical practice, delegation documentation may not be required.
d. Agreements made by the investigator/institution with service providers for trial-related activities should de documented.
e. The investigator/institution should permit monitoring and auditing by the sponsor, inspection by the appropriate regulatory authority(ies) and, in accordance with applicable regulatory requirements, review by IRB(s).

5) Communication with IRB
    a. Submission to the IRB may be made by the investigator/institution or sponsor in accordance with applicable regulatory requirements.
    b. Before initiating a trial, the investigator/institution should have a documented and dated approval from the IRB for the trial protocol, informed consent materials, participant recruitment procedures (e.g., advertisements), and any other trial-related information to be provided to participants.
    c. As part of the investigator's/institution’s or sponsor’s (in accordance with applicable regulatory requirements) submission to the IRB, a current copy of the Investigator's Brochure or basic product information brochure should be provided. If the Investigator's Brochure or basic product information brochure is updated during the trial, the IRB should receive the current version in accordance with applicable regulatory requirements.
    d. As the trial progresses, the investigator/institution or sponsor should provide any updates to the participant information to the IRB in accordance with applicable regulatory requirements.
    e. The investigator or sponsor should submit documented summaries of the trial status to the IRB in accordance with local regulatory requirements or upon request.
    f. The investigator or the sponsor should promptly communicate to the IRB and where applicable, to the institution any changes significantly affecting the conduct of the trial and/or increasing risk to participants.
6) Compliance with Protocol
    a. The investigator/institution should sign the protocol, or an alternative contract, to confirm agreement with the sponsor.
    b. The investigator/institution should comply with the protocol, GCP and applicable regulatory requirements.
    c. The investigator should document all protocol deviations. In addition to those identified by the investigator themselves, protocol deviations related to their trial participants and their conduct of the trial may be communicated to them by the sponsor. In either case, the investigator should review the deviations, and for those deviations deemed important, the investigator should explain the deviation and implement appropriate measures to prevent a recurrence, when applicable.

d. The investigator should follow the protocol and deviate only where necessary to eliminate an immediate hazard(s) to trial participants. In case of deviations undertaken to eliminate immediate hazard to trial participants, the investigator should inform the sponsor promptly.
e. The investigator should report information on the immediate hazard, the implemented change and the subsequent proposed protocol modification, if any, to the IRB and, where applicable, regulatory authorities.

7) Premature Termination or Suspension of a Trial
   a. If the trial is prematurely terminated or suspended for any reason, the investigator/institution should promptly inform the trial participants and should assure appropriate therapy and follow-up for the participants.
   b. Where the investigator terminates or suspends their involvement in a trial without prior agreement by the sponsors, the investigator should promptly inform the institution, where applicable, the sponsor, the IRB, and the regulatory authorities in accordance with applicable regulatory requirements and should provide a detailed explanation of the reasons.
   c. If the sponsor terminates or suspends a trial, the investigator/institution, or the sponsor, in accordance with applicable regulatory requirement(s), should promptly inform the IRB and the regulatory authorities and should provide an appropriate explanation.
   d. If the IRB terminates or suspends its approval of a trial, the investigator should inform the institution, where applicable, and the investigator/institution should promptly notify the sponsor.
8) Participant Medical Care and Safety Reporting
   a. Medical Care of Trial Participants
      i. A qualified physician or, where appropriate, a qualified dentist (or other qualified healthcare professionals in accordance with local regulatory requirements) who is an investigator or a sub-investigator for the trial, should have the responsibility for trial-related medical care and decisions.
      ii. Other appropriately qualified healthcare professionals may be involved in the medical care of trial participants, in line with their normal activities and in accordance with local regulatory requirements.
      iii. During and following participation in a trial, the investigator/institution should ensure that adequate medical care is provided to a participant for any adverse events, including clinically significant laboratory values, related to the trial. The investigator/institution should inform a participant when medical care is needed for intercurrent illness(es) of which the investigator becomes aware.
      iv. The investigator should inform the participant's primary physician about the participant's involvement in the trial if the participant has a primary physician and agrees to the primary physician being informed.
   b. Safety Reporting
      i. Adverse events and/or abnormal test results required for safety evaluations (as outlined in the protocol) should be reported to the sponsor according to the reporting requirements and within the time periods specific in the protocol. Unfavorable medical events occurring in participants before investigational product administration (e.g., during screening) should be considered and reported to the sponsor if required by the protocol.
      ii. All serious adverse events (SAEs) should be reported immediately (after the investigator reasonably becomes aware of the event) to the sponsor. The investigator should also include an assessment of causality. In accordance with applicable regulatory requirements, the protocol may identify SAEs not requiring immediate reporting, for example, deaths or other events that are endpoints. Subsequent information should be submitted as a follow-up report, as necessary.
      iii. For reported deaths, the investigator should supply the sponsor, the IRB and, where applicable, the regulatory authority with any additional requested information (e.g., autopsy reports and terminal medical reports) when they become available.

iv. The investigator may delegate activities for safety reporting to qualified investigator site staff but retains the overall responsibility for safety of participants under their responsibility and compliance with the reporting requirements.

9) Informed Consent of Trial Participants

a. In obtaining and documenting informed consent (paper or electronic format), the investigator should comply with the applicable regulatory requirements and should adhere to GCP and to the ethical principles that have their origin in the Declaration of Helsinki. The informed consent process should include the following:
   i. Prior to consenting and enrolling participants, the investigator should have the IRB's documented approval of the informed consent materials and process;
   ii. The information should be as clear and concise as possible, use simple language and avoid unnecessary volume and complexity. This is to ensure that the trial participants or their legally acceptable representatives have an adequate understanding of the objectives of the trial, alternative treatments, potential benefits and risks, burdens, their rights, and what is expected of the participants to be able to make an informed decision as to their participant in the trial.
   iii. Varied approaches (e.g., text, images, videos and other interactive methods), may be used in the informed consent process including for providing information to the participant. The characteristics of the potential trial population (e.g., participants may lack familiarity with computerized systems) and the suitability of the method of obtaining consent should be taken into consideration when developing the informed consent materials and process. When computerized systems are used to obtain informed consent, trial participants may be given the option to use a paper-based approach as an alternative.
   iv. Obtaining consent remotely may be considered where appropriate.
   v. Whether the informed consent process takes place in person or remotely, the investigator should assure themselves of the identity of the participant (or legally acceptable representative) in accordance with applicable regulatory requirements.
b. The participant or the participant’s legally acceptable representative should be informed in a timely manner if new information becomes available that may be relevant to the participant’s willingness to continue trial participation. The communication of this information and confirmation of the willingness to continue trial participation should be documented. New information that could impact a participant’s willingness to continue participation should be assessed to determine if re-consent is needed (e.g., depending on the stage of the trial, consideration should be given to whether the new information is relevant only to new participants or to existing participants). If re-consent is needed (e.g., information on emerging safety concerns), new information should be clearly identified in the revised informed consent materials. Revised informed consent materials should receive the IRB’s approval in advance of use.
c. Neither the investigator, nor the investigator site staff, should coerce or unduly influence a participant to participate or to continue their participation in a trial.
d. None of the information provided to the participant or the participant’s legally acceptable representative during the informed consent process, should contain any language that causes the participant to waive or to appear to waive any legal rights, or that releases or appears to release the investigator, the institution, the sponsor, or their service providers from liability for negligence.
e. The informed consent process should be conducted by the investigator or other investigator site staff delegated by the investigator, in accordance with applicable regulatory requirements. If the participant is unable to provide consent themselves (e.g., minors, patients with severely impaired decision-making capacity), the participant’s, the subject's legally acceptable representative should provide their consent on behalf of the participant.

f. The information provided during the informed consent process and translations should be relevant, clear, simple, concise and understandable to the participant or the participant's legally acceptable representative and the impartial witness, where applicable.
g. Before informed consent may be obtained, the investigator, or investigator site staff delegated by the investigator, in accordance with the protocol and conditions of IRB approvals, should provide the participant or the participant's legally acceptable representative ample time unless justified (e.g., in an emergency situation) and opportunity to inquire about trial details and to decide whether or not to participate in the trial. Questions about the trial should be answered to the satisfaction of the participant or the participant's legally acceptable representative.
h. Prior to trial participation, the informed consent form should be signed and dated by the participant or by the participant's legally acceptable representative, where appropriate, by an impartial witness and by the investigator or delegated investigator site staff who conducted the informed consent discussion. By signing the consent form, the investigator or delegated investigator site staff attests that the informed consent was freely given by the participant or the participant's legally acceptable representative and the consent information was accurately explained to and apparently understood by the participant or the participant's legally acceptable representative. The informed consent process may involve a physical or an electronic signature and date.
i. In emergency situations, when prior consent of the participant is not possible, the consent of the participant's legally acceptable representative, if present, should be requested. When prior consent of the participant is not possible and the participant's legally acceptable representative is not possible and the participant's legally acceptable representative is not available, enrollment of the participant should require measures described in the protocol and/or elsewhere, with documented approval by the IRB, to protect the participant's rights, safety and well-being and to ensure compliance with applicable regulatory requirements. The participant or the participant's legally acceptable representative should be informed about the trial as soon as possible, and consent as appropriate should be requested.
j. If a participant or the legally acceptable representative is unable to read, an impartial witness should be present (remotely or in-person) during the entire informed consent discussion. After the informed consent form and any other information is read and explained to the participant or the participant's legally acceptable representative, and they have orally consented to the participant's trial participation, and if capable of doing so, have signed and dated the informed consent form, the witness should sign and date the consent form. By signing the consent form, the witness attests that the consent information was accurately explained to, and apparently understood by, the participant or the participant's legally acceptable representative, and that informed consent was freely given by the participant or the participant's legally acceptable representative.
k. Look for indications of dissent: An individual's negative expressions, verbal and/or non-verbal, that they object to participation in the research or research activities.
l. The informed consent discussion and the informed consent materials to be provided to participant should explain the following as applicable:

The purpose of the trial;

i. That the trial involves research and summary of the experimental aspects of the trial;
ii. The trial's investigational product(s)trial and the probability for random assignment to the investigational product, if applicable;
iii. The trial procedures to be followed, including all invasive procedures;
iv. What is expected of the participants;

The reasonably foreseeable risks or inconveniences to the participant and, when applicable, the participant's partner, to an embryo, fetus, or nursing infant;

v. The reasonably expected benefits. When there is no intended clinical benefit to the participant, the participant should be made aware of this;
vi. The alternative procedure(s)procedures or course(s)courses of treatment that may be available to the participant, and their important potential benefits and risks;
vii. The compensation and/or treatment available to the participant in the event of trial related injury;
viii. Any anticipated prorated compensation to the participant for trial participation;
ix. Any anticipated expenses to the participant for trial participation;
x. That the participant's trial participation is voluntary, and the participant may decide to stop taking the investigational product or withdraw from the trial, at any time, without penalty or loss of benefits to which the participant is otherwise entitled;
xi. The follow-up procedure for participants who stopped taking the investigational product, withdrew from the trial or were discontinued from the trial;
xii. The process by which the participant's data will be handled, including in the event of the withdrawal or discontinuation of participation in accordance with applicable regulatory requirements;
xiii. That by agreeing to participant in the trial, the participant or their legally acceptable representative allows direct access to source records, based on the understanding that the confidentiality of the participant's medical record will be safeguarded. This access is limited for the purpose of reviewing trial activities and/or reviewing or verifying data and records by the regulatory authority(ies) and the sponsor's representatives, for example, monitor(s) or auditor(s), and in accordance with applicable regulatory requirements, IRB;

That records identifying the participant will be kept confidential and, to the extent permitted by the applicable regulatory requirements, will not be made publicly available. If the results of the trial are published, the participant's identity will remain confidential. The trial may be registered on publicly accessible and recognized databases, per applicable regulatory requirements;

xiv. That the participant or the participant's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the participant's willingness to continue trial participation;
xv. The person(s)persons to contact for further trial information and the trial participant's rights, and whom to contact in the event of suspected trial-related injury;
xvi. The foreseeable circumstances and/or reasons under which the participant's trial participation may be terminated.
xvii. The expected duration of the participant's trial participation;
xviii. The approximate number of participants involved in the trial;
xix. That trial results and information on the participant's actual treatment, if appropriate, will be made available to them should they desire it when this information is available from the sponsor.

m. Prior to participation, the participant or the participant's legally acceptable representative should receive a copy (paper or electronic) of the signed informed consent form and any other informed consent materials provided, in accordance with applicable regulatory requirements. During trial participation, the participant or the participant's legally acceptable representative should receive a copy of the consent form updates and any other updated informed consent materials provided.

When a minor is to be included as a participant, age-appropriate assent information should be provided and discussed with the minor as part of the consent process, and assent from the minor to enroll in the trial should be obtained as appropriate. A process for re-consent should be considered if, during the course of the trial, the minor reaches the age of legal consent, in accordance with applicable regulatory requirements.

n. The IRB recommends that the informed consent documents apply to the following division of target populations:

10.o.1. Age 18 or older utilizing the adult informed consent document;

10.0.2. Ages 13 to 17 utilizing a combination assent/parental permission form, in the same language as the adult informed consent document;
10.o.3. Ages 7 to 12 utilizing an assent form written simply and at a comprehension level appropriate for a 7-year-old; and
10.o.4. Less than 7 years of age utilizing an oral script in very simple language appropriate for children of this age group.

When a clinical trial includes participant who may only be enrolled in the trial with the consent of the participant's legally acceptable representative, the participants should be informed about the trial in a manner that facilitates their understanding and, if capable, the participant should sign and date the informed consent form or assent form as appropriate.

o. End of Participation in a Clinical Trial

p. When a participant decides to stop treatment with the investigational product, stop trial visits or completely withdraw from a trial; is discontinued from the trial; or reaches the routine end of the trial, the investigator should follow the protocol and other sponsor instructions to determine appropriate follow-up measures. This may include instructions to avoid unnecessary loss of already collected critical data in accordance with applicable regulatory requirements.
q. Although a participant is not obliged to provide a reason(s) for withdrawing prematurely from a trial, the investigator should make a reasonable effort to ascertain the reason(s), while fully respecting the participant's rights. The investigator should consider if a discussion with the participant or the participant's legally acceptable representative is appropriate. This discussion should focus on the reasons for withdrawal to determine if there are ways to address the concerns such that the participant could reconsider withdrawal without unduly influencing the participant's decision. The investigator or delegated investigator site staff should consider explaining to the participant the value of continuing their participation to minimize trial participants withdrawal. In this process, the investigator should ensure that it does not interfere with the participant's decision to refuse or withdraw participation at any time.
r. Where relevant, the investigator should inform the participant about the trial results and treatment received when this information is available from the sponsor after unblinding, with due respect to the participant's preference to be informed.

10) Investigational Product Management
a. Responsibility for investigational product(s), including accountability, handling, dispensing, administration and return, rests with the investigator/institution. The sponsor may facilitate aspects of investigational product management (e.g., by providing forms and technical solutions, such as computerized systems, and arranging distribution of investigational product to trial participants).
b. When the investigator/institution delegates some or all of their activities for investigational product(s) management to a pharmacist or another individual in accordance with local regulatory requirements, the delegated individual should be under the oversight of the investigator/institution.
c. Where the investigator has delegated activities related to investigational product management or aspects of these activities have been facilitated by the sponsor, the level of investigator oversight will depend on a number of factors, including the characteristics of the investigational product, route and complexity of administration, level of existing knowledge about the investigational product's safety and marketing status.
d. The investigator/institution and/or pharmacist or other appropriate individual should maintain records of the product's delivery, the inventory, the use by each participant (including documenting that the participants were provided the doses specified by the protocol), and the return to the sponsor and destruction or alternative disposition of unused product(s). These records should include dates, quantities, batch/serial numbers, expiration dates (if applicable), and the unique code numbers assigned to the investigational product(s) and trial participants.

For authorized medicinal products, alternative approaches to the aforementioned may be considered, in accordance with local regulatory requirements.

e. The investigational product(s) should be stored as specified by the sponsor and in accordance with applicable regulatory requirement(s).
f. The investigator should ensure that the investigational product(s) are used only in accordance with the approved protocol.
g. When applicable, the investigator or a person designated by the investigator/institution should explain the correct use of the investigational product(s) to each participant and should check, at intervals appropriate for the trial, that each participant is following the instructions properly.
h. The investigational product may be shipped to the participant's location or supplied to/dispensed at a location closer to the participant (e.g., at a local pharmacy or local healthcare center). The investigational product may be administered at the participant's location by investigator site staff, the participant themselves, or a caregiver or a healthcare professional.
i. Investigational product management should be arranged and conducted in accordance with applicable regulatory requirements, and safeguards should be in place to ensure product integrity, product use per protocol and participant safety.

11) Randomization Procedures and Unblinding

a. The investigator should follow the trial's randomization procedures, if any, and in the case of an investigator-blinded trial, should ensure that the treatment randomization code is broken only in accordance with the protocol. In the case of an emergency, to protect participant safety, the investigator should be prepared and capable from the start of the trial to perform unblinding without undue delay and hinderance. The investigator should promptly document and explain to the sponsor any premature unblinding (e.g., accidental unblinding, emergency unblinding to protect trial participant, unblinding due to an SAE) of the investigational product(s).

12) Records

a. In generating, recording and reporting trial data, the investigator should ensure the integrity of data under their responsibility, irrespective of the media used.
b. The investigator/institution should maintain adequate source records that include pertinent observations on each of the trial participants under their responsibility. Source records should be attributable, legible, contemporaneous, original, accurate and complete. Changes to source records should be traceable, should not obscure the original entry and should be explained if necessary (via an audit trail). The investigator should define what is considered to be a source record(s), the methods of data capture and their location prior to starting the trial and should update this definition when needed. Unnecessary transcription steps in between the source record and the data acquisition tool should be avoided.
c. The investigator should be provided with timely access to data by the sponsor and be responsible for the timely review of data, including relevant data from external sources that can have an impact on, for example, participant eligibility, treatment or safety (e.g., central laboratory data, centrally read imaging data, other institution's records and, if appropriate, electronic patient-reported outcome (ePRO) data. The protocol may provide exceptions for access, for instance, to protect blinding.
d. The investigator should ensure that data acquisition tools and other systems deployed by the sponsor are used as specified in the protocol or trial-related instructions.
e. The investigator should ensure the accuracy, completeness, legibility and timeliness of the data reported to the sponsor in the data acquisition tools completed by the investigator site (e.g., case report form (CRF)) and in any other required reports (e.g., SAE reports). The investigator should review and endorse the reported data at important milestones agreed upon with the sponsor (e.g., interim analysis).
f. Data reported to the sponsor should be consistent with the source records or the discrepancies explained. Changes or corrections in the reported data should be traceable, should be explained (if necessary) and should not obscure the original entry.

g. The investigator/institution should implement appropriate measures to protect the privacy and confidentiality of personal information or trial participants in accordance with applicable regulatory requirements on personal data protection.
h. Data reported to the sponsor should be identified by an unambiguous participant code that can be tracked back to the identity of the participant by the investigator/institution.
i. For systems deployed by the investigator/institution that maintain and retain trial data/information, the investigator/institution should ensure that such data are protected from unauthorized access, disclosure, dissemination or alteration and from inappropriate destruction or accidental loss.
j. When using computerized systems in a clinical trial, the investigator/institution should do the following:
    i. For systems deployed by the investigator/institution, ensure that appropriate individuals have secure and attributable access;
    ii. For systems deployed by the sponsor, notify the sponsor when access permissions need to be changed or revoked from an individual;
    iii. For system deployed by the investigator/institution specifically for the purposes of clinical trials, ensure the requirements for computerized systems in section 4 of ICH GCP Annex 1[xvi] are addressed proportionate to the risks to participants and to the importance of the data;
    iv. Where equipment for data acquisition is provided to trial participants by the investigator, ensure that traceability is maintained and participants are provided with appropriate training;
    v. Ensure that incidents in the use and operation of computerized systems, which in the investigator/institution's judgment may have a significant and/or persistent impact on the trial data or system security, are reported to the sponsor and, where applicable, to the IRB.
k. The investigator/institution should maintain the trial records as specified in Appendix C of ICH GCP Annex 1 and as required by the applicable regulatory requirement(s). The investigator/institution should have control of all essential records generated by the investigator/institution before and during the conduct of the trial.
l. The investigator/institution should retain the essential records for the required retention period in accordance with applicable regulatory requirements or until the sponsor informs the investigator/institution that these records are no longer needed, whichever is the longest. The investigator/institution should take measures to ensure availability, accessibility and readability and to prevent unauthorized access and accidental or premature destruction of these records.
m. The investigator/institution should keep the sponsor informed of the name of the person responsible for maintaining the essential records during the retention period; for example, when the investigator site closes or an investigator leaves the site.
n. Upon request of the monitor, auditor, IRB, or regulatory authority, the investigator/institution should make available for direct access all requested trial-related records.

13) Reports
    a. Upon completion of the trial, the investigator, where applicable, should inform the institution. The investigator/institution should provide the IRB with a summary of the trial's outcome, and, if applicable, the regulatory authorities with any required reports.

Appendix A-4 *Additional Requirements for Department of Defense (DOD) research*

1) When appropriate, research protocols must be reviewed and approved by the IRB prior to the Department of Defense approval. Consult with the Department of Defense funding component to see whether this is a requirement.
2) For non-exempt Human Subjects Research, must submit to the DoD Human Research Protections Office (HRPO):
    a. documentation that the DoD-supported HSR has been reviewed and approved by an IRB, including scientific merit, modifications and additional reviews
    b. documentation of key investigators' human research protection training
    c. IRB approved protocol documents
    d. current FWA and IRB registration numbers
3) For research that is exempt or does not involve human subjects, must submit to the DoD HRPO:
    a. Institutional documentation of the determination that the research is either Not Human Subjects Research, exempt, or limited IRB review
    b. all protocol documents
4) Civilian researchers attempting to access military volunteers should seek collaboration with a military researcher familiar with service-specific requirements.
5) Employees of the Department of Defense (including temporary, part-time, and intermittent appointments) may not be able to legally accept payments to participate in research and should check with their supervisor before accepting such payments. Employees of the Department of Defense cannot be paid for conducting research while on active duty.
6) Service members must follow their command policies regarding the requirement to obtain command permission to participate in research involving human subjects while on-duty or off-duty.
7) Components of the Department of Defense might have stricter requirements for research-related injury than the DHHS regulations.
8) There may be specific educational requirements or certification required.
9) When assessing whether to support or collaborate with this institution for research involving human subjects, the Department of Defense may evaluate this institution's education and training policies to ensure the personnel are qualified to perform the research.
10) When research involves U.S. military personnel, policies and procedures require limitations on dual compensation:
    a. Prohibit an individual from receiving pay of compensation for research during duty hours.
    b. An individual may be compensated for research if the participant is involved in the research when not on duty.
    c. Federal employees while on duty and non-Federal persons may be compensated for blood draws for research up to $50 for each blood draw.
    d. Non-Federal persons may be compensated for research participating other than blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research.
11) Surveys performed on DOD personnel must be submitted, reviewed, and approved by the DOD Information Management Control Officer (IMCO) after the research protocol is reviewed and approved by the IRB. When a survey crosses DOD components, additional review is required. Consult the Department of Defense funding component to coordinate this review.
12) When research involves large scale genomic data (LSGD) collected on DOD-affiliated personnel, additional protections are required:
    a. Additional administrative, technical, and physical safeguards to prevent disclosure of DoD-affiliated personnel's genomic data commensurate with risk (including secondary use or sharing of de-identified data or specimens)
    b. Research will apply an HHS Certificate of Confidentiality
    c. DoD Component security review

13) Data or information sent to a DOD component under a pledge of confidentiality for exclusively statistical purposes must be used exclusively for statistical purposes and may not be disclosed in identifiable form for any other purpose, except with the informed consent of the respondent.
14) When conducting multi-site research, a formal agreement between institutions is required to specify the roles and responsibilities of each party.
15) The following must be reported to the applicable DOD Component Office of Human Research Protections within 30 days:
    a. When significant changes to the research protocol are approved by the IRB or EC:
        i. Changes to key investigators or institutions.
        ii. Decreased benefit or increased risk to participants in greater than minimal risk research.
        iii. Addition of vulnerable populations as participants.
        iv. Addition of DOD-affiliated personnel as participants.
        v. Change of reviewing IRB.
    b. Transfer of oversight to a different IRB
    c. When the organization is notified by any federal body, state agency, official governing body of a Native American or Alaskan native tribe, other entity, or foreign government that any part of an HRPP is under investigation for cause involving a DOD-supported research protocol.
    d. Any problems involving risks to participants or others, suspension or termination of IRB approval, or any serious or continuing noncompliance pertaining to DOD-supported human participant research.
    e. The results of the IRB's continuing review, if required.
    f. Change in status when a previously enrolled participant becomes pregnant, or when the researcher learns that a previously enrolled participant is pregnant, and the protocol was not reviewed and approved by the IRB in accordance with 45 CFR 46, Subpart B.
    g. Change in status when a previously enrolled participant becomes a prisoner, and the protocol was not reviewed and approved by the IRB in accordance with 32 CFR 219, Subpart C.
    h. Closure of a DOD-supported study.
    i. Must make records that document compliance or noncompliance with this issuance accessible for inspection and copying, as determined by DoD HRPP personnel, by authorized DoD representatives.
16) For human participant research that would not otherwise be approved but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates, written approval from the DOD Office for Human Research Protections must be obtained through the DOD Component Office of Human Research Protections prior to research starting.
17) Other specific requirements of the Department of Defense research be found in the "Additional Requirements for Department of Defense (DOD) Research" section in the IRB's HRP-318 - WORKSHEET - Additional Federal Agency Criteria.

Appendix A-5 ***Additional Requirements for Department of Energy (DOE) Research***

(See DOE Order 443.1C, Chg 1)

1) Research that involves one or more of the following must be submitted to the appropriate IRB for human subjects research (HSR)/not HSR review and determination:
    a. Study of humans in a systematically modified environment. These studies include but are not limited to intentional modification of the human environment:
        i. Study of human environments that use tracer chemicals, particles or other materials to characterize airflow.
        ii. Study in occupied homes or offices that:
            1. Manipulate the environment to achieve research aims.
            2. Test new materials.
            3. Involve collecting information on occupants' views of appliances, materials, or devices installed in their homes or their energy-saving behaviors through surveys and focus groups.
    b. Use of social media data and/or other publicly available data about individuals or publicly available biospecimens, even if the data or biospecimens appear(s) to be de-identified. *Note: DOE follows the Health Insurance Portability and Accountability Act (HIPAA), and guidance issued by the National Institutes of Standards and Technology, as a minimum, in determining identifiability*.Use of social media data.
    c. Human Terrain Mapping (HTM), which is managed as HSR. HTM must be strictly limited to only those projects involving the analysis and modeling of de-identified data.).
2) Ensure that final HSR/not HSR determinations for studies that may constitute HSR, including exempt HSR determinations, are made through the appropriate IRB and/or IRB office. For sites that use one or both Central DOE IRB(s) as their IRB(s) of record, the Central DOE office is the responsible office and coordinates with the site HSR leads, as appropriate, to discuss project specific information and convey study determinations.
3) If you submit studies to DOE central or DOE site IRBs, complete additional DOE-specific training that includes a module on recognizing and addressing bias in the design, review and conduct of Human Research.
4) Personally identifiable information (PII) collected and/or used during HSR projects must be protected in accordance with the requirements of DOE Order 206.1, *Department of Energy Privacy Program*, current version. The Central DOE IRBs require submission of DOE's HRP- 490-CHECKLIST-Reviewing Protocols that use Personally Identifiable Information (PII) if your research includes PII. Contact the CDOE at CDOEIRB@orau.org to obtain a copy.
5) The following must be reported in writing to the DOE human subjects research Program Manager (and, when a National Nuclear Security Administration (NNSA) element is involved, the NNSA HSP Program Manager), even for HSR that meets the regulatory definition of exempt HRS as outlined in 10 Code of Federal Regulations (CFR) Part 745.104.
    a. Prior) prior to initiation of the HSR portion of a new project, involving:
        i. An institution without an established Institutional Review Board (IRB);
        ii. A foreign country;
        iii. The potential for significant controversy (e.g., negative press or reaction from stakeholder or oversight groups);
        iv. Research subjects in a protected class (including the populations identified in Subparts B, C, and D of 45 CFR Part 46), as well as other such as individuals with impaired decision-making capability, or DOE/NNSA Federal or DOE/NNSA contractor employees as human subjects, who may be more vulnerable to coercion and undue influence to participate) that is outside of the reviewing IRB's typical range/scope; or
        v. The generation or use of classified information.

b. Immediately upon a finding of a suspected or confirmed data breach involving PII in printed or electronic form, report to the IRB, the DOE/NNSA HSP Program Manager(s), and the Integrated Joint Cybersecurity Coordination Center (iJC3), in accordance with the requirements of DOE O 206.1. The appropriate HSP Program Manager must also be notified of any corrective actions taken and consulted regarding the plan for any remaining corrective actions.
c. Immediately upon learning of a serious adverse event, report to the IRB and the DOE/NNSA HSP Program Manager(s). The appropriate HSP Program Manager must also be notified of any corrective actions taken and consulted regarding the plan for any remaining corrective actions.
d. The IRB must be notified immediately and the DOE HSP Program Manager (and, when an NNSA element is involved, the NNSA HSP Program Manager) must be notified within two (2) business days of learning of the following and consulted regarding planned corrective actions if any of the following occur:
    i. Unanticipated problems, significant adverse events, and complaints about the research.
    ii. Any suspension or termination of IRB approval of research.
    iii. Any known or potential incidents of non-compliance with requirements of DOE Order 443.1C, Chg.1, 10 CFR Part 745, or 45 CFR Part 46...
    iv. Requirements for human participant protections for classified research apply to all classified research conducted or supported by the DOE and its national laboratories, including contracts, and including Human Terrain Mapping research.

6) Researchers conducting human subjects research in any other country or on citizens or other individuals residing in that country must be cognizant of country-specific human subjects research requirements and consult the IRB regarding applicability of such requirements.
7) No human subjects research conducted with DOE funding, at DOE institutions (regardless of funding source[xvii]), or by DOE or DOE contractor personnel (regardless of funding source or location conducted), whether done domestically or in an international environment, including classified and proprietary research, may be initiated without both a Federalwide Assurance (FWA) or comparable assurance (e.g., Department of Defense assurance) of compliance and approval by the cognizant Institutional Review Board (IRB) in accordance with 10 CFR §745.103.
8) Human subjects research involving multiple DOE sites (e.g., members of the research team from more than one DOE site and/or data or human subjects from more than one DOE site) must be reviewed and approved by one of the Central DOE IRBs prior to initiation, or if authorized by the DOE and/or NNSA HSP Program Manager, other appropriate IRB of record. In all cases, an IRB Authorization Agreement (IAA) or Memorandum of Understanding (MOU) must be in place between the organization(s) conducting the HSR and the organization responsible for IRB review.
9) Human subjects research that involves targeted inclusion of DOE Federal and/or contractor employees or their data must first be reviewed and approved by the appropriate DOE IRB (the DOE site IRB or one of the Central DOE IRBs), or if deemed more fitting by the Federally assured DOE site or Headquarters, other appropriate IRB of record, in accordance with an IAA or MOU negotiated between the DOE site or Headquarters and the organization responsible for IRB review.
10) Classified and unclassified intelligence and intelligence-related HSR regardless of the funding source (including, but not limited to, Strategic Intelligence Partnership Program (SIPP) funded studies, DOE Office of Intelligence and Counterintelligence (DOE-IN) funded studies, and/or studies funded by other DOE program offices that use intelligence datasets), must be reviewed and approved by the Central DOE IRB-Classified.
11) If applicable, federally funded HSR must comply with the requirements of the Paperwork Reduction Act.
12) If applicable, HSR involving visiting student researchers, researchers, and scholars from other countries as members of research teams must comply with Department of State requirements, e.g., those outlined in 22 CFR Part 62, *Exchange Visitor Program*, and *U.S. Department of State Guidance Directive 2024-01*, current version.
13) Equitable payment of human subjects participating in HSR is allowable.
14) Other specific requirements of the DOE research can be found in the “Additional Requirements for Department of Energy (DOE) Research” section in the IRB’s HRP-318 - WORKSHEET - Additional Federal Agency Criteria.

Appendix A-6 *Additional Requirements for Department of Justice (DOJ) Research*

Additional Requirements for DOJ Research conducted in the Federal Bureau of Prisons

1) Implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research.
2) The project must not involve medical experimentation, cosmetic research, or pharmaceutical testing.
3) The research design must be compatible with both the operation of prison facilities and protection of human subjects.
4) Investigators must observe the rules of the institution or office in which the research is conducted.
5) Any investigator who is a non-employee of the Bureau of Prisoners must sign a statement in which the investigator agrees to adhere to the requirements of 28 CFR §512.
6) The research must be reviewed and approved by the Bureau Research Review Board.
7) Incentives cannot be offered to help persuade inmate subjects to participate. However, soft drinks and snacks to be consumed at the test setting may be offered. Reasonable accommodations such as nominal monetary recompense for time and effort may be offered to non-confined research subjects who are both: No longer in Bureau of Prisons custody. Participating in authorized research being conducted by Bureau employees or contractors.
8) A non-employee of the Bureau may receive records in a form not individually identifiable when advance adequate written assurance that the record will be used solely as statistical research or reporting record is provided to the agency.
9) Except as noted in the consent statement to the subject, you must not provide research information that identifies a subject to any person without that subject's prior written consent to release the information. For example, research information identifiable to a particular individual cannot be admitted as evidence or used for any purpose in any action, suit, or other judicial, administrative, or legislative proceeding without the written consent of the individual to whom the data pertain.
10) Except for computerized data records maintained at an official Department of Justice site, records that contain non-disclosable information directly traceable to a specific person may not be stored in, or introduced into, an electronic retrieval system.
11) If you are conducting a study of special interest to the Office of Research and Evaluation but the study is not a joint project involving Office of Research and Evaluation, you may be asked to provide Office of Research and Evaluation with the computerized research data, not identifiable to individual subjects, accompanied by detailed documentation. These arrangements must be negotiated prior to the beginning of the data collection phase of the project.
12) Required elements of disclosure additionally include:
    a. Identification of the investigators.
    b. Anticipated uses of the results of the research.
    c. A statement that participation is completely voluntary and that the subject may withdraw consent and end participation in the project at any time without penalty or prejudice (the inmate will be returned to regular assignment or activity by staff as soon as practicable).
    d. A statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law. For example, an investigator may not guarantee confidentiality when the subject indicates intent to commit future criminal conduct or harm himself or herself or someone else, or, if the subject is an inmate, indicates intent to leave the facility without authorization.
    e. A statement that participation in the research project will have no effect on the inmate subject's release date or parole eligibility.
13) You must have academic preparation or experience in the area of study of the proposed research.
14) The IRB application must include a summary statement, which includes:
    a. Names and current affiliations of the investigators.
    b. Title of the study.
    c. Purpose of the study.

d. Location of the study.
e. Methods to be employed.
f. Anticipated results.
g. Duration of the study.
h. Number of subjects (staff or inmates) required, and amount of time required from each.
i. Indication of risk or discomfort involved as a result of participation.

15) The IRB application must include a comprehensive statement, which includes:
    a. Review of related literature.
    b. Detailed description of the research method.
    c. Significance of anticipated results and their contribution to the advancement of knowledge.
    d. Specific resources required from the Bureau of Prisons.
    e. Description of all possible risks, discomforts, and benefits to individual subjects or a class of subjects, and a discussion of the likelihood that the risks and discomforts will actually occur.
    f. Description of steps taken to minimize any risks.
    g. Description of physical or administrative procedures to be followed to: Ensure the security of any individually identifiable data that are being collected for the study.
    h. Destroy research records or remove individual identifiers from those records when the research has been completed.
    i. Description of any anticipated effects of the research study on institutional programs and operations.
    j. Relevant research materials such as vitae, endorsements, sample consent statements, questionnaires, and interview schedules.
16) The IRB application must include a statement regarding assurances and certification required by federal regulations, if applicable.
17) You must assume responsibility for actions of any person engaged to participate in the research project as an associate, assistant, or subcontractor.
18) At least once a year, you must provide the Chief, Office of Research and Evaluation, with a report on the progress of the research.
19) At least 12 working days before any report of findings is to be released, you must distribute one copy of the report to each of the following: the chairperson of the Bureau Research Review Board, the regional director, and the warden of each institution that provided data or assistance.
20) You must include an abstract in the report of findings.
21) In any publication of results, you must acknowledge the Bureau's participation in the research project.
22) You must expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau.
23) Prior to submitting for publication, the results of a research project conducted under this subpart, you must provide two copies of the material, for informational purposes only, to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons.
24) Other specific requirements of the Department of Justice (DOJ) Research Conducted within the Federal Bureau of Prisons (BOP) can be found in the “Additional Requirements for Department of Justice (DOJ) Research Conducted within the Federal Bureau of Prisons (BOP)” section in the IRB’s HRP-318 - WORKSHEET - Additional Federal Agency Criteria.

Additional Requirements for DOJ Research Funded by the National Institute of Justice

1) The project must have a privacy certificate approved by the National Institute of Justice Human Subjects Protection Officer.
2) All investigators and research staff are required to sign employee confidentiality statements, which are maintained by the responsible investigator.
3) The confidentiality statement on the consent document must state that confidentiality can only be broken if the subject reports immediate harm to subjects or others.
4) Under a privacy certificate, investigators and research staff do not have to report child abuse unless the subject signs another consent document to allow child abuse reporting.

5) A copy of all data must be de-identified and sent to the National Archive of Criminal Justice Data, including copies of the informed consent document, data collection instruments, surveys, or other relevant research materials.
    a. At least once a year, the researcher shall provide the Chief, Office of Research and Evaluation, with a report of the progress of the research.
    b. At least 12 working days before any report of findings is to be released, the researcher shall distribute one copy of the report to each of the following: the chairperson of the Bureau Research Review Board, the regional director, and the warden of each institution that provided data or assistance. The researcher shall include an abstract in the report of findings.
    c. In any publication of results, the researcher shall acknowledge the Bureau's participation in the research project.
    d. The research shall expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau.
    e. Prior to submitting for publication, the results of a research project conducted under this subpart, the researcher shall provide two copies of the material, for informational purposes only, to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons
6) Other specific requirements of the Department of Justice (DOJ) Research Funded by the National Institute of Justice can be found in the “Additional Requirements for Department of Justice (DOJ) Research” section in the IRB’s HRP-318 - WORKSHEET - Additional Federal Agency Criteria.

Appendix A-7 *Additional Requirements for Department of Education (ED) Research*

1) The Family Educational Rights and Privacy Act (FERPA) (20 U.S.C. § 1232g; 34 CFR Part 99) is a federal law that protects the privacy of student education records. The law applies to all schools that receive funds under an applicable program of the U.S. Department of Education.
2) The Protection of Pupil Rights Modification (PPRA) (20 U.S.C. § 1232h; 34 CFR Part 98) applies to programs that receive funding from the U.S. Department of Education (ED). PPRA is intended to protect the rights of parents and students.
3) Each school at which the research is conducted must provide an assurance that they comply with FERPA and the PPRA.
4) Provide a copy of all surveys and instructional material used in the research. Upon request parents of children[xviii] involved in the research[xix] must be able to inspect these materials.

5) The school in which the research is being conducted must have policies regarding the administration of physical examinations or screenings that the school may administer to students.
6) No student shall be required to submit without *prior consent* to psychiatric examination, testing, or treatment, or psychological examination, testing, or treatment, in which the primary purpose is to reveal information concerning one or more of the following:

   a. Political affiliations or beliefs of the student or the student's parent;
   b. Mental and psychological problems potentially embarrassing to the student or his or her family;
   c. Sex behavior and attitudes;
   d. Illegal, anti-social, self-incriminating and demeaning behavior;
   e. Critical appraisals of other individuals with whom the student has close family relationships;
   f. Legally recognized privileged and analogous relationships, such as those of lawyers, physicians, and ministers;
   g. Religious practices, affiliations, or beliefs of the student or student's parent or;
   h. Income, other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under a program.

7) Prior Consent means:
   a. Prior consent of the student, if the student is an adult or emancipated minor; or
   b. Prior written consent of the parent or guardian, if the student is an unemancipated minor.
8) Other specific requirements of the Department of Education (ED) Research can be found in the "Additional Requirements for Department of Education (ED) Research" section in the IRB's HRP-318 - WORKSHEET - Additional Federal Agency Criteria.

Appendix A-8 *Additional Requirements for Environmental Protection Agency (EPA) Research*

1) Research conducted, supported, or intended to be submitted to EPA is subject to Environmental Protection Agency Regulations.
2) Intentional exposure of pregnant women or children to any substance is prohibited.
3) Observational research involving pregnant women and fetuses are subject to additional DHHS requirements for research involving pregnant women (45 CFR §46 Subpart B) and additional DHHS requirements for research involving children (45 CFR §46 Subpart D.)
4) Research involving children must meet category #1 or #2.
5) Other specific requirements of the Environmental Protection Agency (EPA) Research can be found in the "Additional Requirements for Environmental Protection Agency (EPA) Research and Research Intended to be Submitted to the Environmental Protection Agency" section in the IRB's HRP-318 - WORKSHEET - Additional Federal Agency Criteria.

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Appendix A-9 *Additional Requirements for Veterans Administration (VA) Research*

VA research is research that is conducted by researchers (serving on VA compensated, WOC, or IPA appointments) while on VA time or on VA property. The research may be funded by VA, by other sponsors, or be unfunded. VA research must have Research and Development (R&D) Committee approval before it is considered VA Research and before it can be initiated. All research activities approved by the R&D Committee are considered VA Research.

VA-affiliated nonprofit research and education corporations (NPC) are authorized by Congress under 38 U.S.C. 7361-7366 to provide flexible funding mechanisms for the conduct of research and education at one or more VA facilities. Research approved by a facility R&D Committee are considered to be a VA research project or a VA education activity respectively, regardless of the source of funding, the entity administering the funds, or the research or education site (see VHA Handbook 1200.17, Department of Veterans Affairs Nonprofit Research and Education Corporations Authorized by Title 38 U.S.C. Sections 7361 Through 7366, dated April 27, 2016 and revised May 9, 2017).

VA research includes VA-approved research conducted at international sites not within the United States, its territories, or Commonwealths; and includes research where human tissues are sent outside the United States.

The investigator must give first priority to the protection of research subjects, uphold professional and ethical standards and practices, and adhere to all applicable VA and other federal requirements, including the local VA facility's policies and procedures, regarding the conduct of research and the protection of human subjects. The investigator must hold a current VA appointment to conduct VA research.

The responsibilities of the investigator may be defined in the protocol or IRB application. Specifically, the principal investigator's and local site investigator's responsibilities include, but are not limited to:

1) Qualifications to Conduct Human Subjects Research. VA investigators must have the appropriate training, education, expertise, and credentials to conduct the research according to the research protocol.
2) PIs must ensure that all research staff are qualified (e.g., including but not limited to appropriate training, education, expertise, and credentials) to perform procedures assigned to them during the course of the study.
3) Investigators and their staff conducting human subjects research must be credentialed and privileged as required by current local and VA requirements (see VHA Handbook 1100.19 and VHA Directive 2012-030, Credentialing of Health Care Professionals, or successor policy). Investigators and their research staff may only perform those activities in a research study for which they have the relevant credentials and privileges.
4) Investigators and co-investigators must be identified on the IRB application and must provide credentials, conflict of interest statements or other documentation required by VA and local facility policies.
5) All individuals involved in conducting VA human subjects research are required to complete training in ethical principles on which human subjects research is to be conducted. Specific requirements regarding the type and frequency of training are found on ORD's website. All other applicable VA and VHA training requirements at the local and national level must be met (e.g., privacy and information security training).
6) Investigators must prospectively document their research with their supervisor in writing.
7) Investigators must submit exempt protocols that require limited IRB review to the IRB for limited IRB review/approval.
8) Research Protocol. The investigator must develop and submit a research protocol that is scientifically valid, describes the research objectives, background and methodology, provides for fair and equitable recruitment and selection of subjects, minimizes risks to subjects and others, and describes a data and

safety monitoring plan consistent with the nature of the study. The research must be relevant to the health or welfare of the Veteran population. When relevant, the protocol must include the following safety measures:

9) The type of safety information to be collected including AEs;
10) Frequency of safety data collection;
11) Frequency or periodicity of review of cumulative safety data;
12) Statistical tests for analyzing the safety data to determine if harm is occurring; and
13) Conditions that trigger an immediate suspension of the research, if applicable.
14) Approvals. The investigator must submit the protocol for initial review and obtain written approvals from the IRB, other applicable committees, and from the R&D Committee. In addition, the investigator must receive written notice from the ACOS/R&D that the research may commence before initiating the research.
15) An investigator may not self-certify that a study is exempt.
16) Once approved by the IRB, the protocol must be implemented as approved. All modifications to the approved research protocol or consent form must be approved by the IRB prior to initiating the changes except when necessary to eliminate apparent immediate hazards to the subject.
17) The investigator must also obtain continuing review and approval at a frequency established by the IRB, but not less than once every year (except for research subject to the 2018 Requirements where continuing review is not required) and is expected to submit all materials required for continuing review in sufficient time to assure approval prior to the expiration date. No research activities may be conducted at any time without a currently valid IRB approval.
18) Conflict Of Interest. The investigator must disclose to the IRB any potential, actual, apparent, or perceived conflict of interest of a financial, professional, or personal nature that may affect any aspect of the research and comply with all applicable VA and other federal requirements regarding conflict of interest.
19) Initial Contact. During the recruitment process, members of the research team must make initial contact with potential subjects in person or by letter prior to initiating any telephone contact, unless there is written documentation that the subject is willing to be contacted by telephone about the study in question or a specific kind of research as outlined in the study. (NOTE: This does not apply to situations where a Veteran calls in response to an advertisement. If existing information from sources such as a medical record or database, research or non-research, are used to identify human subjects, there must be an IRB approved HIPAA waiver for this activity in the new protocol.)
20) Any initial contact by letter or telephone must provide a telephone number or other means that the potential subject can use to verify that the study constitutes VA research.
21) If a contractor makes the initial contact by letter, the VA investigator must sign the letter.
22) Informed Consent for Research. The investigator must obtain and document legally effective informed consent of the subject or the subject's LAR prospectively (i.e., no screening or other interaction or intervention involving a human subject can occur until after the IRB-approved informed consent requirements have been met) that is in alignment with ethical principles that govern informed consent for research. The only exceptions are if the IRB determines the research is exempt, or approves a waiver of the informed consent process, or approves a waiver of the signed informed consent document.
23) If the investigator does not personally obtain informed consent, the investigator must delegate this responsibility in writing (e.g., by use of a delegation letter) to research staff sufficiently knowledgeable about the protocol and related concerns to answer questions from prospective subjects, and about the ethical basis of the informed consent process and protocol.
    a. If the investigator contracts with a firm, e.g., a survey research firm, to obtain consent from subjects, collect private individually identifiable information from human subjects, or are involved in activities that would institutionally engage the firm in human subjects research, the firm must have its own IRB oversight of the activity. In addition, the PO must determine that there is appropriate authority to allow the disclosure of individual names and other information to the contracted firm.

b. The investigator must ensure that all original signed and dated informed consent documents are maintained in the investigator's research files, readily retrievable, and secure.

24) HIPAA Authorization. The investigator or designee must obtain HIPAA authorization for the use and disclosure of the subject's PHI or obtain an IRB-approved waiver of HIPAA authorization unless there are a limited data set and appropriate DUA. The written HIPAA authorization may either be a standalone document or combined with the research informed consent approved by the IRB. If a standalone document is used as the written HIPAA authorization, VA Form 10-0493: Authorization for Use and Release of Individually Identifiable Health Information Collected for VHA Research, must be used to document the authorization.

25) Reporting. The investigator is responsible for reporting unanticipated problems involving risks to subjects or others, serious unanticipated problems involving risks to subjects or others, apparent serious or continuing noncompliance, any termination or suspension of research; and privacy or information security incidents related to VA research, including: any inappropriate access, loss, or theft of PHI; noncompliant storage, transmission, removal, or destruction of PHI; or theft, loss, or noncompliant destruction of equipment containing PHI, in accordance with local facility or IRB SOPs and VHA Handbook 1058.

a. VA personnel who become aware of the occurrence of research-related events (as described above) are responsible for following VA medical facility established processes and timelines for promptly reporting the events to the appropriate VA medical facility point(s)-of-contact designated to receive such reports at the VA medical facility that approved the research.

Research Records. All written information given to subjects must be in the investigator's research file along with the consent form(s). All records regardless of format (paper, electronic, electronic systems) must be managed per NARA approved records schedules found in VHA RCS 10-1 and therefore must be retained until disposition instructions, as approved by NARA, are published in VHA RCS 10-1. NOTE: Once the disposition schedule is determined, records should be disposed in accordance with VHA RCS 10-1. If the investigator leaves VA, all research records must be retained by the VA facility where the research was conducted.

26) VHA Health Record. A VHA health record must be created or updated, and a progress note created, for all research subjects (Veterans or Non-Veterans) who receive research procedures or interventions as inpatients or outpatients at VA medical facilities that are either used in or may impact the medical care of the research subject at a VA medical facility or at facilities contracted by VA to provide services to Veterans (e.g., Community-Based Outpatient Clinics or nursing homes). Informed consent and HIPAA authorization documents are not required to be in the health record. The name and contact information of the researcher conducting the study should be included.

27) Investigational Drugs and Devices. The investigator must conduct VA human subjects research involving investigational drugs and devices in accordance with all applicable VA policies and other federal requirements including but not limited to: VHA Directive 1200.05 (3), VHA Handbook 1108.04, and applicable FDA regulations. The storage and security procedures for test articles used in research must be reviewed and approved by the IRB and follow all applicable federal rules.

28) The PI or Local Site Investigator (LSI) must provide the Pharmacy Service with the following:

a. Written approval letter signed by the ACOS for R&D that all relevant approvals have been obtained and that the study may be initiated at the site (VHA Directive 1200.01);
b. An IRB approval letter;
c. A copy of the approved study protocol;
d. A copy of VA Form 10-9012, when appropriate;
e. An IB, when appropriate;
f. Any sponsor-provided documents relating to the storage, preparation, dispensing, and accountability of the investigation products;
g. Copies of all correspondence addressed to the Researcher from the FDA specific to the investigational drugs as appropriate;
h. A copy of the consent document for each participating participant with all appropriate signatures;

i. Protocol revisions, modifications, and updates after IRB approval and after the IRB approved the modification;
j. Updates and changes to authorized prescribers after IRB approval;
k. Documentation of IRB continuing review approval;
l. Notice to the Chief, Pharmacy Service, the research pharmacy when applicable and the IRB in writing and the Research and Development Committee when a study involving investigational drugs has been suspended, terminated, or closed.

29) The PI or LSI must provide Pharmacy Service and/or the Research Service Investigational Pharmacy, investigational drug information on each patient receiving an investigational drug through the electronic medical record or other locally approved means. This documentation is to include allergies, toxicities, or adverse drug events related to the investigational drug, or the potential for interaction with other drugs, foods, or dietary supplements (herbals, nutraceuticals).
30) The PI or LSI must place the completed VA Form 10-9012, or electronic equivalent, in the subject's medical record.
31) The PI must comply with all dispensing and documentation requirements, and the dispensing log must be made accessible to the investigational drug pharmacist upon request.
32) Initiation of Research Projects. IRB approval is for a specified time period based on the degree of risk of the study, not to exceed 1 year except for research subject to the 2018 Requirements where continuing review is not required. The IRB determines the expiration date based upon its date of review and communicates that date to the investigator in the written approval letter. The investigator must not initiate the IRB approved research protocol until all applicable requirements in VHA Directive 1200.01 have also been met including obtaining R&D Committee approval.
33) Expiration of IRB Approval. There is no provision for any grace period to extend the conduct of research beyond the expiration date of IRB approval. Therefore, continuing review and re-approval of research must occur on or before the date when IRB approval expires. If approval expires, the investigator must:
    a. Stop all research activities including, but not limited to, enrollment of new subjects, analyses of individually identifiable data, and research interventions or interactions with currently participating subjects, except where stopping such interventions or interactions could be harmful to those subjects; and
    b. Immediately submit to the IRB Chair a list of research subjects who could be harmed by stopping specified study interventions or interactions. The IRB Chair must determine within 2 business days whether or not such interventions or interactions may continue.
34) Documentation of Informed Consent
    a. When documentation of informed consent is not waived by IRB, the investigator or designee must ensure that the informed consent document is signed and dated by the subject or the subject's legally authorized representative,
    b. If consent is obtained electronically, the following must be met:
    c. Authentication controls on electronic consent provide reasonable assurance that such consent is rendered by the proper individual; and
    d. The subject dates the consent as is typical or that the software provides the current date when signed.
35) Vulnerable Subjects
        a. The following populations are considered categorically vulnerable and have specific VA requirements for their inclusion in research
            1. Pregnant Women, Human Fetuses and Neonates
            2. Prisoners
            3. Children
            4. Subjects who Lack Decision-making Capacity.
    b. Research Involving Prisoners
            1. Research involving prisoners cannot be conducted by VA investigators while on official VA duty, at VA facilities, or at VA-approved off-site facilities unless a waiver has been granted by the CRADO.

2. Waiver requests must be submitted electronically to the CRADO by the VA medical facility Director with the following documents:
    1. A letter from the VA medical facility Director supporting the conduct of the VA study involving prisoners;
    2. Rationale for conducting the research involving prisoners to include additional ethical protections taken by the proposed research for prisoners to make voluntary and uncoerced decisions whether or not to participate as subjects in research;
    3. Documentation of the VA investigator's qualifications to conduct the research involving prisoners, such as a biosketch and a list of all research team members;
    4. Location of institutions where the research is proposed to be conducted;
        a. A copy of the IRB approval letter specifically documenting its review determinations according to 45 CFR 46.305(a);
        b. A copy of the IRB minutes approving the research with documentation that at least one member of the IRB included a prisoner or a prisoner representative for the review of the research;
        c. A copy of the IRB-approved research study;
        d. A copy of the IRB-approved informed consent document; and
        e. A copy of the written HIPAA authorization.
    5. If such a waiver is granted, the research must comply with the requirements of 45 CFR 46.301 - 46.306.

c. Research Involving Children
    1. Research involving children must not present greater than minimal risk.
    2. The VA medical facility Director must approve participation in the proposed research that includes children.
    3. Research involving biological specimens or data obtained from children is considered to be research involving children even if de-identified. If the biological specimens or data were previously collected, they must have been collected under applicable policies and ethical guidelines.
    4. The IRB must have the appropriate expertise to evaluate VA research involving children and must comply with the requirements of 45 CFR 46.401 - 46.404 and 46.408.

d. Research Involving Pregnant Women, Human Fetuses and Neonates as Subjects
    1. Neonates: Interventional research enrolling neonates cannot be conducted by VA investigators while on official duty, or at VA facilities, or at VA approved off-site facilities. VA investigators may conduct research involving noninvasive monitoring of neonates if the research is determined by the IRB to be minimal risk. Prospective observational and retrospective record review studies that involve neonates or neonatal outcomes are permitted. The VA medical facility Director must certify that the medical facility has sufficient expertise in neonatal health to conduct the proposed research.
    2. Pregnant Women: The VA medical facility Director must certify that the medical facility has sufficient expertise in women's health to conduct the proposed research if the research includes interventional studies or invasive monitoring of pregnant women as subjects.
    3. Research that involves provision of in vitro fertilization services can be conducted by VA investigators while on official VA duty, at VA facilities, or at VA-approved off-site facilities. This includes prospective and retrospective research involving provision of or the enhancement of FDA-approved methods of in vitro fertilization for studies involving consenting subjects, both male and female, undergoing or who have undergone in vitro fertilization for the treatment of certain forms of

human infertility. In vitro fertilization is any fertilization of human ova that occurs outside the body of a female, either through a mixture of donor human sperm and ova or by any other means.

4. Prospective and retrospective studies that enroll or include pregnant subjects who conceived through in vitro fertilization or other artificial reproductive technologies are permitted.
5. Research that uses human fetal tissue or that focuses on either a fetus, or human fetal tissue, in-utero or ex-utero cannot be conducted by VA investigators while on official VA duty, at VA facilities, or at VA-approved off-site facilities. Use of stem cells shall be governed by the policy set by NIH for recipients of NIH research funding.

e. Research Involving Persons Who Lack Decision-Making Capacity
    1. The protocol must include a plan, that it is appropriate given the population and setting of the research, for how investigators will determine when a legally authorized representative will be required to provide informed consent. In general, the research staff must perform or obtain and document a clinical assessment of decision-making capacity for any subject suspected of lacking decision-making capacity.
    2. When the potential subject is determined to lack decision-making capacity, investigators must obtain consent from the LAR of the subject (i.e., surrogate consent). NOTE: Investigators and IRBs have a responsibility to consult with the Office of General Counsel (OGC) regarding state or local requirements for surrogate consent for research that may supersede VA requirements.
    3. The following persons are authorized to consent on behalf of persons who lack decision-making capacity in the following order of priority:
        1. Health care agent (i.e., an individual named by the subject in a Durable Power of Attorney for Health Care);
        2. Legal guardian or special guardian;
        3. Next of kin: a close relative of the patient 18 years of age or older, in the following priority: spouse, child, parent, sibling, grandparent, or grandchild; or
        4. Close friend.

f. If feasible, the investigator must explain the proposed research to the prospective research subject even when the legally authorized representative gives consent. Although unable to provide informed consent, some persons may resist participating in a research protocol approved by their representatives. Under no circumstances may a subject be forced or coerced to participate in a research study even if the LAR has provided consent.

g. Legally authorized representatives must be told that their obligation is to try to determine what the subjects would do if able to make an informed decision. If the potential subjects' wishes cannot be determined, the legally authorized representatives must be told they are responsible for determining what is in the subjects' best interest.

h. Research Involving Certificates of Confidentiality
    1. If information about the subject's participation will be included as part of the VHA medical record that information must be given to the prospective subject as part of the informed consent process that information regarding study participation will be included in the medical record.
    2. In instances where a written informed consent form is used, inclusion of a statement that the study has been issued a CoC is required.
    3. Investigators should work with the research office in their facility to assure that when Veterans are enrolled in a study protected by a Certificate of Confidentiality, they are not simultaneously enrolled in other interventional

studies unless it is absolutely clear that this enrollment does not raise safety issues.

i. Collaborative Research
    i. This addresses collaborations between VA and non-VA investigators. Collaboration is encouraged when VA investigators have a substantive role in the design, conduct, and/or analysis of the research. VA may also serve as a Coordinating Center for collaborative studies. NOTE: Collaborative studies do not include studies conducted under a CRADA with pharmaceutical companies or other for-profit entities.
    ii. IRB of Record Approval. Each institution is responsible for safeguarding the rights and welfare of human subjects and providing oversight of the research activities conducted at that institution.
        1. Each collaborating institution engaged in human subjects research must obtain approval from its IRB of Record and hold a FWA or another assurance acceptable to VA, e.g. DoD assurance.
        2. VA investigators must submit a protocol or other documentation to their VA IRB of Record that delineates which research activities will be conducted by VA.
        3. Each institution engaged in the collaborative research must use the informed consent document and HIPAA authorization required by their respective institutional policies for subjects recruited from that institution, or procedures requiring participation of the subject at that institution. The informed consent document may contain information on the project as a whole as long as the document clearly describes which procedures will be performed at VA and which will be performed at other institutions.
        4. The VA informed consent document must clearly state when procedures mentioned at other institutions are part of the VA's portion of the study.
        5. The informed consent document and HIPAA authorization must be consistent and include information describing the following:
            i. PHI to be collected and/or used by the VA research team;
            ii. PHI to be disclosed to the other institutions; and
            iii. Purpose for which the PHI may be used.

Waivers. PHI obtained in research for which the IRB of Record has waived the requirements to obtain a HIPAA authorization and a signed informed consent document may not be disclosed outside VA unless the VA facility Privacy Officer ensures and documents VA's authority to disclose the PHI to another institution. A waiver of HIPAA authorization is not sufficient to fulfill the requirements of other applicable privacy regulations such as the Privacy Act of 1974 (5 U.S.C. 552a).

j. Research Data. The protocol, addendum, and/or IRB of Record application must describe the data to be disclosed to collaborators, the entity(ies) to which the data are to be disclosed, and how the data are to be transmitted. This includes data from individual subjects as well as other data developed during the research such as the analytic data and the aggregate data.
k. Each VA facility must retain a complete record of all data obtained during the VA portion of the research in accordance with privacy requirements, the Federal Records Act, and VHA Records Control Schedule (RCS) 10-1.
l. All disclosures and data transmission must meet privacy and security requirements per VA Directive 6500, VHA Handbook 6500, and VHA Handbook 1605.1.
    i. Written agreements. Collaborative research involving non-VA institutions may not be undertaken without a signed written agreement (e.g., a CRADA or a Data Use Agreement (DUA)) that addresses such issues as the responsibilities of each party, the ownership of the data and the reuse of the data for other research. NOTE: Any reuse must be consistent with the protocol, the informed consent document, and the HIPAA authorization.

ii. Photography, Video and/or Audio Recording for Research Purposes
iii. The informed consent for research must include information describing any photographs, video, and/or audio recordings to be taken or obtained for research purposes, how the photographs, video, and/or audio will be used for the research, and whether the photographs, video, and/or audio will be disclosed outside the VA.

m. An informed consent to take a photograph, video, and/or audio recording cannot be waived by the IRB.
n. The consent for research does not give legal authority to disclose the photographs, video, and/or audio recordings outside the VA. A HIPAA authorization is needed to make such disclosures.
    i. International Research
    ii. VA international research is defined as any VA-approved research conducted at international sites (i.e., not within the United States (U.S.), its territories, or Commonwealths), any VA-approved research using either identifiable or de-identified human biological specimens or identifiable or de-identified human data originating from international sites, or any VA-approved research that entails sending such specimens or data out of the U.S. This definition applies regardless of the funding source (funded or unfunded) and to research conducted through any mechanism of support including MOUs, CRADAs, grants, contracts, or other agreements. NOTE: Research conducted at U.S. military bases, ships, or embassies is not considered international research.
o. Sending specimens or data to individuals with VA appointments at international sites (e.g., a WOC appointment, a VA investigator on sabbatical at an international site) is considered international research. Remote use of data that is maintained on VA computers within the U.S. or Puerto Rico and accessed via a secure connection is not considered international research.
p. International research includes multi-site trials involving non-U.S. sites where VA is the study sponsor, a VA investigator is the overall study-wide PI, VA holds the Investigational New Drug (IND), or the VA manages the data collection and the data analyses.
q. International research does not include studies in which VA is only one of multiple participating sites where the overall study-wide PI is not a VA investigator (i.e., the PI for the study as a whole is not a VA investigator).
    i. Before approving international research involving human subjects research, the IRB must ensure that human subjects outside of the U.S. who participate in research projects in which VA is a collaborator receive equivalent protections as research participants inside the U.S. (see OHRP guidance at http://www.hhs.gov/ohrp/international/index.html). NOTE: The VA medical facility Director must approve participation in the proposed international research.
    ii. All international research must also be approved explicitly in a document signed by the VA medical facility Director, except for Cooperative Studies Program activities which must be approved by the CRADO.
    iii. Use Preparatory to Research
    iv. VA investigators may use individually identifiable health information to prepare a research protocol prior to submission of the protocol to the IRB for approval without obtaining a HIPAA authorization or waiver of authorization.
r. VA investigators must not arbitrarily review PHI based on their employee access to PHI until the investigator documents the following required information as “Preparatory to Research” in a designated file that is readily accessible for those required to audit such information (e.g., Health Information Manager or PO):
    i. Access to PHI is only to prepare a protocol;
    ii. No PHI will be removed from the covered entity (i.e., VHA); and

iii. Access to PHI is necessary for preparation of the research protocol.

s. Non-VA researchers may not obtain VA information for preparatory to research activities without appropriate VA approvals (see VHA Directive 1605.01).

t. During the preparatory to research activities the VA investigator:
   i. Must only record aggregate data. The aggregate data may only be used for background information to justify the research or to show that there are adequate numbers of potential subjects to allow the investigator to meet enrollment requirements for the research study;
   ii. Must not record any individually identifiable health information; and
   iii. Must not use any individually identifiable information to recruit research subjects.
   v. Preparatory activities can include reviewing database output (computer file or printout) containing identifiable health information generated by the database owner, if the investigator returns the database output to the database owner when finished aggregating the information

w. Contacting potential research subjects and conducting pilot or feasibility studies are not considered activities preparatory to research.

x. Activities preparatory to research only encompass the time to prepare the protocol and ends when the protocol is submitted to the IRB.

y. Posting of Clinical Trial Consent Forms

For studies subject to the 2018 Requirements, if a VA research study is a clinical trial, one IRB-approved informed consent form used to enroll subjects, unless the IRB waived documentation of informed consent, must be posted by either the investigator or the Federal department or agency conducting or supporting the study. The informed consent form must be posted after the clinical trial is closed to recruitment and no later than 60 days after the last study visit by any subject as described in the IRB-approved protocol. For multi-site studies, it applies when the entire study has closed to subject recruitment. Any proprietary or personal information (such as names and phone numbers) must be redacted prior to posting the informed consent form.

For any ORD-funded clinical trial, the applicable ORD funding service will be responsible for posting the informed consent form.

For a clinical trial funded or supported by a federal agency or department other than VA, the awardee is responsible for posting the informed consent form.

i. For a clinical trial funded or supported by a non-Federal agency or department (e.g., university, industry, nonprofit organization) or not funded, the VA Investigator conducting the clinical trial is responsible for ensuring that the informed consent form is posted. If the clinical trial includes multiple sites engaged in the clinical trial, an agreement must exist specifying who is responsible for posting the informed consent form.

Other specific requirements of Veterans Administration (VA) research can be found in the “Additional Requirements for Veterans Administration (VA) Research” section in the IRB’s HRP-318 – WORKSHEET – Additional Federal Agency Criteria.

Appendix A-10 ***Single IRB Studies***

1) That National Institutes of Health expects that all sites participating in multi-site studies involving non-exempt human subjects research funded by the NIH will use a single Institutional Review Board (sIRB) to conduct the ethical review required by the Department of Health and Human Services regulations for the Protection of Human Subjects at 45 CFR Part 46.
    a. This policy applies to the domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research, whether supported through grants, cooperative agreements, contracts, or the NIH Intramural Research Program. It does not apply to career development, research training or fellowship awards.
    b. This policy applies to domestic awardees and participating domestic sites. Foreign sites participating in NIH-funded, multi-site studies will not be expected to follow this policy.
    c. Exceptions to the NIH policy will be made where review by the proposed sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy. Requests for exceptions that are not based on a legal, regulatory, or policy requirement will be considered if there is a compelling justification for the exception. The NIH will determine whether to grant an exception following an assessment of the need.
2) The Office for Human Research Protections expects that all sites located in the United States participating in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.
3) The following research is not subject to this provision:
    a. Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or
    b. Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.
    c. For research not subject to paragraph (b) of this section, an institution participating in a cooperative project may enter into a joint review arrangement, rely on the review of another IRB, or make similar arrangements for avoiding duplication of effort.

Appendix A-11 *Additional Requirements for Research Subject to EU General Data Protection Regulations (GDPR)*

1) The IRB follows European Union General Data Protection Regulations for the use of identifiable data within countries of the European Union.
2) Human Research involving personal data about individuals located in (but not necessarily citizens of) European Union member states, Norway, Iceland, Liechtenstein, and Switzerland are subject to EU General Data Protection Regulations.
3) For all prospective Human Research subject to EU GDPR, contact institutional legal counsel or your institution's Data Protection Officer to ensure that the following elements of the research are consistent with institutional policies and interpretations of EU GDPR:
    a. Any applicable study design elements related to data security measures.
    b. Any applicable procedures related to the rights to access, rectification, and erasure of data.
    c. Procedures related to broad/unspecified future use consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens.
4) Where FDA or DHHS regulations apply in addition to EU GDPR regulations, ensure that procedures related to withdrawal from the research, as well as procedures for managing data and biospecimens associated with the research remain consistent with Appendices A-1 and A-2 above.

Appendix A-12 *Continuity Planning for Investigators Conducting Human Research*

Investigators conducting human research should be aware of the following additional considerations associated with managing Human Research during an emergency, disaster, or other disruptive event (e.g., extreme weather events, natural disasters, man-made disasters, infectious disease pandemics, loss or failure of facilities, significant and unexpected loss of funding and/or workforce, etc.) related to investigators' ongoing interactions with research subjects and the institutional review board (IRB) in such cases.

During Emergency/Disruption Scenarios: Deciding Whether a Study-Specific Risk Mitigation Plan for Ongoing Research Is Needed

In general, investigators should develop a study-specific emergency/disruption risk mitigation plan for their research unless one of the following is true:

- Research does not involve in-person interaction with research subjects.
- Research can be conducted as written while adhering to additional institution-level and HRPP-level guidance and requirements regarding the emergency/disruption event.
- The research is externally sponsored, and the sponsor has developed a protocol-specific risk mitigation plan for the research.
- The research has been voluntarily placed on hold for recruitment and all research procedures (except for necessary follow-up procedures to be done consistently with additional institution-level and HRPP-level guidance and requirements regarding the emergency/disruption event).

Tools and Resources for Developing Study-Specific Emergency/Disruption Risk Mitigation Plans for Ongoing Research

Review "HRP-108 - FLOWCHART - Study-Specific Emergency-Disruption Risk Mitigation Planning" and "HRP-351 - WORKSHEET - Protocol-Specific Emergency-Disruption Risk Mitigation Planning" for general guidance on developing study-specific risk mitigation plans.

Voluntary Holds on Human Research Activities

Investigators may voluntarily elect to place all recruitment, enrollment and research procedures on temporary hold during emergency/disruption scenarios if doing so will better ensure the safety of research subjects and would not create any additional risks to the safety and welfare of research subjects. Such voluntary holds on research activity do not require IRB notification or review.

In addition, studies may be placed on an "Administrative Hold." An Administrative Hold is an action initiated by the Researcher in response to an IRB request to place specific research activities on hold temporarily pending additional information. An administrative closing is not considered a termination or suspension since the administrative closure is not done in a response to research not being conducted in accordance with the IRB's requirements nor associated with unexpected serious harm to subjects per 21 CFR 56.113 and 45 CFR 46.113.

Submitting Study-Specific Emergency/Disrupton Risk Mitigation Plans for IRB Review

If immediate modification of the research is necessary to eliminate an apparent immediate hazard to a subject, act and notify the IRB within five business days following the standard pathway to submit reportable new information.

For all other study modifications made to ensure the ongoing safety of research subjects during emergency/disruption scenarios, submit a study modification and all relevant new or modified study materials to the IRB.

Other Reportable New Information Considerations During Emergency/Disruption Scenarios

The IRB's list of reportable events includes two items for which additional clarification and guidance may be helpful during emergency/disruption scenarios:

1) ***"Failure to follow the protocol due to the action or inaction of the investigator or research staff."*** Emphasis on action or inaction of the investigator or research staff has been added because this requirement does not include action or inaction of the research subject. For example, study teams may notice an increase in the number of subjects who do not arrive for scheduled research visits under emergency/disruptioncircumstances. Failure of a research participant to appear for a scheduled research visit is not noncompliance due to action or inaction by the investigator or research staff and therefore does not require reporting to the IRB.
2) ***"Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject."*** During emergency/disruption scenarios, there will be cases where there is sufficient time to receive IRB approval of any proposed modifications to previously approved research, and in such cases, investigators should follow standard IRB procedures for submitting modifications. However, there will be other cases where investigators must make more immediate changes to the protocol or investigational plan to minimize or eliminate immediate hazards or to protect the life and well-being of research participants. Such changes may be implemented without IRB approval but are required to be reported to the IRB within five business days afterward in accordance with IRB policies and procedures for submitting reportable new information.

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[i] http://www.hhs.gov/ohrp/policy/subjectwithdrawal.html

[ii] http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126489.pdf

[iii] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.7

[iv] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.60

[v] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.61

[vi] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.62

[vii] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.64

[viii] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.66

[ix] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.68

[x] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.69

[xi] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.100

[xii] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.110

[xiii] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.140

[xiv] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.145

[xv] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.150

[xvi] https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf

[xvii] HSR conducted by researchers from outside institutions at/using DOE/NNSA user facility capabilities may only be initiated if the researchers have provided documentation of study-specific approval or exemption determination from the IRB/ethics board used by their institution.
If the outside institutions using DOE facility capabilities are not funded by DOE, partnering with any DOE or DOE contractor organization, or using DOE or DOE contractor employees or employee data, their studies will not be expected to comply with all other requirements in this order unless the DOE/NNSA site responsible for the user facility requires such compliance.

[xviii] Children are persons enrolled in research not above the elementary or secondary education level, who have not reached the age or majority as determined under state law.

[xix] Research or experimentation program or project means any program or project in any research that is designed to explore or develop new or unproven teaching methods or techniques.

WORKSHEET: Review Materials

The purpose of this worksheet is to provide support for IRB staff who prepare review materials for convened IRB meetings or prepare materials for Non-Committee Review. This worksheet lists the materials that reviewers, including scientific/scholarly reviewers, and consultants, need to conduct their review, based on the submission and review type, and the reviewer's role. For individuals who have electronic (computer) access to all information, this document describes the subset of materials the IRB or reviewer is expected to access and review. For individuals who are provided a subset of the information, this document describes the subset of materials the IRB staff are to provide to the IRB or reviewer for review.

1. GENERAL INFORMATION FOR ALL IRB MEMBERS FOR CONVENED MEETINGS

☐ List of protocols approved using the expedited procedure (For Veterans Administration (VA) Research, include the review category).
☐ Information for other business items
☐ Educational materials

2. FOR EACH PROTOCOL UNDERGOING INITIAL REVIEW

Documents for All IRB Members, Alternate IRB Members, Designated Reviewers and Staff Reviewers

☐ New Study SmartForm
☐ Investigator's Protocol and documents referenced by the Investigator's Protocol
☐ Consent documents, when they exist
☐ Recruitment materials, when they exist
☐ Participating site materials, when they exist

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Include based on the review type:

☐ HRP-310 - WORKSHEET - Human Research Determination
☐ HRP-311 - WORKSHEET - Engagement Determination
☐ HRP-312 - WORKSHEET - Exemption Determination
☐ HRP-314 - WORKSHEET - Criteria for Approval
☐ HRP-314a - WORKSHEET - Criteria for Consent, when applicable

Add when the protocol involves these items:

☐ HRP-315 - WORKSHEET - Advertisements
☐ HRP-316 - WORKSHEET - Payments
☐ HRP-317 - WORKSHEET - Short Form of Consent Documentation
☐ HRP-318 - WORKSHEET - Additional Federal Agency Criteria
☐ HRP-319 - WORKSHEET - Limited IRB Review and Broad Consent
☐ HRP-333 - WORKSHEET - Certificate of Confidentiality
☐ HRP-334 - WORKSHEET - AI
☐ HRP-410 - PI WORKSHEET - Waiver or Alteration of Consent Process
☐ HRP-411 - PI WORKSHEET - Waiver of Written Documentation of Consent
☐ HRP-412 - PI WORKSHEET - Pregnant Women
☐ HRP-413 - PI WORKSHEET - Non-Viable Neonates
☐ HRP-414 - PI WORKSHEET - Neonates of Uncertain Viability
☐ HRP-415 - PI WORKSHEET - Prisoners
☐ HRP-416 - PI WORKSHEET - Children
☐ HRP-417 - PI WORKSHEET - Adults with Impaired Decision-Making Capacity
☐ HRP-418 - WORKSHEET - Non-Significant Risk Device
☐ HRP-419 - WORKSHEET - Waiver of Consent Process for Emergency Research
☐ HRP-441 - PI WORKSHEET - HIPAA Waiver of Authorization

☐ HRP-450 - PI WORKSHEET - International Research

☐ HRP-451 - PI WORKSHEET - Right to Try

☐ HRP-452 - PI WORKSHEET - Information Practices Act

Additional items, as applicable, for the Primary Reviewer, Prisoner Representative, Designated Reviewer, and/or Staff Reviewer

☐ Sponsor protocol
☐ Investigator's brochure
☐ The DHHS-approved sample informed consent document
☐ The complete DHHS-approved protocol
☐ All other materials provided by the investigator
☐ Scientific Review
☐ Copy of the investigator's current curriculum vita or other documentation evidencing qualifications.

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Additional items for the Scientific/Scholarly Reviewer

☐ HRP-320 - WORKSHEET - Scientific or Scholarly Review

☐ Scientific evaluation, when it exists

Items for Consultants

☐ Cover letter to consultants

☐ Appropriate materials provided to any other reviewer.

3. FOR EACH PROTOCOL UNDERGOING CONTINUING REVIEW

Documents for All IRB Members, Alternate IRB Members, and Designated Reviewers

☐ Continuing Review SmartForm
☐ Investigator's Protocol and documents referenced by the Investigator's Protocol
☐ Current and proposed consent document(s), when they exist
☐ HRP-314 - WORKSHEET - Criteria for Approval
☐ HRP-314a - WORKSHEET - Criteria for Consent, when applicable

Add when the protocol involves these items or there is a change in determination:

☐ HRP-315 - WORKSHEET - Advertisements
☐ HRP-316 - WORKSHEET - Payments
☐ HRP-317 - WORKSHEET - Short Form of Consent Documentation
☐ HRP-318 - WORKSHEET - Additional Federal Agency Criteria
☐ HRP-333 - WORKSHEET - Certificate of Confidentiality
☐ HRP-334 - WORKSHEET - AI
☐ HRP-410 - PI WORKSHEET - Waiver or Alteration of Consent Process
☐ HRP-411 - PI WORKSHEET - Waiver of Written Documentation of Consent
☐ HRP-412 - PI WORKSHEET - Pregnant Women
☐ HRP-413 - PI WORKSHEET - Non-Viable Neonates
☐ HRP-414 - PI WORKSHEET - Neonates of Uncertain Viability
☐ HRP-415 - PI WORKSHEET - Prisoners
☐ HRP-416 - PI WORKSHEET - Children
☐ HRP-417 - PI WORKSHEET - Adults with Impaired Decision-Making Capacity
☐ HRP-418 - WORKSHEET - Non-Significant Risk Device
☐ HRP-419 - WORKSHEET - Waiver of Consent Process for Emergency Research
☐ HRP-441 - PI WORKSHEET - HIPAA Waiver of Authorization

Additional items, as applicable for the Primary Reviewer, Prisoner Representative, and/or Designated Reviewer

☐ Sponsor protocol

☐ Any modifications to the sponsor protocol previously approved by the IRB

Items for Consultants

☐ Cover letter to consultants

☐ Appropriate materials provided to any other reviewer

4. FOR EACH PROTOCOL UNDERGOING REVIEW OF MODIFICATIONS

Documents for All IRB Members, Alternate IRB Members, Designated Reviewers and Staff Reviewers

☐ Modification SmartForm

☐ All modified documents

Include based on the review type:

☐ HRP-310 - WORKSHEET – Human Research Determination
☐ HRP-311 - WORKSHEET – Engagement Determination
☐ HRP-314 - WORKSHEET – Exemption Determination

☐ HRP-314 - WORKSHEET - Criteria for Approval
☐ HRP-314a - WORKSHEET - Criteria for Consent, when applicable

Add when modification involves these items or there is a change in determination:

☐ HRP-315 - WORKSHEET - Advertisements
☐ HRP-316 - WORKSHEET - Payments
☐ HRP-317 - WORKSHEET - Short Form of Consent Documentation
☐ HRP-318 - WORKSHEET - Additional Federal Agency Criteria
☐ HRP-319 - WORKSHEET - Limited IRB Review and Broad Consent
☐ HRP-333 - WORKSHEET - Certificate of Confidentiality
☐ HRP-334 - WORKSHEET - AI
☐ HRP-410 - PI WORKSHEET - Waiver or Alteration of Consent Process
☐ HRP-411 - PI WORKSHEET - Waiver of Written Documentation of Consent

☐ HRP-412 - PI WORKSHEET - Pregnant Women
☐ HRP-413 - PI WORKSHEET - Non-Viable Neonates
☐ HRP-414 - PI WORKSHEET - Neonates of Uncertain Viability
☐ HRP-415 - PI WORKSHEET - Prisoners
☐ HRP-416 - PI WORKSHEET - Children
☐ HRP-417 - PI WORKSHEET - Adults with Impaired Decision-Making Capacity
☐ HRP-418 - WORKSHEET - Non-Significant Risk Device
☐ HRP-419 - WORKSHEET - Waiver of Consent Process for Emergency Research
☐ HRP-441 - PI WORKSHEET - HIPAA Waiver of Authorization

Additional items, as applicable, for the Primary Reviewer, Prisoner Representative, Designated Reviewer and Staff Reviewer

☐ All other materials provided by the investigator

Additional items for the Scientific/Scholarly Reviewer

If the modification is substantive, include:
☐ HRP-320 - WORKSHEET - Scientific or Scholarly Review

Items for Consultants

☐ Cover letter to consultants

☐ Appropriate materials provided to any other reviewer

5. FOR EACH REPORT OF NEW INFORMATION

Documents for All IRB Members, Alternate IRB Members, Primary Reviewer, Prisoner Representative, Designated Reviewer and Scientific/Scholarly Reviewer

☐ Report of New Information SmartForm
☐ Investigation report, when they exist or are relevant
☐ Other supporting documents, when they exist or are relevant
☐ Investigator's Protocol and modified documents referenced by the Investigator's Protocol, when they exist or are relevant
☐ Consent document, when they exist or are relevant
☐ HRP-321 - WORKSHEET - Review of Information Items
☐ HRP-314 - WORKSHEET - Criteria for Approval, when applicable
☐ HRP-314a - WORKSHEET - Criteria for Consent when applicable

Items for Consultants

☐ Cover letter to consultants

☐ Appropriate materials provided to any other reviewer

6. FOR USE OF A HUMANITARIAN USE DEVICE (HUD) UNDERGOING INITIAL REVIEW

Documents for All IRB Members and Alternate IRB Members

☐ New Study SmartForm
☐ All submitted materials
☐ HRP-323 - WORKSHEET - Criteria for Approval HUD

Documents for Consultants

☐ Cover letter to consultants

☐ Appropriate materials provided to any other reviewer

7. FOR USE OF A HUMANITARIAN USE DEVICE (HUD) UNDERGOING CONTINUING REVIEW

Documents for All IRB Members, Alternate IRB Members, and Designated Reviewers

☐ Continuing Review SmartForm

☐ All submitted materials

☐ HRP-323 - WORKSHEET - Criteria for Approval HUD

Items for Consultants

☐ Cover letter to consultants

☐ Appropriate materials provided to any other reviewer

8. FOR USE OF A HUMANITARIAN USE DEVICE (HUD) UNDERGOING REVIEW OF MODIFICATIONS

Documents for All IRB Members and Alternate IRB Members

☐ Modification SmartForm

☐ All submitted materials

☐ HRP-323 - WORKSHEET - Criteria for Approval HUD

Documents for Consultants

☐ Cover letter to consultants

☐ Appropriate materials provided to any other reviewer

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WORKSHEET: Approval Intervals

The purpose of this worksheet is to provide support for IRB staff members who send communications after an IRB review where the letter needs to include approval and Expiration Dates. This worksheet describes how to make these calculations.

INITIAL REVIEW APPROVAL INTERVALS

Type of Review	Approval Date	Effective Date	End Approval Date
Convened IRB granted approval	Date of convened IRB meeting	Date of convened IRB meeting	Date of the convened meeting plus the approval interval minus one day[i]
Convened IRB required modifications to secure approval ("M"); subsequently verified by Non-Committee Review	Date of convened IRB meeting	Date the IRB Office (IRB Chair or designee) verified that the required modifications had been made	Date of the convened meeting plus the approval interval minus one day
Designated Reviewer granted approval at Non-Committee Review	Date the Designated Reviewer granted approval	Date the Designated Reviewer granted approval	APPROVAL DATE plus the approval interval minus one day
Designated Reviewer required modifications to secure approval; subsequently verified by Non-Committee Review	Date the IRB Office verified that the required modifications had been made	Date the IRB Office verified that the required modifications had been made	APPROVAL DATE plus the approval interval minus one day

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CONTINUING REVIEW APPROVAL INTERVALS

Type of Review	Approval Date	Effective Date	End Approval Date
Convened IRB granted approval	Date of convened IRB meeting	Date of convened IRB meeting	Date of the convened meeting plus the approval interval minus one day
Convened IRB required modifications to secure approval; subsequently verified by Non-Committee Review	Date of convened IRB meeting	Date the IRB Office verified that the required modifications had been made	Date of the convened meeting plus the approval interval minus one day[ii]
Designated Reviewer granted approval	Date the Designated Reviewer granted approval	Date the Designated Reviewer granted approval	APPROVAL DATE plus the approval interval minus one day
Designated Reviewer required modifications to secure approval; subsequently verified by Non-Committee Review	Date the Designated Reviewer required modifications to secure approval	Date the IRB Office verified that the required modifications had been made	APPROVAL DATE plus the approval interval minus one day

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MODIFICATIONS

Type of Review	Approval Date	Effective Date	End Approval Date
Convened IRB granted approval	Date of convened IRB meeting	Date of convened IRB meeting	Previous END APPROVAL DATE[ii]
Convened IRB required modifications to secure approval; subsequently verified by Non-Committee Review	Date the IRB Office verified that the required modifications had been made	Date the IRB Office verified that the required modifications had been made	Previous END APPROVAL DATE
Designated Reviewer granted approval	Date the Designated Reviewer granted approval	Date the Designated Reviewer granted approval	Previous END APPROVAL DATE
Designated Reviewer required modifications to secure approval; subsequently verified by Non-Committee Review	Date the IRB Office verified that the required modifications had been made	Date the IRB Office verified that the required modifications had been made	Previous END APPROVAL DATE

[i] For example, if the convened IRB approved research on April 15, 2024 for one year, the end date of the approval interval is April 15, 2024 + one year – one day = April 14, 2025. If the convened IRB approved research on April 15, 2024 for six months, the end date of the approval interval is April 15, 2024 + six months – one day = November 14, 2024.

[ii] For example, if the last date of the approval interval was April 14, 2025, and the convened IRB approved a modification on November 16, 2024, the end date of the approval interval remains April 14, 2025.

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WORKSHEET: Communication of Review Results

System-Generated Letter Templates:

The purpose of this worksheet is to provide support for staff who send communications after an IRB review.

IF THE CONVENED IRB, DESIGNATED REVIEWER, OR OTHER DESIGNEE:	COMPLETE THE FOLLOWING TEMPLATE LETTER AND SEND TO ALL INDIVIDUALS LISTED IN CC LIST
Approved protocol	HRP-510 - LETTER – Approval HRP-510a - LETTER - Approval - CR NOT Req
Approved a participating site	HRP-870 - LETTER - Site Approval HRP-870a-LETTER - Site Approval - CR NOT Req
Acknowledged a protocol closure	HRP-511 - LETTER - Closure
Required modifications to protocol to secure approval	HRP-512 - LETTER - Mods Req to Secure Approval
Required site modifications to secure approval	HRP-872 - LETTER - Site Modifications Required to Secure Approval
Determined that the activity is not Human Research	HRP-513 - LETTER - NHR Determination
Determined that the Human Research meets exemption criteria	HRP-514 - LETTER - Exemption
Determined that the activity is Human Research in which the organization is not engaged	HRP-527 - LETTER - Not Engaged
Agreed to provide IRB review for an external site engaged in a multi-site or collaborative study	HRP- 851 - LETTER - Invitation Decision
Declined a request to serve as a sIRB	HRP-850- LETTER - Decline to Serve
Declined a request to cede review to an external IRB	HRP-856 - LETTER - Decline Reliance on an External IRB
Agreed to cede IRB review to an external IRB	HRP-857 - LETTER - Acknowledge External IRB
Acknowledged study modifications approved by an external IRB	HRP-859 - LETTER - Acknowledge External IRB Update
Reviewed an information item	HRP-519 - LETTER - Information Item
Reviewed site information item	HRP-879 - LETTER - Review of Site Information Item
Suspended IRB Approval	HRP-515 - LETTER - Suspension

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Terminated IRB Approval	HRP-515b - LETTER - Termination

THE FOLLOWING DETERMINATIONS CAN ONLY BE MADE BY A CONVENED IRB

IRB DETERMINATION	COMPLETE THE FOLLOWING TEMPLATE LETTER AND SEND TO ALL INDIVIDUALS LISTED IN CC LIST
Deferred protocol	HRP-516 - LETTER - Deferral
Deferred site	HRP-876 - LETTER - Site Deferral
Disapproved protocol	HRP-517 - LETTER - Disapproval
Disapproved site	HRP-877 - LETTER - Site Disapproval
Lifted a suspension	HRP-515a - LETTER - Lifting of Suspension

The purpose of this worksheet is to provide support for staff who send communications after an IRB review or at the discretion of the IRB.

THE FOLLOWING DETERMINATIONS CAN ONLY BE MADE BY A CONVENED IRB

IRB DETERMINATION	COMPLETE THE FOLLOWING TEMPLATE LETTER AND SEND TO ALL INDIVIDUALS LISTED IN CC LIST
Determined that a study submitted under the abbreviated requirements involved a significant risk device (FDA)	HRP-521 - LETTER - SR NSR Device
Approved a waiver of the consent process for planned emergency research	HRP-525 - LETTER - OHRP Notif Emerg Waiver

THE FOLLOWING NOTIFICATIONS ARE SENT AT THE IRB'S DISCRETION

IRB NOTIFICATION	COMPLETE THE FOLLOWING TEMPLATE LETTER AND SEND TO ALL INDIVIDUALS LISTED IN CC LIST
Tabled the protocol	HRP-518 - LETTER - Tabled *(Place on the agenda for the next IRB meeting)*
Reviewed an Unanticipated Problem Involving Risks to Subjects or Others, Serious or Continuing Non-Compliance, or a Suspension or Termination that requires reporting to a federal agency not including OHRP	HRP-520 - LETTER - External Report NOT Including OHRP
Reviewed an Unanticipated Problem Involving Risks to Subjects or Others, Serious or Continuing Non-Compliance, or a Suspension or	HRP-520a - LETTER - External Report OHRP and Other Agencies and OHRP Incident Report Form[i]

Termination that requires reporting to a federal agency and OHRP	
Determined that a study submitted under the abbreviated requirements involved a significant risk device (FDA)	HRP-521 - LETTER - SR NSR Device
Approved research conducted or funded by DHHS or DoD involving prisoners as subjects	HRP-522 - LETTER - Cert Prisoner Research Subpart C Certification Form
Approved not otherwise approvable research involving children, pregnant women, or neonates	HRP-523 - LETTER - Not Otherwise Appro Research
Approved a waiver of the consent process for planned emergency research	HRP-525 - LETTER - OHRP Notif Emerg Waiver
Continuation of subjects in expired research	HRP-532 - LETTER - Conti Subj Expired Research
Investigator Quality Improvement assessment	HRP-534 - LETTER - Investigator QI Assessment
IRB Member Appointment	HRP-560 - LETTER - IRB Member Appointment
IRB Member Thank You	HRP-561 - LETTER - IRB Member Thank You
IRB Member Appreciation	HRP-562 - LETTER - IRB Member Appreciation
Pre-Review of Emergency Use (Criteria Met)	HRP-570 - LETTER - Pre-Rev EU - Crit Met
Pre-Review of Emergency Use (Criteria Not Met)	HRP-571 - LETTER - Pre-Rev EU - Crit Not Met
Review of Emergency Use (Criteria Met)	HRP-572 - LETTER - Review of EU - Crit Met
Review of Emergency Use (Criteria Not Met)	HRP-573 - LETTER - Review of EU - Crit Not Met
Approved compassionate use of a device	HRP-574 - LETTER - Device Compassionate Use
Approved non-emergent individual patient expanded access use of investigational drug	HRP-575 - LETTER - Rev of IRB Waiver for Indiv Pt Drug Exp Access
Failure to Submit Emergency Use Report	HRP-551 - LETTER - Failure to Submit EU Report
Failure to Submit Emergency Use Protocol	HRP-553 - LETTER - Failure to Submit EU Protocol
Permission to Rely on External IRB (prior to Acknowledging External IRB)	HRP-852 - LETTER - Permission to Rely on an External IRB

[i] See: https://oashsps.my.site.com/ohrpwebforms/s/incident-web-form

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WORKSHEET: IRB Composition

The purpose of this worksheet is to provide support for IRB staff reviewing whether the IRB is appropriately composed. Note: All IRB members are voting members. There are no "non-voting IRB members."

1. Objective Composition (Check if "Yes". All must be checked)

☐ The IRB has at least five members, not counting alternate IRB members.

☐ The IRB does not consist entirely of men or entirely of women. *[FDA, DOJ, or when applying the Pre-2018 Common Rule regulations only.]*

☐ The IRB does not consist entirely of members of one profession. *[FDA, DOJ, or when applying the Pre-2018 Common Rule regulations only.]*

☐ The IRB has at least one member who has primary concerns are in scientific areas.

☐ The IRB has at least one member who has primary concerns are in non-scientific areas.

☐ The IRB has at least one member who is unaffiliated with the institution (i.e., not an active alumnus) and whose Immediate Family is unaffiliated with the institution.

2. Subjective Composition (Check if "Yes". All must be checked)

☐ The qualifications of alternate members are comparable to the regular member to be replaced.

☐ The members have varying backgrounds to promote complete and adequate review of research activities commonly reviewed.

☐ The IRB is sufficiently qualified through its experience, expertise, diversity in terms of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes to promote respect for its advice and counsel in safeguarding the rights and welfare of Human Subjects.

☐ The IRB includes persons knowledgeable of institutional commitments and regulations, applicable law, and standards of professional conduct and practice and has the ability to ascertain the acceptability of proposed research in terms of these areas.

☐ The IRB has the ability to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice.

☐ The IRB possesses the professional competence necessary to review research activities.

☐ If the IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, Prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, the IRB includes of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.

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☐ The IRB has at least one member who represents the perspective of research subjects.

☐ The IRB has no members responsible for business development. Individuals with potential competing business interests cannot serve on the IRB or be involved in the day-to-day operations of the review process. For example, the Senior Director of Sponsored Projects, the Vice Chancellor for Research or others who are responsible for raising funds or garnering support for research cannot not serve on the IRB or be involved in the daily operations of the review process.

☐ The IRB has no members that own equity in the organization.

☐ To support American Nurses Credentialing Center Magnet designation each Biomedical IRB includes at least one UCI nurse as a voting member.

3. Additional Requirements (Check if "Yes". All must be checked)

☐ The IRB has an IRB chair.

☐ IRB Chair requirements:

☐ Possess strong leadership skills to effectively organize, influence and expedite IRB meetings, have a strong command of the regulations pertaining to human subjects research, be a tenure track faculty member and have a M.D. for the biomedical committees; or a Ph.D. in a related field for the social-behavioral committee.

a. It is recommended that Chairs serve one year as a Committee member prior to assuming the role of Chair.
b. The Chair shall serve a two-year term and shall be considered for re-appointment at the end of each term.
c. Chairs may be requested to serve six months or longer as a Committee member at the completion of their term to mentor the newly selected Chair to promote consistency and continuity. In addition, this will provide a resource for the newly selected Chair and Committee members on historical perspectives, rationale for decisions made regarding policy, and meeting facilitation skills. d. Chairs are requested to serve as alternate members at the completion of their term.

☐ There are sufficient alternate IRB members.

4. Composition of an IRB that Reviews Research Involving Prisoners (Check if "Yes". If the IRB reviews research involving Prisoners, all must be checked)

☐ A majority of the Board (exclusive of Prisoner members) has no association with the prison(s) involved, apart from their membership on the Board.

☐ At least one voting member of the Board is a Prisoner, or a Prisoner representative with appropriate background and experience to serve in that capacity, including a working knowledge of the population to be recruited, a reasonable familiarity with the operations of the prison or confinement facility, and any other legally imposed restrictive conditions involved in the research. (The Prisoner representative may be an alternate member who becomes a voting member when needed.)

5. Scope and Composition (Check if "Yes". All must be checked)

☐ This IRB conducts: (Select one)

☐ All reviews without limitation.

☐ Limited to the following types of reviews:

☐ The type of research reviewed matches the description in the roster.

☐ The composition of the IRB is appropriate to the types of research reviewed.

List limitation on types of reviews:

Click or tap here to enter text.

6. Composition of an IRB that Reviews Veterans Administration (VA) Research (Check if "Yes". If the IRB reviews VA research, all must be checked)

☐ The IRB has no voting member who is a VA facility research office staff member including, but not limited to, the Associated Chief of Staff (ACOS) for R&D, the Administrative Officer (AO) for R&D, and IRB administrative staff. *They may serve as ex officio, non-voting members or attendees; however, they and the IRB must be sensitive to any potential, actual, apparent, or perceived conflicts of interest and appropriately manage such conflicts.*

☐ The IRB has no member who is a Research Compliance Officer (RCO). RCOs may attend IRB meetings when requested by the IRB or as specified by the IRB's standard operating procedures (SOPs) as consultants.

☐ The Privacy Officer (PO) and the Information System Security Officer (ISSO) serve in an advisory capacity as either non-voting members or as consultants.

☐ The IRB has no member who is a Facility Director, his/her administrative staff, COS, other facility senior administrators such as Associate or Assistant Directors or Chief Nurse, and NPC Administrative.

☐ Alternate members must have qualifications similar to the member they replace.

☐ Every effort has been made to include a Veteran or Veteran representative as part of the fulfillment of the requirement of relevant diversity of experience and expertise. *VA representation on external IRBs, such as academic IRBs, is optional and at the discretion of the IO and the external IRB.*

☐ The IRB has at least one voting member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution. Retired VA employees who are receiving VA retirement benefits are considered to be affiliated when they are members of a VA IRB. Veterans whose only relationship with VA is receiving care at a VA facility or receiving benefits from the Veterans Benefits Administration are considered unaffiliated.

7. Composition of a Veterans Administration (VA) IRB (Check if "Yes". If the IRB is a VA IRB, all must be checked)

☐ The IRB chairs, co-chairs, and vice chairs are paid VA employees (i.e., not have a WOC or IPA appointment).

☐ The IRB chairs, co-chairs, and vice chairs are appointed by the Institutional Official/Organizational Official (IO/OO) for a term of up to three years.

☐ There may be one IRB chair, co-chairs, or a chair and vice chair.

☐ The IRB chair, co-chairs, and vice chairs may be voting members of the IRB.

☐ Voting members are appointed by the IO/OO for a term of up to three years, and may be re-appointed indefinitely.

☐ A VA facility's own internal IRB cannot serve as an IRB of Record for any non-VA entity except a DoD facility, Department of Energy laboratory, or a VA nonprofit research and education corporations (NPC).

WORKSHEET: Quorum and Expertise

The purpose of this worksheet is to provide support for staff who monitor attendance at convened IRB meetings. This worksheet evaluates whether the members present at the meeting comprise a quorum. IRB staff are to consult this worksheet in preparation of meetings and when monitoring attendance at convened meetings. The worksheet does not need to be completed or retained.

1. QUORUM REQUIREMENTS (Check if "Yes" or "NA". All must be checked)

☐ Greater than half of the IRB members *(will be/are)* present.

☐ At least one member whose primary concerns are in scientific areas *(will be/is)* present.

☐ At least one member whose primary concerns are in non-scientific areas *(will be/is)* present.

☐ At least one unaffiliated member *(will be/is)* present.[i]

☐ At least one member who represents the general perspective of subjects *(will be/is)* present.

☐ If both an alternate IRB member and the regular IRB member for whom the alternate IRB member *(will be/is)* substituting (*will be/are*) present, only one *(will be/is)* voting and only one *(will be/is)* counting towards quorum. **("NA" if both an alternate IRB member and the regular IRB member for whom the alternate IRB member *(will be/is)* substituting (*will NOT be/are NOT*) present) NA: ☐**

☐ In order for a DOE IRB to vote on a new or amended protocol that requires full board review, there must be a minimum of five members present, including a scientist, a nonscientist, and an unaffiliated member. For classified research, the unaffiliated member must be a nongovernmental member with the appropriate security clearance. This individual cannot be a current Federal employee or a DOE site contractor. **("NA" if DOE regulations do not apply) NA: ☐**

2. EXPERTISE REQUIREMENTS (Check if "Yes" or "NA". All must be checked)

☐ At least one member or consultant with scientific or scholarly expertise in the area of research *(will be/is/was)* involved in the review.

☐ At least one member or consultant with knowledge of the local context *(will be/is)* involved in the review.

☐ At least one member or consultant able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice.

☐ When the research involves Prisoners as subjects: An IRB member who is a Prisoner or a Prisoner representative with appropriate background and experience to serve in that capacity *(will be/is)* involved in the review as a voting member. The Prisoner representative may attend the meeting by phone, video-conference, or Webinar, as long as the representative is able to participate in the meeting as if they were present in person. **("NA" if no Prisoners.) NA: ☐**

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☐ When the research involves a drug or device: An IRB member who is a licensed physician *(will be/is)* involved in the review[ii]. **("NA" if no drugs or devices.) NA:** ☐

☐ When the research involves populations vulnerable to coercion or undue influence: An IRB member or consultant who is knowledgeable about or experienced in working with such subjects *(will be/is)* involved in the review.[iii] **("NA" if no populations vulnerable to coercion or undue influence.) NA:** ☐

☐ When the research involves other specific expertise: An IRB member or consultant who has that expertise (professional competence) *(will be/is)* involved in the review. **("NA" if no specific expertise needed.). NA:** ☐

☐ When the research is Veterans Administration (VA) research: An IRB member who is a Veterans Administration (VA) representative *(will be/is)* involved in the review, when necessary.[iv] **("NA" if not Veterans Administration (VA) research or VA representation not required.) NA:** ☐

☐ For international research the IRB has knowledge of local laws and the cultural context of the country where research is going to be conducted Including: (Can be through consultation with a local IRB, government agency, or other qualified consultant.) **("NA" if not international research.) NA:** ☐

- Appropriate expertise and knowledge of the country(ies) either through IRB members or consultants.
- Knowledge of cultural context.
- Application of the same processes for initial review, continuing review, and review of modifications to previously approved research; post-approval monitoring; handling of complaints, non-compliance, and unanticipated problems involving risk to subjects or others; and consent process and document and other language issues as applied to domestic research.
- Coordination and communication with local IRBs or ECs when appropriate.

☐ For community-based participatory research the IRB has done one of the following: **("NA" if not community-based participatory research.) NA:** ☐

- Educated IRB members on community-based participatory research.
- Included IRB members with expertise in community-based participatory research.
- Obtained consultation with expertise in community-based participatory research.

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[i] FDA and OHRP allow for quorum to be maintained in the absence of an unaffiliated member, but frequent absences of all unaffiliated members is unacceptable.

- https://www.hhs.gov/ohrp/minutes-institutional-review-board-irb-meetings-guidance-institutions-and-irbs.html-0
- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/minutes-institutional-review-board-irb-meetings

[ii] 46 FR 8958 at 8966, January 27, 1981, Comment 55, FDA wrote that it "...would expect that an IRB that reviews investigational new drug studies will include at least one physician." In comment 58, it notes "...an IRB must retain the necessary expertise to effectively review any protocol submitted to it, and therefore, it may need a number of scientists (whether medical doctors, dentists, technical staff, or others) on the IRB."

[iii] 45 CFR §46.107(a): "If an IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects."

[iv] VHA Directive 1200.05(3) notes the following regarding IRB membership and vulnerable population representation: "IRBs serving VA should also consider including a Veteran or Veteran's representative". Therefore, based on the nature of the research, appropriate VA representation and expertise should be involved in the review, but is not required for quorum.

WORKSHEET: Drugs and Biologics

The purpose of this worksheet is to provide support for IRB staff pre-reviewing research involving drugs or biologics. It does not need to be completed or retained.

1. DRUG OR BIOLOGIC APPLICABILITY

Does the activity involve any the following? **(Check all that apply) If "No" to both, FDA regulations do not apply.**

☐ In the United States: The use of a drug [i] or a biological product (biologic) [ii] in one or more persons other than use of an approved drug in the course of medical practice [iii].

☐ ☐ Data regarding subjects or control subjects submitted to or held for inspection by FDA[iv].

2. IND REQUIREMENTS[v] (Check if "**Yes**". One must be "**Yes**." If all are "**No**" IND information is not complete.)

☐ The drug has a valid IND. (Complete Sections 3 and 4)

☐ The drug is exempt from the IND requirements (Complete Section 5)

☐The research is conducted outside of the United States and is conducted under ICH-GCP.

3. IND VALIDATION (Check if "**Yes**". At least one must be "**Yes**." If all are "**No**" IND cannot be validated.)

☐ Sponsor protocol imprinted with the IND number.

☐ Written communication from the sponsor documenting the IND number.

☐ Written communication from the FDA documenting the IND number. (Required if the investigator holds the IND.)

4. DRUG OR BIOLOGIC CONTROL (Check if "**Yes**". Must be "**Yes**. If "**No**" information regarding drug control is incomplete.)

☐ The plan for storage, control, and dispensing of the drug or biologic is adequate to ensure that only authorized investigators will use the drug and that they will use the drug only in subjects who have provided consent.[vi]

5. IND EXEMPTIONS (Check if "**Yes**". All criteria for one category must be "**Yes**" to be met. If none are met, the drug is not exempt from an IND.)

☐ **Category #1 - Lawfully Marketed Drugs (21 CFR 312.2(b)(1)) or Biologics – NON CANCER[vii]**

☐ The drug or biologic is lawfully marketed in the United States.

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- ☐ The research is not intended to be reported to the FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug.
- ☐ The research is not intended to support a significant change in the advertising for the product.
- ☐ The research does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.
- ☐ The research is conducted in compliance with the marketing limitations described in 21 CFR §312.7.

☐ **Category #2 - Serological Tests (21 CFR 312.2(b)(2))**

- ☐ A clinical investigation for an in vitro diagnostic[viii] biological product that involves one or more of the following: (1) Blood grouping serum; (2) Reagent red blood cells; or (3) Anti-human globulin.
- ☐ The diagnostic test is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure.
- ☐ The diagnostic test is shipped in compliance with 21 CFR §312.160.

☐ **Category #3 - Placebos (21 CFR 312.2(b)(5))**

- ☐ A clinical investigation involving use of a placebo when the investigation does not otherwise require submission of an IND.

☐ **Category #4 - Bioavailability/Bioequivalence Studies (21 CFR 320.31(b) and (d))**

- ☐ The active moiety in the drug product is identical to that in an FDA approved drug.
- ☐ The drug product is not radioactively labeled.
- ☐ The drug product is not cytotoxic.
- ☐ The dose (single or total daily) does not exceed the dose in the labeling of the approved version of the drug product.
- ☐ The sponsor meets the requirements for retention of test article samples in 21 CFR 320.31(d)(1).

☐ **Category #5 - Radioactive Drugs for Research Use (21 CFR 361.1)**

- ☐ The drug has been approved by Radioactive Drug Research Committee as a radioactive drug for certain research use under the criteria in 21 CFR 361.1(b)

☐ **Category #6 - Cold Isotopes for Research Use (FDA enforcement discretion[ix])**

- ☐ The research is intended to obtain basic information regarding the metabolism (including kinetics, distribution, and localization) of a drug labeled with a cold isotope or regarding human physiology, pathophysiology, or biochemistry.
- ☐ The research is not intended for immediate therapeutic, diagnostic, or preventive benefit to the study subject.
- ☐ The dose to be administered is known not to cause any clinically detectable pharmacologic effect in humans based on clinical data from published literature or other valid human studies.
- ☐ The quality of the cold isotope meets relevant quality standard.

6. IND OVERSIGHT FOR INVESTIGATORS WHO HOLD THE IND (Check if "**Yes**". One of the following must be "**Yes**" if the investigator holds the IND.)

☐ The FDA requirements of a sponsor (including GMP when applicable) have been assumed by a contract research organization.

☐ The investigator certifies in writing that they will be compliant with FDA sponsor requirements (including GMP when applicable).

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[i] The term ‘‘drug’’ means:

(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and
(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
(C) articles (other than food and dietary supplements) intended to affect the structure or any function of the body of man or other animals; and
(D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

[ii] The term “biological product” means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

[iii] “Other than the use of an approved drug in the course of medical practice” refers to a practitioner providing an approved drug to a patient because the practitioner believes the drug to be in the best interests of the patient. If the protocol specifies the use of the drug, it is not in the course of medical practice unless use of the drug is completely up to the discretion of the practitioner.

[iv] This is specific to submissions that are part of an application for a research or marketing permit. However, unless otherwise indicated, assume all submissions to FDA meet this requirement.

[v] If there are questions about which category is appropriate, have the investigator apply for an IND following 21 CFR §312.23.

[vi] The investigator or other designated individual must maintain records of the product's delivery to the clinical trial site, the inventory at the site, the use by each subject, and the return to the Sponsor or alternative disposition of unused products. These records include dates, quantities, batch or serial numbers, and expiration dates (if applicable), and the unique code numbers assigned to the investigational products and trial subjects. The investigator must maintain records that document adequately that the subjects are provided the doses specified by the protocol and reconcile all investigational products received from the Sponsor.

[vii] As applicable, see FDA Guidance for Industry IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer.

[viii] An in vitro diagnostic (IVD) products are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. IVD products are devices as defined in section 201(h) of the Act and may also be biological products subject to section 351 of the Public Health Service Act.

[ix] (FDA Guidance for Clinical Investigators, Sponsors, and IRBs Investigational New Drug Applications (INDs)) Determining Whether Human Research Studies Can Be Conducted Without an IND, September 2013: https://www.fda.gov/downloads/drugs/guidances/ucm229175.pdf.

WORKSHEET: Devices

The purpose of this worksheet is to provide support for IRB staff pre-reviewing research involving devices. This worksheet is to be used. It does not need to be completed or retained.

1. DEVICE[i] APPLICABILITY (Check if "Yes". If any are "Yes" use the rest of the worksheet. Otherwise FDA device regulations do not apply.)

Does the activity involve the following? **(Check all that apply)**

☐ In the United States: The use of a device[ii] in one or more persons that evaluates the safety or effectiveness of that device. (If the device is/includes a software function, complete Section 2)

☐ Data regarding subjects or control subjects submitted to or held for inspection by FDA[iii].

☐ Data regarding the use of a device on human specimens (identified or unidentified) submitted to or held for inspection by FDA[iv].

☐ Does this involve a humanitarian use device?

2. SOFTWARE AS A MEDICAL DEVICE[v] [vi](Check if **"Yes"**. If **"Yes"** then the software function is excluded from the definition of device in section 201(h) of the FD&C Act and the FDA device regulations do not apply to that software function.)

☐ Is the device, or does the device include, a software function that does any of the following? **(Check all that apply)**

☐ Administrative support of a health care facility, including the processing and maintenance of financial records, claims or billing information, appointment schedules, business analytics, information about patient populations, admissions, practice and inventory management, analysis of historical claims data to predict future utilization or cost-effectiveness, determination of health benefit eligibility, population health management, and laboratory workflow.

☐ Maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition.

☐ Serve as electronic patient records, including patient-provided information, to the extent that such records are intended to transfer, store, convert formats, or display the equivalent of a paper medical chart, so long as:

i. such records were created, stored, transferred, or reviewed by health care professionals, or by individuals working under supervision of such professionals;

ii. such records are part of health information technology that is certified under section 3001(c)(5) of the Public Health Service Act; and

iii. such function is not intended to interpret or analyze patient records, including medical image data, for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition.

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☐ Transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results, findings by a health care professional with respect to such data and results, general information about such findings, and general background information about such laboratory test or other device, unless such function is intended to interpret or analyze clinical laboratory test or other device data, results, and findings.

3. IDE/HDE REQUIREMENTS[vii] (Check if **"Yes"**. One must be **"Yes"** If all are **"No"** IDE/HDE information is not complete.)

☐ The device has an IDE or HDE. (Complete Sections 4 and 5. Complete Section 8, if applicable.)

☐ The device qualifies for an abbreviated IDE. (Complete Section 5 and 6)

☐ The device is exempt from the IDE requirements. (Complete Section 7)

4. IDE/HDE VALIDATION (Check if **"Yes"**. At least one must be **"Yes"** If all are **"No"**, IDE/HDE cannot be validated.)

☐ Sponsor protocol imprinted with the IDE/HDE number.

☐ Written communication from the sponsor documenting the IDE/HDE number.

☐ Written communication from the FDA documenting the IDE/HDE number. *(Required if the investigator holds the IDE/HDE.)*

5. DEVICE CONTROL (Check if **"Yes"**. Must be **"Yes"** If **"No"**, information regarding device control is incomplete.)

☐ The plan for storage, control, and dispensing of the device is adequate to ensure that only authorized investigators will use the device and that they will use the device only in subjects who have provided consent.[viii]

6. ABBREVIATED IDE (Check if **"Yes"**. All must be **"Yes"**)

☐ The device is not banned by the FDA.

☐ The investigator will label the device in accordance with FDA regulations. (21 CFR §812.5)

☐ The IRB will approve the research under 21 CFR §50 and §56 and determine that the study is not a significant risk[ix] device study using HRP-418 - CHECKLIST - Non-Significant Risk Device.

☐ The investigator will comply with FDA requirements for monitoring investigations. (21 CFR §812.46)

☐ The investigator will comply with FDA requirements for records and reports. (21 CFR §812.140, 21 CFR §812.150)

☐ The investigator will not market or promote the device. (21 CFR §812.7)

7. IDE EXEMPTIONS (Check if **"Yes"**. All criteria under one category must be **"Yes"** for a category to be met. If none of the categories is met, the device is not exempt from an IDE.)

Cat. #1

☐ The device was not regulated as a drug before enactment of the Medical Device Amendments. (Transitional device.)

☐ The device is FDA-approved/cleared or is a Class I or Class II 510(k) exempt device.[xxi]

☐ The device is being used or investigated in accordance with the indications in the FDA approved/cleared labeling.

Cat. #2

☐ The device is a diagnostic device.[xii]

☐ The sponsor will comply with applicable requirements in 21 CFR 809.10(c). (**or check if "NA" because device is not an in vitro diagnostic device**)

☐ The testing is noninvasive.[xiii]

☐ The testing does not require an invasive sampling procedure that presents significant risk.

☐ The testing does not by design or intention introduce energy into a subject

☐ The testing is not used as a diagnostic procedure without confirmation by another, medically established product or procedure

Cat. #3

☐ The device is undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, and the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.

Cat. #4

☐ The device is a custom device as defined in 21 CFR 812.3(b) and is NOT being used to determine safety or effectiveness for commercial distribution.

8. IDE OVERSIGHT FOR INVESTIGATORS WHO HOLD THE IDE (Check if **"Yes"**. One of the following must be **"Yes"** if the investigator holds the IDE)

☐ The FDA regulatory requirements of a sponsor (including GMP when applicable) have been assumed by a contract research organization.

☐ The investigator certifies in writing that they will be compliant with FDA sponsor requirements (including GMP when applicable).

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[i] This includes software functions the FDA considers to be medical devices. Examples of software functions the FDA considers to be a medical device (along with examples of devices that the FDA does NOT consider a medical device) can be found in FDA's Policy for Device Software Functions and Mobile Medical Applications. Note that for certain cases where the FDA is exercising enforcement discretion, such software functions are still subject to the Investigational Device Exemption (IDE) requirements in 21 CFR 812, unless exempt as per 21 CFR 812.2(c).

[ii] The term ''device'' means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
(3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Due to changes to Section 3060 of the 21st Century Cures act, the term "device" does not include **software function** that is intended for:

a. administrative support of a health care facility, including the processing and maintenance of financial records, claims or billing information, appointment schedules, business analytics, information about patient populations, admissions, practice and inventory management, analysis of historical claims data to predict future utilization or cost-effectiveness, determination of health benefit eligibility, population health management, and laboratory workflow;
b. maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;
c. serve as electronic patient records, including patient-provided information, to the extent that such records are intended to transfer, store, convert formats, or display the equivalent of a paper medical chart, so long as—
    i. such records were created, stored, transferred, or reviewed by health care professionals, or by individuals working under supervision of such professionals;

ii. such records are part of health information technology that is certified under section 3001(c)(5) of the Public Health Service Act; and
iii. such function is not intended to interpret or analyze patient records, including medical image data, for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition; or

d. transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results, findings by a health care professional with respect to such data and results, general information about such findings, and general background information about such laboratory test or other device, unless such function is intended to interpret or analyze clinical laboratory test or other device data, results, and findings.

To review the FDA's guidance regarding the changes to the existing medical definition due to the 21st Century Cures Act, please visit this website: https://www.fda.gov/media/109622/download.
To review software functions that are the focus of the FDA's regulatory oversight, please review the following guidance: https://www.fda.gov/media/80958/download.

[iii] This is specific to submissions that are part of an application for a research or marketing permit. However, unless otherwise indicated, assume all submissions to FDA meet this requirement.

[iv] This is specific to submissions that are part of an application for a research or marketing permit. However, unless otherwise indicated, assume all submissions to FDA meet this requirement.

[v] Due to changes to Section 3060 of the 21st Century Cures act, the term "device" does not include **software function** that is intended for the functions listed in this section.:
To review the FDA's guidance regarding the changes to the existing medical definition due to the 21st Century Cures Act, please visit this website: https://www.fda.gov/media/109622/download.
To review software functions that are the focus of the FDA's regulatory oversight, please review the following guidance: https://www.fda.gov/media/80958/download.

[vi] Guidance (including IRB risk considerations) for studies involving Digital Health Technologies (DHTs) can be found here: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/digital-health-technologies-remote-data-acquisition-clinical-investigations.

[vii] If there are questions about which category is appropriate, have the investigator apply for an IDE following 21 CFR §812.20.

[viii] The investigator or other designated individual must maintain records of the product's delivery to the clinical trial site, the inventory at the site, the use by each subject, and the return to the Sponsor or alternative disposition of unused products. These records include dates, quantities, batch or serial numbers, and expiration dates (if applicable), and the unique code numbers assigned to the investigational products and trial subjects.

[ix] The risk determination is based on the proposed use of a device in an investigation, and not on the device alone. (See http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm126418.pdf)

[x] In commercial distribution immediately before May 28, 1976, or FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the indications in the labeling FDA reviewed under subpart E of part 807 in determining substantial equivalence.

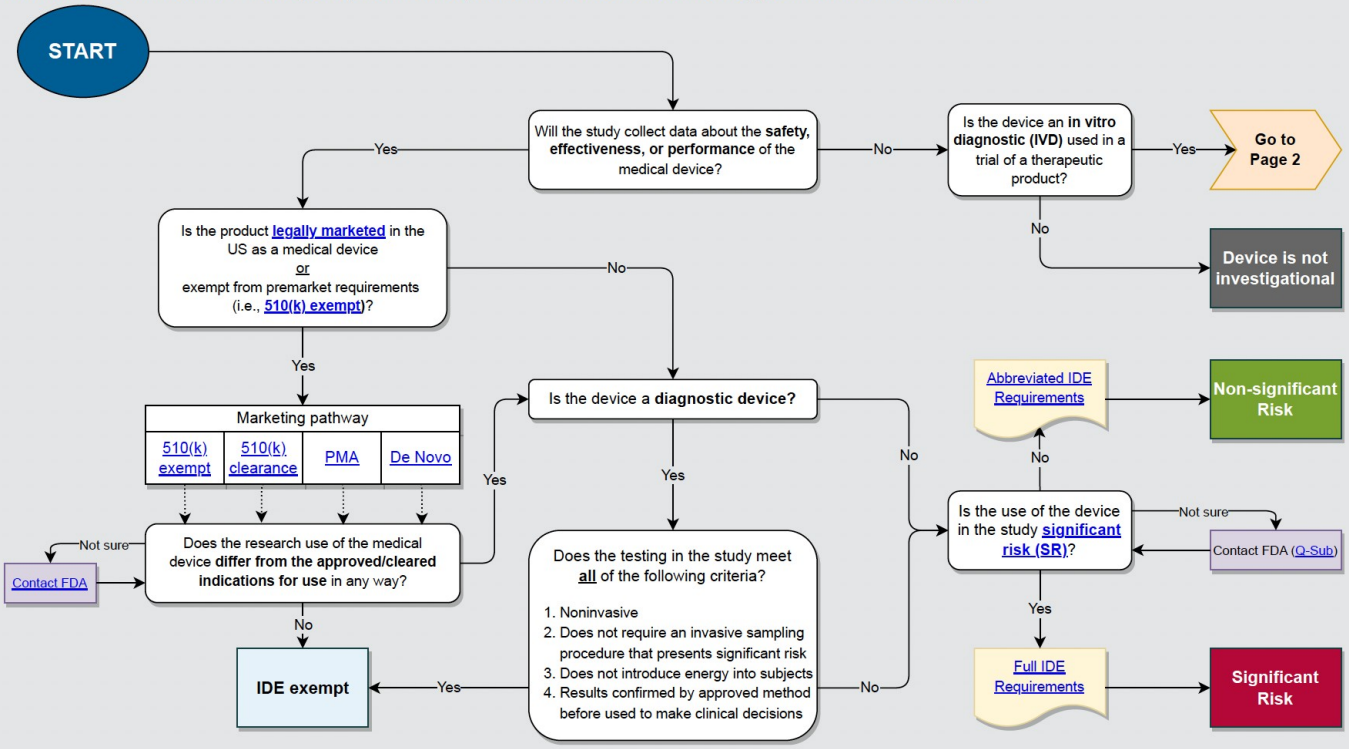
[xi] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm

[xii] In addition to in vitro diagnostic devices, studies with other types of diagnostic devices (e.g., SaMD), are eligible to qualify as exempt studies under 21 CFR 812.2(c)(3) *(per FDA correspondence dated March 12, 2024 and Question #6 https://blog.primr.org/webinar-follow-up-irb-oversight-and-fda-review-of-studies-that-include-ivds/?_ga=2.56835114.1853572302.1710178902-1380167154.1707514316)*

[xiii] Blood sampling that involves venipuncture is considered non-invasive for purposes of this exemption. The use of surplus samples of body fluids or tissues that are left over from samples taken for non-investigational purposes is also considered non-invasive. http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071230.pdf

DECISION TREE:
COMMON IDE SCENARIOS FOR MEDICAL DEVICE RESEARCH

*If a study involves administering a medical device[1] or has aims related to medical device products, use the decision tree to determine which of the **most common medical device research scenarios** applies to the research and whether or not an IDE may be required. Please note, the decision tree does not account for every possible scenario or IDE exemption.*



[1] "Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory, which is: (1) recognized by the FDA as an approved device; (2) intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or other conditions; or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

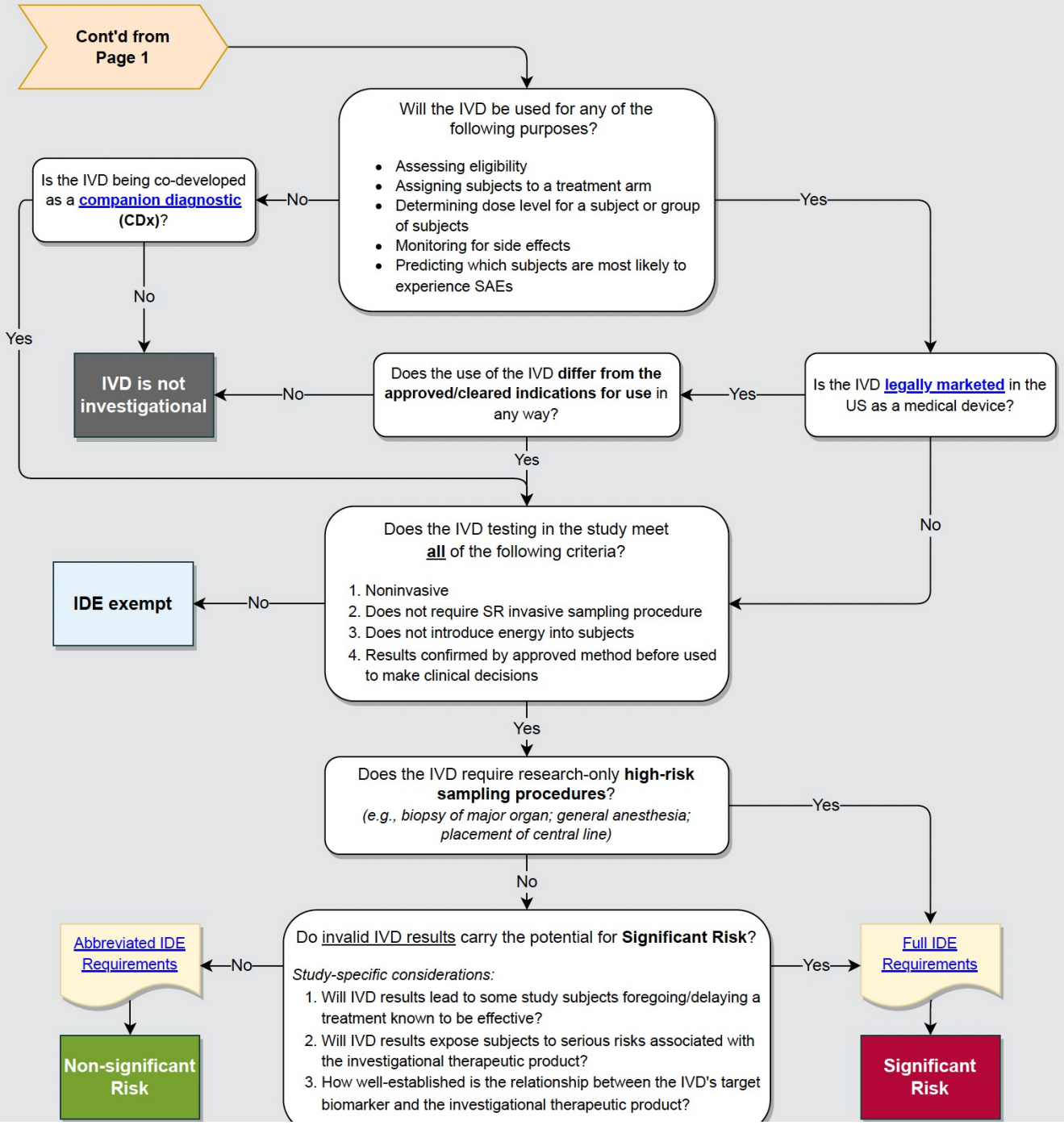
This decision tree is provided for educational purposes only and should not be considered an official regulatory document.

Rev. 11/08/23. Tool adapted from materials developed by The Ohio State University.

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DECISION TREE:
IVDs USED IN STUDIES OF THERAPEUTIC PRODUCTS

When an investigational in vitro diagnostic (IVD) device is used to guide management of subjects in clinical investigations of therapeutic products, the use may be subject to 21 CFR 812. Use the decision tree to determine if the investigational IVD requires an IDE.



WORKSHEET: Pre-Review

The purpose of this worksheet is to provide support for IRB staff conducting screening submission materials.

1. All Reviews

☐ Determine the Human Research regulations that apply to the Human Research and indicate in the "Regulatory Oversight" section of the Pre-Review Activity. See Appendix 1 for guidance on determining regulatory oversight.

☐ Determine whether the Human Research has received all required ancillary reviews (per HRP-309 - WORKSHEET - Ancillary Review Matrix) and approval by the appropriate committees and officials.

☐ Determine whether the Human Research involves medical experimentation requiring that individuals be provided the Subject's Bill of Rights as part of the informed consent process.

☐ If the Human Research could be subject to EU GDPR, or other international privacy laws send for privacy officer review.

☐ If there is a HIPAA authorization, review using HRP-330 - WORKSHEET - HIPAA Authorization.

☐ If a HIPAA waiver of authorization is required, grant using HRP-441 - PI WORKSHEET - HIPAA Waiver of Authorization.

☐**Note any missing materials necessary for review in the "Missing Materials" section of the Pre-Review Activity:**

☐ Completed Huron IRB application

☐ Investigator Protocol

☐ Consent document(s) or script(s)

☐ Data collection instruments

☐ Written material to be seen or heard by subjects

☐ Determine whether any new information has been provided (For example, a new risk.) If so, follow HRP-024 - SOP - New Information)

2. INITIAL REVIEW and MODIFICATION (when the modification affects one of the following)

☐ If the submission includes a request to serve as the single IRB of record (sIRB) for a Cooperative Study or Multi-Site Study, determine if an authorization agreement is needed using HRP-801 - SOP - Establishing Reliance Agreements.

☐ For initial reviews, determine whether the principal investigator is Restricted. If so, list the principal investigator's name and the reasons in the "Restrictions" section of the Pre-Review Activity.

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☐ If the research involves the use of a drug use the HRP-306 - WORKSHEET - Drugs.

☐ If the research involves the use of a device use the HRP-307 - WORKSHEET - Devices.

☐ Note any special determinations that need to be made by the convened IRB or Designated Reviewer in the "Special Determinations" section of the Pre-Review Activity.

☐ If the device meets the abbreviated IDE requirements, note "Non-significant risk device determination" in the "Special Determinations" section of the Pre-Review Activity.

☐ If the research is NIH-funded (regardless of whether the investigator has indicated the use of a Certificate of Confidentiality), note the presence of a Certificate of Confidentiality in the Protocol Tracking section of the Pre-Review Worksheet.

☐ If the research is NIH-funded, confirm the protocol includes information regarding the inclusion of women and minority populations, or it includes a justification for the exception to the NIH policy.[i]

Note any missing materials necessary for review in the "Missing Materials" section of the Pre-Review Activity:

☐ Qualifications of the key personnel

☐ Complete sponsor protocol (including DHHS protocol)

☐ DHHS-approved sample consent document

☐ Investigator brochure for investigational drug

☐ Package insert for marketed drugs

☐ Institutional Profile

☐ Executed Reliance Agreement(s)

☐ Product information for medical devices

☐ For Department of Education (ED) research ensure that a permission letter has been submitted attesting compliance with FERPA and PPRA

Note missing/inappropriately answered Investigator Protocol sections in the "Missing Materials" section of the Pre-Review Activity:

☐ IRB Review History

☐ Objectives

☐ Background

☐ Setting

☐ Resources Available

☐ Prior Approvals

☐ Study Design

☐ Recruitment Methods

☐ Inclusion/Exclusion Criteria

☐ Compensation for Injury

☐ Local Number of Subjects

☐ Total Number of Subjects

☐ Study Timelines

☐ Study Endpoints

☐ Procedures Involved

☐ Data and Specimen Banking

☐ Data Management

☐ Confidentiality

☐ Provisions to Monitor Data

☐ Withdrawal of Subjects

☐ Risks to Subjects

☐ Potential Benefits to Subjects

☐ Provisions to Protect Privacy

☐ Economic Burden to Subjects

☐ Consent Process

☐ Consent Documentation

☐ Vulnerable Populations

☐ Drugs or Devices

☐ Multi-Site Research

☐ Community Based Participatory Research

☐ Sharing of Results

"Notes" section of the Pre-Review Activity:

☐ Research is subject to regulations not overseen or conducted by the organization

☐ Positive financial declaration without a Conflict of Interest report

☐ Protocol information relates to an item in the list of institutional financial interests

☐ An IND is required and there is no IND

☐ An IND is required and there is insufficient documentation

☐ An IDE/HDE is required and there is no IDE/HDE

☐ An IDE/HDE is required and there is insufficient documentation

☐ There are inadequate provisions to control the drug(s)

☐ There are inadequate provision to control the device(s)

☐ There are inadequate provisions for an investigator held IND

☐ There are inadequate provisions for an investigator held IDE

☐ External site(s) getting federal funds from the organization does not have a federalwide assurance (FWA)

☐ The research involves adults unable to consent and statements by the investigator and legal counsel regarding which individuals are Legally Authorized Representatives (LAR) do not match or do not align with UC guidance.

☐ The research involves children and statements by the investigator and legal counsel regarding who can provide permission for the child if an individual is not a parent do not match or do not align with UC Guidance.

3. INITIAL REVIEW and MODIFICATIONS FOR pSITES RELYING ON THIS IRB (when the modification affects one of the following)

☐ pSite Consent Process

- ☐ Protocol procedures are consistent with pSite age of majority state law as indicated in Institutional Profile.
- ☐ Protocol procedures are consistent with any pSite policies on assent as indicated in Institutional Profile.

☐ pSite Consent Documents

- ☐ Submission includes tracked version of the lead study approved version of consent document(s) (to ensure previously reviewed information and any modifications requested are present).
- ☐ pSite consent documents include pSite name and PI contact information.
- ☐ pSite consent documents contain any pSite required language (e.g., injury language, genetic testing/future use of genetic material, pregnancy reporting, barcode, logo) as indicated in Institutional Profile.

☐ HIPAA Authorization

- ☐ HIPAA authorization format is consistent with pSite requirement (e.g., separate or combined with consent)
- ☐ If HIPAA authorization language is included in the consent form, includes any pSite required language as indicated in HRP-815 - FORM - Institutional Profile (e.g., state law on expiration period).

☐ Privacy Board

- ☐ Determine if the IRB is serving as the Privacy Board (documented in HRP-830-WORKSHEET-Communication and Responsibilities in the Institutional Profile), for the study for purposes of review and approval of waivers of HIPAA authorization.
- ☐ HIPAA is not applicable to this study.

☐Recruitment and subject-facing materials

☐ Materials are consistent with the materials approved for the lead site.

☐ Materials are consistent with local pSite name/logo information.

☐ Protocol and/or Site Supplement and/or Basic Site Information Form

☐ Drug and Device Storage plan is present (if different from protocol) and consistent with pSite policy where indicated in Institutional Profile.

☐ If the drug/device storage plan is different from the parent protocol, use HRP-306 - WORKSHEET - Drugs and Biologics.

☐ Study procedures consider relevant tribal, state, or non-US laws, regulations, or policies (i.e., special populations, genetic testing, future use of genetic material) where indicated in Institutional Profile.

☐ Completed Local Funding Sources Page (if relevant)

☐ pSite Without an IRB/HRPP

☐ Qualifications and training of pSite key personnel have been provided (may request proof of human subjects and GCP training, confirmation of any special degrees or certifications needed for study procedures).

☐ If a possible conflict exists for pSite personnel is indicated in the submission materials, the COI office has been notified.

4. CONTINUING REVIEW

☐ If Continuing review is not required, ask the investigator to discard the submission.

☐ Note missing Continuing review form in the “Missing Materials” section of the Pre-Review Activity.

5. MODIFICATION

☐ Note missing modification form in the “Missing Materials” section of the Pre-Review Activity.

6. STUDY CLOSURE

☐ Confirm that the research meets the criteria for closure and note in the Study Closure Section the Pre-Review Activity.

APPENDIX 1: GUIDANCE ON DETERMINING REGULATORY OVERSIGHT

1. DHHS (Department of Health and Human Services)
    a. Applies when research is conducted or funded by the U.S. Department of Health and Human Services (HHS). This includes agencies such as the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and Centers for Medicare & Medicaid Services (CMS). The complete list of HHS agencies can be found at: https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html. (Note: If the research is funded or conducted by the FDA, check HHS, but not check if the research is only FDA regulated.)
2. Common Rule

a. Applies when the research is not federally funded and the institution has “checked the box” on the FWA indicating that it will apply the Common Rule to all non-exempt human subjects research regardless of source of support; or the institution is otherwise required to apply the Common Rule to all research.

3. FDA (Food and Drug Administration)
    a. Applies to clinical investigations (drugs and devices) regulated by the FDA involving human subjects. Reference HRP-310 - WORKSHEET - Human Research Determination to determine if the research is Human Research under FDA regulations.
4. OCR (Office of Civil Rights) - HIPAA
    a. Applies when the research is subject to the Health Insurance Portability and Accountability Act (HIPAA) Privacy, Security, and Breach Notification Rules. This would apply when the organization is a covered entity or when the organization is a hybrid entity and the research is conducted by or part of the health care component(s). Reference HRP-329 - WORKSHEET - HIPAA Applicability for additional information.
5. ICH GCP (International Conference of Harmonization Good Clinical Practice)
    a. Applies when the funding agreement, contract, protocol, and/or institutional policy outlines a requirement that the research will adhere to ICH-GCP (Note: This is typically specific to ICH GCP E6).
6. DOD (Department of Defense)
    a. Applies to research that is supported or conducted by the Department of Defense (DoD), or that involves DoD personnel as subjects.
7. DOE (Department of Energy)
    a. Applies to research conducted or funded by DOE or performed by DOE employees or contractors.
8. NSF (National Science Foundation)
    a. Applies when the research is conducted or funded by NSF.
9. DOJ (Department of Justice)
    a. Applies to research conducted or funded by DOJ; and recipients of DOJ funding, which could include:
        i. National Institute of Justice
        ii. Research conducted in the Bureau of Prisons
10. ED (Department of Education)
    a. Applies to research conducted or supported by ED.
    b. Applies to research involving education records subject to The Family Educational Rights and Privacy Act (FERPA), which governs the disclosure of personally identifiable information from “education records” (any record containing personally identifiable information (PII) directly related to the student. PII is not limited to name but may include indirect identifiers as well) and access to education records by parents and eligible students. FERPA applies to all public

elementary and secondary schools as well as post-secondary institutions that receive federal funding through the U.S. Department of Education.

c. Applies to research subject to The Protection of Pupil Rights Amendment (PPRA) which is a federal law that affords certain rights to parents of minor students with regard to surveys, analysis, or evaluation of sensitive personal topics – certain requirements apply depending on if the study is ED funded or being conducted in a school that receives ED funding.

11. EPA (Environmental Protection Agency)
    a. Applies when the research is conducted or funded by the EPA.
12. VA (Department of Veterans Affairs)
    a. VA research is research that is conducted by researchers (serving on VA compensated, WOC, or IPA appointments) while on VA time or on VA property. The research may be funded by VA, by other sponsors, or be unfunded. VA research must have Research and Development (R&D) Committee approval before it is considered VA Research and before it can be initiated. All research activities approved by the R&D Committee are considered VA Research.
13. Other Federal Agency
    a. Applies when the research is conducted or funded by any federal agency that is not specifically listed.
14. EU GDPR (General Data Protection Regulation)
    a. Likely applies when research activities involve:
        i. Personal data being collected from one or more research participants physically located in the European Economic Area (EEA) at the time of data collection; or
        ii. The transfer of personal data collected under the GDPR from an EEA country to a non-EEA country.
15. Tribal Law
    a. Applies when a tribal nation law is applicable to the research.
16. None of the above
    a. Applies when the research is unfunded and the institution has “unchecked the box” on the FWA indicating that it will NOT apply the Common Rule to all non-exempt human subjects research regardless of source of support.

[i] The NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research can be found here: NOT-OD-25-131: Revision: NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research

WORKSHEET: Ancillary Review Matrix

Ancillary reviews are reviews by other compliance groups or individuals that inform the IRB's review of a new study or a modification to an existing study.

- Ancillary reviews may be assigned by either the researcher or the IRB.
- The IRB typically assigns ancillary reviews during the pre-review of a submission.
- Once an ancillary review is triggered, researchers should work directly with those entities to ensure compliance.
- The ancillary review in Huron IRB is intended to support compliance across multiple oversight groups and not replace review processes by other compliance groups.
- Ancillary reviews are not assigned by the IRB if a project does not meet the federal definition of Human Subject Research.

The impact of an ancillary review group's approval on the IRB's review process varies.

- Typically, final IRB approval is held until the ancillary group concludes their review.
- In some instances, the IRB will not initiate its review without documentation of approval by critical review entities.
- The IRB will not hold for the completion of ancillary reviews for studies that meet exempt criteria.
- Documentation of approval by an ancillary review group is provided to the researcher. The researcher is responsible for uploading that documentation in the "Supporting Documents" section of the Huron IRB application to which it relates.
- In rare instances, either the ancillary review group or an IRB member may request deviations from the typical review path. An IRB member may recommend holding a submission until an ancillary approval is granted from a key committee **OR** an ancillary review group may recommend IRB review move forward while a required approval is still pending.
- Ancillary reviews that are required for IRB review/approval are not the same requirements for study activation. Study activation requirements are different and managed by Clinical Research Administration.

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The table below highlights the ancillary review groups available and illustrates the typical impact an ancillary review has on IRB review. Please contact the IRB or relevant ancillary review contacts (listed below) with any questions about the ancillary review process or specific requirements.

Organization	Review Type	Ancillary Review Triggered by	Affected IRB Submission Types	Contact Info	How to Obtain Review	Impact on IRB Review (prior to, after, or parallel with)
Cannabis Research Review Committee **(CRRC)**	Feasibility and compliance	Research involving cannabis	Initial review and amendment	Ms. Grace Park parkgj@uci.edu	Ms. Grace Park: parkgj@uci.edu	CRRC review may occur in parallel with the IRB
Center for Clinical Research **(CCR)**	Feasibility and compliance	Clinical trials using UCI Health items and services, for the purpose of Qualified Clinical Trial (QCT) determination and subsequent Coverage Analysis (CA).	Initial review	UCIclinicaltrials@hs.uci.edu	UCIclinicaltrials@hs.uci.edu	CCR review may occur in parallel with the IRB
Chao Family Comprehensive Cancer Center **(CFCCC)** Protocol Review and Monitoring Committee **(PRMC)**	Feasibility and compliance	Research that is cancer-related and hypothesis driven. The research involves interaction with participants including obtaining consent.	Initial review; renewal if the IRB determines confirmation of review and/ or review comments may impact the IRB determination.	CancerCenter_Committees@hs.uci.edu	CancerCenter_Committees@hs.uci.edu	Investigator-initiated studies that are greater than minimal risk require Cancer Center approval prior to IRB submission

Organization	Review Type	Ancillary Review Triggered by	Affected IRB Submission Types	Contact Info	How to Obtain Review	Impact on IRB Review (prior to, after, or parallel with)
Clinical Engineering **(CE)**	Safety	When research is in an area that operatives under the medical center license and/ or equipment used for hospital patients and research subjects	Initial review and amendment	714-456-5366	714-456-5366	CE review may occur in parallel with the IRB
Conflict of Interest Oversight Committee **(COIOC)**	Disclosable financial conflict of interest	When researchers report a disclosable financial conflict of interest	Initial review and amendment	Ms. Nadia Wong nadiaw@uci.edu	Ms. Nadia Wong nadiaw@uci.edu	COIOC review may occur in parallel with the IRB
Dual Use Research Committee **(DURC)**	Feasibility and compliance	When research could be misapplied to pose a threat	Initial review and amendment	Ms. Grace Park parkgj@uci.edu	Ms. Grace Park: parkgj@uci.edu	DURC review may occur in parallel with the IRB
Environmental Health and Safety **(EHS)**	Feasibility and compliance	When research involves a controlled substance on campus	Initial review and amendment	occhlth@uci.edu	occhlth@uci.edu	EHS review may occur in parallel with the IRB
Epidemiology and Infection Prevention **(EIP)**	Safety	When research involves devices or biologic or infectious agents (e.g. live vaccine, probiotic)	Initial review and amendment	714-456-5221	714-456-5221	EIP review may occur in parallel with the IRB
Export Control Review Process **(EXP CTRL)**	Feasibility and compliance	When research involves sanctioned nations	Initial review and amendment	exportcontrol@uci.edu	exportcontrol@uci.edu	EXP CTRL review may be in parallel; IRB may grant conditional approval if more than a general license is needed

Organization	Review Type	Ancillary Review Triggered by	Affected IRB Submission Types	Contact Info	How to Obtain Review	Impact on IRB Review (prior to, after, or parallel with)
Human Stem Cell Research Oversight Committee (**hSCRO**)	Feasibility and compliance	When research involves human material (e.g., gametes, embryos, fetal tissue and pluripotent cells, etc.). See website for full requirements.	Initial review and amendment	hSCRO@uci.edu	hSCRO@uci.edu	hSCRO review may be in parallel; IRB may grant conditional approval pending hSCRO approval.
Institutional Biosafety Committee (**IBC**)	Safety	When research involves hazardous biomaterials and recombinant / synthetic nucleic acids, human gene transfer and blood draws that are done for research, on campus. See website for full requirements	Initial review and amendment	Ms. Alice Lee: 949-824-8024, ibc@uci.edu	Ms. Alice Lee: 949-824-8024, ibc@uci.edu	IBC review may be in parallel; IRB may grant conditional approval pending IBC approval.
Investigational Drug Service (**IDS**)	Safety, feasibility and compliance	When research involves an investigational drug. When a study is an Investigator Initiated Trial (IIT), IDS approval is required prior to final IRB approval	Initial review and amendment	Dr. Zahra Azadbadi, IDS Supervisor 714-456-7833, zazadbad@uci.edu	Dr. Zahra Azadbadi, IDS Supervisor 714-456-7833, zazadbad@uci.edu	IDS review may be in parallel for IITs; IRB may grant conditional approval pending IDS approval of an IIT.
Laser Safety Committee (**LSC**)	Safety	When research involves a laser on campus	Initial review and amendment	radsafety@uci.edu	radsafety@uci.edu	LSC review may occur in parallel with the IRB

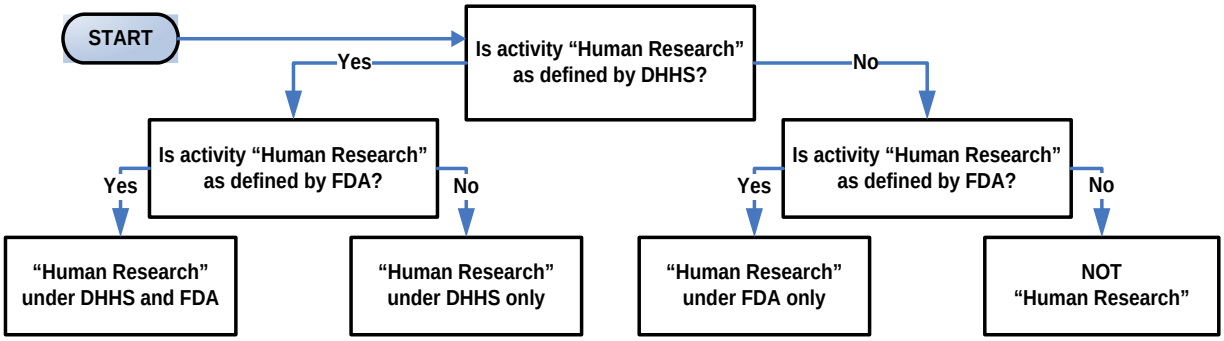
Organization	Review Type	Ancillary Review Triggered by	Affected IRB Submission Types	Contact Info	How to Obtain Review	Impact on IRB Review (prior to, after, or parallel with)
OR/Procedural Services Committee	Feasibility and compliance	When research involves the surgical units	Initial review and amendment	Ms. Laura Bruzzone: lbruzzon@uci.edu	Ms. Laura Bruzzone: lbruzzon@uci.edu	Review may occur in parallel with the IRB
Pathology Clearance **(PATH)**	Feasibility and compliance	When research involves specimens from clinical care	Initial review and amendment	Dr. Robert Edwards: (redwards@uci.edu) or Delia Tifrea: (dtifrea@hs.uci.edu).	Dr. Robert Edwards: (redwards@uci.edu) or Delia Tifrea: (dtifrea@hs.uci.edu).	PATH review may occur in parallel with the IRB
Radiation Safety Committee **(RSC)**	Safety, feasibility and compliance	When research involves radiation in research. See website for applications and additional information.	Initial review and amendment	Barbara Hamrick: 714-456-5607, bhamrick@uci.edu	Barbara Hamrick: 714-456-5607, bhamrick@uci.edu	RSC review may be in parallel; IRB may grant conditional approval pending RSC approval
Radioactive Drug Research Committee **(RDRC)**	Safety, feasibility and compliance	When research involves the use of radioactive materials in research **Important Note: RDRC is inactive at UCI**	Initial review and amendment	Contact HRP Staff	Contact HRP Staff	RDRC comments and approval (or evidence of an IND) is required prior to IRB review
Research Revenue Integrity (**RRI**)	Feasibility and compliance	When researchers use UCI Health services (RRI to ensure services are identified, coded, recharged or billed correctly)	Initial review and amendment	ResearchRevenueIntegrityCRBCRFA@hs.uci.edu	ResearchRevenueIntegrityCRBCRFA@hs.uci.edu	RRI review may be in parallel with the IRB

Organization	Review Type	Ancillary Review Triggered by	Affected IRB Submission Types	Contact Info	How to Obtain Review	Impact on IRB Review (prior to, after, or parallel with)
Restricted Party Screening (**RPS**) exportcontrol@uci.edu	Feasibility and compliance	Within the UC System, we use Visual Compliance to perform Restricted Party Screenings (RPS) to ensure we are not interacting with restricted, denied, or debarred parties in violation of U.S. law. Without proper authorization such as an export license, the government prohibits U.S. individuals and organizations from collaborating with or providing materials, services, and financial support to these restricted parties.	Initial review and amendment	Exportcontrol@uci.edu	Exportcontrol@uci.edu	RPS review may be in parallel with the IRB

Organization	Review Type	Ancillary Review Triggered by	Affected IRB Submission Types	Contact Info	How to Obtain Review	Impact on IRB Review (prior to, after, or parallel with)
Scientific Review (Statistical Methods) (**SR**)	Feasibility and compliance	When research has not received prior scientific method / peer review. Typically, the research is greater than minimal risk. The IRB Chair can require SR review for minimal risk research as well.	Initial review	Contact HRP Staff	Contact HRP Staff	SR comments and conditional approval is required for IITs prior to IRB review

WORKSHEET: Human Research Determination

The purpose of this worksheet is to provide support for individuals in determining whether an activity is Human Research or how it is regulate.



1. Research as Defined by DHHS Regulations[i] (Check if "Yes")

☐ Is the activity an investigation? (Investigation: a searching inquiry for facts; detailed or careful examination.)

☐ Is the investigation systematic? (Systematic: having or involving a system, method, or plan.)

☐ Is the systematic investigation designed to develop or contribute to knowledge? (Designed: observable behaviors used to develop or contribute to knowledge. Develop: to form the basis for a future contribution. Contribute: to result in. Knowledge: truths, facts, information.)

☐ Is the knowledge the systematic investigation is designed to develop or contribute generalizable? (Generalizable: universally or widely applicable.)

2. Human Subject Under DHHS Regulations (Check if "Yes")

☐ Is the investigator conducting the Research gathering information or biospecimens *about living* individuals?

☐ Determine whether the non-Human Research involves State of California issued death certificates and indices containing personal identifying information. The State of California requires IRB review.

3. Human Subject Under DHHS Regulations (Check if "Yes")

☐ Will the investigator use, study, or analyze information or biospecimens obtained through either of the following mechanisms? Specify which mechanism(s) apply, if yes:

- ☐ Physical procedures or manipulations of those individuals or their environment for Research purposes ("Intervention").
- ☐ Communication or interpersonal contact with the individuals. ("Interaction").

4. Human Subject Under DHHS Regulations (Check if "Yes")

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☐ Will the investigator gather data that is either? Specify which category(s) apply if yes:

- ☐ The data are about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place (i.e. "Private information").
- ☐ Individuals have provided the data for specific purposes in which the individuals can reasonably expect that it will NOT be made public, such as a medical record (i.e. "Private information").

☐ Can the individuals' identities be readily ascertained or associated with the information by the investigator (i.e. "Identifiable Private Information")?

5. Human Subject Under DHHS Regulations (Check if "**Yes**")

☐ Will the investigator gather biospecimens?

☐ Can the individuals' identities be readily ascertained or associated with the biospecimens by the investigator (i.e. "Identifiable Biospecimen")?

If all items are checked under 1, 2, and 3 or 1, 2, 4 and/or 5, the activity is Human Research under DHHS regulations.

6. Human Research Under DHHS Regulations (Check if "Yes")

☐ Has a department or agency head, covered by the Common Rule, retained final judgment (consistent with the ethical principles of the Belmont Report) that the activity is Human Research under DHHS regulations?

If checked, the activity is Human Research under DHHS regulations.

7. Human Research Under FDA Regulations (Check if "Yes")

☐ Does the activity involve any of the following? (Check all that apply)

- ☐ In the United States: The use of a drug [ii] in one or more persons other than use of an approved drug in the course of medical practice [iii].
- ☐ In the United States: The use of a device [iv] in one or more persons that evaluates the safety or effectiveness of that device.
- ☐ Data regarding subjects or control subjects submitted to or held for inspection by FDA [v].
- ☐ Data regarding the use of a device on human specimens (identified or unidentified) submitted to or held for inspection by FDA [vi].

If "Yes", the activity is Human Research under FDA regulations.

8. Human Research under Organizational Policy

If the activity is Human Research under DHHS regulations or under FDA regulations, it is Human Research under organizational policy.

9. Engagement (Complete if the activity is Human Research. (Check if "Yes")

☐ The organization is engaged in Human Research. Use HRP-311 - WORKSHEET - Engagement Determination.

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[i] The following activities conducted or supported by the Department of Defense (DOD) are NOT research involving human subjects: Activities carried out solely for purposes of diagnosis, treatment, or prevention of injury and disease in Service members and other mission essential personnel under force health protection programs of the Department of Defense, including health surveillance

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pursuant to section 1074f of Reference (g) and the use of medical products consistent with DoD Instruction 6200.02. Authorized health and medical activities as part of the reasonable practice of medicine or other health professions undertaken for the sole purpose of patient treatment. Activities performed for the sole purpose of medical quality assurance consistent with 10 USC 1102 and DoDD 6025.13. Activities performed solely for an OT&E project where the activities and project meet the definition of OT&E as defined in 10 USC 139(a)(2)(A). Activities performed solely for assessing compliance of individuals and organizations with requirements applicable to military, civilian, or contractor personnel or to organizational units, including such activities as occupational drug testing, occupational health and safety reviews, network monitoring, and monitoring for compliance with requirements for protection of classified information. Activities, including program evaluation, customer satisfaction surveys, user surveys, outcome reviews, and other methods, designed solely to assess the performance of DoD programs where the results of the evaluation are only for the use of Government officials responsible for the operation or oversight of the program being evaluated and are not intended for generalized use beyond such program. Survey, interview, or surveillance activities and related analyses performed solely for authorized foreign intelligence collection purposes, as authorized by DoDD 5240.01.

[ii] The term ‘‘drug’’ means:

(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and
(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
(C) articles (other than food and dietary supplements) intended to affect the structure or any function of the body of man or other animals; and
(D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

[iii] “Other than the use of an approved drug in the course of medical practice” refers to a practitioner providing an approved drug to a patient because the practitioner believes the drug to be in the best interests of the patient. If the protocol specifies the use of the drug, it is not in the course of medical practice unless use of the drug is completely up to the discretion of the practitioner.

[iv] The term ‘‘device’’ means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

[v] This is specific to submissions that are part of an application for a research or marketing permit. However, unless otherwise indicated, assume all submissions to FDA meet this requirement.

[vi] This is specific to submissions that are part of an application for a research or marketing permit. However, unless otherwise indicated, assume all submissions to FDA meet this requirement.

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WORKSHEET: Engagement

The purpose of this worksheet is to provide support for Designated/Staff Reviewers making engagement determinations when there is uncertainty regarding whether the organization is engaged in Human Research. For the purpose of this worksheet, "Engagement" means that the organization's human research protection program is responsible for the Human Research. For the purposes of being subject to DHHS or other federal agency that has adopted "The Common Rule" engagement applies only to non-exempt Human Research. This worksheet does not need to be completed or retained.

1. FDA Exception for "Engagement" (Check if "Yes")

☐ **ONLY** FDA regulations apply to this Human Research as indicated in the "Regulatory Oversight" section on HRP-401 - WORKSHEET - Pre-Review/Submit Pre-Review activity (DHHS regulations or any other Federal agency that has adopted the Common Rule are NOT checked in in the "Regulatory Oversight" section on HRP-401 - WORKSHEET - Pre-Review /Submit Pre-Review activity).

If ONLY FDA regulations apply, **STOP**. The FDA does not have a comparable process that aligns with OHRP's engagement guidance since FDA regulations govern sponsors (and parties they contract with), clinical investigators, and IRBs (and do not address institutions/organizations). If an organization is conducting certain activities of FDA (only) regulated Human Research, determining whether an institution/organization requires IRB oversight depends on many details such as:

- What type of activities are being conducted.
- What the protocol requires.
- Who is conducting the activities.
- Where the activities are being conducted.
- For what purpose the activities are being conducted.

FDA recommends referring to FDA Information Sheet "Use of Investigational Products When Subjects Enter a Second Institution, *Guidance for Institutional Review Boards and Clinical Investigators* (January 1998)" for guidance and to contact the sponsor and/or applicable FDA review division for assistance.[i]

The organization is engaged in the research if the first item in section 2 is true regardless of whether the organization's involvement is limited to one or more of the items in section 3.

The organization is engaged in the research if any item other than the first item in section 2 is true except when the organization's involvement is limited to one or more of the items in section 3.

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2. Conditions Under Which an Organization is Engaged

☐ The organization receives an award through a grant, contract, or cooperative agreement directly from a federal agency for non-exempt Human Research, even where all activities involving Human Subjects are carried out by employees or agents[ii] of another organization.

☐ The organization's employees or agents intervene for Research purposes with any Human Subject of the Research by performing invasive or noninvasive procedures.

☐ The organization's employees or agents intervene for Research purposes with any Human Subject of the Research by manipulating the environment.

☐ The organization's employees or agents interact for Research purposes with any Human Subject of the Research.

☐ The organization's employees or agents obtain the informed consent of Human Subjects for the Research.

☐ The organization's employees or agents obtain for Research purposes identifiable private information or identifiable biological specimens from any source for the Research. It is important to note that, in general, the organization whose employees or agents obtain identifiable private information or identifiable specimens for non-exempt Human Research are considered engaged in the Research, even if the organization's employees or agents do not directly interact or intervene with Human Subjects.

3. Conditions Under Which an Organization is Not Engaged Even Though a Condition in Section 2 is Met

☐ The organization's employees or agents perform commercial or other services for investigators provided that **ALL** of the following conditions also are met:

- ☐ The services performed do not merit professional recognition or publication privileges.
- ☐ The services performed are typically performed by those organizations for non-Research purposes.
- ☐ The organization's employees or agents do not administer any study intervention being tested or evaluated under the protocol.

☐ The organization is not selected as a Research site but its employees or agents provide clinical trial-related medical services that are dictated by the protocol that would typically be performed as part of routine clinical monitoring or follow-up of Human Subjects enrolled at a study site by clinical trial investigators provided that **ALL** of the following conditions also are met:

- ☐ The organization's employees or agents do not administer the study interventions being tested or evaluated under the protocol.
- ☐ The clinical trial-related medical services are typically provided by the organization for clinical purposes.
- ☐ The organization's employees or agents do not enroll Human Subjects or obtain the informed consent of any Human Subject for participation in the Research.
- ☐ When appropriate, investigators from an organization engaged in the Research retain responsibility for ALL of the following:
  - ☐ Overseeing protocol-related activities.

- ☐ Ensuring appropriate arrangements are made for reporting protocol-related data to investigators at an engaged organization, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol.

☐ The organization was not initially selected as a Research site but the organization's employees or agents administer the study interventions being tested or evaluated under the protocol limited to a one-time or short-term basis where an investigator from an organization engaged in the Research determines that it would be in the Human Subject's best interest to receive the study interventions being tested or evaluated under the protocol and **ALL** of the following are true:

- ☐ The organization's employees or agents do not enroll Human Subjects or obtain the informed consent of any Human Subject for participation in the Research.
- ☐ Investigators from the organization engaged in the Research retain responsibility for **ALL** of the following:
  - ☐ Overseeing protocol-related activities.
  - ☐ Ensuring the study interventions are administered in accordance with the IRB-approved protocol.
  - ☐ Ensuring appropriate arrangements are made for reporting protocol-related data to investigators at the engaged organization, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol.
- ☐ An IRB designated on the engaged organization's federalwide assurance (FWA) is informed that study interventions being tested or evaluated under the protocol have been administered at an organization not selected as a Research site.

☐ The organization's employees or agents do **ANY** of the following:

- ☐ Inform prospective Human Subjects about the availability of the Research.
- ☐ Provide prospective Human Subjects with information about the Research but do not obtain Human Subjects' consent for the Research or act as representatives of the investigators.
- ☐ Provide prospective Human Subjects with information about contacting investigators for information or enrollment.
- ☐ Seek or obtain the prospective Human Subjects' permission for investigators to contact them.

☐ The organization is permitting use of its facilities for intervention or interaction with Human Subjects by investigators from another organization.

☐ The organization's employees or agents release to investigators at another organization identifiable private information or identifiable biological specimens pertaining to the Human Subjects of the Research.

☐ The organization's employees or agents:

- ☐ Obtain coded private information or human biological specimens from another organization involved in the Research that retains a link to individually identifying information; and
- ☐ Are unable to readily ascertain the identity of the Human Subjects to whom the coded information or specimens pertain.

☐ The organization's employees or agents access or utilize individually identifiable private information only while visiting an organization that is engaged in the Research, provided their Research activities are overseen by the IRB of the organization that is engaged in the Research.

☐ The organization's employees or agents access or review identifiable private information for purposes of study auditing.

☐ The organization's employees or agents receive identifiable private information for purposes of satisfying U.S. Food and Drug Administration reporting requirements.

☐ The organization's employees or agents author a paper, journal article, or presentation describing a Human Research study.

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[i] Huron email correspondence with FDA GCP Program dated October 13, 2020.

[ii] An organization's employees or agents refers to individuals who: (1) act on behalf of the institution; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities. "Employees and agents" can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation. See HRP-101 - SOP - Human Research Protection Plan for this institution's definition of "agent" and contact legal counsel for additional information regarding whether an individual is an agent of the organization.

WORKSHEET: Exemption

The purpose of this worksheet is to provide support for Designated/Staff Reviewers granting exemption determinations. It does not need to be completed or retained**.**

1. GENERAL EXCLUSIONS FROM EXEMPTIONS (Check if **"Yes"**. If any are checked, the research is not exempt.)

☐ The research is FDA-regulated.[i]
☐ The research involves Prisoners, conducted or funded by DHHS, Dept. of Defense (DOD)[ii], or Veterans Administration (VA), and is NOT aimed at involving a broader subject population that only incidentally includes prisoners.
☐ The research involves interactions with Prisoners**.**
☐ The research is classified and conducted or funded by the Department of Energy (DOE) (may be reviewed by convened IRB only).[iii]
☐ UCI does not use Exempt Category 4iii[iv].
☐ UCI does not use Exempt Categories 7 or 8[v]. Researchers interested in Category 8 should consider Expedited Category 5.

2. Criteria for approval of exempt research (Check if "Yes")

☐ The research involves no more than Minimal Risk to subjects. **(Must be checked.)**
☐ Selection of subjects is equitable. (That is, the research is appropriate for the population being studied.) **(Must be checked).**
☐ There is recording of identifiable information**.** (If checked, the following must also be checked.)
  ☐ There are adequate provisions to maintain the confidentiality of the data**.**
☐ There are interactions with subjects: **(If checked, all of the following must also be checked.)**
  ☐ There will be a consent process**.**
  ☐ The consent process will disclose that the activities involve research.
  ☐ The consent process will disclose the procedures to be performed.
  ☐ The consent process will disclose that participation is voluntary.
  ☐ The consent process will disclose the name and contact information for the investigator.
  ☐ There are adequate provisions to maintain the privacy interests of subjects.
  ☐ Permission for use of data can be withdrawn for exempt research activities involving the collection and use of identifiable data.
  ☐ Contact information for the VA researcher.

NOTE: If this study is DOJ-regulated[vi] skip to section 5 below for the Pre-2018 Requirements.

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3. 2018 Requirements: The research falls into one or more of the following categories (One or more categories must be checked). **Categories in blue bold qualify for exempt self-determination, see Section 4 below.**

☐ **1. Research conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.**

☐ **2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:**

- ☐ **(i) The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects cannot be readily ascertained, directly or indirectly through identifiers linked to the subjects; OR**
- ☐ **(ii) Any disclosure of Human Subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; OR**
- ☐ (iii) The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects can be readily ascertained, directly or indirectly through identifiers linked to the subjects, AND an IRB conducts limited IRB review. **(See HRP-319 – WORKSHEET – Limited IRB Review and Broad Consent)**
- ☐ If the research involves children and is conducted, funded, or subject to regulation by DHHS, Dept. of Defense (DOD), Dept. of Education (ED), or Veterans Administration (VA), or the Environmental Protection Agency (EPA), the procedures are limited to (1) the observation of public behavior when the investigator(s) do not participate in the activities being observed or (2) the use of educational tests and at least one of the following criteria is met:
  - ☐ (i) The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects cannot readily be ascertained, directly or indirectly through identifiers linked to the subjects; OR
  - ☐ (ii) Any disclosure of Human Subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational achievement, or reputation.

☐ **3(i). Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:**

- ☐ **(A) The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects cannot readily be ascertained, directly or indirectly, through identifiers linked to the subjects; OR**
- ☐ **(B) Any disclosure of the Human Subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; OR**

☐ (C) The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects can readily be ascertained, directly or indirectly, through identifiers linked to the subjects; AND an IRB conducts limited IRB review[vii]. (See HRP-319 - WORKSHEET - Limited IRB Review and Broad Consent)

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else. [viii]

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

☐ **4. Secondary research for which consent is not required: secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:**

☐ **(i) The identifiable private information or identifiable biospecimens are publicly available; OR**

☐ (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; OR

☐ (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

☐ 5. Research and demonstration projects which are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine: public benefit or service programs, including procedures for obtaining benefits or services under those programs. [ix] [x]

☐ (i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision This research or demonstration project must be published on this list prior to commencing the research involving human subjects.

☐ 6.[xi]Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without without additives arendand consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agriculture chemical or environmental contaminant at or

below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the Dept. of Agriculture.

4. Criteria for exempt self-determination (Check if "Applicable"). If applicable, protocol must complete exempt self-determination process.

☐ The research involves one of the following categories: **(Must be checked if applicable.)**
☐ Category 1: *Must not be likely to adversely impact student's opportunity to learn or assessment of educators.*
☐ Category 2i, 2ii: *Category 2iii requires IRB review where disclosure outside the research would place subjects at risk.*
☐ Category 3i: Category 3(i)(A), 3(i)(B): *For all Category 3 studies, 3(ii) intervention must be brief (minutes to hours in a single day); 3(iii) subject must authorize use of deception via consent. Category 3(i)(C) requires IRB review where disclosure outside the research would place subjects at risk.*
☐ Category 4i: *Must be secondary use of identifiable private information or identifiable biospecimens that are publicly available and external to UCI.*

If the protocol qualifies for exempt self-determination, it must not involve the following. If any of the following are checked, exempt self-determination is not allowed. IRB review is required.

☐ The use or disclosure of UC/UCI records (e.g., medical, student, employment, when the California Information Practices Act (CIPA) is applicable etc.)
☐ Creation, **access to, use, or disclosure** of medical records**; or observations of clinical care** [i.e., Protected Health Information (PHI)]
☐ A targeted recruitment of children (this includes UC students / employees under the age of 18)
☐ A targeted recruitment of adults (age 18 or older) with Impaired Decision-Making Capacity (who may not be legally/mentally/cognitively competent to consent)
☐ A targeted recruitment of prisoners (may include parolees)
☐ A targeted recruitment of American Indian/Alaska Native tribes
☐ A targeted recruitment of undocumented people
☐ International Research
☐ A request for UCI to serve as IRB of Record for non-UCI individuals engaged in human subjects research. Note: To initiate a request for UCI to serve in this capacity, the LR must have a dual affiliation with the non-UCI entity and IRB review is required to formalize the reliance process.
☐ A study team member has a Disclosable Financial Interest

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5. Pre-2018 Requirements: The DOJ regulated research falls into one or more of the following categories. (One or more categories must be checked.)

☐ 1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. (Both the procedures involve normal education practices and the objectives of the research involve normal educational practices.)

☐ 2. Research involving the use of educational tests[xii] (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that Human Subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the Human Subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. In addition:

☐ If the research involves children and is conducted, funded, or subjects to regulation by DHHS, Dept. of Defense (DOD), Dept. of Education (ED), Veterans Administration (VA), or the Environmental Protection Agency (EPA), the procedures are limited to (1) the observation of public behavior when the investigator(s) do not participate in the activities being observed and (2) the use of educational tests. **("NA" if the research does not involve children or is not conducted, funded, or otherwise subject to by these agencies.)**

☐ 3. Research involving the use of educational tests survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the Human Subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

☐ 4. [xiii]Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. (**For research conducted, funded, or otherwise subject to regulation by any federal agency "existing" means "existing at the time the research is proposed." Otherwise, it means "existing at the time the research is proposed or will exist in the future for non-research purposes."**)

☐ 5. Research and demonstration projects which are conducted by or subject to the approval of Dept. or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs. In addition: (Check if "**Yes**". All must be checked)

☐ The program under study delivers a public benefit[xiv] or service.[xv]

☐ The research or demonstration project is conducted pursuant to specific federal statutory authority.

☐ There is no statutory requirement that the project be reviewed by an IRB.

☐ The project does not involve significant physical invasions or intrusions upon the privacy of subjects.

☐ The funding agency concurs with the exemption.

☐ 6. [xvi]Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the Dept. of Agriculture.

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[i] The organization's policy is to not grant exemptions to FDA-regulated research in category (6).

[ii] Human participant research involving prisoners that would otherwise meet exemption criteria may be conducted but must first be approved by an IRB and meet the requirements of Subpart C and DoDI 3216.02.

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[iii] DOE O 443.1C, Chg.1.
[iv] In 2020, the UC Office of the President (UCOP) Counsel has stated that Exempt 4iii does not apply to activities outside of the Covered Entity's use of the Protected Health Information (PHI).
[v] UCI's interpretation of broad consent is that it is a system-wide program that allows institutions to track via a central system biospecimens and data for which individuals provide their broad consent, or decline, as well as the terms of the broad consent to determine which future research uses remain within scope. This interpretation aligns with the Health and Human Services (HHS) Secretary's Advisory Committee on Human Research Protections (SACHRP) interpretation.
[vi] Submit protocol for expedited review.
[vii] For VA Research, the limited IRB review must be completed prior to approval by the R&D committee.
[viii] Per OHRP correspondence dated September 26, 2004, in general, eye-tracking (all types) can be considered for data collection in this exemption.
[ix] Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.
[x] When following Veterans Administration (VA) regulations and guidance, the determination of exempt status for research and demonstration projects meeting the criteria for exempt category 5 must be made by the Under Secretary for Health on behalf of the Secretary of VA, after consultation with Office of Research and Development (ORD), Office of Research Oversight (ORO), Office of General Counsel (OGC), and other experts, as appropriate.
[xi] Note that for FDA-regulated research exemption (6) is an exemption from IRB review in 21 CFR §56, but unlike DHHS regulations is not an exemption from FDA requirements for consent in 21 CFR §50. If an organization's policy is to grant exemptions to FDA-regulated research in category (6), then additional criteria for such exemptions would be that consent will be obtained in accordance with 21 CFR §50.20 and §50.25, and the consent will be either be documented in writing in accordance with 21 CFR§50.27 or waived in accordance with 21 CFR §56.109(c)(1).
[xii] Includes cognitive, diagnostic, aptitude, and achievement tests.
[xiii] "If these sources are publicly available" was removed because public data cannot be private, and if there is no collection of private identifiable data, there can be no Human Subjects.
[xiv] For example, financial or medical benefits as provided under the Social Security Act.
[xv] For example, social, supportive, or nutrition services as provided under the Older Americans Act.
[xvi] Note that for FDA-regulated research exemption (6) is an exemption from IRB review in 21 CFR §56, but unlike DHHS regulations is not an exemption from FDA requirements for consent in 21 CFR §50. If an organization's policy is to grant exemptions to FDA-regulated research in category (6), then additional criteria for such exemptions would be that consent will be obtained in accordance with 21 CFR §50.20 and §50.25, and the consent will be either be documented in writing in accordance with 21 CFR§50.27 or waived in accordance with 21 CFR §56.109(c)(1).

WORKSHEET: Expedited Review

The purpose of this worksheet is to provide support for Designated Reviewers conducting reviews using the expedited procedure. It does not need to be completed or retained.

1. Humanitarian Use Device (HUD) (Check if "Yes" or "NA". Must be checked)

☐ Continuing review of non-research HUD using the expedited procedure[i] ("**NA**" if not HUD) ☐ **NA**

2. Additional Criteria for Research Involving Prisoners[ii] (Check if "Yes" or "NA". Must be checked)

☐ The research involves interaction with prisoners, is minimal risk, the prisoner representative concurs with this determination, and the prisoner representative must review the research[iii]. (**"NA"** if no prisoners as subjects, no prisoner interaction, or for modifications that do not involve interaction with prisoners.) ☐ **NA**

3. Additional Criteria for Research Involving Collection of Blood in a Non-Clinical / Non-Therapeutic Setting (Check if "Yes" or "NA". Must be checked)

☐ It is the responsibility of the Principal Investigator to ensure that all personnel listed on an IRB application have the appropriate training and experience to perform their assigned duties. Collection of blood for research purposes must be performed by California licensed physicians, nurses or clinical lab scientists, or other licensed professionals where phlebotomy is in their scope of practice, or by certified phlebotomists able to provide documentation of competency. For researchers who cannot meet these standards, the UCI Center for Clinical Research nursing staff provide blood collection services for a fee. ☐ **NA**

4. Additional Criteria for Research Involving UCIMC Anatomical Pathology / Surgical Pathology (Check if "Yes" or "NA". Must be checked)

☐ Specimens removed from clinic or the operating room must be sent to pathology for review and documentation by a pathologist, with the exception of specimens considered exempt. For exempt categories, the Principal Investigator should review UCIMC Anatomical Pathology/Surgical Pathology - Procedure Number: S-23. Of non-exempt specimens, only remnants are to be used for research. A remnant is defined as tissue not needed for diagnosis. Only a faculty pathologist may make the determination of whether or not a specimen is to be released for research. ☐ **NA**

5. Additional Expedited Category # 13 for Skin Punch Biopsy for Children and Adults Where Research is NOT Federally Funded, NOT Subject to FDA Regulations (Check if "Yes" or "NA". Must be checked)

☐ Category "13" allows for a skin punch biopsy of no greater than 2 mm for both children

Initial or continuing review must meet criteria set 7. Modifications can meet either criteria set 6 or 7.

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6. Minor Modifications to Greater than Minimal Risk Research (Check if "**Yes**" or "**NA**". All must be checked)

☐ The modifications do not affect the design of the research.

☐ The modifications add no more than Minimal Risk to subjects.

☐ All added procedures fall into categories (1)-(7) below. ("**NA**" if no added procedures) ☐ **NA**

7. Initial Review, Continuing Review, or Modifications (Check if "**Yes**" or "**NA**". All must be checked)

☐ The research activities (or remaining research activities) present no more than Minimal Risk to Human Subjects. (**"NA"** if the research falls into category (8)(b))

☐ Identification of the subjects or their responses (or the remaining procedures involving identification of subjects or their responses) will **NOT** reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than Minimal Risk. (**"NA"** if the research falls into category (8)(b))

☐ The research is **NOT** classified[iv].

☐ The research (or remaining research) falls into one or more of the following categories: **(Check all that apply)**

- ☐ (1)(a) Clinical studies of drugs when an IND is not required.
- ☐ (1)(b) Clinical studies of medical devices when an IDE is not required, or the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- ☐ (2)(a) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from healthy, non-pregnant adults who weigh ≥110 pounds where the amount drawn is ≤550 ml[v]/8 week period and collection occurs at most 2 times/week.
- ☐ (2)(b) Collection of blood samples[vi] by finger stick, heel stick, ear stick, or venipuncture from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected (50 ml or 3 ml/kg,[vii] whichever is less, per 8 week period), and the frequency with which it will be collected (at most 2 times/week).
- ☐ (3) Prospective collection of biological specimens for research purposes by noninvasive[viii] means.[ix]
- ☐ (4) Collection of data through noninvasive procedures[x] (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing.[xi]
- ☐ (5) Research involving materials (data, documents, records, or specimens) that: have previously been collected (retrospective) for non research purposes, have previously been collected (retrospective) for research purposes provided the materials were not collected for the currently proposed research, will be collected (prospective) solely for non research purposes.
- ☐ (6) Collection of data from voice, video, digital, or image recordings made for research purposes.
- ☐ (7)(a) Research on individual or group characteristics or behavior[xii].
- ☐ (7)(b) Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

  For research approved on or after 1/21/2019, this does not include scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship),

including the collection and use of information, that focus directly on the specific individuals about whom the information is collected; this is deemed not to be research per 45 CFR 46. 102(l)(1).

☐ (8)(a) Continuing review of research previously approved by the convened IRB where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects[xiii]. (For a multi-center protocol, an expedited review procedure may be used by the IRB at a particular site whenever these conditions are satisfied for that site.)

☐ (8)(b) Continuing review of research previously approved by the convened IRB where no subjects have ever been enrolled at a particular site and neither the investigator nor the IRB at a particular site has identified any additional risks from any site or other relevant source[xiv].

☐ (8)(c) Continuing review of research previously approved by the convened IRB where the remaining research activities are limited to data analysis. (For a multi-center protocol, an expedited review procedure may be used by the IRB at a particular site whenever these conditions are satisfied for that site.)

☐ (9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories (2) through (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than Minimal Risk and no additional risks have been identified.[xv] [xvi]

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[i] Humanitarian Device Exemption (HDE) Program Guidance for Industry and Food and Drug Administration Staff Document issued on September 6, 2019 states, "For continuing review [of the HUD], an IRB may use an expedited review procedure in which a chairperson or one or more experienced reviewers carries out the review, similar to the expedited review procedure described at 21 CFR 56.110(b)."

[ii] OHRP Prisoner Research FAQs https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/prisoner-research/index.html.

[iii] For research that does not involve interaction with prisoners (e.g. existing data, record review) review by a prisoner representative is not required (AAHRPP Tip Sheet 18: Review of Research involving Prisoners and the Role of the Prisoner Representative).

[iv] Classified information is sensitive information to which access is restricted by law or regulation to particular groups of persons. A formal security clearance is required to handle classified documents or access classified data. In the United States classified research involving human subjects is where the protocol, information required by the IRB for review and oversight, or information provided by the research subjects includes classified information, as defined in Executive Order 13526, "Classified National Security Information," December 29, 2009.

[v] Volume pertains to amount collected for research purposes; does not include volume drawn for clinical care purposes. *Per correspondence with OHRP dated October 2019.*

[vi] Collection of blood samples from other adults and children may include a draw from an existing peripheral indwelling catheter; however, all draws from central lines are considered to be greater than minimal risk. *Per correspondence with OHRP dated April 2023.*

[vii] Volume pertains to amount collected for research purposes; does not include volume drawn for clinical care purposes. *Per correspondence with OHRP dated October 2019.*

[viii] Non-invasive procedures include, but are not limited to: (1) vaginal swabs that do not go beyond the cervical os; (2) rectal swabs that do not go beyond the rectum; and (3) nasal swabs that do not go beyond the nares (refer to 21 CFR 812.3).

[ix] Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum-base or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

[x] Non-invasive procedures include, but are not limited to: (1) vaginal swabs that do not go beyond the cervical os; (2) rectal swabs that do not go beyond the rectum; and (3) nasal swabs that do not go beyond the nares (refer to 21 CFR 812.3).

[xi] Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

[xii] Examples: Research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior.

[xiii] Long term follow up includes research interactions that involve no more than minimal risk to subjects (e.g., quality of life surveys); and collection of follow-up data from procedures or interventions that would have been done as part of routine clinical practice to monitor a subject for disease progression or recurrence, regardless of whether the procedures or interventions are described in the research protocol. Long term follow-up excludes research interventions that would not have been performed for clinical purposes, even if the research interventions involve no more than minimal risk.

[xiv] OHRP recommends that IRBs use their discretion "to determine otherwise" under §46.109(f)(1) to determine that continuing review of research should be conducted at intervals appropriate to their degree of risk, but not less than once per year for research that is subject to the 2018 Requirements for expedited categories (8)(b) and (9). OHRP 2018 Requirements FAQs https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/2018-requirements-faqs/index.html.

[xv] Ibid.

[xvi] A nonsignificant risk (NSR) study that is determined to be minimal risk by a convened board would be eligible for expedited review for continuing review under Category 9 (per OC GCP correspondence from FDA dated January 2015).

WORKSHEET: Criteria for Approval

The purpose of this worksheet is to provide support for IRB members reviewing research. It does not need to be completed or retained. (LAR = "subject's Legally Authorized Representative").

1. General Considerations (Check if "Yes" or "NA". All must be checked)

☐ The convened IRB (or Designated Reviewer) has, or has obtained through consultation, adequate expertise.

☐ For initial review the principal investigator is not Restricted. **("NA" if not initial review) NA:** ☐

☐ Materials are complete.

2. Criteria for Approval (Check if "Yes" or "NA". All must be checked) (Applies to initial, continuing, and modifications)

☐ Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk.

☐ Risks to subjects are minimized by using procedures already being performed on the subjects for diagnostic or treatment purposes. **("NA" if none) NA:** ☐

☐ Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.[i]

☐ Selection of subjects is equitable.[ii] (Consider the purpose and setting of the research, involvement of vulnerable subjects, selection criteria, and recruitment, enrollment, and payment procedures.)

☐ The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. **("NA" if ≤ Minimal Risk) NA:** ☐ [iii]

☐ There are adequate provisions to protect the privacy of subjects.[iv]

☐ There are adequate provisions to maintain the confidentiality of data. [v]

☐ Additional safeguards have been included in the study to protect the rights and welfare of subjects vulnerable to coercion or undue influence. **("NA" if no vulnerable subjects) NA:** ☐

☐ The informed consent process meets one of these worksheets or worksheets:

- ☐ **HRP-314a - WORKSHEET - Criteria for Consent**
- ☐ **HRP-410 - PI WORKSHEET - Waiver or Alteration of Consent Process**
- ☐ **Permanently closed to enrollment**

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☐ The informed consent documentation meets one of these worksheets or worksheets:

- ☐ **HRP-314a - WORKSHEET - Criteria for Consent**
- ☐ **HRP-317 - WORKSHEET - Short Form**
- ☐ **HRP-411 - PI WORKSHEET - Waiver of Written Documentation of Consent**
- ☐ **HRP-410 - PI WORKSHEET - Waiver or Alteration of Consent Process**
- ☐ **Permanently closed to enrollment**

☐ Additional applicable criteria[vi] are met **("NA" if none) NA:** ☐

3. Additional Considerations (Check all that apply.)

☐ Does the research involve no more than Minimal Risk to subjects?

☐ Does the research require Continuing review? (**Note that for UCI, FDA or DOJ overseen research Continuing review is required. For non-FDA or non-DOJ overseen research, a 3-year approval may be granted**)

- ☐ The research is eligible for expedited review. **(See HRP-313 – WORKSHEET - Expedited Review)**

☐ Should review take place more often than annually?[vii] If so, specify period.

☐ Is verification needed from sources other than the investigator that no material changes have occurred since prior review?[viii] **("NA" if initial) NA:** ☐

☐ Does information need to be provided to subjects because it may affect their willingness to continue participation? **("NA" if initial) NA:** ☐

4. Primary Reviewer Criteria for Initial Review (Check if "Yes" or "NA". All must be checked; May be determined by a primary reviewer)

☐ The research has the resources necessary to protect subjects. (Time to conduct and complete the research; adequate facilities, subject pool, and medical/psychosocial resources; qualified investigators and research staff; appropriate qualifications for international research.)

☐ The plan for communication among sites is adequate to protect subjects. **("NA" if not a Multi-Site Study where PI is the lead or not initial) NA:** ☐

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[i] In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

[ii] In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

[iii] When the IRB determines that data and safety monitoring is appropriate, the IRB will evaluate the adequacy of those plans by considering such issues as reporting mechanisms, the frequency of the monitoring, the entity that will conduct the monitoring, the specific data to be monitored, procedures for analysis and interpretation of the data, actions to be taken upon specific events or end points, and procedures for communication from the data monitor to the IRB and sites. (AAHRPP Tip Sheet #6, section 5)

[iv] The IRB will consider it appropriate to include adequate provisions to protect the privacy of subjects when there is a reasonable expectation that prospective research subjects will want to control how, and with whom, they interact and communicate, particularly on issues that may be “sensitive” or “private.” The IRB will determine whether there are adequate provisions to protect the privacy of subjects by considering subjects’ potential comfort with the procedures being performed, comfort with the research setting, and comfort with the information being sought.

[v] The Secretary of HHS will, after consultation with the Office of Management and Budget’s privacy office and other Federal departments and agencies that have adopted this policy, issue guidance to assist IRBs in assessing what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of data. In the interim, the IRB will consider it appropriate to make adequate provisions to maintain confidentiality of data any time confidentiality is promised by the investigator, or when there are legal/ethical requirements to maintain data confidentiality. The IRB will determine whether there are adequate provisions to maintain the confidentiality of that data based on a review of the procedures that are in place to meet those promises or legal/ethical requirements (e.g. What information is included in the data, how it is stored, how long it will be stored, who will have access to it, and who will be responsible for receiving/transmitting it.) (AAHRPP Tip Sheet #4 section 2b-c)

[vi] HRP-315 - WORKSHEET - Advertisements; HRP-316 - WORKSHEET - Payments; HRP-318 - WORKSHEET - Additional Federal Agency Criteria; HRP-412 - PI WORKSHEET - Pregnant Women; HRP-413 - PI WORKSHEET - Non-Viable Neonates; HRP-414 - PI WORKSHEET - Neonates of Uncertain Viability; HRP-415 - PI WORKSHEET - Prisoners; HRP-416 - PI WORKSHEET - Children; HRP-417 - PI WORKSHEET - Adults with Impaired Decision-Making Capacity; HRP-418 - WORKSHEET - Non-Significant Risk Device.

[vii] Consider nature and level of risks; degree of uncertainty regarding the risks; subject vulnerability; investigator experience; IRB’s experience with investigator or sponsor; projected rate of enrollment; and whether study involves novel procedures.

[viii] Implement when the veracity of the information provided is questioned.

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WORKSHEET: Criteria for Consent

The purpose of this worksheet is to provide support for IRB members reviewing research consent process(es) and documentation. It does not need to be completed or retained. (LAR = "subject's Legally Authorized Representative").

1. Consent Process (Check if "**Yes**". All must be checked)

☐ The investigator will obtain the legally effective informed consent of the subject or LAR[i].

☐ The circumstances of consent provide the prospective subject or LAR sufficient opportunity to consider whether to participate.

☐ The circumstances of consent minimize the possibility of coercion or undue influence.

☐ Information to be given to the subject or LAR will be in language understandable[ii] to the subject or LAR.

☐ The prospective subject or the LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information. (**NA if research is subject to Pre-2018 Requirements) NA:** ☐

☐ Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or LAR's understanding of the reasons why one might or might not want to participate. (**NA if research is subject to Pre-2018 Requirements) NA:** ☐

☐ There is no exculpatory language[iii] through which the subject or LAR is made to waive or appear to waive the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability from negligence.

☐ Consent will disclose the elements in **Section 3: Elements of Consent Disclosure**

2. Long Form of Consent Documentation (Check if "**Yes**" or "**NA**". All must be checked.)

☐ The written consent document is accurate, complete, and consistent with the protocol.

☐ The written consent document embodies the elements in **Section 3: Elements of Consent Disclosure**

☐ The investigator will give either the subject or LAR adequate opportunity to read the consent document before it is signed.

☐ The subject or LAR will sign and date the consent document.

☐ The person obtaining consent will sign and date the consent document.

☐ A copy of the signed and dated consent document will be given to the person signing the document.

☐ If there is a LAR or parent signature line, the IRB has approved inclusion of adults unable to consent or children. **("NA" if no signature line) NA:** ☐

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☐ When a subject or LAR is unable to read and the elements of consent are orally presented to the subject or LAR: A short form and written summary is used and an impartial witness will be present during the entire consent discussion and the consent document notes that the witness attests that the information in the consent document and any other information provided was accurately explained to, and apparently understood by, the subject or LAR, and that consent was freely given. **("NA" if all subjects are able to read) NA:** ☐

3. Elements of Consent Disclosure[iv] (Check if "**Yes**" or "**NA**". All must be checked.)

Required Elements

*(*Can be omitted if there are none.)*

☐ The study involves research.

☐ The purposes of the research.

☐ The expected duration of the subject's participation.

☐ The procedures to be followed.

☐ Identification of any procedures, which are experimental.*

☐ Any reasonably foreseeable risks or discomforts to the subject.*

☐ Any benefits to the subject or to others, which may reasonably be expected from the research.*[v]

☐ Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.*

☐ The extent, if any, to which confidentiality of records identifying the subject will be maintained.*

☐ How to contact the research team for questions, concerns, or complaints about the research.

☐ How to contact someone independent of the research team for questions, concerns, or complaints about the research; questions about the subjects' rights; to obtain information; or to offer input.

☐ Whom to contact in the event of a research-related injury to the subject.

☐ Participation is voluntary.

☐ Refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.

☐ The subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

☐ One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

- ☐ A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the LAR, if this might be a possibility; or
- ☐ A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

(NA if research is subject to Pre-2018 Requirements) NA: ☐

Required for More than Minimal Risk Research

☐ Whether any compensation is available if injury occurs and, if so, what it consists of, or where further information may be obtained.

☐ Whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

Required for Clinical Trials that Follow ICH-GCP

☐ The trial's investigational product(s) and probability for random assignment to each treatment, if applicable.

☐ What is expected of the participants.

☐ When applicable, the reasonably foreseeable risks or inconveniences and benefits to the participant's partner, to an embryo, fetus, or nursing infant.

☐ The important potential benefits and risks of the alternative procedures or courses of treatment that may be available to the subject.

☐ When there is no intended clinical benefit to the participant, the participant should be made aware of this.

☐ The process by which the participant's data will be handled, including in the event of withdrawal or discontinuation of participation in accordance with regulatory requirements.

☐ That by agreeing to participate in the trial, the participant or their legally acceptable representative allows direct access to source records, based on the understanding that the confidentiality of the participant's medical record will be safeguarded. This access is limited for the purpose of viewing trial activities and/or revising or verifying data and records by the regulatory authority(ies) and the sponsor's representatives, for example, monitor(s) or auditor(s), and in accordance with applicable regulatory requirements, the IRB.

☐ If the results of the trial are published, the participant's identity will remain confidential. The trial may be registered on publicly accessible and recognized databases, per applicable regulatory requirements.

☐ Trial results and information on the participant's actual treatment, if appropriate, will be made available to them should they desire it.

Required for FDA-Regulated Research[vi]

☐ The possibility that the Food and Drug Administration may inspect the records and should not state or imply that FDA needs permission from the subject for access to the records[vii].

☐ The data collected on the subject to the point of withdrawal remains part of the study database and may not be removed.

☐ The investigator should ask a subject who is withdrawing whether the subject wishes to provide further data collection from routine medical care.

☐ For controlled drug/device trials (except Phase I drug trials) and pediatric device surveillance trials: "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of

the results. You can search this Web site at any time."

Additional Elements as appropriate

☐ The particular treatment or procedure may involve risks to the subject, which are currently unforeseeable.

☐ If the subject is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable.

☐ Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

☐ Any additional costs to the subject that may result from participation in the research.

☐ The consequences of a subject's decision to withdraw from the research.

☐ Procedures for orderly termination of participation by the subject.

☐ Significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation will be provided to the subject.

☐ Approximate number of subjects involved in the study.

☐ Amount and schedule of all payments.

☐ A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit. At UCI, the More Clause must be used (see below). **(NA if research is subject to Pre-2018 Requirements)**

☐ A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions. **(NA if research is subject to Pre-2018 Requirements)**

☐ For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen). **(NA if research is subject to Pre-2018 Requirements)**

☐ Any additional information which should be given to subjects when in the IRB's judgement the information would meaningfully add to the protection of the rights and welfare of subjects.[viii]

Additional Information Required by Federal or International Entities

☐ NIH:

- ☐ Data Management and Sharing (DMS)
- ☐ Digital Health Technologies (see #5 below)
- ☐ Genomic Data Sharing (GDS)
- ☐ NCI: Clinical Trials Reporting Program[vi]

☐ When the study involves genetic testing, a statement that outlines the protections afforded to the subject under the Genetic Information Nondiscrimination Act (GINA). In California, CalGINA language must be used (see below).

☐ China: Personal Information Protection Law (PIPL)

☐ EEA/UK: General Data Protection Regulation (GDPR)

Required for Research Conducted in California

☐ HIV / Hepatitis / COVID-19 testing disclosure for positive test[ix]

☐ Guidelines for lotteries, raffles, and/or drawings[x]

☐ Subject rights when providing electronic consent[xi]

☐ Protections afforded to the subject under the California Genetic Information Nondiscrimination Act (CalGINA)[xii]

- ☐ Standard CalGINA template language for use when the study involves genetic testing or access to genetic information.
- ☐ Alternate CalGINA template language for research that involves individuals who have a diagnosis and/or are being treated for a genetic disease or disorder

☐ Stem Cell Research[xiii]

- ☐ HRP-502c - Consent for Donation of Somatic Cells For Human Stem Cell Research
- ☐ HRP-502b - Consent For Donation Of Embryo(s) or Gametes For Human Stem Cell Research

☐ "Medical experiments" include the Experimental Bill of Rights[xiv]

Required for Research Conducted at UCI

☐ List study team members authorized to finalize informed consent[xv]

☐ Incidental findings[xvi]

☐ Gender inclusive language for reproductive / contraception risks

☐ Study compensation processed through the UCI Office of Accounting[xvii]

- ☐ If compensation is over $2000, tax reporting requirement

☐ Medical care statement pertaining to the withholding of medical record[xviii]

☐ Biospecimens collected/obtained for research

- ☐ Biospecimens will be discarded or destroyed or
- ☐ Biospecimens (such as blood, tissue, or saliva) collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research, and shared with other organizations. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them (Moore Clause)[xix]

☐ Financial interest of study team[xx]

- ☐ Study team personnel have significant financial interest in either the sponsor or another interested party. The nature of this financial interest and the design of the study have been reviewed by the UCI Conflict of Interest Oversight Committee or
- ☐ No one on the study team has significant interest in the outcome of the study

☐ COVID subject injury language[xxi]

☐ Data retention requirements

☐ UCI IRB current contact information

☐ UCI Witness Signature box[xxii]

4. Additional Considerations for Electronic Consent (Check if "**Yes**" or "**NA**". All must be checked)

☐ Electronic consent document includes all elements in **Section 3-Elements of Consent Disclosure**

☐ The date of the electronic signature will be captured. **(NA if waiver of documentation of consent is requested and justified) NA:** ☐

☐ Questions or methods to gauge subject comprehension of key study elements are clearly defined in the informed consent procedures.

☐ Electronic consent process includes age-appropriate materials to facilitate comprehension.

☐ Electronic consent process is suitable to the study population or procedures are outlined to accommodate subject's needs.

☐ Electronic consent document/process allows subjects to proceed forward or backward or pause for review later.

☐ Measures are present to ensure that subjects have access to all of the consent related materials, including hyperlinks or other external documents.

☐ Plans are adequate to maintain external hyperlinks or documents and subject access to these documents throughout the lifespan of the study until completion are detailed in the informed consent procedures.

☐ The informed consent process outlines in detail how any included documents will be utilized.

☐ Measures are present to ensure that the identity of the signer and the integrity of the data can be verified when consent is not witnessed by the study team.

☐ For FDA-Regulated Clinical Trials including children as research subjects, if the parent or guardian initially documents the child's assent, procedures are in place to verify the child's identify and assent when the child initially presents to the investigator. **(NA if the research is not a FDA-Regulated Clinical Trial) NA:** ☐

5. Consent Form Considerations for NIH-Funded Research with Digital Health Technologies[xxiii] (Check if "**Yes**" or "**NA**". All must be checked)

☐ Indicate if use of the digital health technology is mandatory for participation in the study. Indicate the technological capability(ies) needed for successful participation, including but not limited to WiFi, Bluetooth, smartphone model, data plans, or access to other devices and if these technological capabilities will be provided by the study

☐ Specify which digital health technology will be used and whether it is proprietary to the research team or an outside entity, such as a commercial company (e.g., manufacturers and/or software developers). The software model used can have significant implications for privacy and security, may determine who owns, has access, or rights to distribute the data, and potentially affects the integrity of and confidence in the data associated with the technology.

☐ If appropriate, disclosure of any relationship (e.g. financial, board position, advisor) between investigators and the company that owns the digital health technology used in the study

☐ Clear description of how the digital health technology will be used including the types of data collected and the frequency it will be shared with the study team. This should include a statement that describes under what conditions and how frequently participants will be asked to use or interact with the digital health technology for study purposes (e.g., turn on, use, enter data), whether data will be collected without purposeful participation (i.e., passive data types such as location data, steps, heart rate), and how the technology may impact their daily activities. Expectations about what participants should not do (e.g., move a device, turn it off) should also be clearly communicated

☐ A statement explaining if the interactions with the digital health technology will involve notifications or communications from computer generated sources and at what frequency.

☐ A statement explaining the device(s) being used in the study and that they will need to agree to the standard terms and conditions for the use of the device(s) and instructed use. Clear instructions should be provided on how to install, configure, and use the study-related digital health technology.

☐ A statement explaining if the study team will provide the digital health technology, if the participant will be asked to connect hardware or install software on a personal digital device, the expected duration of the use of the digital health technology, and when and if the participant must return study-provided devices or discontinue any subscription services (e.g., if the participant withdraws from the study, or at the study's conclusion). Indicate what happens if a device is not returned per instructions.

☐ When participants are familiar with the technology outside the study context, state any key differences between use of the technology for the purposes of the study compared to use in the general population.

☐ Indicate the names of all third parties that may have access to participant data, including the frequency of their access and level of detail they may have.

☐ A statement informing participants if their personal health care providers will receive information collected by the digital health technology (including atypical readings or alarms from the digital health technology), whether providers will receive this information (e.g., real-time, specific intervals), and if data will be integrated with a participant's electronic health record (EHR). Also indicating under what circumstances clinically actionable data will be shared and with whom it will be shared. Participants should be informed if they will have direct access to their collected digital health technology data, how often they will be able to directly access this data, and how this can be done.

☐ Participants should be alerted to the steps to stop the collection and/or sharing of their data with the study team, which may include discontinuing use of wearables, removing sharing permissions, and/or uninstalling software application(s).

☐ A statement clarifying whether any portion of a study incentive is dependent on participant use of the device or application

☐ A statement indicating whether the data collected by the digital health technology is owned by the company and whether the data may be sold or shared to third parties without explicit participant consent. Provide awareness of end user agreements, terms and conditions, and terms of service that participants will need to accept, including hyperlinks to these documents. Educate participants about the implications on the use of their data as part of these agreements.

☐ If applicable, a statement explaining the potential risk (including mitigation steps and how to notify participants) of reidentification as capabilities evolve to enable linkages between digital health data and

disparate data sources, consider the risk of re-identification and its implications on participant's privacy and confidentiality.

☐ If applicable, a statement of where and how the study team or others involved in the research store and manage participant data and how to contact the digital health technology company (e.g., their website) for questions about how it stores data. Explain what security protections will be put in place by the study team, who has access to the data, and the controls to prevent unauthorized data access, noting that data held by a digital health technology company may not be protected in the same way.

☐ A statement informing participants about the length of time their data will be retained for the study, purposes for which data could be used during and after the study (i.e., repositories or future studies) and if additional consent will be required for any further activities

☐ A statement explaining if the digital health technology may store, collect, and/or display additional information as part of the technology's normal functioning that is beyond the scope of the research study

☐ A statement outlining the reasonably foreseeable risks and/or discomforts that may be associated with digital health technologies being used in the study. This includes possible privacy and security risks (e.g., location data), along with physical or psychosocial discomforts (e.g., skin irritation, allergic reaction, broken skin, anxiety). Investigators will need to be aware of any changes that might alter the risks of the study and consider these with the IRB for the purposes of notification to participants. Study teams should prioritize selecting technologies capable of the study measures needed while presenting the least amount of risk to participants.

☐ A statement addressing the potential risk of continued data collection after the study ends should the digital health technology remain on a participant's device or continue to be used by the participant.

☐ A statement informing participants if there could be updates to software, privacy policies, or terms of service agreements during the study period and the potential risks these updates may pose. This includes informing participants that companies deploying a commercial digital health technology may not be required to follow the same study privacy rules as the research team and the company's rules can change at any time without notice. The study team should include language explaining whether the privacy policies for the digital health technology used in the study can or cannot be changed by the research team

☐ A statement informing participants how linking or using multiple technologies might impact who has access to the participant's data and how much data they might have access to. If the participant has a digital health technology that can be accessed by others (e.g., shared devices or accounts with family members, relatives, neighbors), they need to be informed that this might result in less privacy and an inability to maintain confidentiality

☐ A statement providing participants with a clear understanding of how their study data is being protected, who might have access to it, and the steps being taken to minimize possible privacy risks that could arise

☐ A statement explaining if the interactions with the digital health technology will involve notifications or communications from computer generated sources and at what frequency.

☐ A statement helping participants understand the role they can play in protecting their confidentiality and private information when using digital health technologies (e.g., creating a secure password).

☐ A statement addressing the potential risks for breaches of participant study data.

☐ When the digital health technology used in the study could collect information on other individuals, especially when those individuals may not know their data is being collected (e.g., participant's social networks, or home and other surroundings), language should be added to inform participants of the possible

risks (e.g., security risks) for non-participants and whether/how these risks can be mitigated by the study team and/or participant☐ A statement addressing the potential risks for breaches of participant study data.

☐ A statement addressing any potential risks that arise from adding the digital health component to a participant's existing technology, including the potential for interference with another technology the participant currently uses.

☐ A statement outlining any anticipated direct benefits related to their use of digital health technologies during the research study.

☐ If the participant will be using their own device and/or needs a cellular service/ internet connection to transmit data, clearly outline who is expected to cover the cost of the required cellular service/internet connection (i.e., any reimbursement provided to cover or offset the costs).

☐ If the study provides paid access/subscription to a digital technology, clearly specify how long the participant will have access to the application and whether they will have to pay for the service after the study ends should they wish to continue use.

☐ When applicable, if there could be situations where the device breaks, is lost or stolen, is faulty, or needs maintenance (e.g., replacement parts including batteries). Specify what to do in such situations and under what circumstances the participant or the study will be responsible for paying for the maintenance or replacement of the device

☐ If considering commercial technologies that may offer in-app paid features, describe who is responsible for those costs and explicitly state what will be provided as part of the study

☐ A statement informing participants whether the study team and/or the digital health technology company may be able to keep and use participant data after the study ends or a participant withdraws from the study.

☐ A statement informing participants if their study data cannot be removed even upon withdrawing from the study.

☐ A statement informing participants if the digital health technology will continue to collect data until the device and/or the software application have been removed, uninstalled, or the associated account is deactivated or closed.

☐ A statement informing participants if the digital health technology will continue to collect data until the device and/or the software application have been removed, uninstalled, or the associated account is deactivated or closed.

☐ A statement that establishes and clearly communicates a protocol for addressing participant use of the technology as outlined in the study, defining specific criteria and time frames for non-adherence (e.g., 30 days of no interaction), using multiple methods (emails, calls, letters) for attempts to re-establish contact, and ensuring ethical considerations are met before formally withdrawing participants who do not explicitly request to drop out but show complete lack of adherence to required study activities.

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[i] LAR = "subject's Legally Authorized Representative"

[ii] "Understandable" means the information presented to prospective subject is in a language and at a level the subjects can comprehend (including an explanation of scientific and medical terms) *FDA's Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023)*

[iii] FDA considers exculpatory language to be language that has the general effect of freeing or appearing to free an individual or an entity from malpractice, negligence, blame, fault, or guilt *FDA's Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023)*

[iv] For additional guidance for FDA-regulated research on the elements of consent (including examples and recommendations on language), please see *FDA's Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023)*

[v] If payments, including reimbursement for research-related expenses incurred by subjects due to participation, are provided, the consent process should not identify them as benefits *FDA's Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors*

(August 2023)

[vi] The FDA generally recommends against including statements such as "FDA has given permission for the clinical investigation to proceed" or "FDA has approved the clinical investigation" in the informed consent process, because such statements may suggest to subjects that the investigation has FDA's endorsement. *FDA's Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023)*

[vii] *FDA's Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023)*

[viii] 21 CFR 56.109 (b): (b) An IRB shall require that information given to subjects as part of informed consent is in accordance with 50.25. The IRB may require that information, in addition to that specifically mentioned in 50.25, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

[ix] CA Health and Safety Code: Sections 120500-120605 & Sections 120975–121023; CARES Act: Section 18115

[x] CA Constitution: Section 19 & CA Penal Code: Sections 319–326

[xi] CA Civil Code: Sections 1633.1 - 1633.17

[xii] CA Gov Code: Sections 1290-12923

[xiii] CA Health and Safety Code: 125118; CDPH Guidelines for Human Stem Cell Research & Informed Consent Form Checklist for Research Involving Human Oocyte Retrieval

[xiv] CA Health and Safety Code: Sections 24170–24179.5

[xv] HRP-SOP 090

[xvi] SACHRP Recommendations: Attachment F - Recommendations on Reporting Incidental Findings

[xvii] UCI Policy Section 701-03

[xviii] CARES Act

[xix] UC Research Policy Analysis & Coordination (RPAC) Guidance Memo: 14-07

[xx] UCI Office of Research Policy Section 481-3

[xxi] Countermeasures Injury Compensation Program (CICP) & UC Legal Clinical Research Alert: *Covid-19 Related Research and the PREP Act*

[xxii] ICH E6(R3) Guidelines

[xxiii] NIH Guidance: Blue and White Professional Modern Business Report Cover Page (nih.gov). According to this guidance, digital health technology refers to wearable devices, sensor technologies, and mobile software applications ("apps") most often used with tablets, watches, or phones.

WORKSHEET: Advertisements

The purpose of this worksheet is to provide support for the convened IRB or Designated/Staff Reviewers when evaluating advertisements meant to be seen or heard by subjects.

1. Context (Check if "Yes". All must be checked)

☐ The application describes the mode of communication.

☐ For printed advertisements, the final copy is being reviewed.

☐ For non-FDA regulated research, the text of the master recruitment template can be reviewed.

☐ For audio/video recording, the recording is the final version.

2. The advertisement: (Check if "Yes". All must be checked)

☐ Does NOT state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.

☐ Does NOT promise "free treatment," when the intent is only to say subjects will not be charged for taking part in the research.

☐ Does NOT include exculpatory language.

☐ Does NOT emphasize the payment or the amount to be paid, by such means as larger or bold type.

☐ The advertisement is limited to the information prospective subjects need to determine their eligibility and interest, such as:

- The name and address of the investigator or research facility.
- The condition under study or the purpose of the research.
- In summary form, the criteria that will be used to determine eligibility for the study.
- A brief list of participation benefits, if any.
- The time or other commitment required of the subjects.
- The location of the research and the person or office to contact for further information.

3. For FDA-regulated research, the advertisement: (Check if "Yes". All must be checked)

☐ Does NOT make claims, either explicitly or implicitly, that the drug, biologic or device is safe or effective for the purposes under investigation.

☐ Does NOT make claims, either explicitly or implicitly, that the test article is known to be equivalent or superior to any other drug, biologic or device.

☐ Does NOT use terms, such as "new treatment," "new medication" or "new drug" without explaining that the test article is investigational.

☐ Does NOT include a coupon good for a discount on the purchase price of the product once it has been approved for marketing.

4. For research recruiting UCI students as a class component: (Check if **Applicable**)

☐ The IRB may approve the giving of course credit or extra credit to students who are expected to participate in research activities as part of a class curriculum only when alternative means of obtaining course credit or extra credit is made available to students who do not wish to volunteer as research participants. Students must be given other options for fulfilling the research participation component that are comparable in terms of time, effort, and educational benefit. For example, short papers, special projects, book reports, and brief quizzes on additional reading may be offered in lieu of research participation.

☐ These research studies may not involve more than minimal risk and students must be told that they can withdraw from the study at any time without losing the extra credit.

☐ The use of extra credit points for participation in research studies should be limited as a reward, used only when the research is closely tied to the course subject matter, and should not raise the student's grade by more than one-half of a letter grade (e.g., B to B+).

☐ Students should be recruited through the Social Sciences Human Subjects Pool, bulletin board postings or online advertisements, rather than individual solicitations.
☐ Research interventions should not be conducted during class time.
☐ Principal Investigators should be cautious about recruiting students into research of a coercive or sensitive nature (e.g., drug use, alcoholism, sexual preferences, etc.).

5. For research recruiting UCI students: (Check if **Applicable**)

☐ UC Irvine is subject to the provisions of Federal law known as the Family Educational Rights and Privacy Act (also referred to as FERPA). This act affords matriculated students certain rights with respect to their educational records.
☐ Generally, students have the right to consent to disclosures of personally identifiable information contained in the student's education records to third parties (such as researchers). Investigators must obtain student's consent to access personally identifiable information in the student's educational records, even if consent to participate in the research may have been waived by the IRB. There are some exceptions however.

6. For research recruiting UCI medical students: (Check if **Applicable**)

☐ The IRB has the authority to review and approve research involving medical students.
☐ Medical school students may only participate in research involving minimal risk and minimal interruption of time.
☐ Principal Investigators should be cautious about recruiting medical students into research of a coercive or sensitive nature (e.g., drug use, alcoholism, sexual preferences, etc.).
☐ Any IRB concerns regarding the use of medical students should be promptly forwarded to the Senior Associate Dean for Educational Affairs for review.

7. For research recruiting UCI employees: (Check if **Applicable**)

☐ Employees should be recruited through general announcements or advertisements, rather than individual solicitations.
☐ Employees of a particular Investigator or laboratory should not be directly recruited for participation in any study conducted by that Investigator or laboratory, although such employees may, on their own, volunteer to participate.
☐ Principal Investigators should minimize the likelihood that employees who participate in research programs perceive that the decision will affect performance evaluations or job advancement.
☐ Principal Investigators who include colleagues or subordinates as research participants should be able to provide a rationale other than convenience for selecting those individuals and should show that the recruitment methods do not lead colleagues to think that they will be compromised by not participating.

8. For Veterans Administration (VA)-Regulated research, the advertisement: (Check if "Yes". All must be checked)

☐ Does NOT use the VA Facebook page as a method of advertising non-VA studies at VA facilities.

☐ If the research is non-VA research being conducted at a VA facility, the advertisement includes a clear and legible disclaimer that states:

- The research is not VA research.
- The research will not be conducted by the VA.
- The research has not been reviewed by VA's Institutional Review Board.

The research is not endorsed by VA.

WORKSHEET: Payments

The purpose of this worksheet is to provide support for the convened IRB or Designated/Staff Reviewers when evaluating payments to subjects or their Legally Authorized Representatives.

1. Requirements for Payments[i] (Check if "**Yes**". All must be checked)

☐ All payments are described in the protocol including: (Check if "Yes". All must be checked)
- ☐ Amount
- ☐ Method
- ☐ Timing of disbursement

☐ Credit for payment accrues as the study progresses.
☐ Payment is not contingent upon completing the entire study.
☐ The amount of payment and the proposed method and timing of disbursement is neither coercive nor presented undue influence.
☐ Any amount paid as a bonus for completion is reasonable and not so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn and is evaluated in context of any reimbursement or compensation payment included in the study.
☐ All information concerning payment, including the amount and schedule of payments, is in the informed consent document.
☐ Compensation does not include a coupon good for a discount on the purchase price of the product once it has been approved.
☐ The study team is to provide the UCI Office of Accounting and Fiscal Services the name and social security number of participants who receive payments more than $2000 per calendar year preferably on Form W-9 for processing the Form 1099-Misc to be forwarded to the IRS.
☐ The IRB will determine whether lotteries, raffles, and/or drawings may be used to recruit or retain participants. For the IRB to consider approving the use of lotteries, raffles, and/or drawings, the following must be considered:
- ☐ The study involves minimal risk to participants (Exempt or Expedited).
- ☐ The prize is less than $600 and will not unduly influence participation in the research.
- ☐The subject compensation process must include the following:
  - ☐ Procedures to ensure that any individual who is asked to participate in the research study but declines, who consents/assents to enroll in the study, or who fails to complete the study, will be given equal compensation by having an equal chance of winning. In other words, if an individual is eligible to participate in the study, and therefore the lottery, raffle and/or drawing, they are not required to participate in the study to be eligible to participate in the lottery, raffle, and/or drawing;

  - ☐ Procedures for the inclusion of an individual who is not asked to participate in the study but wishes to be included in the lottery, raffle, and/or drawing;

☐ A fair method of choosing the winner and how the winner will be notified; and
☐ Disclosure of the approximate chance of winning (e.g., no less than 1 in 1000) in the consent/assent.

[i] FDA Information Sheet, “Guidance for Institutional Review Boards and Clinical Investigators, Payment and Reimbursement to Research Subjects” January 2018.

WORKSHEET: Short Form of Consent Documentation

The purpose of this worksheet is to provide support for IRB members or Designated Reviewers using HRP-314 - WORKSHEET - Criteria for Approval when reviewing research involving the short form of consent documentation.

1. Short Form of Consent Documentation (Check if **"Yes"**. All must be checked)

☐ The written consent document states that the elements of consent have been presented orally to the subject or the subject's Legally Authorized Representative (LAR).

☐ There is written summary of what is to be said to the subject or LAR that embodies the required and appropriate additional elements in Section 7: ELEMENTS OF CONSENT DISCLOSURE in HRP-314 - WORKSHEET - Criteria for Approval.

☐ The consent document and summary are accurate and complete.

☐ An impartial witness[i] is present during the entire consent discussion.

☐ For subjects who do not speak English the witness is conversant in both English and the language of the subject or the subject's LAR.

☐ The subject or the subject's LAR will sign and date the short form consent document.

☐ The witness will sign and date the short form consent document and the summary.

☐ The person obtaining consent will sign and date the summary.

☐ When a subject or the subject's LAR is unable to read: An impartial witness will be present during the entire consent discussion and the consent document notes that the witness attests that the information in the consent document and any other information provided was accurately explained to, and apparently understood by, the subject or the subject's LAR, and that consent was freely given.

☐ A copy of the signed and dated summary will be given to the subject or the subject's LAR.

☐ A copy of the signed and dated short form consent document will be given to the subject or the subject's LAR.

☐ A copy of the Experimental Subject's Bill of Rights (in a language understandable to the participant) should also be provided to all research participants considering participation in a medical experiment, per California Health & Safety Code. These are available on the IRB Forms page under the heading, 'Human Research Protections / Foreign Language Translations'.

☐ If there is a signature line for a LAR or parent, the IRB has approved inclusion of adults unable to consent or children.

☐ Once the participant has consented and eligibility is confirmed, the IRB approved English version of the consent document must be translated into the participant 's language by a professional or certified translator. *The translated consent form must be provided to the*

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participant *within one month from the date that eligibility is confirmed.*

[i] The FDA recommends "…that an impartial third party not otherwise connected with the clinical investigation (for example, clinical staff not involved in the research, a patient advocate or an independent interpreter) serve as the witness. The witness must be present physically or by some other means, for example, by phone or video conference, during the oral presentation, not just the signing of the consent form (21 CFR 50.27(b)(2))." *FDA's Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023)* https://www.fda.gov/media/88915/download.

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WORKSHEET: Additional Federal Agency Criteria

The purpose of this worksheet is to provide support for IRB members reviewing research regulated by specific federal agencies. It does not need to be completed or retained.

1. Additional Criteria for Veterans Administration (VA) Research (Check if "Yes" or "NA". All must be checked)

☐ The research does not involve the creation of a human embryo or embryos solely for research purposes or research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and Section 498B of the Public Health Service Act (42 U.S.C. 289g(b)).

☐ The research is not an Intervention involving neonates.

☐ The research is not classified.

☐ The research is not planned emergency research that involves a waiver of the consent process.

☐ The protocol and consent document are consistent with the HIPAA authorization.

☐ The consent process and document will disclose:

- ☐ A statement that VA will provide treatment for research related injury in accordance with 38 CFR 17.85.

When applicable:

- ☐ A statement that VA research subjects and/or their insurance will not be charged any costs related to the research except that some veterans are required to pay co-payments for medical care and services provided by VA and that these co-payment requirements will continue to apply to VA-provided medical care and services that are not part of this study.
- ☐ Information describing any photographs, video, and/or audio recordings to be taken or obtained for research purposes, how the photographs, video, and/or audio recordings will be used for the research, and whether the photographs, video, and/or audio recordings will be disclosed outside VA.
- ☐ The required VA PREP Act statement for research studying a drug, biological product, device, or vaccine designed to treat, diagnose, cure or prevent COVID-19. [i]

☐ If the research includes broad consent:

- ☐ Broad consent can only be obtained for the use of information or biospecimens that are collected initially for research purposes.
- ☐ Documentation of informed consent for broad consent cannot be waived by the IRB.

The broad consent process and document will disclose:

- ☐ A statement that VA will provide treatment for research related injury in accordance with applicable federal regulations.

☐ When applicable: A statement that informs VA research subjects that they or their insurance will not be charged for any costs related to the research.

☐ If the research involves pregnant women as subjects, the VA medical facility Director must certify that the medical facility has sufficient expertise in women's health to conduct the research if the research includes interventional studies or invasive monitoring of pregnant women as subjects.

☐ The research does not involve clinical interventions with the potential of greater than Minimal Risk for children who are pregnant.

☐ If the research involves biological specimens and data obtained from children, it is considered research involving children even if de-identified.

☐ If the research involves neonates, the VA medical facility Director must certify that the medical facility has sufficient expertise in neonatal health to conduct the proposed research.

☐ If the research involves fetal tissue, it meets the requirements of the NIH Reminder of Legal Requirements Regarding the Acquisition and Use of Human Fetal Tissue for Research Purposes and NIH Policy on Informed Consent for Human Fetal Tissue Research.

☐ If the research involves stems cells, it meets the requirements of the NIH Guidelines for Stem Cell Research.

☐ If the research involves Prisoners as subjects, a waiver shall be granted by the Chief Research and Development Officer.

☐ If the research involves children as subjects, the research must not present greater than minimal risk and the VA medical facility Director must approve participation in the research.

☐ If the research is international research, approval has been granted from the VA medical facility Director and an approval document signed by the VA medical facility Director is provided.

☐ If the research is an international Cooperative Studies Program activity, it has been approved by the Chief Research and Development Officer.

☐ If the research includes taking a photograph, video and/or audio recording, the informed consent cannot be waived by the IRB.

☐ If the research is exempt and involves Interaction with human subjects or obtaining information by educational tests, survey or interview procedures, or behavioral interventions, the following information must be given to the prospective human subject as applicable in writing or orally:

- Permission to participate can be withdrawn;
- Permission for use of data can be withdrawn for exempt research activities involving the collection and use of identifiable data; and
- Contact information for the VA Investigator.

2. Additional Criteria for Veterans Administration (VA) Research for Multi-Site Research When the Investigator is the Multi-Site Study PI for All Participating Facilities and the VA Central IRB is Not Being Used (Check if "Yes" or "NA". All must be checked)

☐ Each Participating Site (pSite) has an active FWA.

☐ Each pSite has provided documentation of all relevant approvals, including approval of its IRB of record.

☐ The IRB has approved the study-wide protocol and sample informed consent document to be provided to each pSite.

☐ The study-wide protocol contains a mechanism for ensuring that any differences in the protocol or informed consent at engaged local pSites are justified by the local site investigators, and that they are approved by the principal investigator before being implemented.

☐ There are clear Adverse Event reporting requirements, a data monitoring committee if applicable (or other reliable monitoring mechanism) with clear procedures and requirements, and a clearly defined feedback loop to the investigator's or study sponsor's IRB.

☐ The PI's plan for communicating appropriate critical information (e.g., reports of data and safety monitoring) to engaged pSites is adequate.

☐ The principal investigator and all local site investigators will obtain written approvals from the relevant local VA facilities' IRBs of record and all other local committees, subcommittees, and other approvals according to the respective applicable local, VA and other federal requirements.

☐ Research will not be initiated at any given site until the local investigator has obtained written notification that the research can be initiated from the local associate chief of staff for research and development.

☐ Confidentiality and information security requirements are met for information storage at and transmission to statistical or coordinating centers.

☐ Data monitoring committees will provide reports to the IRB.

3. Additional Criteria for Veterans Administration (VA) when Serving as the sIRB Reviewing VA Collaborative Research (Check if "Yes" or "NA". All must be checked)

☐ For reliance agreements, records of an IRB are addressed in the MOU for the VA Facility's use of another entity's IRB. The MOU ensures that all applicable Federal and VA regulations are met.[ii]

☐ The protocol or other documentation submitted to the VA IRB of Record must clearly delineate which research activities will be conducted as the VA portion of the overall Collaborative Research study (e.g., by VA researchers on VA time or VA property).

☐ The VA informed consent document must clearly state when procedures conducted at other non-VA institutions are part of the VA's portion of the study.

☐ Each institution engaged in the collaborative research must use the informed consent document required by its respective institutional policies for participants recruited from that institution, or procedures requiring participation of the participants at that institution. The informed consent document may contain information on the project as a whole as long as the document clearly describes which procedures will be performed under VA's auspices and which will be performed under a non-VA institution's auspices.

☐ The protocol, addendum, and/or IRB of Record application must describe the data to be disclosed to collaborators, the entities to which the data are to be disclosed, how the data are to be transmitted, and how the transmitted data will be stored, retained, destroyed, and/or further disclosed and to whom. This includes data from individual participants as well as other data developed during the research such as the analytic data and the aggregate data.

☐ Refer to HRP-833 - PI WORKSHEET - Considerations for Serving as the Reviewing IRB for considerations when serving as the sIRB for VA research.

4. Additional Criteria for Department of Justice (DOJ) Research Conducted within the Federal Bureau of Prisons (BOP) (Check if "Yes" or "NA". All must be checked)

☐ The investigator and research staff are aware of and have been educated about the specific requirements of DOJ research within the BOP.

☐ The project does not involve medical experimentation, cosmetic research, or pharmaceutical testing.

☐ The research design is compatible with both the operation of prison facilities and protection of human subjects.

☐ The investigator will observe the rules of the institution or office in which the research is conducted.

☐ Investigators who are not BOP employees have signed a statement agreeing to adhere to the requirements of 28 CFR 512.

☐ All research proposals will be reviewed by the BOP IRB.

☐ The project has an adequate research design and will contribute to the advancement of knowledge about corrections.

☐ The selection of subjects within any one organization is equitable.

☐ Incentives will not be offered to help persuade inmate subjects to participate. Soft drinks and snacks to be consumed at the test setting may be offered. Reasonable accommodations such as nominal monetary recompense for time and effort may be offered to non-confined research subjects who are no longer in BOP custody and are participating in authorized research being conducted by BOP employees or contractors.

☐ If a non-employee of the BOP will receive records in a form not individually identifiable, advance adequate written assurance that the record will be used solely as a statistical research or reporting record has been provided to the agency.

☐ Except as noted in the consent statement to the subject, the investigator will not provide research information that identifies a subject to any person without that subject's prior written consent to release the information. For example, research information identifiable to a particular individual cannot be admitted as evidence or used for any purpose in any action, suit, or other judicial, administrative, or legislative proceeding without the written consent of the individual to whom the data pertain.

☐ Except for computerized data records maintained at an official Department of Justice site, records that contain non-disclosable information directly traceable to a specific person will not be stored in, or introduced into, an electronic retrieval system.

☐ Required elements of disclosure include all of the following:

- ☐ Anticipated uses of the results of the research.
- ☐ A statement that participation is completely voluntary and that the subject may withdraw consent and end participation in the project at any time without penalty or prejudice (the inmate will be returned to regular assignment or activity by staff as soon as practicable).
- ☐ A statement that participation in the research project will have no effect on the inmate subject's release date or parole eligibility.
- ☐ Identification of the investigators.
- ☐ A statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law. For example, a investigator may not

guarantee confidentiality when the subject indicates intent to commit future criminal conduct or harm himself or herself or someone else, or, if the subject is an inmate, indicates intent to leave the facility without authorization.

☐ The investigator has academic preparation or experience in the area of study of the proposed research.

☐ The IRB application includes a statement regarding assurances and Certification required by federal regulations, if applicable.

☐ The investigator will assume responsibility for actions of any person engaged to participate in the research project as an associate, assistant, or subcontractor to the Researcher.

5. Additional Criteria for Department of Justice (DOJ) Research Funded by National Institute of Justice (NIJ) (Check if "Yes" or "NA". All must be checked)

☐ The investigator and research staff are aware of and have been educated about the specific requirements of DOJ research funded by NIJ.

☐ Projects have a privacy certificate approved by the NIJ human subjects protection officer. For studies that involve human subjects, the IRB Chair / representative should sign as the authorized institutional representative.[iii]

☐ All investigators and research Staff have signed employee confidentiality statements, which are maintained by the investigator.

☐ Identification of the funding agency(ies).

☐ A statement describing the extent to which confidentiality of records identifying the subject will be maintained. For studies sponsored by the NIJ the subject should be informed that private, identifiable information will be kept confidential and will only be used for research and statistical purposes. If, due to sample size or some unique feature, the identity of the individual cannot be maintained, the participants need to be explicitly notified. If the researcher intends to disclose any information, the participant needs to be explicitly informed what information would be disclosed under what circumstances, and to whom. The participant must be informed of any risks that might result from this disclosure and must explicitly provide written consent prior to participating in the research.

☐ Under a privacy certificate, investigators and research staff do not have to report child abuse unless the subject signs another consent document to allow child abuse reporting.

☐ A copy of all data will be de-identified and sent to the National Archive of Criminal Justice Data, including copies of the informed consent document, data collection instruments, surveys, or other relevant research materials.

- ☐ At least once a year, the researcher shall provide the Chief, Office of Research and Evaluation, with a report on the progress of the research.
- ☐ At least 12 working days before any report of findings is to be released, the researcher shall distribute one copy of the report to each of the following: the chairperson of the Bureau Research Review Board, the regional director, and the warden of each institution that provided data or assistance. The researcher shall not include an abstract in the report of findings.
- ☐ In any publication of results, the research shall acknowledge the Bureau's participation in the research project.

☐ The research shall expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau.
☐ Prior to submitting for publication the results of a research project conducted under this subpart, the research shall provide two copies of the material, for informational purposes only, to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons.

6. Additional Criterion for the Environmental Protection Agency (EPA) Research and Research Intended to be Submitted to the Environmental Protection Agency (Check if "Yes" or "NA". All must be checked)

☐ The research does not involve the intentional exposure of pregnant women, nursing women, or children to any substance.

☐ If the results of research involving an intentional exposure of human subjects are intended to be submitted to or held for inspection by the Environmental Protection Agency (EPA) the IRB's determinations and approval will be submitted to the Environmental Protection Agency (EPA) Human Subjects Research Review official for final review and approval before the research can begin.

☐ If the research involves children, the research must either be:

☐ observational research not involving greater than Minimal Risk or
☐ observational research involving greater than Minimal Risk but presenting prospect of direct benefit.

☐ If the research involves intentional exposure of subjects to a pesticide, the subjects of the research must be informed of the identity of the pesticide and the nature of its pesticidal function.

☐ If the research involves the use of Broad Consent, the research can only be Exempt under category 7: Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of Identifiable Private Information or Identifiable Biospecimens for potential secondary research.

7. Additional Criteria for Department of Energy (DOE) Research (Check if "Yes" or "NA". All must be checked)

☐ For research that involves Personally Identifiable Information (PII) or Protected Health Information (PHI), the protocol addresses the following DOE requirements:

- Keeping PII/PHI confidential.
- Protecting PII/PHI during storage and transmission.
- Releasing PII/PHI, when required, only under a procedure approved by the responsible IRB and DOE.
- Using PII/PHI only for purposes of the IRB-approved project.
- Handling and marking documents containing PII/PHI as "containing PII or PHI."
- Establishing reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of PII/PHI.
- Making no further use or disclosure of the PII/PHI except when approved by the responsible IRB and DOE, where applicable, and then only under the following circumstances: (a) in an emergency affecting the health or safety of any individual; (b) for use in another research project under these same conditions and with DOE written authorization; (c) for disclosure to a person authorized by the DOE program office for the purpose of an audit related to the project, as required by Office of

Management and Budget Circular No. A-133; (d) when required by law; or (e) with the consent of the participant/guardian.

- Protecting PII/PHI data stored on removable media (CD, DVD, USB Flash Drives, etc.), network drives and stand-alone computers using encryption products that are Federal Information Processing Standards (FIPS) 140-2 certified.
- Using passwords to protect PII/PHI used in conjunction with FIPS 140-2 certified encryption products that meet the current DOE password requirements:
    - Minimum of twelve (12) non-blank characters
    - Must contain a lowercase letter
    - Must contain an uppercase letter
    - Must contain a number or special character
    - Must contain a nonnumeric in the first and last position
    - Must not contain the user ID
- Sending removable media containing PII, as required, by express overnight service with signature and tracking capability, and shipping hard copy documents double wrapped.
- Encrypting data files containing PII that are being sent by e-mail with FIPS 140-2 certified encryption products.
- Accessing data via a secure, encrypted internet connection or through an Electronic Data Interface using TLS 1.1 or newer.
- Sending passwords that are used to encrypt data files containing PII separately from the encrypted data file, i.e. separate e-mail, telephone call, separate letter.
- Using TLS 1.1 encryption methods or higher for websites established for the submission of information that includes PII.
- Using two-factor authentication for logon access control for remote access to systems and databases that contain PII/PHI. (Two-factor authentication is contained in the National Institute of Standards and Technology (NIST) Special Publication 800-63).
- Reporting the loss or suspected loss of PII/PHI immediately upon discovery to (1) the DOE funding office program manager, or, if funded by a DOE laboratory, the DOE laboratory Program Manager and (2) the DOE Human Subject Protection (HSP) Program Manager and the NNSA HSP Program Manager. If these individuals are unreachable, immediately notify the DOE-CIRC by phone at 1-866-941-2472, by fax at 702-932-0189, or by e-mail at circ@jc3.doe.gov. For additional information, see: http://energy.gov/cio/office-chief-information-officer/services/incident-management/jc3-incident-reporting.
- Classified projects that use PII/PHI must also comply with all requirements for conducting classified research.

☐ For classified human subjects research (in whole or in part):

- All information related to classified human subject research (HSR) must be managed in accordance with applicable DOE directives and other requirements (Executive Orders (E.O.s), laws, regulations), and researchers involved in the conduct of such HSR must have security clearances at the appropriate level to access such information.
- Exemptions (as per 10 CFR §745.104) and expedited review cannot be used. If the research meets a particular exemption or expedited category it may be noted, but full IRB review is required.
- A waiver of informed consent may only be granted by the convened IRB for minimal risk research that qualifies for exemption under 10 CFR §745.104.

- The identity of the sponsoring Federal agency will be disclosed to subjects, unless the sponsor requests that it not be done, because doing so could compromise intelligence sources or methods; the research involves no more than Minimal Risk to subjects; and the IRB determines that by not disclosing the identity, the investigators will not adversely affect the subjects.
- The informed consent document will state that the project is classified, what that means for the purposes of that project, and what part of the research that applies to.
- The IRB must determine whether the potential human subjects need access to classified information to make a valid informed consent decision.
- Any IRB member can appeal an approval decision to the DOE IO, Secretary of Energy, Director of the Office of Science and Technology Policy (OSTP) or designee, and then the Director of National Intelligence (ODNI) or designee, in that order. The Director of OSTP (or designee), or the ODNI (or designee) will review and approve or disapprove the research, or will convene or designate an IRB that is, to the extent possible, made up of unaffiliated members with the appropriate qualifications and clearance to approve or disapprove the research.
- Information on each project that is classified must be submitted annually (or in accordance with the directions and schedules provided by the appropriate HSP Program Manager) by the responsible HSP Program Managers. The HSP Program Managers will compile this information and prepare a summary document, for signature by the DOE IO and delivery to OSTP and/or ODNI, in accordance with E.O.s and other Federal requirements.
- If the IRB believes that the project, in whole or in part, can be thoroughly reviewed in an unclassified manner, a request for a waiver from some or all of the requirements of classified HSR can be submitted. The study-specific waiver request must be signed by the IRB Chair and reviewed and approved by the appropriate HSP Program Manager. If the waiver request relates to an intelligence-related project, DOE Office of Intelligence and Counterintelligence (DOE-IN) must also review and approve the waiver. A list of waiver requests and the actions taken will be provided.
- HSR that is classified, in whole or in part, must not be initiated without IRB approval. After IRB approval, the DOE IO reviews and determines whether he/she will approve/disapprove the project or brief the Secretary about the project prior to his/her approval/disapproval.
- All records related to IRB review/approval of classified HSR as well as key research records must be maintained permanently. During and following the completion of classified research, copies of all signed classified consent forms must be stored in a separate but secure location (e.g., security policy office or IRB), other than the researchers' office, and participants of such research must be notified during the consenting process regarding how to access a copy of their individual signed classified consent forms should they want to in the future.

☐ For research involving protected classes:

- Research involving the vulnerable populations identified in Subparts B, C, and D of 45 CFR 46 must be conducted in accordance with those Subpart(s). Appropriate protections should be afforded to subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.• Care must also be taken to ensure the proper protections are in place for DOE/NNSA Federal and/or contractor employees who become human subjects of research and may be subject to coercion or undue influence. An employee cannot be recruited or consented by a direct supervisor who is the PI and/or member of the research team, except in unusual circumstances approved by the IRB. DOE and DOE site employees are considered vulnerable subjects when participating in research and additional care must be taken to ensure their participation is truly voluntary (e.g., by ensuring they

do not report to members of the research team) and that data collected about them is kept confidential.

☐ For Human Subjects Research Database (HSRD) Reporting (DOE site IRB responsibility):

- All HSR projects (excluding classified and/or intelligence-related HSR) conducted with DOE funding, by DOE or DOE contractor researchers (regardless of funding source or location), or that involve targeted inclusion or current or former DOE site or contractor employees or their data must be reported annually to the HSRD in accordance with directions and schedules provided by the HSP Program Manager.
- Such annual reporting is also required when HSR is minimal risk (including exempt HSR) and when a DOE IRB is not the IRB of record. In cases where a DOE site IRB defers to an external IRB for the review of a study the DOE site is engaged in, the DOE site IRB will still be responsible for ensuring HSRD reporting requirements are met.
- In cases where a DOE Headquarters program officer funds outside institutions to conduct HSR, the program office will be responsible for ensuring HSRD reporting requirements are met.

8. Additional Criterion for Department of Education (ED) Research (Check if "Yes" or "NA". All must be checked)

☐ If prior consent [iv] or written documentation of consent or parental permission is waived, the research does NOT involve gathering information about any of the following:

- Political affiliations or beliefs of the student or the student's parent
- Mental or psychological problems of the student or the student's family
- Sex behavior or attitudes
- Illegal, anti-social, self-incriminating, or demeaning behavior
- Critical appraisals of other individuals with whom respondents have close family relationships
- Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers
- Religious practices, affiliations, or beliefs of the student or student's parent
- Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program)

9. Additional Criteria for Department of Defense (DOD) Research (Check if "Yes" or "NA". All must be checked)[v]

☐ The investigator and research staff are aware of the specific DOD requirements and have been educated about these requirements.

☐ The review has considered (and will document) the scientific merit of the research; within consideration of scientific merit, feasibility, of study completion should be considered. [vi]

☐ For research that involves DOD-affiliated personnel, the key investigator must receive approval from the DOD-affiliated personnel's command or DOD Component Human Research Protection Program (HRPP) to conduct the research.

☐ For research that takes place on a DOD facility, the key investigator must receive approval from the command or DOD Component HRPP or its delegate responsible for the facility.

☐ The research does NOT involve Prisoners of war or detainees as subjects. [vii]

☐ The research does not involve the testing of chemical or biological agents, which is prohibited, pursuant to Section 1520a of Title 50, U.S.C, unless exceptions for research for prophylactic, protective, or other peaceful purposes apply,

  ☐ Explicit written approval from DOHRP was obtained prior to the initiation of excepted testing of chemical or biological agents involving HSR.

☐ Military personnel will not be paid for research conducted while on duty. [viii]

☐ If the research involves DOD-affiliated personnel as subjects, when applicable, the following is required: (Check if "Yes." Or "NA". All must be checked):

  ☐ If the research includes risks to their fitness for duty (e.g. health, availability to perform job, data breach), then informed consent form must inform DOD-affiliated personnel about these risks and that they should seek command or Component HRPP guidance before participating.
  ☐ Research involves greater than Minimal Risk and recruitment will occur in a group setting: The IRB has appointed an ombudsperson [ix] who does not have a conflict of interest with the research or be a part of the research team, and will be present during the recruitment to explain that participation is voluntary and that the information provided about the research is consistent with the IRB-approved script and materials, including digitally provided materials. The ombudsman should be available to address concerns about participation.
  ☐ If the study involves Large-scale genomic data (LSGD) collected from DoD-affiliated personnel (including the secondary uses or sharing of de-identified data or specimens) then the following is required:

    - The research is subject to DOD Component security review and DOHRP approval.
    - The research will apply an HHS Certificate of Confidentiality
    - Administrative, technical, and physical safeguards are considered, as the disclosure of the data may pose a risk to national security.

☐ If the research is subject to Section 980 of Title 10, U.S.C., consent will be obtained unless waived by the DOHRP.[x] The IRB may waive or alter some elements of informed consent for research involving human beings as experimental subjects, so long as it preserves the informed consent of the participant (i.e., the consent indicates that participation in the research is voluntary and the participant/representative is informed of research risks).

☐ The key investigator must receive approval from the DOD-affiliated personnel's command or DOD Component Human Research Protection Program (HRPP) for research that requires a waiver of informed consent pursuant to Paragraph (b) of Section 980 of Title 10, U.S.C.

☐ If consent is obtained from the experimental subjects legal representative (for adults with impaired decision-making capacity), the intention of the research must be to be beneficial to the subject[xi] .

☐ Military and civilian supervisors, officers, and others in the chain of command will not influence the decisions of their subordinates regarding participation in research.[xii]

☐ Military and civilian supervisors, officers, and others in the chain of command will not be present at any recruitment sessions or during the consent process for any DoD-affiliated personnel.

☐ When a subject is a Service member, all Research Component, and/or National Guard members in a federal duty status are considered to be adults. If a Service Member, Research Component, or Guard member in

federal duty status, student at a Service Academy, or trainee is under 18 years of age, the recruitment process and the necessity of including such member as a human subject is considered during IRB review.

☐ The disclosure regarding provisions for research-related injury follows the requirements of the DOD component.

☐ When conducting multi-site research a formal agreement is required to specify the roles and responsibilities of each party including a Statement of Work (SOW) and specific assignment of responsibilities.

☐ Research involving fetal tissue must comply with the US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g.[xiii]

- Research or experimentation may not be conducted, in the United States or in any other country, on a nonviable living human fetus ex utero or a living human fetus ex utero for whom viability has not been ascertained unless the research or experimentation:
  - o May enhance the well-being or meet the health needs of the fetus or enhance the probability of its survival to viability; or
  - o Will pose no added risk of suffering, injury, or death to the fetus and the purpose of the research or experimentation is the development of important biomedical knowledge which cannot be obtained by other means.
- The risk standard must be the same for fetuses which are intended to be aborted and fetuses which are intended to be carried to term.

☐ If the research would not otherwise be approved but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates, written approval from the DOHRP must be obtained through the COHRP prior to research starting.

☐ If the research involves emergency medicine research, the DOHRP, on behalf of the Secretary of Defense, must approve a waiver of the advance informed consent in accordance with provision 10 USC 980.

☐ If the research involves Human Subjects who are not U.S. citizens or personnel of the DOD, and is conducted outside the United States, its territories, and its possessions: **(Check if "Yes" or "NA". All must be checked.)**

- ☐ Applicable national laws and requirements of the foreign country will be followed.
- ☐ When a DoD-affiliated person who is also a citizen of the host nation is a research subject, where differences in applicable standards exist between the United States and the host nation, the standard that is most protective of human subjects will be applied.
- ☐ Take into consideration the cultural sensitivities in the setting where the research will take place [xiv].

☐ For research that is conducted in a foreign country, unless it is conducted by a DOD overseas institution, or involves subjects who are DOD-affiliated personnel that are U.S. citizens, the key investigator must receive approval from the DOD-affiliated personnel's command or DOD Component Human Research Protection Program (HRPP) to conduct the research.

☐ When Broad Consent is used, DOHRP notification is required.

☐ Refer to HRP-833 - PI WORKSHEET - Considerations for Serving as the Reviewing IRB for considerations when serving as the sIRB for a DOD institution.

10. Additional Criteria for Department of Defense (DOD) Research Involving Classified Information [xv] (Check if "Yes" or "NA". All must be checked)

☐ The convened IRB approved the research.

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☐ Approval from the DOD-affiliated personnel's command or DOD Component Human Research Protection Program (HRPP) and DOHRP approval will be obtained.[xvi]

☐ No DoD agency within the Intelligence Community may sponsor, contract for, or conduct non-exempt HSR except in accordance with Paragraph 2.10 of Executive Order 12333 and DoD 5240.01.

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[i] The verbatim VA PREP Act consent form language can be found in the Veterans Health Administration (VHA) Office of Research and Development (ORD) Guidance: Implementation of the Public Readiness and Emergency Preparedness Act (PREP Act) for COVID-19 Research Activities).

[ii] VHA Directive 1200.05(2) section 16.a.(9) and VHA Directive 1058.03

[iii] https://nij.ojp.gov/sites/g/files/xyckuh171/files/media/document/NIJ_pccr_fillable.pdf

[iv] Prior consent means prior consent of the student, if the student is an adult or emancipated minor; or prior written consent of the parent or guardian, if the student is an un-emancipated minor. Schools and contractors obtain prior written parental consent before minor students are required to participate in any survey, analysis, or evaluation funded by the Department of Education.

[v] DoD Instruction (DoDI) 3216.02 "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and -Supported Research

[vi] The IRB may rely on outside experts to provide an evaluation of the scientific merit.

[vii] This includes any person captured, detained, held, or otherwise under the control of DOD personnel (military, civilian, or contractor employee). Such persons include: Enemy Combatant, Lawful Enemy Combatant, Unlawful Enemy Combatant, Enemy Prisoner of War, Retained Person, and Civilian Internee. Such persons do not include personnel of the DOD being held for law enforcement purposes. It does not include persons being held primarily for law enforcement purposes, except where the United States is the occupying power. This prohibition does not apply to activities covered by investigational new drug or investigational device provisions when the purpose is for diagnosis or treatment of a medical condition in a patient. Such treatment (e.g., an investigational new drug) may be offered to detainees or prisoners of war with their informed consent when the medical products are subject to FDA regulations investigational new drugs or investigational medical devices, and only when the same product may be available to DOD-affiliated personnel consistent with established medical practice.

[viii] Although federal personnel participating as human subjects in DOD-conducted research while on duty may be compensated up to $50 for each blood draw for scientific and research purposes in connection with the care of any person entitled to treatment at government expense, this IRB allows no such compensation when compensation is otherwise prohibited. Federal employees while on duty and non-Federal persons may be compensated for blood draws for research up to $50 for each blood draw. Non-Federal persons may be compensated for research participating other than blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research.

[ix] A person who acts as an impartial and objective advocate for human subjects participating in research.

[x] Section 980 of Title 10, U.S.C. applies to research financed by DOD appropriated funds. The requirement for consent may be waived by the DOHRP if the following three conditions are met: (1) The research is necessary to advance the development of a medical product for the Military Services. (2) The research may directly benefit the individual experimental subject. (3) The research is conducted in compliance with all other applicable laws and regulations. Research involving a human being as an experimental subject is an activity, for research purposes, where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction. Research involving a human being as an experimental subject is a subset of research involving human subjects. This definition does not include exempt research involving human subjects.

[xi] Section 980 of Title 10, U.S.C.

[xii] If applicable, excluded superiors or those in the chain of command may participate in separate human subjects research recruitment sessions.

[xiii] See: http://codes.lp.findlaw.com/uscode/42/6A/III/H/289g (This is the enabling statute for 45 CFR 46.205. Compliance with Subpart B complies with this statute.) See also: http://codes.lp.findlaw.com/uscode/42/6A/III/H/289g-1, and http://codes.lp.findlaw.com/uscode/42/6A/III/H/289g-2

[xiv] SECNAVINST 3900.39E 29 MAY 2018, Section 3.d.

[xv] DOD-supported research is considered classified when:

- Classified information is required for IRB review and oversight of the research.
- Classified information must be provided to human subjects, or their guardians, during the HSR recruitment or informed consent process in order to achieve fully effective legal consent.
- Classified information is provided to, or by, research subjects.

DOD-conducted or -supported research is not considered classified when:

- The research is a part of a classified program, but the research itself is not classified; if the information required in the research protocol is not classified; if the information needed by the IRB is not classified; or if the information required by the human subject is not classified. For the purposes of the annual report for classified research, unclassified HSR that falls into the criteria listed in this paragraph should be included in the report.

- Research that requires subjects to hold a clearance as a means of creating ease of entry or access to controlled spaces where the research will occur does not constitute classified HSR unless one of the conditions described in Sections 3.13.b.(1) or (3) also exist.
- If the research constitutes an authorized operation activity, then it is not HSR.

[xvi] The DOHRP is the final approval authority for all DoD-conducted or DoD-supported classified HSR. The SDO prospectively conducting or supporting the HSR must submit a package to the DOHRP for approval to conduct the classified HSR.

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WORKSHEET: Limited IRB Review

The purpose of this worksheet is to provide support for IRB members performing limited IRB reviews[i]. It does not need to be completed or retained.

Method for limited IRB review: (check one)

☐ Limited IRB review, for research as a condition of exemption, conducted via expedited review[ii]

☐ Limited IRB review, for research as a condition of exemption, performed by the convened IRB.

1. The research falls into one the following exempt categories: (One or more categories must be checked)

☐ Category 2 (iii): Research that only includes Interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) where the information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects can readily be ascertained, directly or through identifiers linked to the subjects. The following must be true[iii]: (**Check if "Yes"**)

- ☐ There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

☐ Category 3 (i)(C): Research involving benign behavioral Interventions[iv] in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the Intervention and information collection and the information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects can readily be ascertained, directly or through identifiers linked to the subjects. The following must be true [v] [vi]:**(Check if "Yes")**

- ☐ There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

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[i] For VA Research,
- If an exempt activity requires a limited IRB review, the limited IRB review must be completed prior to approval by the R&D Committee.
- Research that has undergone limited IRB review and determined to be exempt requires approval by the R&D Committee and requires continuing review by the R&D Committee unless it is under the oversight of another subcommittee (e.g., Safety Review Subcommittee).

[ii] 45 CFR §46.110(b)(1)
[iii] 45 CFR §46.111(a)(7)
[iv] For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.
[v] 45 CFR §46.111(a)(7)

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[vi] If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

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WORKSHEET: Scientific or Scholarly Review

The purpose of this worksheet is to provide support for individuals responsible for the scientific review of research. Use this worksheet to determine whether the research has scientific or scholarly validity. Consultants providing scientific or scholarly review are to complete this worksheet and provide it to IRB staff who will retain it in the files.

1. Overall Scientific and Scholarly Validity (Check if **"Yes"**. All must be checked)

☐ The protocol accurately describes the research in a clear, detailed protocol in terms of:

- Objectives
- Background
- Setting
- Procedures
- Data and safety monitoring plan
- Risks
- Potential benefits
- Alternatives to participation

☐ There is no other way to do this research that would reduce risks to subjects and still answer the scientific question.

☐ There are no other monitoring procedures needed that would reduce risks to subjects and not affect the science.

☐ The research is likely to answer its proposed question.

☐ The protocol fairly portrays the knowledge expected to result.

2. Clinical Trials (Check if "**Yes**" or "**NA**". All must be checked if the research is a Clinical Trial.)

☐ The available nonclinical and clinical information on an investigational product is adequate to support the Clinical Trial.

☐ The investigator has demonstrated (e.g., based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period.

☐ The investigator has sufficient time to properly conduct and complete the trial within the agreed trial period.

☐ The investigator has available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely.

☐ The investigator will ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions.

☐ A qualified physician or, where appropriate, a qualified dentist (or other qualified healthcare professionals in accordance with local regulatory requirements) who is an investigator or a sub-investigator for the trial will have the overall responsibility for trial-related medical care and decisions.

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WORKSHEET: Review of Information Items

The purpose of this worksheet is to provide support for the convened IRB* reviewing Serious Non-Compliance, Continuing Non-Compliance, Unanticipated Problem Involving Risks to Subjects or Others, Participant Complaint, Suspension of IRB Approval, and Termination of IRB Approval.

*IRB Coordinator must present information to an IRB Chair, IRB Vice Chair, HRP Leadership or Designee prior to IRB review. This worksheet is uploaded in ZOT IRB.

1. SUBMISSION INFORMATION

1.1 Basic Information:

1.1.1 IRB Study Number[1]: Click or tap here to enter text.
1.1.2 Short Title: Click or tap here to enter text.

2. Pre-Review Comments (Check if "Yes" and specify; information is not ready for preliminary IRB Subcommittee review. If all are "No" information is ready for preliminary IRB Subcommittee review.)

☐ More information is needed before a preliminary determination can be made (*e.g.: If HIPAA required but wasn't obtained, has it since been obtained by the study team?*). Review HRP-025 if an "investigation" is needed.

☐ Referral is needed before IRB review (e.g., *CPO re significance of HIPAA breach, coverage analysis re cost language, subject matter expertise to determine risk, etc.).*

Click or tap here to enter text.

3. Preliminary Assessment of Event (Check if "Possible" or "Yes" to event type and provide rationale; convened IRB review is required alert Compliance Manger. If all are "No" information can be acknowledged IRB Subcommittee review.)

☐ Serious Non-Compliance ('noncompliance' and at least one 'serious' are checked)

- ☐ Noncompliance: The event, information or timing of the report is a failure to comply with law, regulations and/ or IRB determinations.
- ☐ Serious: The non-compliance has an impact on rights, safety or welfare of subjects.
- ☐ Serious: The non-compliance places subjects at increased risk of harm; affects willingness to participate.
- ☐ Serious: The non-compliance has a significant adverse impact on the integrity of the data.

[1] The IRB study number is generated when the submission is created in ZOT IRB. Please enter the number prior to final submission to the IRB.

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Click or tap here to enter text.

☐ Continuing Non-Compliance ('noncompliance' and at least one 'continuing' are checked)

- ☐ Noncompliance: The event, information or timing of the report is a failure to comply with law, regulations and/ or IRB determinations.
- ☐ Continuing: There is a pattern that suggests unwillingness to comply.
- ☐ Continuing: There is a pattern that suggests inability to comply.

Click or tap here to enter text.

☐ Unanticipated Problem Involving Risks to Subjects or Others (all are checked)

- ☐ The new information is unexpected given protocol documents and the subject population being studied,
- ☐ The new information is related or possibly related to participation in the research, **and**
- ☐ The new information suggests that the research places subjects or others at a greater risk of (any type of harm) previously known or recognized.

Click or tap here to enter text.

☐ Additional information needed before the convened IRB meeting.

Click or tap here to enter text.

4. Corrective and Preventative Action (CAPA) Plan to Protect Human Subjects (Check as appropriate and specify.)

☐ Interim measures needed to immediately protect human subjects or the integrity of the data before the convened IRB meeting.

☐ Make arrangements for clinical care outside the research.

☐ Require follow-up of subjects for safety reasons.

☐ Allow continuation of some research activities under the supervision of an independent monitor.

☐ Modify the protocol.

☐ Subject notification required (select all that apply)

- ☐ Modify the information disclosed during the consent process.
- ☐ Have current subjects to re-consent.
- ☐ Provide additional information to current subjects (whenever the information may relate to the subject's willingness to continue).
  1. Specify how current subjects should be notified (e.g., letter, re-consent).

2. Specify if UC Irvine Legal should review notification letter or consent.
3. If any of the above answers are unclear, specify what information is needed to decide

☐ Provide additional information to past subjects.

1. Specify how current subjects should be notified (e.g., letter, re-consent).
2. Specify if UC Irvine Legal should review notification letter or consent.
3. If any of the above answers are unclear, specify what information is needed to decide

☐ Increase the frequency of continuing review.

☐ Observe the research and/or ☐ Observe the consent process.

☐ Require additional training of the investigator.

☐ Require adverse events or outcomes to be reported to the IRB and the sponsor.

☐ Notify UCI Research Partners. ☐ Notify investigators at other sites.

1. Specify who should be immediately notified and why (i.e., breach of protected health information (PHI) requires prompt notification to UC Irvine Health Compliance and Privacy (CPO)).

☐ Consider whether changes without prior IRB review and approval were consistent with ensuring the subject's continued welfare.

☐ Transfer subjects to another investigator.

☐ Suspend IRB approval: An action of the IRB, IRB designee, Institutional Official/Organizational Official, or designee of the Institutional Official/Organizational Official to temporarily or permanently withdraw IRB approval of some or all research procedures short of a Termination of IRB Approval. Suspended studies remain open and are subject to continuing review. Suspension may be granted outside of Committee when in the opinion of the IRB chair subjects may be at risk of adverse effects on their rights and welfare before action may be considered by the convened IRB. Refer to and follow procedures in HRP-026.

1. Specify why suspension is necessary to protect human subjects.
2. Specify which parts of the study should be suspended (e.g., new enrollment, ongoing study procedures, etc.).
3. Specify when allowances be made for current subjects.
4. If any of the above answers are unclear, specify what information is needed to decide.

☐ Lift prior suspension of IRB approval.

☐ Terminate IRB approval: An action of the IRB, IRB designee, Institutional Official/Organizational Official, or designee of the Institutional Official/Organizational Official to permanently withdraw IRB approval of all research procedures. Terminated studies are permanently closed and no longer require continuing review. Refer to and follow procedures in HRP-026.

1. Specify why termination is necessary to protect human subjects.
2. If the above answer is unclear, specify what information is needed to decide.

☐ Other

Click or tap here to enter text.

5. Convened IRB Review

Assessment of Event (see #2 above)

☐ Agree with preliminary assessment.

☐ Do **not** agree with preliminary assessment (#2 above); provide rationale

☐ Deferred: Additional information needed before the next convened IRB meeting; specify.

Click or tap here to enter text.

CAPA (see #3 above)

☐ Take no further action because the CAPA already taken are sufficient.

☐ CAPA is **not** sufficient; specify revisions.

Click or tap here to enter text.

Resolution

☐ Event resolved

☐ Event **not** resolved; specify.

Click or tap here to enter text.

PI WORKSHEET: Emergency Use

The purpose of this worksheet is to provide support for investigators conducting an emergency use of unapproved drug, biologic, or device in a life-threatening situation, and to provide support Designated Reviewers reviewing such uses. For more information, visit: Expanded Access to Unapproved Drugs or Biologics or Expanded Access to Unapproved Devices.

Attach this worksheet and other supplemental documentation to a Reportable New Information (RNI) submission in ZOT IRB. Do not submit an IRB application.

1. SUBMISSION INFORMATION

1.1 Basic Information:
1.1.1 IRB Study Number[1]: Click or tap here to enter text.
1.1.2 Short Title: Click or tap here to enter text.

2. RESEARCH MUST MEET ONE OF THE FOLLOWING SETS OF CRITERIA (COMPLETE 2.1 OR 2.2.)

2.1 Emergency Use of an Unapproved Drug or Biologic[i]

2.1.1 Emergency Use Criteria: (Check if "Yes". All must be checked.)
☐ The patient is (was) confronted by a disease or condition that is (was) either:
- ☐ Life-threatening (diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival). The criteria for life-threatening do not require the condition to be immediately life-threatening or to immediately result in death. Rather, the subjects must be in a life-threatening situation requiring intervention before review at a convened meeting of the IRB is feasible.

- ☐ Severely debilitating (diseases or conditions that cause major irreversible morbidity). Examples of severely debilitating conditions include blindness, loss of arm, leg, hand or foot, loss of hearing, paralysis or stroke.

Provide specific findings justifying this determination. Click or tap here to enter text.

☐ The situation necessitates (necessitated) the use of the investigational drug or biologic.
- ☐ This is the first emergency use of this test article at UCI. See list of prior Emergency Uses. Subsequent use of test article in the same or different patient requires a new IRB application for Committee review.[2]

[1] The IRB study number is generated when the submission is created in ZOT IRB. Please enter the number prior to final submission to the IRB.
[2] FDA regulations require that any subsequent use of the investigational product at the institution have prospective IRB review and approval. However, in guidance documents, FDA acknowledges that it would be inappropriate to deny emergency treatment to a

Provide specific findings justifying this determination. Click or tap here to enter text.

☐ No generally acceptable alternative for treating the patient is (was) available.
- ☐ The patient does not meet the criteria of an existing study protocol, or an IRB approved protocol does not exist.

Provide specific findings justifying this determination. Click or tap here to enter text.

☐ There is (was) insufficient time to obtain IRB approval. Specify the date the test article will be (was) administered.

Provide specific findings justifying this determination. Click or tap here to enter text.

☐ The treating physician will document (has documented) in the medical record that the above findings were met, when necessary.

☐ The treating physician will report (has reported) the use to the IRB within 5 working days with documentation that the above findings were met.

☐ The FDA has (had) issued an IND or ☐ will authorize (has authorized) shipment of the test article in advance of the IND submission. Attach supporting documentation.

☐ The use is (was) **NOT** subject to DHHS regulation See HRP-310 - WORKSHEET - Human Research Determination. Any data generated may not be claimed as research. The outcome of this emergency use may not be included in any report of research activity, except possibly for case reports.

2.1.2 Consent Process: (Check the option that applies.)

☐ **Consent Obtained:** Informed consent will be (was) sought from the patient or the patient's Legally Authorized Representative (LAR), in accordance with and to the extent required by 21 CFR §50. See HRP-314 - WORKSHEET - Criteria for Approval.
- ☐ Informed consent will be (was) documented using HRP-506 - CONSENT - Expanded Access in accordance with and to the extent required by 21 CFR §50.27. See HRP-314 - WORKSHEET - Criteria for Approval.
- ☐ The patient's signed HIPAA Research Authorization will be (was) obtained.
- ☐ If this study includes a non-English-speaking patient, the English version of the consent/HIPAA materials will be (was) translated for non-English speaking participant or their LAR.

☐ **Exception of Consent:** (Check if "Yes". All must be checked.)
- ☐ The patient is (was) confronted by a life-threatening situation necessitating the use of the test article.
- ☐ Informed consent cannot (could not) be obtained from the patient because of an inability to communicate with, or obtain legally effective consent from, the patient.

Provide specific findings justifying this determination. Click or tap here to enter text.

- ☐ Time is (was) insufficient to obtain consent from the patient's LAR.

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second individual if the only obstacle is that the IRB has not had sufficient time to convene a meeting to review the protocol.

Provide specific findings justifying this determination. Click or tap here to enter text.

☐ There is (was) no available alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the patient.

Provide specific findings justifying this determination. Click or tap here to enter text.

☐ The treating physician will document (has documented) in the medical record that the above findings were met, when necessary.

☐ The treating physician will report (has reported) the use to the IRB within 5 working days with documentation that the above findings were met.

☐ A physician uninvolved in the clinical Investigation (i.e., independent physician) will certify (has certified) in the medical record that the above findings were met.

☐ Review and sign the Physician Attestation - Emergency Use of an Unapproved Drug or Biologic. See section 6 of the form.

☐ If certification took place after the use of the drug or biologic, all of the following are true: ("NA" if certification took place before the use.)

☐ N/A

☐ Immediate use of the test article is (was), in the investigator's opinion, required to preserve the life of the patient.

Provide specific findings justifying this determination. Click or tap here to enter text.

☐ Time is (was) insufficient time to obtain the independent determination a physician uninvolved in the clinical Investigation.

Provide specific findings justifying this determination. Click or tap here to enter text.

☐ The treating physician will document (has documented) in the medical record that the above findings were met.

☐ The treating physician' report to the IRB within 5 working days will document that the above findings were met.

2.2 Emergency Use of an Unapproved Device[ii]

2.2.1 Emergency Use Criteria: (Check if "Yes" or "N/A". All must be checked.)

☐ The patient is (was) confronted by a life-threatening disease or a serious condition requiring immediate use of the device.

Provide specific findings justifying this determination. Click or tap here to enter text.

☐ The situation necessitates (necessitated) the immediate use of the device.

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☐ This is the first emergency use of this test article at UCI. See list of prior Emergency Uses. Subsequent use of test article in the same or different patient requires a new IRB application for Committee review.

Provide specific findings justifying this determination. Click or tap here to enter text.

☐ No generally acceptable alternative for treating the patient is (was) available.
- ☐ The patient does not meet the criteria of an existing study protocol, or an IRB approved protocol does not exist.

Provide specific findings justifying this determination. Click or tap here to enter text.

☐ There is (was) insufficient time to use existing procedures to obtain FDA approval of an IDE. Specify the date the test article will be (was) administered.

Provide specific findings justifying this determination. Click or tap here to enter text.

☐ There is (was) substantial reason to believe that benefits will (would) exist.

Provide specific findings justifying this determination. Click or tap here to enter text.

☐ The treating physician will document (has documented) in the medical record that the above findings were met, when necessary.
☐ The treating physician will report (has reported) the use to the IRB within 5 working days with documentation that the above findings were met.
☐ A physician uninvolved in the emergency use will certify (has certified) in the medical record that the above findings were met.
☐ One of the following is true:
- ☐ There is (was) no IDE.
- ☐ The treating physician wants (wanted) to use the device in a way not approved under an existing IDE.
- ☐ The treating physician is (was) not part of the IDE study.

☐ One of the following is true:
- ☐ There is an IDE and the treating physician has (had) authorization from the sponsor.
- ☐ There is no IDE and the treating physician will notify (has notified) FDA of the emergency use within 5 working days. This include a description of device used, details of the case, and the patient protection measures that were followed. Send to:

Food and Drug Administration
Center for Devices and Radiological Health
10903 New Hampshire Ave
Document Control Center
WO66 Rm G-609
Silver Spring, MD 20993

☐ The treating physician will follow (has followed) the procedures below if time permits (check all that apply):
- ☐ Concurrence of the IRB Chair.
- ☐ Informed consent from the patient or LAR (use HRP-506 - TEMPLATE CONSENT DOCUMENT - Expanded Access).
- ☐ The patient's signed HIPAA Research Authorization will be (was) obtained.
- ☐ If this study includes a non-English-speaking patient, the English version of the consent materials will be (was) translated for non-English speaking participant or their LAR.

☐ The use is (was) **NOT** subject to DHHS regulation See (HRP-310 - WORKSHEET - Human Research Determination. Any data generated may not be claimed as research. The outcome of this emergency use may not be included in any report of research activity, except possibly for case reports.

3. FINANCIAL CONSIDERATIONS FOR PATIENTS

3.1 Patient Cost: If the patient will pay for the emergency use treatment, provide specific details.

Click or tap here to enter text.

4. TREATMENT PLAN

4.1 Treatment Plan: Specify the treatment plan including the dosage (as applicable) and duration of treatment. Do not include patient identifiable data nor protective health information (PHI).

☐ ***This is included in a separate treatment plan attached.***

Click or tap here to enter text.

5. COMPLETE REPORT

5.1 Complete Report: If complete information is not available at the time of submission, provide a report to the IRB within 5 working days of the administration of treatment.

☐ ***This is included in a separate report attached or*** ☐ ***will be included in a subsequent Reportable New Information submission.***

Click or tap here to enter text.

6. PHYSICIAN ATTESTATION – EMERGENCY USE OF AN UNAPPROVED DRUG, BIOLOGIC OR DEVICE

☐ ***This section is not applicable.***

6.1 Physician Attestation: Complete this section to address the documentation requirements. Confirm the following information and provide both signatures below.

As the treating physician or the physician uninvolved in the clinical investigation (i.e., independent physician), I have:

1. Confirmed that the patient is confronted with a life-threatening situation necessitating the use of the test article; and

2. Confirmed that informed consent cannot be obtained from the patient because of an inability to communicate with, or obtain legally effective consent from the patient; and

3. Confirmed that time is not sufficient to obtain consent from the patient's legal representative; and

4. Confirmed/ agree that there is no available alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the patient.

_____

Name of Treating Physician

_____ _____

Signature of Treating Physician **Date**

_____

Name of Independent Physician

_____ _____

Signature of Independent Physician **Date**

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[i] Emergency use of an unapproved drug or biologic is a clinical investigation and must comply with 21 CFR §50 and 21 CFR §56, 102(d) and 104(c).

[ii] FDA does not consider the emergency use of an unapproved device to be clinical investigation and FDA does not require compliance with 21 CFR §50 and 21 CFR §56. The requirements are based on FDA guidance at http://www.fda.gov/downloads/Training/CDRHLearn/UCM180888.pdf, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051345.htm#compassionateuse, and http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf.

PI WORKSHEET: Humanitarian Use Device (HUD)

The purpose of this worksheet is to provide support for the convened IRB when evaluating an initial application to use a Humanitarian Use Device (HUD), and for Designated Reviewers when evaluating a continuing review submission. For more information, visit: Humanitarian Use Devices.

Answer all questions succinctly using non-technical language as much as possible.

- If a question is not applicable to the research, state "N/A".
- If a question is not answered, EQUIP does not know if the question was overlooked. This will result in unnecessary "back and forth" for clarification.

Attach this protocol to the "Basic Study Information" section of the ZOT IRB application. Other supplemental documentation (i.e. consent, recruitment, other) can be attached in "Local Site Documents".

1. SUBMISSION INFORMATION

1.1 Basic Information:

1.1.1 IRB Study Number[1]: Click or tap here to enter text.

1.1.2 Short Title: Click or tap here to enter text.

2. HUD INFORMATION

2.1 HUD Use: (Check if "Yes". All must be checked.)

☐ The FDA has issued an approved Humanitarian Device Exemption (HDE) for this device. Attach supporting documentation.

☐ The HUD is **not** being used to evaluate its safety and effectiveness. (If the HUD is being used to evaluate its safety and effectiveness HRP-314 - WORKSHEET - Criteria for Approval applies.)

2.2 Research Use: Is there an intention of doing research?

☐ Yes. The use of the HUD is outside the indications in the Humanitarian Device Exemption (HDE). An Investigational Device Exemption (IDE) will be obtained from the Food and Drug Administration (FDA). Complete Section 5. Data and Safety Monitoring.

☐ No. The use of the HUD is within the indications of the HDE.

2.3 Proposed Use:

2.3.1 Describe the proposed use of this device (on label or off label use) including the screening procedures and HUD procedures. Do not include patient identifiable data. Do not include protective health information (PHI).

2.3.2 Describe any follow-up visits, tests, or procedures.

Click or tap here to enter text.

[1] The IRB study number is generated when the submission is created in ZOT IRB. Please enter the number prior to final submission to the IRB.

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2.4 Safety and Benefits: Attach the HUD brochure and provide a summary of safety and benefits. This includes:

2.4.1 Generic and trade name of device;
2.4.2 FDA HDE number;
2.4.3 Date of HUD designation;
2.4.4 Indications for use of the device;
2.4.5 Description of the device;
2.4.6 Contradictions, warning, and precautions for use of the device;
2.4.7 Adverse effects of the device on health;
2.4.8 Alternative procedures;
2.4.9 Marketing history;
2.4.10 Summary of studies using the device.

Click or tap here to enter text.

2.5 Number of Participants Consented: Provide the max number of individuals consented for treatment. If applicable, include screen failures and withdrawals.

Click or tap here to enter text.

2.6 Patient Cost: If the patient will pay for the HUD treatment, provide specific details.

Click or tap here to enter text.

3. CRITERIA FOR APPROVAL OF HUD (Check if "yes". All must be checked.)

☐ Risks to patients are minimized by using procedures, which do not unnecessarily expose patients to risk.

Provide specific findings justifying this determination. Click or tap here to enter text.

☐ Risks to patients are reasonable in relation to the proposed use of the device.

Provide specific findings justifying this determination. Click or tap here to enter text.

☐ There are adequate provisions to protect the privacy of patients.

Provide specific findings justifying this determination. Click or tap here to enter text.

☐ There are adequate provisions to maintain the confidentiality of patient data.

Provide specific findings justifying this determination. Click or tap here to enter text.

☐ The proposed use of the HUD is within the scope of the indication approved in the HDE. Attach supporting documentation of the approved indication.
☐ The institution has approved the use of the HUD as a clinical service.

4. CONSENT PROCESS (Check if "Yes". All must be checked.)

☐ The HUD labeling states that the device is a humanitarian use device and that, although the device is authorized by Federal Law, the effectiveness of the device for the specific indication has not been demonstrated.
☐ Although not required, per standard practice at UCI, written consent will be sought from the patient or their Legally Authorized Representative (LAR).
☐ Informed consent will be documented using HRP-499 – CONSENT – Humanitarian Use Device. Attach the consent form.
☐ Patients or their LAR will be informed of the patient labeling provided by the manufacturer.
☐ Patients or their LAR will be given sufficient opportunity to consider whether or not to receive/use the HUD; or when HUD is used in emergent situations, patients or their LAR will be given information about the HUD after its use/receipt.

Provide specific findings justifying this determination. Click or tap here to enter text.

☐ HIPAA Research Authorization is not required unless the IRB has access to PHI (unusual).
☐ The California Bill of Rights is not required.
☐ Information regarding the HUD will be communicated in language understandable to the patient.
☐ The English version of the consent materials will be translated for non-English speaking participants or their LAR once IRB approval is granted.

5. DATA SAFETY MONITORING

5.1 Data Safety Monitoring Plan: UCI IRB requires that all clinical investigations involving greater than minimal risk to subjects develop a data and safety monitoring plan to assure the safety and welfare of the research subject/patient**.**

5.1.1 Provide details of those individuals who will be responsible for the safety oversight of the protocol, including the relevant experience/expertise of everyone (for UCI PI-initiated studies conducted only at UCI, provide the names and titles as well).
5.1.2 List who will be *locally* monitoring and collecting information on adverse events and/or unanticipated problems (e.g., UCI PI, Research Coordinator, etc.). Include the name, title and experience of the individual(s) and further describe each individual's role in the oversight of participant participating in the protocol.
5.1.3 Specify how frequently accumulated protocol information will be reviewed and evaluated for participant safety, protocol conduct and progress, and, when appropriate, efficacy.
5.1.4 Describe the events that would trigger an unscheduled review. Include stopping rules, rules for withdrawing participants, and un-blinding rules as appropriate.
5.1.5 Describe the plan for annual reporting of the participants' safety, and the protocol's conduct, progress, and efficacy, when appropriate.

Click or tap here to enter text.

5.2 Data Safety Monitoring Board (DSMB): For clinical protocols involving a test article, it is common to have an *independent* Data Safety Monitoring Board (DSMB). Specify whether the following requisite documentation is available and attach to ZOT IRB.

☐ Not applicable, this study does not have an independent DSMB
☐ Signed DSMB recommendation forms available
☐ The finalized DSMB charter available
☐ The finalized DSMB charter will be submitted before enrollment begins

6. [IRB STAFF TO CONFIRM] GENERAL CONSIDERATIONS (Check all that apply.)

☐ The convened IRB (or Designated Reviewer) has adequate expertise to review this HUD application. (If "No", obtain consultation.)
☐ Materials are complete. (If "No," the HUD application cannot be approved.)
☐ For Initial Review: Should there be any limitations on the use of the HUD? (e.g., Limitations based on one or more measures of disease progression, prior to use and failure of any alternative treatment modalities, reporting requirements to the IRB or IRB chair, or appropriate follow-up precautions and evaluations.)
☐ For Continuing Review and Modifications: Is there information that needs to be provided to current patients because it may affect their willingness to receive/use the HUD?
☐ For Continuing Review: If the Committee agrees, the renewal may be reviewed by a Non-Committee as Expedited Category 9.

PI WORKSHEET: Expanded Access

The purpose of this worksheet is to provide support for investigators conducting non-emergency individual patient/small group expanded access for an unapproved drug or medical device (commonly known as Compassionate Use) and to provide support Designated Reviewers reviewing such uses. For more information, visit: Expanded Access to Unapproved Drugs or Biologics or Expanded Access to Unapproved Devices.

Answer all questions succinctly using non-technical language as much as possible.

- If a question is not applicable to the research, state "N/A".
- If a question is not answered, EQUIP does not know if the question was overlooked. This will result in unnecessary "back and forth" for clarification.

Attach this protocol to the "Basic Study Information" section of the ZOT IRB application. Other supplemental documentation (i.e. consent, other) can be attached in "Local Site Documents".

1. SUBMISSION INFORMATION

1.1 Basic Information:

1.1.1 IRB Study Number[1]: Click or tap here to enter text.
1.1.2 Short Title: Click or tap here to enter text.

2. RESEARCH MUST MEET ONE OF THE FOLLOWING SETS OF CRITERIA (Complete 2.1, 2.2, or 2.3.)

2.1. Individual Patient use of an Investigational New Drug (IND)

2.1.1 Form 3926: Attach completed FDA Form 3926.
☐ Check here if Form 3926 allows for alternative IRB review procedures (item 10.b on the form).

2.1.2 Medical Condition: Provide a thorough patient history that includes the following information. (Do not include patient identifiable data or protective health information).

2.1.2.1 Diagnosis and summary of prior therapy (including response to such therapy).
2.1.2.2 Reason for request, including an explanation of why the patient lacks other therapeutic options.
  2.1.2.2.1 Explain why the use of the test article is required.
  2.1.2.2.2 Describe why other Food and Drug Administration (FDA) approved treatment options or standard of care options are not viable.
2.1.2.3 Information regarding a patient's relevant clinical characteristics (such as comorbid conditions and concomitant medications) that is necessary to assess the potential for increased risks of the drug.

☐ ***This is included in a separate document attached.***

Click or tap here to enter text.

[1] The IRB study number is generated when the submission is created in ZOT IRB. Please enter the number prior to final submission to the IRB.

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2.1.3 Treatment Plan: Provide a thorough treatment plan that includes the following information.
2.1.3.1 Proposed daily dose, route, and frequency of administration of planned treatment.
2.1.3.2 Duration of planned treatment.
2.1.3.3 Criteria for discontinuation of treatment.
2.1.3.4 Planned dose modifications for adverse event.

☐ ***This is included in a separate treatment plan attached.***

Click or tap here to enter text.

2.1.4 Drug Risks: Provide a summary of known risks of the drug.

☐ ***This is included in a separate treatment plan attached.***

Click or tap here to enter text.

2.1.5 Safety, Monitoring, and Data: Provide a safety and monitoring plan that includes the following information.
2.1.5.1 Describe planned monitoring for adverse events, response to treatment, and changes in clinical status.
2.1.5.2 Describe proposed modifications to the treatment plan to mitigate risks to the patient if appropriate.

Click or tap here to enter text.

2.2 Compassionate Use of an Unapproved Device[i]

2.2.1 Criteria for Compassionate Use of an Unapproved Device (Check if "Yes." All must be checked.)
☐ The patient is confronted by a serious disease or condition. Explain and include any other relevant details of the case. Do not include patient identifiable data or protective health information (PHI).

Provide specific findings justifying this determination. Click or tap here to enter text.

☐ No generally acceptable alternative for treating, diagnosing, or monitoring the patient is (was) available.

Provide specific findings justifying this determination. Click or tap here to enter text.

☐ The probable risk to the patient is not greater than the probable risk from the disease.

Provide specific findings justifying this determination. Click or tap here to enter text.

☐ The patient does not meet the inclusion criteria for an IDE study.

Provide specific findings justifying this determination. Click or tap here to enter text.

☐ The treating physician will document in the medical record that the above findings were met.
☐ The treating physician has/will obtain approval from FDA for the use. Attach the FDA authorization.
☐ If an IDE exists for the device, the sponsor has authorized its use. Attach supporting documentation.

☐ An independent assessment from an uninvolved physician will be included in the submission to FDA.
☐ All institutional clearances have been obtained.
☐ [IRB staff to confirm] Concurrence of an IRB Chair has been (will be) obtained. (Non-Committee review is acceptable.)
☐ The treating physician will report any problems as a result of the device use to the IRB and sponsor.
☐ The treating physician will provide follow-up information (if applicable) of the use and give it to the sponsor, the FDA and the IRB. Report to the IRB via a Reportable New Information submission.
☐ The use is **NOT** research subject to DHHS regulation See HRP-310 - WORKSHEET - Human Research Determination. Any data generated may not be claimed as research. The outcome of this emergency use may not be included in any report of research activity, except possibly for case reports.

2.2.2 Treatment Plan: Specify the treatment plan including the duration of treatment. Attach the device/product manual and any other relevant information (i.e. patient-facing materials, etc.).

☐ ***This is included in a separate treatment plan attached.***

Click or tap here to enter text.

2.3 More than One Patient IND or More than One Patient IDE

2.3.1 Medical Condition:
2.3.1.1 Describe the medical condition and explain why the use of the test article is required.
2.3.1.2 Describe why other Food and Drug Administration (FDA) approved treatment options or standard of care options are not viable.

Click or tap here to enter text.

2.3.2 Eligibility Criteria:
2.3.2.1 Specify the inclusion/exclusions criteria.
2.3.2.2 Provide a breakdown per subject cohort, as applicable (e.g., adults vs parents vs children).

Click or tap here to enter text.

2.3.3 Number of Individuals Pre-screened: If subject eligibility is verified prior to recruitment/consent, address the following for each participant group (e.g., experimental vs control).
2.3.3.1 Specify the number of individuals prescreened prior to recruitment/consent.
2.3.3.2 Explain how the pre-screen number was determined (e.g., cohort discovery, anticipated rate of screen failure).

Click or tap here to enter text.

2.3.4 Number of Participants Consented: Provide the max number of individuals consented for each participant group (e.g., experimental vs control). If applicable, include screen failures and withdrawals.

Click or tap here to enter text.

2.3.5 Expected/Target Number of Participants:
2.3.5.1 Provide the expected/targeted number of participants needed to complete the study

2.3.5.2 Explain how the target sample size was determined (e.g., power analysis; precision estimation).
2.3.5.3 Power analysis should (at least) match the primary outcome/endpoint.
2.3.5.4 Provide justification of the effect size for the primary outcome based on preliminary information, current knowledge/literature and/or cost consideration.
2.3.5.5 If applicable, provide justification for any significant difference between the max and expected numbers listed above.
2.3.5.6 If applicable, provide sample size justification for secondary outcomes.

Click or tap here to enter text.

2.3.6 Multi-site Number: If applicable, specify total number of subjects across all sites (UCI & other sites).

Click or tap here to enter text.

2.3.7 Treatment Procedures: Provide a detailed chronological description of the procedures.

☐ ***This is included in a separate treatment plan attached.***

Click or tap here to enter text.

2.3.8 Data Use: If data collected for expanded access will be used beyond just reporting of adverse events, address the following:
2.3.8.1 Specify the type of data will that be shared and how.
2.3.8.2 Explain how the data will be used.
2.3.8.3 Specify if the patients have the option to refuse data collection and still get the desired treatment.
2.3.8.4 Explain if data collection is going to be onerous on the patient.
2.3.8.5 Explain if there is a quality assurance mechanism for the data collection.

Click or tap here to enter text.

2.3.9 Data Safety Monitoring Plan: UCI IRB requires that all clinical investigations involving greater than minimal risk to subjects develop a data and safety monitoring plan to assure the safety and welfare of the research subject/patient**.**
2.3.9.1 Provide details of those individuals who will be responsible for the safety oversight of the protocol, including the relevant experience/expertise of everyone (for UCI PI-initiated studies conducted only at UCI, provide the names and titles as well).
2.3.9.2 List who will be *locally* monitoring and collecting information on adverse events and/or unanticipated problems (e.g., UCI PI, Research Coordinator, etc.). Include the name, title and experience of the individual(s) and further describe each individual's role in the oversight of participant participating in the protocol.
2.3.9.3 Specify how frequently accumulated protocol information will be reviewed and evaluated for participant safety, protocol conduct and progress, and, when appropriate, efficacy.
2.3.9.4 Describe the events that would trigger an unscheduled review. Include stopping rules, rules for withdrawing participants, and un-blinding rules as appropriate.
2.3.9.5 Describe the plan for annual reporting of the participants' safety, and the protocol's conduct, progress, and efficacy, when appropriate.

Click or tap here to enter text.

2.3.10 Data Safety Monitoring Board (DSMB): For clinical protocols involving a test article, it is common to have an *independent* Data Safety Monitoring Board (DSMB). Specify whether the following requisite documentation is available and attach to ZOT IRB.

☐ Not applicable, this study does not have an independent DSMB
☐ Signed DSMB recommendation forms available
☐ The finalized DSMB charter available
☐ The finalized DSMB charter will be submitted before enrollment begins

3. CONSENT PROCESS

3.1 Consent criteria (Check if "Yes". All must be checked)

☐ Informed consent will be sought from the patient or the patient's Legally Authorized Representative (LAR).[ii]
☐ Informed consent will be documented using HRP-506 – CONSENT - Expanded Access.[iii] Attach the consent form template that will be (was) used. Do **not** attach the document signed by the patient.
☐ The patient's signed HIPAA Research Authorization will be (was) obtained. Attach the HIPAA Form template that will be (was) used. Do **not** attach the document signed by the patient.
☐ If this study includes a non-English-speaking patient, the English version of the consent materials will be (was) translated for non-English speaking participant or their LAR.

4. FINANCIAL CONSIDERATIONS FOR PATIENTS

4.1 Patient Cost: If the patient will pay for the emergency use treatment, provide specific details.

Click or tap here to enter text.

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[i] FDA does not consider the compassionate use of an unapproved device to be a clinical investigation and FDA does not require compliance with 21 CFR §50 and 21 CFR §56. The requirements are based on FDA guidance at https://www.fda.gov/medical-devices/investigational-device-exemption-ide/expanded-access-medical-devices, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051345.htm#compassionateuse, and http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf.

[ii] FDA does not require the consent process to follow the informed consent requirements at 21 CFR §50.

[iii] FDA does not require the documentation of consent to follow the informed consent requirements at 21 CFR §50.27.

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WORKSHEET: Performance Evaluation for IRB Chairs

The purpose of this worksheet is to provide support for the Institutional Official/ Organizational Official (IO/OO) or designee when evaluating the performance of the IRB Chair(s) as part of the annual HRPP evaluation conducted in HRP-060 - SOP - Annual Evaluations of the HRPP.

1. Considerations when evaluating IRB Chairs

Objective Criteria (Check if satisfactory or not applicable. If needed, work with the IRB Chair to develop a plan to address any unchecked items per HRP-060 - SOP - Annual Evaluations of the HRPP.)

- ☐ Number of meetings attended and chaired out of total number of meetings
- ☐ Number of protocols reviewed via Non-Committee Review
- ☐ Number of protocols reviewed that went to the convened IRB
- ☐ Number of reviews completed as the primary reviewer
- ☐ Timeliness of reviews
- ☐ Completion of required worksheets
- ☐ Completion of educational requirements
- ☐ Attendance at educational sessions

2. Consideration when evaluating IRB Chairs

Subjective Criteria (Check if satisfactory or not applicable. If needed, work with the IRB Chair to develop a plan to address any unchecked items per HRP-060 - SOP - Annual Evaluations of the HRPP.)

- ☐ Leadership of the IRB
- ☐ Ability to lead meetings
- ☐ Preparedness for meetings
- ☐ Knowledge of regulations and identification of areas for improvement
- ☐ Communication with investigators
- ☐ Communication with organizational officials
- ☐ Communication with IRB staff
- ☐ Ability to work with IRB staff
- ☐ Ability to help investigators
- ☐ Issues related to being a general IRB member

3. Notes

Click or tap here to enter notes.

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WORKSHEET: Performance Evaluation for IRB Members

The purpose of this worksheet is to provide support for the IRB Chair or IRB Manager when evaluating the performance of the IRB Members and Alternates as part of the annual HRPP evaluation conducted in HRP-060 - SOP - Annual Evaluations of the HRPP.

1. Considerations when evaluating regular and alternate IRB members

Objective Criteria (Check if satisfactory or not applicable. If needed, work with the IRB Member or Alternate to develop a plan to address any unchecked items per HRP-060 - SOP - Annual Evaluations of the HRPP.)

- ☐ Number of meetings attended out of total number of meetings
- ☐ Number of exempt determinations made
- ☐ Number of protocols reviewed via Non-Committee Review
- ☐ Number of protocols reviewed that went to the convened IRB
- ☐ Number of reviews completed as the primary reviewer
- ☐ Timeliness of reviews
- ☐ Completion of required worksheets
- ☐ Completion of educational requirements
- ☐ Attendance at educational sessions
- ☐ Number of educational sessions conducted

2. Considerations when evaluating regular and alternate IRB members

Subjective Criteria (Check if satisfactory or not applicable. If needed, work with the IRB Member or Alternate to develop a plan to address any unchecked items per HRP-060 - SOP - Annual Evaluations of the HRPP.)

- ☐ Preparedness for meetings
- ☐ Contribution to IRB meetings
- ☐ Quality of reviews
- ☐ Knowledge of regulations and identification of areas for improvement
- ☐ Knowledge of organizational policies and procedures and identification of areas for improvement
- ☐ Communication with investigators
- ☐ Communication with IRB staff
- ☐ Ability to work with IRB staff

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WORKSHEET: Performance Evaluation for IRB Staff

The purpose of this worksheet is to provide support for the IRB Chair or IRB Manager when evaluating the annual performance of the IRB staff as part of the annual HRPP evaluation conducted in HRP-060 – SOP – Annual Evaluations of the HRPP.

1. Considerations when evaluating IRB staff

Objective Criteria (Check if satisfactory or not applicable. If needed, work with the IRB staff member(s) to develop a plan to address any unchecked items per HRP-060 – SOP – Annual Evaluations of the HRPP.)

- ☐ Workload – handles workload efficiently
- ☐ Number of protocols reviewed via Non-Committee Review
- ☐ Number of protocols processed
- ☐ Timeliness of processing materials
- ☐ Completion of worksheets and documentation
- ☐ Prepares agendas in a timely manner
- ☐ Prepares convened IRB minutes in a timely manner
- ☐ Completion of educational requirements
- ☐ Attendance at educational sessions
- ☐ Number of educational sessions conducted
- ☐ Attainment and maintenance of certification (e.g., CIM or CIP)

2. Considerations when evaluating IRB staff

Subjective Criteria (Check if satisfactory or not applicable. If needed, work with the IRB staff member(s) to develop a plan to address any unchecked items per HRP-060 – SOP – Annual Evaluations of the HRPP.)

- ☐ Preparedness for meetings
- ☐ Quality of pre-reviews
- ☐ Completes and maintains convened IRB minutes and records efficiently and correctly
- ☐ Knowledge of regulations and identifications of areas for improvement
- ☐ Knowledge of organizational policies and procedures and identification of areas for improvement
- ☐ Communication with IRB chairs, IRB staff, investigators, and study staff
- ☐ Ability to help investigators

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WORKSHEET: HIPAA Applicability

The purpose of this worksheet is to provide support for IRB staff and researchers in determining whether the Privacy Rule[i] applies to a research[ii] study. It does not need to be completed or retained.

1. Identifying Covered Entities

Is the research conducted partially or solely by a Covered Entity?[iii] [iv](Check all that apply; if any are checked continue. If none are checked, the HIPAA Privacy Rule does not apply to the research.[v])

- ☐ This institution[vi] is a Covered Entity
- ☐ This institution is a Hybrid Covered Entity and at least one researcher is an employee or workforce member of a health care component

2. Identifying Protected Health Information (PHI)

☐ Does the research involve the use or disclosure of health information[vii] for any reason? (Check all that apply; if any are checked continue. If none are checked, the HIPAA Privacy Rule does not apply to the research.)

- ☐ Derived from medical records
- ☐ Added to medical records
- ☐ Created or collected as part of health care
- ☐ Used to make healthcare decisions

☐ Does the information include any of the following identifiers? (Check all that apply; if any are checked complete the section below. If none are checked, the information is considered de-identified and therefore the HIPAA Privacy Rule does not apply because it does not meet the definition of PHI.)

- ☐ Names
- ☐ Geographic information smaller than a state
- ☐ Dates (except year) directly related to an individual
- ☐ Phone numbers
- ☐ Fax numbers
- ☐ Email addresses
- ☐ Social Security numbers
- ☐ Medical record numbers
- ☐ Health plan beneficiary numbers
- ☐ Account numbers
- ☐ Certificate/license numbers
- ☐ Vehicle identifiers and serial numbers
- ☐ Device identifiers and serial numbers
- ☐ Web URLs
- ☐ IP addresses
- ☐ Biometric identifiers (e.g., fingerprints)

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☐ Full-face photographs and comparable images
☐ Any other unique identifying number, characteristic, or code

3. Identifying Authorization or Other Data Use Permissions (One must be checked)

☐ The use is limited to preparatory to research activities in order to design a research protocol. A waiver or alteration of authorization by a Privacy Board or IRB is requested for the use and/or disclosure of PHI for research purposes. See HRP-441- PI WORKSHEET - HIPAA Waiver of Authorization.[viii]
☐ The use or disclosure being sought is solely for research on the protected health information of decedents[ix]
☐ The data is a Limited Data Set (LDS)[x] subject to an executed Data Use Agreement (DUA).
☐ Authorization has been or will be obtained from Human Research participants for the use and/or disclosure of PHI for research purposes. See HRP-330 - WORKSHEET - HIPAA Authorization.
☐ A waiver or alteration of authorization by a Privacy Board or IRB is requested for the use and/or disclosure of PHI for research purposes. See HRP-441 - PI WORKSHEET - HIPAA Waiver of Authorization.

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[i] 45 CFR § 160 and § 164

[ii] 45 CFR 164.501 defines research as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

[iii] 45 CFR § 160.103 covered entity means:

(1) A health plan.
(2) A health care clearinghouse.
(3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

[iv] HIPAA FAQ: When does a covered entity have discretion to determine whether a research component of the entity is part of their covered functions, and therefore, subject to the HIPAA Privacy Rule? https://www.hhs.gov/hipaa/for-professionals/faq/315/when-does-a-covered-entity-have-discretion-to-determine-covered-functions/index.html

[v] Where no members of the research team are part of a Covered Entity (CE), but a CE has agreed to share Protected Health Information (PHI) with the research team, HIPAA does not apply to the research, but the CE remains subject to HIPAA and responsible for the accounting of disclosures.

[vi] The institution that is conducting the research.

[vii] 45 CFR § 160.103 health information means any information, including genetic information, whether oral or recorded in any form or medium, that:

(1) Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and
(2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

[viii] Whether a researcher needs a waiver of authorization for protocol development activities and recruitment/identifying of potential participants prior to obtaining authorization depends on the Covered Entity's (from which the data is being accessed) interpretation of the Privacy Rule. Contact the HIPAA Privacy Office for any certification requirements for the use of the PHI for preparatory to research activities.

[ix] 45 CFR 164.512(i)(1)(iii) Uses and disclosures for which an authorization or opportunity to agree or object is not required.

[x] 45 CFR §164.514(e) a Limited Data Set is protected health information that excludes the following identifiers of the individual or of relatives, employers, or household members: Names, Postal address, telephone numbers, fax numbers, email addresses, social security numbers, medical record numbers, health plan beneficiary numbers, account numbers, certificate/license numbers, vehicle identifiers and serial numbers, device identifiers and serial numbers, URLs, IP address, biometric identifiers, including finger and voice points. An LDS can contain dates related to the individual (birth date, death date, etc.), dates of services, and geographic information at the level of town or city, state and 5-digit zip code.

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WORKSHEET: HIPAA Authorization

The purpose of this worksheet is to provide support for IRB staff when evaluating whether a HIPAA authorization is valid. IRB staff are to consult this worksheet to review HIPAA authorizations.

1. CORE ELEMENTS (Check if "**Yes**". All must be checked)

☐ A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.

☐ The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure.

☐ The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure.

☐ A description of each purpose of the requested use or disclosure.

☐ An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. (The statement "end of the research study," "none," or similar language is sufficient if the authorization is for a use or disclosure of protected health information for research, including for the creation and maintenance of a research database or research repository.)

☐ Signature of the individual and date. If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual must also be provided.

2. REQUIRED STATEMENTS (Check if "**Yes**". All must be checked)

☐ The individual's right to revoke the authorization in writing.

☐ The authorization either:

- Describes the exceptions to the right to revoke the authorization.
- References the Notice for Privacy Practices for Protected Health Information which describes the exceptions to the right to revoke the authorization.

☐ The ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization, by stating either of the following:

- The covered entity may not condition treatment, payment, enrollment or eligibility for benefits on whether the individual signs the authorization.
- The consequences to the individual of a refusal to sign the authorization when the covered entity can condition treatment, enrollment in the health plan, or eligibility for benefits on failure to obtain such authorization.

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☐ The potential for information disclosed pursuant to the authorization to be subject to redisclosure by the recipient and no longer be protected by this authorization.

3. OTHER REQUIREMENTS (Check if "**Yes**". All must be checked)

☐ The authorization is written in plain language.

☐ The individual will be provided with a copy of the signed authorization.

☐ If the marketing involves direct or indirect remuneration to the covered entity from a third party, the authorization must state that such remuneration is involved.

☐ The authorization is either a separate document or incorporated into the written consent document for research.

☐ No material information in the authorization is known to be false.

WORKSHEET: FERPA Compliance

The purpose of this worksheet is to provide support for the FERPA officer determining whether personally identifiable information can be released from student education records [i] or personal education information from an education program (defined as: any program principally engaged in the provision of education, including, but not limited to, early childhood education, elementary and secondary education, postsecondary education, special education, job training, career and technical education, and adult education).

Requirements for Disclosure (one of the following categories must be met)

☐ The parent or eligible student will provide a signed and dated written consent that discloses:

- ☐ The records that may be disclosed;
- ☐ The purpose of the disclosure
- ☐ The party or class of parties to whom the disclosure may be made
- ☐ If a parent or adult student requests, the school will provide him or her with a copy of the records disclosed
- ☐ If the parent of a student who is not an adult so requests, the school will provide the student with a copy of the records disclosed.

☐ The disclosure is to other school officials, including teachers, within the agency or institution whom the agency or institution has determined to have legitimate educational interests. A contractor, consultant, volunteer, or other party to whom an agency or institution has outsourced institutional services or functions may be considered a school official under this paragraph provided that the outside party—

- Performs an institutional service or function for which the agency or institution would otherwise use employees;
- Is under the direct control of the agency or institution with respect to the use and maintenance of education records; and
- Is subject to the requirements of §99.33(a) governing the use and redisclosure of personally identifiable information from education records.

☐ The disclosure is, subject to the requirements of 34 CFR §99.34, to officials of another school, school system, or institution of postsecondary education where the student seeks or intends to enroll, or where the student is already enrolled so long as the disclosure is for purposes related to the student's enrollment or transfer.

☐ The disclosure is, subject to the requirements of 34 CFR §99.35, to authorized representatives of—

- The Comptroller General of the United States;
- The Attorney General of the United States;
- The Secretary; or
- State and local educational authorities.

☐ The disclosure is in connection with financial aid [ii] for which the student has applied or which the student has received, if the information is necessary for such purposes as to:

- Determine eligibility for the aid;
- Determine the amount of the aid;
- Determine the conditions for the aid; or
- Enforce the terms and conditions of the aid.

☐ The disclosure is to State and local officials or authorities to whom this information is specifically—

- Allowed to be reported or disclosed pursuant to State statute adopted before November 19, 1974, if the allowed reporting or disclosure concerns the juvenile justice system and the system's ability to effectively serve the student whose records are released; or
- Allowed to be reported or disclosed pursuant to State statute adopted after November 19, 1974, subject to the requirements of 34 CFR §99.38. (A State from further limiting the number or type of State or local officials to whom disclosures may be made.)

☐ The disclosure is to organizations conducting studies for, or on behalf of, educational agencies or institutions to: Develop, validate, or administer predictive tests; Administer student aid programs; or Improve instruction. Where:

- ☐ The study is conducted in a manner that does not permit personal identification of parents and students by individuals other than representatives of the organization that have legitimate interests in the information;
- ☐ The information is destroyed when no longer needed for the purposes for which the study was conducted
- ☐ The school enters into a written agreement with the organization that:
    - ☐ Specifies the purpose, scope, and duration of the study or studies and the information to be disclosed
    - ☐ Requires the organization to use personally identifiable information from education records only to meet the purpose or purposes of the study as stated in the written agreement;
    - ☐ Requires the organization to conduct the study in a manner that does not permit personal identification of parents and students, as defined in this part, by anyone other than representatives of the organization with legitimate interests
    - ☐ Requires the organization to destroy or return to the school all personally identifiable information when the information is no longer needed for the purposes for which the study was conducted and specifies the time period in which the information must be returned or destroyed

☐ The disclosure is to accrediting organizations to carry out their accrediting functions.

☐ The disclosure is to parents, as defined in 34 CFR §99.3, of a dependent student, as defined in section 152 of the Internal Revenue Code of 1986.

☐ The disclosure is to comply with a judicial order or lawfully issued subpoena where one of the following is true:

- ☐ The school makes a reasonable effort to notify the parent or eligible student of the order or subpoena in advance of compliance, so that the parent or eligible student may seek protective action, unless the disclosure is in compliance with—

- A Federal grand jury subpoena and the court has ordered that the existence or the contents of the subpoena or the information furnished in response to the subpoena not be disclosed;
- Any other subpoena issued for a law enforcement purpose and the court or other issuing agency has ordered that the existence or the contents of the subpoena or the information furnished in response to the subpoena not be disclosed; or
- An ex parte court order obtained by the United States Attorney General (or designee not lower than an Assistant Attorney General) concerning investigations or prosecutions of an offense listed in 18 U.S.C. 2332b(g)(5)(B) or an act of domestic or international terrorism as defined in 18 U.S.C. 2331.

☐ The disclosure is to the court when the school initiates legal action against a parent or student
☐ The disclosure is to the court when a parent or eligible student initiates legal action against the school,

☐ The disclosure is in connection with a health or safety emergency, under the conditions described in §99.36.

☐ The disclosure is information the school has designated as “directory information”, under the conditions described in §99.37.

☐ The disclosure is to the parent of a student who is not an eligible student or to the student.

☐ The disclosure, subject to the requirements in 34 CFR §99.39, is to a victim of an alleged perpetrator of a crime of violence or a non-forcible sex offense. The disclosure may only include the final results of the disciplinary proceeding conducted by the institution of postsecondary education with respect to that alleged crime or offense. The institution may disclose the final results of the disciplinary proceeding, regardless of whether the institution concluded a violation was committed.

☐ The disclosure [iii] is to a parent of a student at an institution of postsecondary education regarding the student's violation of any Federal, State, or local law, or of any rule or policy of the institution, governing the use or possession of alcohol or a controlled substance if—

- The institution determines that the student has committed a disciplinary violation with respect to that use or possession; and
- The student is under the age of 21 at the time of the disclosure to the parent.

☐ The disclosure concerns sex offenders and other individuals required to register under section 170101 of the Violent Crime Control and Law Enforcement Act of 1994, 42 U.S.C. 14071, and the information was provided to the school under 42 U.S.C. 14071 and applicable Federal guidelines.

☐ The disclosure is of records in which the school or other party has made a reasonable determination that a student's identity is not personally identifiable, whether through single or multiple releases, and taking into account other reasonably available information. “Not personally identifiable” means information that includes none of the following:

- Student’s name and other direct personal identifiers, such as the student’s social security number or student number.
- Indirect identifiers, such as the name of the student’s parent or other family members; the student’s or family’s address, and personal characteristics or other information that would make the student’s identity easily traceable; date and place of birth and mother’s maiden name.
- Biometric records, including one or more measurable biological or behavioral characteristics that can be used for automated recognition of an individual, including fingerprints, retina and iris patterns, voiceprints, DNA sequence, facial characteristics, and handwriting.

- Other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant circumstances, to identify the student with reasonable certainty.

☐ The disclosure is of records in which are de-identified student level data from education records for the purpose of education research by attaching a code to each record that may allow the recipient to match information received from the same source, provided that—

- The school or other party that releases de-identified data does not disclose any information about how it generates and assigns a record code, or that would allow a recipient to identify a student based on a record code;
- The record code is used for no purpose other than identifying a de-identified record for purposes of education research and cannot be used to ascertain personally identifiable information about a student; and
- The record code is not based on a student's social security number or other personal information.

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[i] The term “education records” is defined to mean, with certain exceptions, those records that are: (1) directly related to a student, and (2) maintained by an educational agency or institution or by a party acting for the agency or institution. 20 U.S.C. § 1232g(a)(4)(A); 34 CFR § 99.3 (definition of “education records”). For instance, a student’s health records, including immunization records, maintained by an educational agency or institution (such as by an elementary or secondary school nurse) would generally constitute education records subject to FERPA. Joint Guidance on the Application of the Family Educational Rights and Privacy Act (FERPA) And the Health Insurance Portability and Accountability Act of 1996 (HIPAA) To Student Health Records

[ii] Financial aid means a payment of funds provided to an individual (or a payment in kind of tangible or intangible property to the individual) that is conditioned on the individual's attendance at an educational agency or institution.

[iii] This section does not supersede any provision of State law that prohibits an institution of postsecondary education from disclosing information.

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WORKSHEET: NIH GDS Institutional Certification

The purpose of this worksheet is to allow the IRB Director or designee to evaluate whether an investigator's genomic data sharing plan meets the criteria for submission to an NIH-designated data repository.

1. Institutional Certification Requirements (ALL must be checked "Yes")

Yes or No?	Institutional Certification Requirement
☐ Yes ☐ No	The data submission is consistent, as appropriate, with applicable national, tribal, and state laws and regulations as well as relevant institutional policies.
☐ Yes ☐ No	Limitations on the research use of the data, as expressed in the informed consent documents, are delineated. ☐ **NA for submission to an unrestricted-access database.**
☐ Yes ☐ No	The identities of research participants will not be disclosed to NIH-designated data repositories.
☐ Yes ☐ No	The protocol for collection of genomic and phenotype data is consistent with 45 CFR §46.
☐ Yes ☐ No	Data submission and subsequent data sharing for research purposes are consistent with the informed consent and explicitly disclosed to study participants from whom the data were or will be obtained.[i]
☐ Yes ☐ No	Consideration was given to risks to individual participants and their families associated with the data submitted to NIH-designated data repositories and subsequent sharing, including unrestricted access to genomic summary results.
☐ Yes ☐ No	To the extent relevant and possible, consideration was given to risks to groups or populations associated with submitting data to NIH-designated data repositories and subsequent sharing, including unrestricted access to genomic summary results.
☐ Yes ☐ No	The investigator's plan for de-identifying datasets is consistent with the standards outlined in Section IV.C.1 of the NIH Final Genomic Data Sharing Policy. (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html)

If you cannot select "Yes" to all items above, then stop. You cannot certify that the data submission criteria have been met. Communicate with the investigator to let her or him know that you cannot proceed with the Institutional Certification process without changes to the investigator's data sharing plan.

2. Unrestricted- or Controlled-Access Database

Choose the type of database to which the investigator will submit:

☐ Unrestricted-Access Database[ii] ☐ Controlled-Access Database[iii]

Check if applies:

☐ Sensitive genomic summary results[iv] are only to be made available through controlled-access.

Explanation: Click or tap here to enter text.

If Controlled-Access Database selected above, specify one of the data use limitations[v] below for appropriate secondary use. These limitations must be included in the GDS Institutional Certification to the NIH.

☐ General Research Use: Use of the data is limited only by the terms of the Data Use Certification: these data will be added to the dbGaP Collection.
☐ Health/Medical/Biomedical: Use of the data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
☐ Disease-specific: Use of the data must be related to the specific disease.

List disease: Click or tap here to enter text.

☐ Other: Click or tap here to enter text.

Additional modifiers, if appropriate (check all that apply):

☐ IRB Approval Required	☐ Publication Required	☐ Collaboration Required	☐ Not-for-profit Use Only	☒ Methods Development Research	☐ Genetic Studies Only

[i] For studies using data from specimens collected before the effective date of the GDS Policy, January 25, 2015, review should ensure the data submission is not *inconsistent* with the informed consent provided by the research participant. NIH will accept data derived from de-identified cell lines or clinical specimens lacking consent for research use that were created or collected before the effective date of the GDS Policy. After the Policy effective date, NIH expects *explicit* consent for broad sharing and for data that will be submitted to unrestricted-access data repositories. https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html
[ii] Data made publicly available to anyone.
[iii] Data made available for secondary research only after investigators have obtained approval from NIH to use the requested data for a particular project.
[iv] Genomic summary results (GSR) are results from primary analyses of genomic research that convey information relevant to genomic associations with traits or diseases across datasets rather than data specific to any one individual research participant (e.g., genotype counts and frequencies; allele counts and frequencies; effect size estimates and standard errors; likelihoods; and p-values). GSR may be considered to have particular sensitivities related to individual privacy or potential for group harm.
[v] Standard NIH data use limitations: https://osp.od.nih.gov/wp-content/uploads/standard_data_use_limitations.pdf. Additional modifiers to standard data use limitations may be indicated if appropriate and should have a basis in the informed consent from the participants or in special knowledge of the preferences of the original study population.

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WORKSHEET: Certificate of Confidentiality

The purpose of this worksheet is to provide support for the convened IRB or Designated/Staff Reviewers when evaluating whether a Certificate of Confidentiality is required or appropriate for a study.

1. Considerations for Certificate of Confidentiality (Check if "Yes")

☐ The research is funded by the National Institutes of Health (NIH) and is biomedical, clinical, or other research.[i] If "**Yes**," a COC is automatically issued through the award. Other HHS agencies provide a CoC for funded research upon request.[ii]

☐ The research is health-related biomedical, behavioral, clinical, or other research that is not funded by HHS.[iii] *(2025 Note: Currently NIH is not considering CoC applications for research not funded by NIH. Check their website for updates.)*

If "**Yes**," answer the following:

☐ The research is collecting personally identifiable information.
☐ The research is sensitive.[iv]
☐ The research is collecting information that if disclosed could significantly harm or damage the participant.

2. Certificate of Confidentiality for Research Language is included in Consent (If "Yes" in #1, must be "Yes")

☐ The consent document includes information describing the CoC and its purpose and its applicability to the research.

3. Additional Considerations for Studies where a Certificate of Confidentiality is Required or Appropriate (If "Yes" in #1, must be "Yes")

☐ The research will not utilize third parties or entities to collect or store information (e.g., contractors, online platform vendors) that cannot or will not protect against the compelled disclosure of the personally identifiable information.[v]

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[i] NOT-OD-17-109: Notice of Changes to NIH Policy for Issuing Certificates of Confidentiality; https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html
[ii] To identify appropriate HHS agency for CoC request; https://grants.nih.gov/policy/humansubjects/coc/how-to-apply.htm#step1
[iii] Online Certificate of Confidentiality System; https://public.era.nih.gov/commonsplus/public/coc/request/init.era

[iv] Examples of sensitive research activities include but are not limited to the following: collecting genetic information; collecting information on psychological well-being of subjects; collecting information on subjects' sexual attitudes, preferences, or practices; collecting data on substance abuse or other illegal risk behaviors' studies where subjects may be involved in litigation related to exposures under study (e.g., breast implants, environmental or occupational exposures).
[v] Institutional Assurance Statement; https://grants.nih.gov/policy/humansubjects/coc/required-institutional-assurances.htm; Investigator and Institutional CoC Responsibilities - 3. Uphold CoC protections.https://grants.nih.gov/policy/humansubjects/coc/information-institutional-responsibilities.htm

WORKSHEET: Human Research Involving Artificial Intelligence

The purpose of this worksheet is to provide support for IRB members when evaluating specific uses of Artificial Intelligence (AI) technology[i] in non-exempt Human Research. This worksheet acts as a supplement to HRP-314 - WORKSHEET - Criteria for Approval and HRP-314a - WORKSHEET - Criteria for Consent. It does not need to be completed or retained.

1. UCI Considerations for AI in Human Research

☐ Review Artificial Intelligence and Human Subject Research for current legal considerations, restrictions, and best practices when involving AI in human research.
IMPORTANT! Protected Health Information (PHI) or any other restricted UCI Health data must not be entered/stored into external (non-UCI) consumer environments unless they are explicitly approved for institutional use (see BFB-IS-3: Electronic Information Security).

2. Background and Context Considerations

The following may be relevant in providing a high-level understanding of the AI technology use prior to the more detailed considerations included in subsequent sections. There are no “correct” or “incorrect” answers.

☐ How is the AI technology in the protocol being used? Is the purpose of the study to develop new AI technology or is the study utilizing existing AI technology (e.g., as part of study procedures)?
☐ Will research subjects interact with the AI technology in the study intervention or interaction associated with the proposed research?
☐ Will the study team interact with AI technology in the administration, conduct, or analysis of the research?
☐ Is the use of AI technology limited to the standard use of pre-existing and generally available tools (e.g., publicly or commercially available) in a manner consistent with institutional policies and norms?
☐ Has the investigator obtained any required institutional reviews or approvals for the use of AI technology as outlined in HRP-309 - WORKSHEET - Ancillary Review?
☐ Is the proposed research utilizing (or planning to develop) novel AI technology, or will it utilize pre-existing AI technology in a novel way?

3. General Considerations for the Use of AI Technology

The following general considerations may be used as a supplement to inform IRB members’ decision making when considering the regulatory criteria for IRB approval in HRP-314 - WORKSHEET - Criteria for Approval. Consider whether the protocol clearly describes the following, where applicable.

☐ The applicability of FDA investigational device requirements if the technology is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or in support of a FDA marketing application. See HRP-307 - WORKSHEET - Devices.
☐ The specific intended use of the AI technology in the protocol.
☐ A general overview of how the AI technology in the protocol operates. For example, whether the AI technology outputs are generated strictly from pre-programmed rules and knowledge (which are predictable and easily verified), or whether the AI technology’s decision-making is autonomous or semi-autonomous (making outputs less predictable and less easily verified).

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☐ Description of how research subject data will be used.
☐ Whether individual participant data may be re-identified.
☐ Any measures in place to reduce the risk of re-identification of research subjects and data.
☐ Whether existing "Terms of Use" apply to the collection of data used to train or test the algorithm (e.g., social media platforms).
☐ Plans to review the data during the conduct of the research to mitigate potential bias, errors, or output discrepancies, including:
  ☐ A description of who will review the data.
  ☐ A description of what data will be reviewed.
  ☐ The frequency or timelines for data review.
☐ If there will be continuous data updates to the AI technology, whether there are mechanisms in place to assess the impact of those changes on risks to participants to ensure the reliability of AI outputs.
☐ Any metrics used to assess the AI technology's performance over time.
☐ A description of how research subjects or study staff will interact with the AI technology.
☐ Whether the AI technology's outputs are being shared directly with research subjects without prior review by the investigator.
☐ Whether the AI technology's outputs will influence clinical decision making.
☐ Whether measures will exist to ensure transparency if any changes to standard clinical care result from the outputs of AI technology.
☐ If investigators and study staff will be interacting directly with the AI technology, plans for training and oversight to ensure appropriate usage and interaction with the AI technology and its resulting outputs.
☐ If research subjects will be interacting directly with the AI technology, plans for ensuring that research subjects will have the necessary training and resources to access and use the AI technology.
☐ A description of any known limitations of the AI technology or its outputs impacting the design and conduct of the research.

4. Additional Considerations for Using AI Technology in the Administration of Research

The following additional considerations may be used to supplement the general considerations above for research activities involving AI technology use by investigators and study staff in the administration of research activities. Consider whether the protocol clearly describes the following, where applicable.

☐ The role that AI technology will play in the administration and conduct of the Human Research, and how it will be utilized.
☐ The suitability of the AI technology for its intended use in the research.
☐ A description of any study team responsibilities associated with utilizing the technology.
☐ Plans to monitor the AI technology's outputs and take corrective action if discrepancies occur.
☐ A description of any additional risks posed by the administration or use of the technology.
☐ Plans for data sharing, storage, and use, including whether the AI technology platform will be open source (posted for public use).
☐ Plans for training and oversight of investigators and study team personnel to ensure appropriate usage and interaction with the AI technology and its resulting outputs.

5. Additional Considerations for Research Involving Novel AI Technology Tools

The following additional considerations may be used to supplement the general considerations above for research activities involving the development, testing, or deployment of novel AI technology (e.g., uses other than the standard use of pre-existing and generally available tools). Consider whether the protocol clearly describes the following, where applicable.

☐ The data sources used in the development of the specific AI technology in the protocol.
☐ The extent to which source data is sufficient and representative of the research population under study.

☐ For discovery stage research involving the use of secondary or integration of external datasets, confirmation from ancillary review functions, or submission materials provided by investigators, that any necessary contractual or legal agreements are in place to use the data (e.g., Business Associate Agreements, Data Use Agreements, Material Transfer Agreements, etc.).
☐ Whether the Investigator commits to following Good Machine Learning Practices (GMLP).[ii]

6. Additional Considerations for Informed Consent, Where Applicable

The following additional considerations for informed consent may be used as a supplement to inform IRB members' decision making when considering HRP-314a - WORKSHEET - Criteria for Consent. Consider whether the protocol and consent document clearly describe the following, where applicable.

☐ The consent process will clearly communicate the intended use of the AI technology to research subjects. Any unique risks posed by the AI technology are clearly described in the informed consent document.
☐ The intended use of the AI technology and its resulting outputs described in the informed consent document is consistent with the description in the protocol.
☐ If collected data cannot be removed from the AI technology's database once collected, an explanation to this effect.
☐ If data is to be used from prior research studies, prior informed consent included the provision for future research use of participant data. (**N/A** if eligible for waiver of informed consent processes in the current study and the use is consistent with prior consent obtained or waivers granted.)

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[i] AI is a broad concept, inclusive of many subsets: machine learning, deep learning, generative AI, large language models, etc.
[ii] Good Machine Learning Practice for Medical Device Development: Guiding Principles | FDA.

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WORKSHEET: Protocol-Specific Emergency-Disruption Risk Mitigation Planning

The purpose of this worksheet is to provide investigators with general guidance and considerations when developing study-specific plans to manage risks resulting from an emergency/disruption situation impacting the investigator's ability to ensure the ongoing safety of research subjects and the integrity of the research. Refer to HRP-108 - FLOWCHART - Study-Specific Emergency-Disruption Risk Mitigation Planning to determine whether a formal risk mitigation plan is necessary.

The considerations below do not represent an exhaustive list of considerations; they are intended to serve as a starting point to guide an ongoing discussion between investigators, study staff, sponsors and Institutional Review Boards (IRBs) in their efforts to address challenges posed by current or anticipated emergencies. All actions taken must comply with applicable institutional-level and HRPP-level guidance and requirements regarding the emergency/disruption.

1. General Considerations for Creating a Protocol-Specific Emergency/Disruption Risk Mitigation Plan.

The following are considerations for investigators when determining the various elements of their research that must be modified to ensure the ongoing safety of research subjects during an emergency/disruption situation.

☐ Modifications to Recruitment and Enrollment Processes: (Select any that are appropriate for the research.)

- ☐ Temporarily discontinue study recruitment efforts and initiatives.
- ☐ Temporarily discontinue enrollment of new research subjects.
- ☐ Incorporate additional screening procedures for research subjects or study personnel that will be completed prior to recruitment and enrollment (e.g., for infectious disease outbreaks).
- ☐ Other relevant actions should be taken. Describe: Click or tap here to enter text.

☐ Additional Modifications to Minimize Risk: (Select any that are appropriate for the research.)

- ☐ Withdraw some or all current research subjects from the research.
- ☐ Modify study visit procedures so that visits can be completed remotely (e.g., via phone, web applicable, or video conferencing).
- ☐ Modify study visit procedures so that visits can be completed at subjects' home, local lab, clinical or imaging center.
- ☐ Incorporate additional screening, referral, and/or follow-up procedures for research subjects or study personnel that will be completed prior to or following in-person visits (e.g., for infectious disease outbreaks).
- ☐ Incorporate other/additional safety monitoring procedures. Describe: Click or tap here to enter text.
- ☐ Assess and modify, when appropriate, the data and safety monitoring plan to accommodate changes in study procedures and/or the mechanism(s) in which data and safety monitoring is accomplished.
- ☐ Assess and modify the data management plan, when appropriate.

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- ☐ If planned on-site monitoring visits are no longer possible, consider optimizing use of central and remote monitoring programs to maintain oversight of clinical sites.
- ☐ Modify timing and scope of specific study visits to account for essential versus nonessential study procedures.
- ☐ Other relevant actions should be taken. Describe: Click or tap here to enter text.

☐ Additional Modifications for FDA-Regulated Research Regarding Investigational Drug/Biologic/Device Access and Administration: (Select any that are appropriate for the research.)

- ☐ For any investigational products that can typically be distributed for self-administration, modify the protocol to allow for alternative secure delivery and disposal methods (e.g., investigational product can be shipped to the subject's residence).
- ☐ For any investigational products that are normally administered in a healthcare setting, consult FDA review divisions on plans for alternative administration (e.g., home nursing or alternative sites by trained but non-study personnel).
- ☐ Other relevant actions should be taken. Describe: Click or tap here to enter text.

2. Research Record and Study Documentation. The following are additional considerations for investigators when maintaining research records that reflect the impact of the emergency/disruption.

☐ For protocol wide study restrictions or modifications necessitated by the emergency/disruption, document the following in the research record where applicable and appropriate:

- ☐ A description of the emergency/disruption and its impact on the research,
- ☐ Changes in study conduct, including procedures not completed, on account of the emergency/disruption,
- ☐ Duration of those changes,
- ☐ Which trial participants were impacted,
- ☐ How those trial participants were impacted,
- ☐ Other relevant actions that were taken. Describe: Click or tap here to enter text.

☐ When the emergency/disruption directly impacts research records (e.g., missing or destroyed records), document the following, as applicable:

- ☐ Complete description/list of what research records were impacted and how,
- ☐ Measures taken to re-construct the records and/or address the data loss, including consultation with local IT support and/or electronic system vendors, when appropriate.

☐ For FDA-regulated research where there are individual instances when efficacy endpoints are not collected, document the reasons for failing to obtain the efficacy assessment (e.g., explain the basis of any missing data, including the relationship to the emergency/disruption for missing protocol-specified information).

☐ For FDA-regulated research where changes in the protocol include any of the following, document that changes were made in consultation with the applicable FDA review division where feasible and appropriate:

- ☐ Amendments to data management and/or statistical analysis plans,
- ☐ Alternative administration of investigational products that are normally administered in a healthcare setting (e.g., home nursing or alternative sites by trained but non-study personnel),
- ☐ Protocol modifications for the collection of efficacy endpoints, such as use of virtual assessments, delays in assessments and alternative collection of research-specific specimens.

3. Communication Plan to Subjects. The following are additional considerations for investigators when informing research subjects of the impact of the emergency/disruption on the research.

☐ If the circumstance warrants subject notification, develop a research subject communication plan that includes the following:

- ☐ What information will be communicated to subjects, including current (and where applicable, completed and/or prospective) research subjects,
- ☐ Who will communicate the information,
- ☐ When the information will be communicated,
- ☐ How the information will be communicated.

4. IRB Notification and Approval. One of the following must be true.

☐ If immediate modification of the research is necessary to eliminate an apparent immediate hazard to a subject, take action and notify the IRB within five business days following the standard pathway to submit reportable new information.

☐ For all other study modifications, submit a study amendment to the IRB.

5. Additional Notifications. Complete as applicable.

☐ When necessary, report events that result from the emergency/disruption as reportable new information, as described in HRP-103 - Investigator Manual.

☐ Notify applicable ancillary review committees, including study-specific data and safety monitoring boards/committees.

☐ For FDA regulated research where the principal investigator holds the Investigational New Drug (IND) or Investigational Device Exemption (IDE), submit a modification in accordance with 21 CFR 312.30 and 21 CFR 812.35, respectively.

WORKSHEET: Additional Emergency-Disruption Review Considerations

The purpose of this worksheet is to provide IRB members with additional considerations that may become relevant when reviewing Human Research during an emergency/disruption situation. These considerations may provide additional and necessary flexibility for study teams while continuing to ensure research subject safety during the emergency/disruption. This worksheet is to be used when directed to do so by the IRB Chair or staff. It does not need to be completed or retained.

1. More widespread use of waivers of documentation of consent for minimal risk research. Additional use of waivers of documentation of consent may be appropriate if the following items are true. (Check if "Yes." All must be checked.)

☐ The emergency/disruption creates challenges in obtaining initial or ongoing written (or electronic) informed consent.

☐ The research meets one of the eligibility categories for waiver of written documentation of consent, as confirmed via HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent.

2. Alternate mechanisms for safety monitoring. (Check if "Yes." All must be checked.)

☐ The research involves protocol-specified visits to the investigational site.

☐ Research subjects are not able to come to the investigational site for protocol-specified visits due to the emergency/disruption.

☐ Alternative methods for safety assessments (e.g., phone contact, virtual visit, alternative location for assessment, including local labs or imaging centers) are available.

☐ Alternative methods for safety assessments can feasibly be implemented.

☐ Alternative methods for safety assessments would be sufficient to ensure the safety of trial participants.

3. Additional flexibility in oversight of research not subject to federal regulations. (Check if "Yes." All must be checked.)

☐ The research is not covered by federal regulations, as documented via the Submit Pre-Review activity.

☐ One or more of the following options is feasible and appropriate during the emergency/disruption to provide necessary flexibility for study teams while continuing to assure research subject safety:

- ☐ Extend continuing review dates during the anticipated period of the emergency.
- ☐ Allow minor changes to be reported to the IRB or EC without requiring IRB or EC approval prior to implementation during the emergency/disruption.

4. Other mechanisms for additional flexibility not described above. In addition to the options above, additional considerations in providing added flexibility to study teams during emergency/disruption situations may be appropriate where any of the following is true. (Check if "Yes," if applicable.)

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☐ Additional institution-level information related to managing the emergency/disruption (and not otherwise specified above) is issued and provides guidance in providing additional flexibility or support resources to study teams.

☐ Federal guidance or communications related to managing research during the emergency is issued and provides additional flexibility or resources.

WORKSHEET: Pre-Review

The purpose of this worksheet is to provide support for IRB Staff conducting Pre-review.

Regulatory Oversight *(Check all that apply)*

☐ **Common Rule Requirements prior to January 21, 2019**

☐ DHHS
☐ Common Rule (Not federally funded, but required to apply Common Rule)
☐ FDA
☐ OCR (HIPAA)
☐ ICH-GCP
☐ DOD
☐ DOE
☐ NSF
☐ DOJ
☐ ED
☐ EPA
☐ VA
☐ Other Federal Agency
☐ EU GDPR
☐ Tribal Law
☐ None of the above

Restrictions (Check if applicable)

☐ Principal Investigator is Restricted

Missing Materials

Click or tap here to enter text.

Special Determinations (Check all that apply)

☐ Children
☐ Wards
☐ Pregnant women
☐ Prisoners
☐ Students
☐Employees
☐ Not significant risk device (FDA)
☐ Non-viable neonates
☐ Neonates of uncertain viability
☐ Adults with impaired decision-making capacity
☐ Waiver/alteration of the consent process
☐ Waiver of HIPAA authorization
☐ Waiver of consent documentation
☐ Waiver of consent for emergency research

Protocol Tracking (Check all that apply)

☐ Social/Behavioral/Education
☐ Single-Site Study

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☐ Deception

☐ Certificate of Confidentiality

☐ Biomedical/Clinical

☐ Collaborative Study (Lead Site)

☐ Collaborative Study (Participating Site)

☐ Other

☐ Clinical Trial

☐ Multi-Site Study (Lead Site)

☐ Multi-Site Study (Participating Site)

STUDY CLOSURE

☐ Research can be closed.

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WORKSHEET: Non-Committee Review

The purpose of this worksheet is to provide support for Designated Reviewers conducting Non-Committee Review.

1. Submission Information

Type of submission:

☐ Initial Review

☐ Modification

☐ Continuing Review

☐ Request for Human Research or engagement determination

☐ Review of Modifications Required to Secure Approval

2. Reviewer Criteria (Check if "**Yes**." **Otherwise, sign the form, and return all materials**.)

☐ I do **not** have a Conflicting Interest

3. Review Level (Select one of the following)

☐ Not Human Research (use HRP-310 - WORKSHEET - Human Research Determination)

☐ Human Research Not Engaged (use HRP-311 - WORKSHEET - Engagement Determination)

☐ Exempt (use HRP-312 - WORKSHEET - Exemption Determination, HRP-319 - WORKSHEET - Limited IRB Review)

- ☐ (1) Educational settings
- ☐ (2)(i) Tests, surveys, interviews, or observation (non-identifiable)
- ☐ (2)(ii) Tests, surveys, interviews, or observation (low risk)
- ☐ (2)(iii) Tests, surveys, interviews, or observation (identifiable); and for which limited IRB review was conducted via expedited review
- ☐ (3)(i)(A) Benign behavioral interventions (non-identifiable)
- ☐ (3)(i)(B) Benign behavioral interventions (low risk)
- ☐ (3)(i)(C) Benign behavioral interventions (identifiable); and for which limited IRB review was conducted via expedited review
- ☐ (4) Secondary research on data or specimens (no consent required)
- ☐ (5) Demonstration projects
- ☐ (6) Taste and food quality
- ☐ (7) Storage or maintenance of data or specimens (broad consent required); and for which limited IRB review was conducted via expedited review

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☐ (8) Secondary research use of data or specimens (broad consent required); and for which limited IRB review was conducted via expedited review

☐ Expedited (use HRP-313 - WORKSHEET - Expedited Review, HRP-314 - WORKSHEET - Criteria for Approval)

- ☐ Minor modifications to previously approved research
- ☐ (1)(a) Drug studies
- ☐ (1)(b) Device studies
- ☐ (2)(a) Blood samples from healthy, non-pregnant adults
- ☐ (2)(b) Blood samples from others
- ☐ (3) Noninvasive biological specimens
- ☐ (4) Noninvasive procedures
- ☐ (5) Data, documents, records, or specimens
- ☐ (6) Voice, video, digital, or image recordings
- ☐ (7)(a) Behavioral research
- ☐ (7)(b) Social science methods
- ☐ (8)(a) Long-term follow-up
- ☐ (8)(b) No subjects enrolled
- ☐ (8)(c) Data analysis
- ☐ (9) Convened IRB determined Minimal Risk
- ☐ HUD continuing review

☐ IRB Chair Concurrence

- ☐ Non-emergency individual patient drug expanded access
- ☐ Non-emergency individual/small group compassionate use of a device

4. Determination (Select one of the following)

☐ Meets criteria

☐ Modifications required to meet criteria

☐ Send to convened IRB

5. Additional Information

Describe modifications required to secure approval, if required in section 3 above. Or, if review must be sent to the convened IRB, provide rationale for this determination (e.g. describe why research cannot be approved via expedited review, explain why research appearing on the expedited review list is actually more than Minimal Risk, etc.):

PI WORKSHEET: Waiver or Alteration of Consent Process

This worksheet is required for the following submission types when research involves waiver or alteration of the consent process: Expedited research or Full Committee research.

The purpose of this worksheet is to provide support for IRB members or the Designated Reviewer following HRP-314 – WORKSHEET - Criteria for Approval when research involves waiver or alteration of the consent process. The PI completes this worksheet to document determinations required by the regulations along with protocol specific findings justifying those determinations. For more information, visit: Drafting the Informed Consent Form.

Attach this worksheet to the "Local Site Documents" section of the ZOT IRB application.

Use a separate worksheet for each waiver or alteration determination for a study.

1. SUBMISSION INFORMATION

1.1 Basic Information:

1.1.1 IRB Study Number[1]: Click or tap here to enter text.

1.1.2 Short Title: Click or tap here to enter text.

2. RESEARCH MUST MEET ONE OF THE FOLLOWING SETS OF CRITERIA (Complete 2.1, 2.2, 2.3, 2.4, or 2.5.)

2.1 Waiver or Alteration of Consent Process[i] (Check if "Yes." All must be checked.)

☐ The research is **NOT** FDA-regulated.
☐ The research does **NOT** involve non-viable neonates.
☐ The research involves no more than Minimal Risk to the subjects.
☐ The research could **NOT** practicably[ii] be carried out without the waiver or alteration. (Check if "Yes". One must be checked.)
- ☐ It would not be feasible to individually contact the large numbers of potential subjects in the study.
- ☐ It would not be possible to locate many of the individuals whose records would be used for the study.
- ☐ Many of the individuals, whose records would be used for the study, are now deceased.
- ☐ Requiring informed consent may introduce systemic bias into the information.
- ☐ The risk of contacting the subjects to obtain informed consent is greater than the risk of the study procedures.
- ☐ Other, provide scientifically and ethically justifiable rationale.

Click or tap here to enter text.

[1] The IRB study number is generated when the submission is created in ZOT IRB. Please enter the number prior to final submission to the IRB.

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☐ If the research involves using Identifiable Private Information or Identifiable Biospecimens, the research could **NOT** practicably be carried out without using such information or biospecimens in an identifiable format. ☐ **NA if research does not use identifiable private information or biospecimens, or if the research is not subject to the 2018 Rule.**

☐ The waiver or alteration will **NOT** adversely affect the rights and welfare of the subjects.

☐ Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation (e.g., debriefed).[iii] ☐ **NA, the research involves deception (an alteration of consent) and there will be no debrief. OR ☐ NA, does not apply to retrospective research conducted under a waiver (e.g., review of existing records).**

☐ Waiver of consent for the storage, maintenance, or secondary research use of the Identifiable Private Information or Identifiable Biospecimens cannot be granted for those who refused to provide broad consent. ☐ **NA if broad consent not used for the research, or if the research is not subject to the 2018 Rule.**

☐ Alteration of the consent process can only omit or alter the basic and/or additional elements of consent.[iv] ☐ **NA if waiving informed consent, or if the research is not subject to the 2018 Rule.**

2.2 Waiver or Alteration of Consent Process[v] (Check if "Yes." All must be checked.)

☐ The research **IS** FDA-regulated.

☐ The clinical investigation involves no more than Minimal Risk (as defined in 21 CFR 50.3(k) or 56.102(i)) to the subjects.[vi]

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ The clinical investigation could not practicably[ii] be carried out without the requested waiver or alteration.

Provide scientifically and ethically justifiable rationale. Click or tap here to enter text.

☐ If the clinical investigation involves using Identifiable Private Information or Identifiable Biospecimens, the clinical investigation could not practicably be carried out without using such information or biospecimens in an identifiable format. ☐ **NA if research does not use identifiable private information or biospecimens.**

☐ The waiver or alteration will not adversely affect the rights and welfare of the subjects.

☐ Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

2.3 Waiver or Alteration of Consent Process[vii] (Check if "Yes." All must be checked.)

☐ The research is **NOT** FDA-regulated.

☐ The research does **NOT** involve non-viable neonates.

☐ The research or demonstration project is to be conducted by or subject to the approval of state or local government officials.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ The research or demonstration project is designed to study, evaluate, or otherwise examine one or more of the following: (Check all boxes that are true. One must be checked)

- ☐ Public benefit or service programs.
- ☐ Procedures for obtaining benefits or services under those programs.
- ☐ Possible changes in or alternatives to those programs or procedures.
- ☐ Possible changes in methods or levels of payment for benefits or services under those programs.

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Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ The research could **NOT** practicably[ii] be carried out without the waiver or alteration.

Provide scientifically and ethically justifiable rationale. Click or tap here to enter text.

☐ Waiver of consent for the storage, maintenance, or secondary research use of the Identifiable Private Information or Identifiable Biospecimens cannot be granted for those who refused to provide broad consent.
☐ **NA if broad consent not used for the research, or if the research is not subject to the 2018 Rule.**

☐ Alteration of the consent process can only omit or alter the basic and/or additional elements of consent.
☐ **NA if waiving informed consent, or if the research is not subject to the 2018 Rule.**

2.4 Waiver of the Consent Process for FDA-Regulated Research Involving Anonymous Tissue Specimens[viii] (Check if "Yes." All must be checked.)

☐ The research does not involve Human Subjects as Defined by DHHS.
☐ The study involves an in vitro diagnostic device investigation.
☐ The testing is noninvasive.
☐ The testing does not require an invasive sampling procedure that presents significant risk.
☐ The testing does not by design or intention introduce energy into a subject.
☐ The device is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.
☐ For a product in the laboratory research phase of development, and not represented as an effective in vitro diagnostic product, all labeling bears the statement, prominently placed: "For Research Use Only. Not for use in diagnostic procedures."
☐ For a product being shipped or delivered for product testing prior to full commercial marketing (for example, for use on specimens derived from humans to compare the usefulness of the product with other products or procedures which are in current use or recognized as useful), all labeling bears the statement, prominently placed: "For Investigational Use Only. The performance characteristics of this product have not been established."
☐ The study uses one of more of the following: (Check all boxes that are true. One must be checked.)
  ☐ Specimens collected for routine clinical care or analysis that would have been discarded.
  ☐ Specimens obtained from specimen repositories.
  ☐ Leftover specimens that were previously collected for other research purposes.
☐ The identity of the subject is not known to the investigator or any other individuals associated with the investigation, including the sponsor meaning neither the investigator nor any other individuals associated with the investigation, including the sponsor can readily ascertain the identity of the subject.
☐ One of the following is true: (Check all boxes that are true. One must be checked.)
  ☐ Specimens are not coded where "Coded" means that 1) a number, letter, symbol, or combination thereof (i.e., the code) has replaced identifying information (such as name or social security number) that would enable the investigator or any other individuals associated with the investigation, including the sponsor to readily ascertain the identity of the individual to whom the specimen pertains; and 2) a key to decipher the code exists, enabling linkage of the identifying information to the specimen.
  ☐ Neither the investigator(s) nor any other individuals associated with the investigation or the sponsor can link the specimen to the subject from whom the specimen was collected, either directly or indirectly through coding systems.
☐ One of the following is true: (Check all boxes that are true. One must be checked.)
  ☐ The specimens are not accompanied by clinical information.
  ☐ Clinical information that accompanies the specimens does not make the specimen source identifiable to the investigator or any other individual associated with the investigation, including the sponsor.

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☐ The individuals caring for the patients are different from those conducting the investigation and do not share information about the patient with those conducting the investigation.
☐ The specimens are provided to the investigator(s) without identifiers.
☐ The supplier of the specimens has established policies and procedures to prevent the release of personal information.

2.5 Waiver of Informed Consent for Planned Emergency Research[ix]

☐ The research meets the criteria in HRP-419 - PI WORKSHEET - Waiver of Consent for Emergency Research.

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[i] 45 CFR §46.116(f)

[ii] Practicably means capable of being done; it should not be determined by considerations of convenience, cost, or speed.

[iii] This criterion is intended to refer to the need to consider debriefing after research is conducted. In these situations it may be ethically required or determined to be respectful to provide the subject with pertinent information after the research is complete. IRBs may want to consider this mechanism when subjects are included in so-called "deception research," in which some aspects of the study are not fully disclosed upfront so that subject responses are not biased. Under most circumstances, this criterion does not apply to retrospective research conducted under a waiver (e.g., review of existing records).

[iv] An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in 45 CFR 46.116(b) and (c). An IRB may not omit or alter any of the requirements described in 45 CFR 46.116(a). If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under 45 CFR 46.116(d).

[v] 21 CFR § 50.22

[vi] A survey of patient records to determine sufficient number or preliminary review of the patient's record and recording of limited information is considered preparation for a clinical investigation, does not fall within the definition of a clinical investigation, and, therefore, does not require informed consent. *FDA's Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023)* https://www.fda.gov/media/88915/download

[vii] 45 CFR §46.116(e)

[viii] Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable – April 25, 2006. FDA's response to comments on the addition of section 50.22 **(**2023-27935.pdf (govinfo.gov) **)** "We believe that most IVD device investigations falling within the scope of the policy described in section IV of the Leftover Specimen Guidance will satisfy the criteria at § 50.22. However, to the extent that there are IVD device investigations that fall within the scope of the Leftover Specimen Guidance but do not satisfy the waiver criteria in § 50.22, FDA is retaining the Leftover Specimen Guidance at this time to help avoid potential disruption to IVD device investigations as IRBs gain experience implementing the new waiver provision in § 50.22 for FDA-regulated clinical investigations."

[ix] 21 CFR §50.24 and 45 CFR §46 Waiver of Informed Consent Requirements in Certain Emergency Research – November 1, 1996

PI WORKSHEET: Waiver of Written Documentation of Consent

This worksheet is required for the following submission types when research involves a waiver of written documentation of consent: Expedited research or Full Committee research.

The purpose of this worksheet is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when research involves the waiver of written documentation of consent. The PI completes this worksheet to document determinations required by the regulations along with protocol specific findings justifying those determinations. For more information, visit: Drafting the Informed Consent Form.

Attach this worksheet to the "Local Site Documents" section of the ZOT IRB application.

Use a separate worksheet for each waiver or alteration determination for a study.

1. SUBMISSION INFORMATION

1.1 Basic Information:

1.1.1 IRB Study Number[1]: Click or tap here to enter text.

1.1.2 Short Title: Click or tap here to enter text.

2. RESEARCH MUST MEET ONE OF THE FOLLOWING SETS OF CRITERIA (Complete 2.1, 2.2, or 2.3.)

2.1 Waiver of Written Documentation of Consent[i] - Written Consent is Not Normally Required (Check if "Yes." All must be checked.)

☐ The written script of the information to be provided orally (if consent is obtained in person) and all written information to be provided or electronically displayed include all required and appropriate additional elements of consent disclosure in Section 7: ELEMENTS OF CONSENT DISCLO**SURE** in HRP-314 - WORKSHEET - Criteria for Approval.

☐ The research presents no more than Minimal Risk of harm to subjects.

☐ The research involves no procedures for which written consent is normally required outside of the research context.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

Select one of the following: (One must be checked)

☐ Written information describing the research is to be provided to the subject or the subject's Legally Authorized Representative (LAR).

☐ Written information describing the research does not need to be provided to the subject or the subject's LAR.

[1] The IRB study number is generated when the submission is created in ZOT IRB. Please enter the number prior to final submission to the IRB.

2.2 Waiver of Written Documentation of Consent[ii] - Potential Harm Resulting from a Breach of Confidentiality (Check if "Yes." All must be checked.)

☐ The research is not FDA-regulated.
☐ The written script of the information to be provided orally and all written information to be provided include all required and appropriate additional elements of consent disclosure in Section 7: ELEMENTS OF CONSENT DISCLOSURE in HRP-314 - WORKSHEET: Criteria for Approval**.**
☐ The only record linking the subject and the research would be the consent document.
☐ The principal risk of a signed consent document would be the potential harm resulting from a breach of confidentiality.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ Each subject or Legally Authorized Representative (LAR) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

Select one of the following: (One must be checked)

☐ Written information describing the research is to be provided to the subject or the subject's LAR.
☐ Written information describing the research does not need to be provided to the subject or the subject's LAR.

2.3 Waiver of Written Documentation of Consent[iii] - A Distinct Cultural Group or Community (Check if "Yes." All must be checked.)

☐ The research is not FDA-regulated.
☐ The research is subject to the 2018 Rule.
☐ The written script of the information to be provided orally and all written information to be provided include all required and appropriate additional elements of consent disclosure in Section 7: ELEMENTS OF CONSENT DISCLOSURE in HRP-314 - WORKSHEET- Criteria for Approval**.**
☐ The subjects or subject's Legally Authorized Representative (LAR) are members of a distinct cultural group or community in which signing forms is not the norm.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ The research presents no more than Minimal Risk of harm to subjects.
☐ There is an appropriate alternative mechanism for documenting that informed consent was obtained.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

Select one of the following: (One must be checked)

☐ Written information describing the research is to be provided to the subject or the subject's LAR.
☐ Written information describing the research does not need to be provided to the subject or the subject's LAR.

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[i] 21 CFR §56.109(c)(1) and 45 CFR §46.117(c)(1)(ii)

[ii] 45 CFR §46.117(c)(1)(i)

[iii] 45 CFR §46.117(c)(1)(iii)

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PI WORKSHEET: Pregnant Women

This worksheet is required for the following submission types when the research involves pregnant women: Expedited research or Full Committee research.

The purpose of this worksheet is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when research involves pregnant women as subjects. The PI completes this worksheet to document determinations required by the regulations along with protocol specific findings justifying those determinations. For more information about research involving pregnant women, visit: Vulnerable Populations.

Attach this worksheet to the "Local Site Documents" section of the ZOT IRB application.

1. SUBMISSION INFORMATION

1.1 Basic Information:

1.1.1 IRB Study Number[1]: Click or tap here to enter text.
1.1.2 Short Title: Click or tap here to enter text.

2. RESEARCH MUST MEET ONE OF THE FOLLOWING SETS OF CRITERIA (Complete 2.1 or 2.2.)

2.1 Research Involving Pregnant[i] Women[ii] (Check if "Yes". All must be checked.)

☐ Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses. ☐ **NA if not scientifically appropriate.**

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ One of the following is true: (Check box that is true)

- ☐ The risk to the fetus[iii] is caused solely by Interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus.
- ☐ There is no prospect of benefit to the fetus, the risk to the fetus is **NOT** greater than Minimal Risk, and the purpose of the research is the development of important biomedical[iv] knowledge which cannot be obtained by any other means.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ Any risk is the least possible for achieving the objectives of the research.

[1] The IRB study number is generated when the submission is created in ZOT IRB. Please enter the number prior to final submission to the IRB.

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Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is NOT greater than Minimal Risk and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, consent of the mother is obtained. ☐ **NA if research does not hold out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus.**

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ If the research holds out the prospect of direct benefit solely to the fetus, the consent of the pregnant woman and the father is obtained, except that the father's consent need NOT be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest. ☐ **NA if research does not hold out the prospect of direct benefit to the fetus.**

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ For children who are pregnant, assent and permission[v] are obtained in accord with the provisions of subpart D. ☐ **NA if research does not enroll children who are pregnant.**

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ No inducements, monetary or otherwise, will be offered to terminate a pregnancy.

☐ Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.

☐ Individuals engaged in the research will have no part in determining the viability of a neonate.

2.2 Research Involving Pregnant Women that is NOT Otherwise Approvable (Check if "Yes". All must be checked.) **Follow HRP-044 - SOP - Not Otherwise Approvable Research**

☐ The research does **NOT** meet the requirements of §46.204.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ The research presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.

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Provide protocol specific findings justifying this determination. Click or tap here to enter text.

3. ADDITIONAL CONSIDERATIONS (Check if "Yes".)

☐ Prior to obtaining informed consent from a subject for assisted oocyte production (AOP) or any alternative method of ovarian retrieval on a subject for the purpose of procuring oocytes for research or the development of medical therapies, a physician and surgeon shall provide to the subject a standardized medically accurate written summary of health and consumer issues associated with AOP and any alternative methods of oocyte retrieval.

☐ Per California Law, pregnancy test results may be provided to a minor's parent(s) or guardian only with the minor's permission.

☐ For research reviewed by Committee, the Investigator states whether study procedures may involve risks to the subject (embryo or fetus if subject is or may become pregnant) that are currently unforeseeable.

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[i] "Pregnancy" encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

[ii] 45 CFR §46.204

[iii] "Fetus" means the product of conception from implantation until delivery.

[iv] For Department of Defense (DOD) research, the phrase "biomedical knowledge" can be replaced with "generalizable knowledge."

[v] American Academy of Pediatrics v. Lungren (1997) 16 Cal.4th 307. **A minor may consent to an abortion without parental consent and without court permission.** California Health and Safety Code remains unchanged (California Family Code Section 6925; Health and Safety Code Section 123450 for abortion).

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PI WORKSHEET: Non-Viable Neonates

This worksheet is required for the following submission types when research involves non-viable neonates: Expedited research or Full Committee research.

The purpose of this worksheet is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when research involves non-viable neonates as subjects. The PI completes this worksheet to document determinations required by the regulations along with protocol specific findings justifying those determinations. For more information about research involving non-viable neonates, visit: Vulnerable Populations.

Attach this worksheet to the "Local Site Documents" section of the ZOT IRB application.

1. SUBMISSION INFORMATION

1.1 Basic Information:

1.1.1 IRB Study Number[1]: Click or tap here to enter text.

1.1.2 Short Title: Click or tap here to enter text.

2. RESEARCH MUST MEET ONE OF THE FOLLOWING SETS OF CRITERIA (Complete 2.1 or 2.2.)

2.1 Research Involving Non-Viable[i] Neonates[ii] (Check if "Yes." All must be checked.)

☐ Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.

☐ Individuals engaged in the research will have no part in determining the viability of a neonate.

☐ Vital functions of the neonate will not be artificially maintained.

☐ The research will not terminate the heartbeat or respiration of the neonate.

☐ There will be no added risk to the neonate resulting from the research.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

[1] The IRB study number is generated when the submission is created in ZOT IRB. Please enter the number prior to final submission to the IRB.

☐ The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ The legally effective informed consent of both parents of the neonate is obtained, unless one parent is unable to consent because of unavailability, incompetence, or temporary incapacity and the consent of the father need not be obtained if the pregnancy resulted from rape or incest.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ The consent of a Legally Authorized Representative (LAR) of either or both of the parents of a nonviable neonate will not be obtained.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

2.2 Research Involving Neonates that is Not Otherwise Approvable (Check if "Yes." All must be checked)
Follow HRP-044 - SOP - Not Otherwise Approvable Research

☐ The research does **NOT** meet the requirements of §46.205.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ The research presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

[i] "Viable," as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.
[ii] 45 CFR §46.205

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PI WORKSHEET: Neonates of Uncertain Viability

This worksheet is required for the following submission types when research involves neonates of uncertain viability: Expedited research or Full Committee research.

The purpose of this worksheet is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when research involves neonates of uncertain viability as subjects. The PI completes this worksheet to document determinations required by the regulations along with protocol specific findings justifying those determinations. For more information about research involving neonates of uncertain viability, visit: Vulnerable Populations.

Attach this worksheet to the "Local Site Documents" section of the ZOT IRB application.

1. SUBMISSION INFORMATION

1.1 Basic Information:

1.1.1 IRB Study Number[1]: Click or tap here to enter text.
1.1.2 Short Title: Click or tap here to enter text.

2. RESEARCH MUST MEET ONE OF THE FOLLOWING SETS OF CRITERIA (Complete 2.1 or 2.2.)

2.1 Neonates[i] of Uncertain Viability[ii] (Check if "Yes". All must be checked.)

☐ Where scientifically appropriate, pre-clinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ Individuals engaged in the research will have no part in determining the viability of a neonate.

☐ One of the following is true: (Check box that is true)
- ☐ The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective.
- ☐ The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate. ☐ **NA if the consent process is waived.**

[1] The IRB study number is generated when the submission is created in ZOT IRB. Please enter the number prior to final submission to the IRB.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's Legally Authorized Representative (LAR) is obtained in accord with the regulations, except that the consent of the father or his LAR need not be obtained if the pregnancy resulted from rape or incest.
☐ **NA if the consent process is waived.**

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

2.2 Research Involving Neonates of Uncertain Viability that is Not Otherwise Approvable (Check if "Yes". All must be checked.) **Follow HRP-044 - SOP - Not Otherwise Approvable Research**

☐ The research does **NOT** meet the requirements of §46.205.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ The research presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

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[i] "Viable," as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.
[ii] 45 CFR §46.205

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PI WORKSHEET: Prisoners

This worksheet is required for the following submission types when research involves prisoners: Expedited research or Full Committee research. The Exempt research categories do not apply to research involving prisoners.

The purpose of this worksheet is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when research involves Prisoners as subjects. The PI completes this worksheet to document determinations required by the regulations along with protocol specific findings justifying those determinations. For more information about research involving prisoners, visit: Vulnerable Populations and GUIDANCE: Prisoner Research.

Attach this worksheet to the "Local Site Documents" section of the ZOT IRB application.

1. SUBMISSION INFORMATION

1.1 Basic Information:

1.1.1 IRB Study Number[1]: Click or tap here to enter text.

1.1.2 Short Title: Click or tap here to enter text.

2. PRISONER DEFINITION[i,ii] (Check if "Yes" below to confirm inclusion of prisoners.)

☐ Individuals involuntarily confined or detained in a penal institution.

☐ Individuals detained in a residential facility for court-ordered substance abuse treatment as a form of sentencing or alternative to incarceration are prisoners. *(Individuals receiving non-residential court-ordered substance abuse treatment and are residing in the community are not prisoners.)*

☐ Individuals with psychiatric illnesses committed involuntarily to an institution as an alternative to a criminal prosecution or incarceration are prisoners. *(Individuals voluntarily admitted to an institution for treatment of a psychiatric illness, or who have been civilly committed to non-penal institutions for treatment because their illness makes them a danger to themselves or others, are not prisoners.)*

☐ Parolees detained in a treatment center as a condition of parole are prisoners. *(Individuals living in the community and sentenced to community-supervised monitoring, including parolees, are not prisoners.)*

3. UCI IRB COMMITTEE REVIEW (Check if "Yes" or "NA".)

☐ At UCI research that involves **an interaction with a prisoner** requires an initial committee review. Future reviews may occur under the expedited review procedure (subcommittee) should the *committee* agree the research involves minimal risk. ☐ **NA**

[1] The IRB study number is generated when the submission is created in ZOT IRB. Please enter the number prior to final submission to the IRB.

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4. CALIFORNIA PROHIBITS BIOMEDICAL PRISONER RESEARCH EXCEPT FOR THE FOLLOWING (Check if "Yes" or "NA".)

☐ A physician treating a prisoner has determined that access to a drug or treatment which is available only under a treatment IND or a treatment protocol is in the best interest of the prisoner. In this case, consent from the subject is required. California Department of Corrections must also make confirmations. ☐ **NA**

☐ The research involves records-based research, using existing information. In this case, either written consent from the subject is required or a waiver of authorization may be granted. California Research Advisory Committee must approve of the use or disclosure. ☐ **NA**

5. RESEARCH MUST MEET ONE OF THE FOLLOWING SETS OF CRITERIA (Complete 5.1, 5.2, or 5.3.)

5.1 Non-DHHS-Regulated Research Where a Subject Becomes Incarcerated (Check if "Yes". All must be checked.)

☐ The research is **NOT** conducted or funded by DHHS or Veterans Administration (VA).
☐ The subject was not incarcerated at the time of enrollment and subsequent incarceration was unexpected.
☐ The incarceration does not put the rights and wellbeing of the subject in jeopardy.
☐ [IRB staff to confirm] The Prisoner representative has been consulted.
☐ The terms of the subject's confinement does not inhibit the ethical conduct of the research.
☐ There are no other significant issues preventing the research from continuing as approved.
☐ This approval is limited to the individual subject and does not allow recruitment of Prisoners.
☐ One of the following is true: (Check all that are true.)
- ☐ The subject will be at increased risk of harm if withdrawn from the research.
- ☐ The research presents no more than Minimal Risk[iii] and no more than inconvenience to the subjects.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

5.2 Non-DHHS Regulated Minimal Risk Research (Check if "Yes". All must be checked.)

☐ The research is **NOT** conducted, funded, or otherwise subject to regulation by DHHS or Veterans Administration (VA).
☐ The research does not involve interaction with prisoners (e.g. existing data, record review).
☐ The research presents no more than Minimal Risk.
☐ The research is reviewed by the expedited procedure.

5.3 Research Involving Prisoners as Subjects (Check if "Yes" or "NA". All must be checked.)

☐ The research under review represents one of the following categories of research: (At least one must be checked.)
- ☐ Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than Minimal Risk and no more than inconvenience to the subjects.
- ☒ Study of prisons as institutional structures or of Prisoners as incarcerated persons, provided that the study presents no more than Minimal Risk and no more than inconvenience to the subjects.
- ☐ Research on conditions particularly affecting Prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults).[iv]

☐ Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject where one of the following is true: (One must be checked.)

- ☐ All groups may benefit from the research.
- ☐ Prisoners are assigned to control groups which may not benefit from the research.
  1. Provide justification for the study design including a control group that may not benefit from the research.
  2. Specify if control participants are selected randomly from the group of available prisoners who meet the characteristics needed for this study.
     a. If the participants for the control group in this study *are not selected randomly*, provide justification for the proposed selection of control participants.

Click or tap here to enter text.

☐ Epidemiologic studies in which the sole purpose is to describe the prevalence or incidence of a disease by identifying all cases or to study potential risk factor associations for a disease, the research presents no more than Minimal Risk[ii] and no more than inconvenience to the subjects, and Prisoners are not a particular focus of the research.[v]

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ Any possible advantages accruing to the Prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ The risks involved in the research are commensurate with risks that would be accepted by non-Prisoner volunteers.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ Procedures for the selection of subjects within the prison are fair to all Prisoners and immune from arbitrary Intervention by prison authorities or Prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available Prisoners who meet the characteristics needed for that particular research project.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ The information is presented in language which is understandable to the subject population. ☐ **NA if no prisoner interaction.**

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ Adequate assurance exists that parole boards will not take into account a Prisoner's participation in the research in making decisions regarding parole, and each Prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole. ☐ **NA if no prisoner interaction.**

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ [IRB staff to confirm] If the IRB finds there may be a need for follow-up examination or care of subjects after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual Prisoners' sentences, and for informing subjects of this fact. ☐ **NA if no prisoner interaction.**

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ [IRB staff to confirm] A Prisoner representative reviewed the research focusing on the requirements of this worksheet.[vi] ☐ **NA if no prisoner interaction.**

☐ [IRB staff to confirm] The Prisoner representative received all materials pertaining to the research. ☐ **NA if no prisoner interaction.**

☐ [IRB staff to confirm] If the research is reviewed by convened IRB review, the Prisoner representative presented either orally or in writing at the meeting. If the research is reviewed by the expedited procedure, the Prisoner representative concurred that the research involves no more than Minimal Risk to the Prisoner subjects. ☐ **NA if no prisoner interaction.**

☐ If the research is DHHS-regulated, the research may proceed only after the institution has certified to OHRP that the duties of the Board under this section have been fulfilled.[vii] ☐ **NA**

☐ If the research is conducted or funded by the Department of Defense (DOD), the research may proceed only after the institution has demonstrated to the Senior Designated Official that the IRB has fulfilled its duties under this section. ☐ **NA**

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[i] "Prisoner" means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

[ii] Probationers and individuals wearing monitoring devices are generally not prisoners; however, situations of this kind frequently require an analysis of the particular circumstances of the planned participant population. Institutions may consult with OHRP when questions arise about research involving these populations.

[iii] "*Minimal risk*" for research involving prisoners is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

[iv] If the research is DHHS-regulated and involves prisoners as a class or control, the research may proceed only after OHRP has reviewed and approved the research. If the research is conducted or funded by the Department of Defense (DOD), the research may proceed only after the institution has demonstrated to the Senior Designated Official that the IRB has fulfilled its duties under this section. 45 CFR §46.306(a)(2)(iii) and (iv)

[v] 03-15580.pdf (govinfo.gov)

[vi] For review using the expedited procedure, the prisoner representative may be the Designated Reviewer or may serve as a consultant to the Designated Reviewer.

[vii] If the research is DHHS-regulated, the research may proceed only after the institution has certified to OHRP that the duties of the Board under this section have been fulfilled. If the research is conducted or funded by the Department of Defense (DOD), the research may proceed only after the institution has demonstrated to the Senior Designated Official that the IRB has fulfilled its duties under this section. 45 CFR §46.305(c).

PI WORKSHEET: Children

This worksheet is required for the following submission types when research involves children: Expedited research or Full Committee research.

It is not required for Exempt research. The purpose of this worksheet is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when research involves children as subjects. The PI completes this worksheet to document determinations required by the regulations along with protocol specific findings justifying those determinations. For more information about research involving children, visit: Vulnerable Populations.

Attach this worksheet to the "Local Site Documents" section of the ZOT IRB application.

Use a separate worksheet for each child determination for a study.

1. SUBMISSION INFORMATION

1.1 Basic Information:

1.1.1 IRB Study Number[1]: Click or tap here to enter text.

1.1.2 Short Title: Click or tap here to enter text.

2. CALIFORNIA DEFINITION OF A CHILD (MINOR) (Check if "YES".)

☐ Prospective subjects are under the age of 18 years and permission from a parent or legally authorized representative, or the court is required (unless waived by the IRB).

☐ Prospective subjects are over the age of 12 years **and** they may consent on their own without permission from a parent or legally authorized representative, or the court because the study involves the following: (Select the rationale that applies.)

- ☐ Mental health and medical care related to diagnosis or treatment of infectious, contagious or communicable diseases, including a sexually transmitted disease (required to be reported to the local health officer)
- ☐ Medical care related to diagnosis, treatment of the condition and collection of medical evidence about an alleged rape or sexual assault
- ☐ Care and (medical, counseling) related to the diagnosis and treatment of alcohol or drug problem
- ☐ A minor may consent to an abortion.

3. RESEARCH MUST MEET ONE OF THE FOLLOWING SETS OF CRITERIA (Complete 3.1, 3.2, 3.3. or 3.4.)

3.1 Minimal Risk: Research involving children under 21 CFR §50.51/45 CFR §46.404 (Check if "Yes." All must be checked.)

[1] The IRB study number is generated when the submission is created in ZOT IRB. Please enter the number prior to final submission to the IRB.

☐ No greater than Minimal Risk to children is presented.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

3.2 Greater than Minimal Risk with Direct Benefit to Subjects: Research involving children under 21 CFR §50.52/45 CFR §46.405 (Check if "Yes." All must be checked.)

☐ The research involves greater than Minimal Risk to subjects

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ The research presents the prospect of direct benefit to the individual subjects.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ One of the following is true. (Check box that is true.)

- ☐ The risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject.
- ☐ The risk to children is presented by a monitoring procedure that is likely to contribute to the subject's well-being.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ The risk is justified by the anticipated benefit to the subjects.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

3.3 Minor Increase over Minimal Risk with Generalizable Knowledge: Research involving children under 21 CFR §50.53/45 CFR §46.406 (Check if "Yes." All must be checked.)

☐ The research involves greater than Minimal Risk to children presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ The risk represents a minor increase over Minimal Risk where the researcher has presented sufficient evidence that the procedures, population, and the qualifications of research personnel support all of the following to be true[i]: (Check if "Yes". All must be checked.)

☐ The increase in the probability and magnitude of harm is only slightly more than minimal risk.
☐ Any potential harms associated with the procedure will be transient and reversible in consideration of the nature of the harm (restricted to time of procedure or short post-experimental period).
☐ There is no, or an extremely small probability, that participants will experience as severe the potential pain, discomfort, stress, or harm associated with the procedure.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

3.4 Not Otherwise Approvable Research: Not otherwise approvable research involving children under 21 CFR §50.54/45 CFR §46.407 (Check if "Yes." All must be checked.) **Follow HRP-044 - SOP - Not Otherwise Approvable Research**

☐ The research does not meet the requirements of Options 1, 2, or 3.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

4. RESEARCH INVOLVING WARDS OF THE STATE (One determination must be checked and documented.)

☐ **Option 1:** This research does NOT involve Wards of the State

☐ **Option 2:** This research does involve Wards of the State or any other agency, institution, or entity under 21 CFR §50.56/45 CFR §46.409 and one of the following risk levels is checked in Section 3: Option 1 (21 CFR §50.51/45 CFR §46.404) or Option 2 (21 CFR §50.52/45 CFR §46.405)**.**

☐ **Option 3:** This research does involve Wards of the State or any other agency, institution, or entity under 21 CFR §50.56/45 CFR §46.409 and Option 3 (21 CFR §50.53/45 CFR §46.406) or Option 4 (21 CFR §50.52/45 CFR §46.407) is checked in Section 3. **(Complete table below**.)

Check if "Yes"	Wards of the State: Option 3 Criteria (*All of the following must be checked and*	Provide protocol specific findings justifying this

	***documented)*:**	**determination**
☐	One of the following is true: (Check box that is true) ☐ The research is related to their status as wards. ☐ The research is conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.	Click or tap here to enter text.
☐	An advocate will be appointed for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis for research approved under §50.53 or §50.54/§46.406 or §46.407.	Click or tap here to enter text.
☐	The advocate will have the background and experience to act in, and will agree to act in, the best interests of the child for the duration of the child's participation in the research.	Click or tap here to enter text.
☐	The advocate is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.	Click or tap here to enter text.

5. ADEQUATE PROVISIONS TO SOLICIT THE ASSENT[ii] OF CHILDREN (Check if "Yes". All must be checked.)

☐ **Assent will be obtained from:** (Check box that is true.)

☐ **All children**. (NOTE: The protocol needs to describe the process of assent documentation.)

☐ Describe the study team's response should a child objects or resists participation (including non-verbal indications).

☐ Describe any plans to obtain consent for children when they reach the legal age of consent.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ **Some children.** (Check is "Yes" and **complete the Table for Waiver of Assent** below to document the reason why assent is not necessary 45 CFR §46.408(a)/21 CFR §50.55(c) The protocol needs to describe which children will not be asked for assent.)

☐ Describe the study team's response should a child objects or resists participation (including non-verbal indications).

☐ Describe any plans to obtain consent for children when they reach the legal age of consent.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ **None of the children.** (Check if "Yes" and **complete the Table for Waiver of Assent** to document the reason why assent is not necessary 45 CFR §46.408(a)/21 CFR §50.55(c).)

Check if "Yes"	**Table for Waiver of Assent** **Reason Why Assent is Not Necessary** **45 CFR §46.408(a)/21 CFR §50.55(c)** *One or more of the following are true. (Check all boxes that are true.)*
☐	The capability of these children (taking into account the ages, maturity, and psychological state of the children involved) is so limited that they cannot reasonably be consulted.[iii]

☐	The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research.[iii]
☐	Assent is waived using the following criteria 45 CFR §46.408(a)/45 CFR §46.116(f)/21 CFR §50.55(d): ☐ The research involves no more than Minimal Risk to the subjects. ☐ The waiver or alteration will not adversely affect the rights and welfare of the subjects. ☐ The research could not practicably be carried out without the waiver or alteration ☐ Whenever appropriate, the subjects will be provided with additional pertinent information after participation. ☐ If the research involves using identifiable private information or identifiable biospecimens, the research could NOT practicably be carried out without using such information or biospecimens in an identifiable format. ☐ **NA if research is FDA regulated, is subject to Pre-2018 Requirements OR if does not use identifiable private information or biospecimens.** ☐ A child's indication of dissent should be respected.
☐	Waiver of Child Assent under 45 CFR §46.408(a)/45 CFR §46.116(3) (Check if "Yes". All must be checked.) ☐ The research is not FDA-regulated. ☐ The research or demonstration project is to be conducted by or subject to the approval of state or local government officials. ☐ The research or demonstration project is designed to study, evaluate, or otherwise examine one or more of the following: (Check all boxes that are true. At least one must be checked.) ☐ Public benefit or service programs. ☐ Procedures for obtaining benefits or services under those programs. ☐ Possible changes in or alternatives to those programs or procedures. ☐ Possible changes in methods or levels of payment for benefits or services under those programs. ☐ The research could not practicably be carried out without the waiver or alteration. ☐ A child's indication of dissent should be respected.

6. ADEQUATE PROVISIONS ARE MADE FOR SOLICITING THE PERMISSION OF PARENTS OR GUARDIANS[iv] (Check if "Yes". One of the following must be checked.)

☐ Permission is to be obtained from both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

☐ Permission of one parent is sufficient even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child. (**Cannot be selected for the following Pediatric risk levels**: Section 3.3 - 21 CFR §50.53/45 CFR §46.406 or Section 3.4 - 21 CFR §50.54/45 CFR §46.407)

☐ Individuals other than parents. Describe how the study team will determine that the individual providing permission has the authority to do so.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ Parental permission is waived (Complete documentation in Section 7.)

7. WAIVER OF PARENTAL PERMISSION (To be completed only if a parental waiver was checked in Section 6. One of the following must be checked and documented.)

☐ **Waiver of Parental Permission under 45 CFR §46.408(c)** (Check if "Yes". All must be checked.)

- ☐ The research is not FDA-regulated.
- ☐ The research does not involve non-viable neonates.
- ☐ The research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

- ☐ An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

- ☐ The waiver is not inconsistent with Federal, State, or local law.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ **Waiver of Parental Permission under 45 CFR §46.116(f)** (Check if "Yes". All must be checked.)

- ☐ The research is not FDA-regulated.
- ☐ The research does not involve non-viable neonates.
- ☐ The research involves no more than Minimal Risk to the subjects.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

- ☐ The waiver or alteration will not adversely affect the rights and welfare of the subjects.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

- ☐ The research could not practicably be carried out without the waiver or alteration

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

- ☐ Whenever appropriate, the subjects will be provided with additional pertinent information after participation. ☐ **NA**

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

- ☐ If the research involves using identifiable private information or identifiable biospecimens, the research could NOT practicably be carried out without using such information or biospecimens in an identifiable format. ☐ **NA if research is subject to Pre-2018 Requirements OR if research does not use identifiable private information or biospecimens.**

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ Waiver of consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens cannot be granted for those who refused to provide broad consent. ☐ **NA if research is subject to Pre-2018 Requirements OR broad consent not used for the research.**

☐ Alteration of the consent process can only omit or alter the basic and/or additional elements of consent[v]. ☐ **NA if research is subject to Pre-2018 Requirements OR if waiving informed consent.**

☐ **Waiver of Parental Permission under 21 CFR § 50.22** (Check if "Yes." All must be checked.)

☐ The research **IS** FDA-regulated.

☐ The clinical investigation involves no more than minimal risk (as defined in 21 CFR 50.3(k) or 56.102(i)) to the subjects.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ If the clinical investigation involves using Identifiable Private Information or Identifiable Biospecimens, the clinical investigation could not practicably be carried out without using such information or biospecimens in an identifiable format. ☐ **NA if research does not use identifiable private information or biospecimens.**

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ The waiver or alteration will not adversely affect the rights and welfare of the subjects.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ **Waiver of Parental Permission under 45 CFR §46.408(c)/45 CFR §46.116(e)** (Check if "Yes". All must be checked.)

☐ The research is not FDA-regulated.

☐ The research does not involve non-viable neonates.

☐ The research or demonstration project is to be conducted by or subject to the approval of state or local government officials.

- ☐ Public benefit or service programs.
- ☐ Procedures for obtaining benefits or services under those programs.
- ☐ Possible changes in or alternatives to those programs or procedures.
- ☐ Possible changes in methods or levels of payment for benefits or services under those programs.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

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☐ The research could not practicably be carried out without the waiver or alteration.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

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[i] Where “minor increase over minimal risk” is based on SACHRP *Recommendations regarding risk in research involving children*; 18-Apr-2005.

[ii] “Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent, 45 CFR §46.402(b).

[iii] Additionally, in such circumstances, a child's dissent which should normally be respected may be overruled by the child's parents at the IRB's discretion. When research involves the provision of experimental therapies for life-threatening diseases such as cancer, however, the IRB should be sensitive to the fact that parents may wish to try anything, even when the likelihood of success is marginal and the probability of extreme discomfort is high. Should the child not wish to undertake such experimental therapy, difficult decisions may have to be made. In general, if the child is a mature adolescent and death is imminent, the child's wishes should be respected.

[iv] “Guardian” means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

[v] An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in 45 CFR 46.116(b) and (c). An IRB may not omit or alter any of the requirements described in 45 CFR 46.116(a). If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under 45 CFR 46.116(d).

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PI WORKSHEET: Adults with Impaired Decision-Making Capacity

This worksheet is required for the following submission types research involves adults with impaired decision-making capacity: Expedited research or Full Committee research.

The purpose of this worksheet is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when both of the following are true:

1. The research involves adults with impaired decision-making capacity as subjects, AND
2. The research involves a consent process or other intervention or interaction with the impaired decision-making capacity subject(s).

This checklist does not need to be used for reviews where the research qualifies for waiver or alteration of consent processes per HRP-410 - PI WORKSHEET Waiver or Alteration of Consent Process, and where there will be no interventions or interactions with the subjects. The PI completes this worksheet to document determinations required by the regulations along with protocol specific findings justifying those determinations. For more information about research involving adults with impaired decision-making capacity, visit: Vulnerable Populations and Use of Surrogate Consent in Research.

Attach this worksheet to the "Local Site Documents" section of the ZOT IRB application.

1. SUBMISSION INFORMATION

1.1 Basic Information:

1.1.1 IRB Study Number[1]: Click or tap here to enter text.

1.1.2 Short Title: Click or tap here to enter text.

2. RESEARCH MUST MEET ONE OF THE FOLLOWING SETS OF CRITERIA (Complete 2.1 or 2.2.)

2.1 Research Involving Adults with Impaired Decision-Making Capacity with Anticipated Direct Benefit to the Subject (Check if "Yes". All must be checked.)

☐ One of the following is true: (Check box that is true)

- ☐ Subjects have a disease or condition for which the procedures involved in the research hold out a prospect of direct benefit to the individual subject that is unavailable outside the research context.
- ☐ The objectives of the trial cannot be met by means of study of subjects who can give consent personally.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ Risks to subjects are reasonable in relation to the anticipated benefits to subjects.

[1] The IRB study number is generated when the submission is created in ZOT IRB. Please enter the number prior to final submission to the IRB.

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Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ The trial is not prohibited by law (e.g., psychiatric hold).

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ Subjects will be particularly closely monitored.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ Subjects will be withdrawn if they appear to be unduly distressed.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ Specify the plan for assessment of the decision-making capacity. Include who will be performing the decision-making capacity evaluation, their credentials, expertise, and experience performing the evaluation.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ The subject will be informed about the research to the extent compatible with the subject's understanding.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ Describe the study team's response should the adult subject object or resist participation (including non-verbal indications) or to the use of surrogate.

Click or tap here to enter text.

☐ Assent will be obtained from: (One of the following must be checked.)
- ☐ All subjects.
- ☐ Some subjects, specify: Click or tap here to enter text.
- ☐ None of the subjects.

☐ Surrogate consent will be obtained. The consent document includes a signature line for a Legally Authorized Representative (LAR).

☐ If capable, the subject will sign and personally date the written informed consent.

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2.2 Research Involving Adults with Impaired Decision-Making Capacity with NO Anticipated Direct Benefit to the Subject (Check if "Yes". All must be checked.)

☐ Subjects have a disease or condition for which the procedures involved in the research are intended.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ The objectives of the trial cannot be met by means of study of subjects who can give consent personally.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ The foreseeable risks to the subjects are low.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ The negative impact on the subject's well-being is minimized and low.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ The trial is not prohibited by law (e.g., psychiatric hold).

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ Subjects will be particularly closely monitored.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ Subjects will be withdrawn if they appear to be unduly distressed.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ The proposed plan for the assessment of the capacity to consent is adequate.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ The subjects will be informed about the research to the extent compatible with the subject's understanding.

☐ Describe the study team's response should the adult subject object or resist participation (including non-verbal indications) or to the use of surrogate.

Click or tap here to enter text.

☐ Assent will be obtained from: (One of the following must be checked)

☐ All subjects.
☐ Some subjects, specify:

Click or tap here to enter text.

☐ None of the subjects.

☐ Surrogate consent will be obtained. The consent document includes a signature line for a (LAR).

☐ If capable, the subject will sign and personally date the written informed consent.

3. INVESTIGATOR CERTIFICATION OF SURROGATE DECISION MAKERS FOR POTENTIAL SUBJECT'S PARTICIPATION IN UNIVERSITY OF CALIFORNIA RESEARCH (Check if "Yes". All must be checked)

☐ Surrogate consent will be utilized as specified in the applicable version of the HRP-503 Protocol Narrative.
☐ The protocol-specific plan for assessment of the decision-making capacity by the investigator of any research participants who may require the consent of a legally authorized representative will be followed. This may include the use of the Decision Making Capacity Assessment Tool.
☐ The Principal Investigator and study team will follow the Investigator Certification of Surrogate Decision Makers for Potential Subject's Participation in University of California Research process when identifying a surrogate.

WORKSHEET: Non-Significant Risk Device

The purpose of this worksheet is to provide support for IRB members when research involves an abbreviated IDE.

1. Significant Risk Device Study (Check if "Yes." If any are checked, the device is a significant risk device.)

☐ Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject.

☐ Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject.

☐ Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject.

☐ Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

2. Non-Significant Risk Device Study (Check if "Yes.")

☐ Meets none of the above criteria.

3. Rationale

IRB Considerations[i]*:*

- *The risk determination is based on the proposed use of a device in an investigation, and not on the device alone.*
- *Consider the potential harm any additional procedures the subject will need to undergo as part of the investigational study (e.g., surgical procedure)*

[i] Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors, Significant Risk and Nonsignificant Risk Medical Device Studies, January 2006, https://www.fda.gov/media/75459/download

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PI WORKSHEET: Waiver of Consent Process for Emergency Research

This worksheet is required for the following submission types when research involves waiver of consent for planned emergency research: Expedited research or Full Committee research.

The purpose of this worksheet is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when research involves waiver of consent for planned emergency research. The PI completes this worksheet to document determinations required by the regulations along with protocol specific findings justifying those determinations.

Attach this worksheet to the "Local Site Documents" section of the ZOT IRB application.

1. SUBMISSION INFORMATION

1.1 Basic Information:

1.1.1 IRB Study Number[1]: Click or tap here to enter text.

1.1.2 Short Title: Click or tap here to enter text.

2. WAIVER OF THE INFORMED CONSENT PROCESS FOR PLANNED EMERGENCY RESEARCH (Check if "Yes." All must be checked.)

☐ The research is **NOT** subject to regulation by a Common Rule agency other than DHHS.

☐ The research does **NOT** involve prisoners as subjects.

☐ The research does **NOT** involve pregnant women, fetuses, non-viable neonates, or neonates of uncertain viability.

☐ [IRB staff to confirm] The IRB has reviewed and approved consent procedures and a consent document in accordance with HRP-314 - WORKSHEET - Criteria for Approval.

☐ The Human Subjects are in a life-threatening situation.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ Available treatments are unproven or unsatisfactory.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

[1] The IRB study number is generated when the submission is created in ZOT IRB. Please enter the number prior to final submission to the IRB.

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☐ The collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ Obtaining informed consent is not feasible because the subjects will not be able to give their informed consent as a result of their medical condition.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ Obtaining informed consent is not feasible because the intervention under investigation must be administered before consent from the subject's Legally Authorized Representative (LAR) is feasible.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ Obtaining informed consent is not feasible because there is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the research.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ Participation in the research holds out the prospect of direct benefit to the subjects because they are facing a life-threatening situation that necessitates intervention.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ Appropriate animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the intervention to provide a direct benefit to the individual subject.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ Risks associated with the investigation are reasonable in relation to what is known about the medical condition of the potential class of subjects, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ The research could not practicably be carried out without the waiver.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ The proposed investigational plan defines the length of the potential therapeutic window based on scientific evidence, and the investigator has committed to attempting to contact a LAR for each subject within that

window of time and, if feasible, to asking the LAR contacted for consent within that window rather than proceeding without consent. The investigator will summarize efforts made to contact LARs and make this information available to the IRB at the time of continuing review.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ Additional protections of the rights and welfare of the subjects will include consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the research will be conducted and from which the subjects will be drawn.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ Additional protections of the rights and welfare of the subjects will include public disclosure to the communities in which the research will be conducted and from which the subjects will be drawn, prior to initiation of the research, of plans for the investigation and its risks and expected benefits.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ Additional protections of the rights and welfare of the subjects will include public disclosure of sufficient information following completion of the research to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ Additional protections of the rights and welfare of the subjects will include establishment of an independent data monitoring committee to exercise oversight of the research.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ If obtaining informed consent is not feasible and a LAR is not reasonably available, the investigator has committed, if feasible, to attempting to contact within the therapeutic window the subject's family member who is not a LAR, and asking whether he or she objects to the subject's participation in the research. The investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ Procedures are in place to inform, at the earliest feasible opportunity, each subject, or if the subject remains incapacitated, a LAR of the subject, or if such a representative is not reasonably available, a family member, of the subject's inclusion in the research, the details of the investigation and other information contained in the informed consent document.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ There is a procedure to inform the subject, or if the subject remains incapacitated, a LAR of the subject, or if such a representative is not reasonably available, a family member, that he or she may discontinue the subject's participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ If a LAR or family member is told about the research and the subject's condition improves, the subject is also to be informed as soon as feasible.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ If a subject is entered into research with waived consent and the subject dies before a LAR or family member can be contacted, information about the research is to be provided to the subject's LAR or family member, if feasible.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ The investigator will interpret "family member" to mean any one of the following legally competent persons: spouses; parents; children (including adopted children); brothers, sisters, and spouses of brothers and sisters; and any individual related by blood or affinity whose close association with the subject is the equivalent of a family relationship.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ [IRB staff to confirm] The IRB has reviewed and approved procedures and information to be used when providing an opportunity for a family member to object to a subject's participation in the research consistent with this waiver.

Provide protocol specific findings justifying this determination. Click or tap here to enter text.

☐ If the research is FDA-regulated, the protocol is being performed under a separate investigational new drug application (IND) or investigational device exemption (IDE) that clearly identifies this protocol as including subjects who are unable to consent (even if an IND for the same drug product or an IDE for the same device already exists). ☐ **NA if not FDA-regulated.**

☐ If the research is FDA-regulated, a licensed physician who is a member of or consultant to the IRB and who is not otherwise participating in the research has concurred with the above findings. ☐ **NA if not FDA-regulated.**

☐ If the research is NOT FDA-regulated, the research is also not subject to regulations codified by the FDA at title 21 CFR part 50. ☐ **NA if not FDA-regulated.**

If an IRB determines that it cannot approve a protocol because it does not meet the criteria in the exception or because of other relevant ethical concerns, the IRB must document its findings and provide these findings promptly (no longer than within 30 days) in writing to the investigator and the sponsor.

PI WORKSHEET: Investigator Quality Improvement Assessment

The purpose of this worksheet is to allow investigators to conduct a quality improvement self-assessment and for IRB staff to conduct a quality improvement assessment of investigators. (LAR = "subject's Legally Authorized Representative)

General Research (Not Clinical Trials)

Basic Information	Quality Improvement Details
Principal Investigator	Click or tap here to enter text.
Protocol Name	Click or tap here to enter text.
Name of Person Completing Worksheet	Click or tap here to enter text.
Date Completed	Click or tap here to enter text.

1. Regulatory Documentation for Each Study

Response	Regulatory Document
☐ Yes ☐ No ☐ NA	Grant
☐ Yes ☐ No ☐ NA	Annual progress reports for grant
☐ Yes ☐ No ☐ NA	Most recent version of the IRB approved protocol
☐ Yes ☐ No ☐ NA	Previously IRB approved versions of the protocol
☐ Yes ☐ No ☐ NA	IRB approved amendments to the protocol
☐ Yes ☐ No ☐ NA	Most recent version of the IRB approved consent document
☐ Yes ☐ No ☐ NA	Previous versions of the IRB approved consent document
☐ Yes ☐ No ☐ NA	Most recent versions of the IRB approved information provided to subjects
☐ Yes ☐ No ☐	Previous versions of IRB approved information provided to subjects

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NA	
☐ Yes ☐ No ☐ NA	Currently approved recruitment materials
☐ Yes ☐ No ☐ NA	Previous versions of approved recruitment materials
☐ Yes ☐ No ☐ NA	IRB roster associated with each approval letter
☐ Yes ☐ No ☐ NA	Correspondence with the IRB on file: (look for signature and date when needed for submission)
☐ Yes ☐ No ☐ NA	Initial IRB application
☐ Yes ☐ No ☐ NA	Continuing review applications. **Number:** Click or tap here to enter text.
☐ Yes ☐ No ☐ NA	Modification applications: **Number:** Click or tap here to enter text.
☐ Yes ☐ No ☐ NA	Initial IRB approval
☐ Yes ☐ No ☐ NA	Continuing review approvals
☐ Yes ☐ No ☐ NA	Modification approvals
☐ Yes ☐ No ☐ NA	Interim reports
☐ Yes ☐ No ☐ NA	Notifications of IRB disapproval, deferral, modifications required to secure approval
☐ Yes ☐ No ☐ NA	Responses to IRB actions
☐ Yes ☐ No ☐ NA	Suspension of IRB Approval or Termination of IRB Approval
☐ Yes ☐ No ☐ NA	Copies of email correspondence with the IRB
☐ Yes ☐ No ☐ NA	Other communications with the IRB
☐ Yes ☐ No ☐ NA	Records of investigator and staff training
☐ Yes ☐ No ☐ NA	Signed agreements/contracts between parties
☐ Yes ☐ No ☐ NA	Correspondences to and from the funding agency

2. Document Retention

Response	Retention Requirement

☐ Yes ☐ No ☐ NA	In accordance with UC Office of the President policy, research records must be retained for 10 years after the end of the calendar year in which the research is completed unless otherwise specified in the award agreement. If research involves the investigation of FDA regulated products: Information/biospecimens must be retained for two years after an approved marketing application. If approval is not received, the information/biospecimens will be kept for 2 years after the investigation is discontinued and the FDA is notified per FDA sponsor requirements.

3. Informed Consent

Response	Informed Consent Requirement
☐ Yes ☐ No ☐ NA	An investigator seeks consent only under circumstances that provide the prospective subjects or the Legally Authorized Representative (LAR) sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.
☐ Yes ☐ No ☐ NA	The information given to the subjects or the LAR is in language understandable to the subject or the LAR.
☐ Yes ☐ No ☐ NA	Investigators do not disclose any exculpatory language, through which the subject or the LAR is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.
☐ Yes ☐ No ☐ NA	Investigators disclose to the subject the information in the consent document.
☐ Yes ☐ No ☐ NA	Investigators give either the subject or LAR adequate opportunity to read the consent document before it is signed.
☐ Yes ☐ No ☐ NA	A copy of the signed and dated consent document is given to the person signing the document.
☐ Yes ☐ No ☐ NA	Investigators provide the prospective subject or the LAR with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information. **(NA if research is subject to Pre-2018 Requirements) ☐ NA**
☐ Yes ☐ No ☐ NA	The Informed consent document begins with a concise and focused presentation of the key information that is most likely to assist a prospective subjects or LAR in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. **(NA if research is subject to Pre-2018 Requirements) ☐ NA**
☐ Yes ☐ No ☐ NA	Informed consent as a whole presents information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or LAR's understanding of the reasons why one might or might not want to participate. **(NA if**

	research is subject to Pre-2018 Requirements) ☐ NA

4. Informed Consent Disclosures

Informed Consent Requirement	Response
Required (*Can be omitted if there are none.)	☐ The study involves research. ☐ The purposes of the research. ☐ The expected duration of the subject's participation. ☐ The procedures to be followed. ☐ Identification of any procedures, which are experimental.* ☐ Any reasonably foreseeable risks or discomforts to the subject.* ☐ Any benefits to the subject or to others, which may reasonably be expected from the research.* ☐ Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.* ☐ The extent, if any, to which confidentiality of records identifying the subject will be maintained.* ☐ How to contact the research team for questions, concerns, or complaints about the research. ☐ How to contact someone independent of the research team for questions, concerns, or complaints about the research; questions about the subjects' rights; to obtain information; or to offer input. ☐ Whom to contact in the event of a research-related injury to the subject. ☐ Participation is voluntary. ☐ Refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled. ☐ The subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. ☐ One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens: ☐ A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the LAR, if this might be a possibility; or ☐ A statement that the subject's information or biospecimens collected as part

	of the research, even if identifiers are removed, will not be used or distributed for future research studies. (**NA if research is subject to Pre-2018 Requirements) NA:** ☐
Required for More than <u>Minimal Risk</u> Research	☐ Whether any compensation is available if injury occurs and, if so, what it consists of, or where further information may be obtained. ☐ Whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
Additional: (Include when appropriate.)	☐ The particular treatment or procedure may involve risks to the subject, which are currently unforeseeable. ☐ If the subject is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable. ☐ Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent. ☐ Any additional costs to the subject that may result from participation in the research. ☐ The consequences of a subject's decision to withdraw from the research. ☐ Procedures for orderly termination of participation by the subject. ☐ Significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation will be provided to the subject. ☐ Approximate number of subjects involved in the study. ☐ Amount and schedule of all payments. ☐ A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit. (**NA if research is subject to Pre-2018 Requirements)** ☐ A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions. (**NA if research is subject to Pre-2018 Requirements)** ☐ For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.,* sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen). (**NA if research is subject to Pre-2018 Requirements)** ☐ Any additional information which should be given to subjects when in the IRB's judgement the information would meaningfully add to the protection of the rights and welfare of subjects.[i] ☐ When the study involves genetic testing, a statement that outlines the protections afforded to the subject under the Genetic Information Nondiscrimination Act (GINA).

Clinical Trials

Basic Information	Quality Improvement Details
Principal Investigator	Click or tap here to enter text.
Protocol Name	Click or tap here to enter text.
Name of Person Completing Worksheet	Click or tap here to enter text.
Date Completed	Click or tap here to enter text.

5. Regulatory Documentation for Each Study

Response	Regulatory Documentation Category
☐ Yes ☐ No ☐ NA	Grant
☐ Yes ☐ No ☐ NA	Annual progress reports for grant
☐ Yes ☐ No ☐ NA	Most recent version of the IRB approved protocol
☐ Yes ☐ No ☐ NA	Previously IRB approved versions of the protocol
☐ Yes ☐ No ☐ NA	IRB approved amendments to the protocol
☐ Yes ☐ No ☐ NA	Most recent version of the IRB approved consent document
☐ Yes ☐ No ☐ NA	Previous versions of the IRB approved consent document
☐ Yes ☐ No ☐ NA	Most recent versions of the IRB approved information provided to subjects
☐ Yes ☐ No ☐ NA	Previous versions of IRB approved information provided to subjects
☐ Yes ☐ No ☐ NA	Currently approved recruitment materials
☐ Yes ☐ No ☐ NA	Previous versions of approved recruitment materials
☐ Yes ☐ No ☐	IRB roster associated with each approval letter

NA	
☐ Yes ☐ No ☐ NA	Correspondence with the IRB on file: (look for signature and date when needed for submission)
☐ Yes ☐ No ☐ NA	Initial IRB application
☐ Yes ☐ No ☐ NA	Continuing review applications. **Number:** Click or tap here to enter text.
☐ Yes ☐ No ☐ NA	Modification applications: **Number:** Click or tap here to enter text.
☐ Yes ☐ No ☐ NA	Initial IRB approval
☐ Yes ☐ No ☐ NA	Continuing review approvals
☐ Yes ☐ No ☐ NA	Modification approvals
☐ Yes ☐ No ☐ NA	Interim reports
☐ Yes ☐ No ☐ NA	Notifications of IRB disapproval, deferral, modifications required to secure approval
☐ Yes ☐ No ☐ NA	Responses to IRB actions
☐ Yes ☐ No ☐ NA	Suspension of IRB Approval or Termination of IRB Approval
☐ Yes ☐ No ☐ NA	Copies of email correspondence with the IRB
☐ Yes ☐ No ☐ NA	Other communications with the IRB
☐ Yes ☐ No ☐ NA	Records of investigator and staff training
☐ Yes ☐ No ☐ NA	Signed agreements/contracts between parties
☐ Yes ☐ No ☐ NA	Subject screening log **Number screened:** Click or tap here to enter text.
☐ Yes ☐ No ☐ NA	Subject identification code list
☐ Yes ☐ No ☐ NA	Subject enrollment log **Number enrolled:** Click or tap here to enter text.
☐ Yes ☐ No ☐	Record of retained body fluids/tissue samples

NA	
☐ Yes ☐ No ☐ NA	Correspondences to and from the sponsor or CRO
☐ Yes ☐ No ☐ NA	Letters
☐ Yes ☐ No ☐ NA	Meeting notes
☐ Yes ☐ No ☐ NA	Notes of telephone calls
☐ Yes ☐ No ☐ NA	CVs or other relevant documents evidencing qualifications of PI, co-investigators, and all study personnel
☐ Yes ☐ No ☐ NA	CVs or other relevant information have been updated within the past two years
☐ Yes ☐ No ☐ NA	CVs or other relevant information are signed and dated
☐ Yes ☐ No ☐ NA	Instructions for handling of investigational product(s) and trial-related materials (if not in protocol or investigator's brochure)
☐ Yes ☐ No ☐ NA	Decoding procedures for blinded trials
☐ Yes ☐ No ☐ NA	Normal lab values
☐ Yes ☐ No ☐ NA	Updates to normal lab values
☐ Yes ☐ No ☐ NA	Lab certification (e.g., CLLIA)?
☐ Yes ☐ No ☐ NA	Updates to lab certification (e.g., CLIA)?
☐ Yes ☐ No ☐ NA	Lab director's CV
☐ Yes ☐ No ☐ NA	Updates to lab director's CV
☐ Yes ☐ No ☐ NA	Monitoring/auditing log. How often is monitoring taking place: Click or tap here to enter text.
☐ Yes ☐ No ☐ NA	Site Initiation report or visit documentation
☐ Yes ☐ No ☐ NA	Study close-out report or visit documentation
☐ Yes ☐ No ☐	DSMB reports

NA	
☐ Yes ☐ No ☐ NA	Staff signature log
☐ Yes ☐ No ☐ NA	Signature log reflects current staff working on the study
☐ Yes ☐ No ☐ NA	Staff working on the study are IRB approved
☐ Yes ☐ No ☐ NA	Delegation of responsibility (The Investigator maintains a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.)
☐ Yes ☐ No ☐ NA	Most recently approved sample case report forms (CRF)
☐ Yes ☐ No ☐ NA	For marketed products, a package insert/product information

6. Study Records (IND studies)

Response	Study Record Category
☐ Yes ☐ No ☐ NA	A signed current FDA 1572
☐ Yes ☐ No ☐ NA	Previous signed versions of FDA 1572
☐ Yes ☐ No ☐ NA	A current signed financial disclosure form submitted to the sponsor
☐ Yes ☐ No ☐ NA	Previous versions of signed financial disclosure forms submitted to the sponsor
☐ Yes ☐ No ☐ NA	Valid licensure for each investigator/staff member listed on the 1572 or in the Investigator Statement
☐ Yes ☐ No ☐ NA	Current investigator brochure
☐ Yes ☐ No ☐ NA	Previous versions of or updates to the investigator brochure
☐ Yes ☐ No ☐ NA	There is shipping log for each drug. These include:
☐ Yes ☐ No ☐ NA	Date shipment received
☐ Yes ☐ No ☐ NA	Shipment number from packing slip study drug or device
☐ Yes ☐ No ☐	Batch number, lot number, code mark

NA	
☐ Yes ☐ No ☐ NA	Expiration date
☐ Yes ☐ No ☐ NA	Number of boxes, kits, or devices per lot number
☐ Yes ☐ No ☐ NA	Number of bottles, vials, inhalers, or devices per box or kit
☐ Yes ☐ No ☐ NA	Condition of study drug or device shipment (Intact, damaged)
☐ Yes ☐ No ☐ NA	Receiver's name
☐ Yes ☐ No ☐ NA	There is an accountability log for each drug under investigation. These include:
☐ Yes ☐ No ☐ NA	Subject ID number, initials, or name
☐ Yes ☐ No ☐ NA	Lot or kit number
☐ Yes ☐ No ☐ NA	Number of bottles, vials, etc.
☐ Yes ☐ No ☐ NA	Amount of study drug per bottle, vial, etc..
☐ Yes ☐ No ☐ NA	Total amount dispensed
☐ Yes ☐ No ☐ NA	Initials
☐ Yes ☐ No ☐ NA	Date dispensed
☐ Yes ☐ No ☐ NA	Number of bottles, vials, etc. returned
☐ Yes ☐ No ☐ NA	Total amount returned
☐ Yes ☐ No ☐ NA	Balance: number dispensed less number returned
☐ Yes ☐ No ☐ NA	Comments: subject lost, discarded, etc.
☐ Yes ☐ No ☐ NA	Person who dispensed the drug
☐ Yes ☐ No ☐	The investigator furnishes all reports to the sponsor of the drug

NA	
☐ Yes ☐ No ☐ NA	An investigator shall promptly report to the sponsor any adverse effect that may reasonably be regarded as caused by, or probably caused by, the drug. If the adverse effect is alarming, the investigator shall report the adverse effect immediately.
☐ Yes ☐ No ☐ NA	An investigator shall provide the sponsor with an adequate report shortly after completion of the investigator's participation in the investigation.

7. Study Records (IDE studies)

Response	Study Record Category
☐ Yes ☐ No ☐ NA	A signed Investigator Statement
☐ Yes ☐ No ☐ NA	Previous versions of signed Investigator Statements
☐ Yes ☐ No ☐ NA	A current signed financial disclosure form submitted to the sponsor
☐ Yes ☐ No ☐ NA	Previous versions of signed financial disclosure forms submitted to the sponsor
☐ Yes ☐ No ☐ NA	Valid licensure for each investigator/staff member listed on the 1572 or in the Investigator Statement
☐ Yes ☐ No ☐ NA	There is shipping log for each device. These include:
☐ Yes ☐ No ☐ NA	Date shipment received
☐ Yes ☐ No ☐ NA	Shipment number from packing slip study device
☐ Yes ☐ No ☐ NA	Batch number, lot number, code mark
☐ Yes ☐ No ☐ NA	Expiration date
☐ Yes ☐ No ☐ NA	Number of boxes, kits, or devices per lot number
☐ Yes ☐ No ☐ NA	Number of bottles, vials, inhalers, or devices per box or kit
☐ Yes ☐ No ☐ NA	Condition of study drug or device shipment (Intact, damaged)
☐ Yes ☐ No ☐ NA	Receiver's name
☐ Yes ☐ No ☐	There is an accountability log for each device under investigation. These include:

NA	
☐ Yes ☐ No ☐ NA	Subject ID number, initials, or name
☐ Yes ☐ No ☐ NA	Study device lot, batch number, or code mark
☐ Yes ☐ No ☐ NA	Date dispensed
☐ Yes ☐ No ☐ NA	Device disposition
☐ Yes ☐ No ☐ NA	Comments, such as malfunctions, device failure, disposition of unused devices (returned to sponsor or destroyed) or any other pertinent information concerning the device.
☐ Yes ☐ No ☐ NA	Person who dispensed the device
☐ Yes ☐ No ☐ NA	Correspondence with another investigator, an IRB, the sponsor, a monitor, or FDA, including required report
☐ Yes ☐ No ☐ NA	Reports of unanticipated adverse device effects. The investigator submits to the sponsor and to the reviewing IRB a report of any unanticipated adverse device effect occurring during an investigation as soon as possible, but in no event later than 10 working days after the investigator first learns of the effect.
☐ Yes ☐ No ☐ NA	Reports of withdrawal of IRB approval. The investigator reports to the sponsor, within 5 working days, a withdrawal of approval by the reviewing IRB of the investigator's part of an investigation.
☐ Yes ☐ No ☐ NA	Progress reports. The investigator submits progress reports on the investigation to the sponsor, the monitor, and the reviewing IRB at regular intervals, but in no event less often than yearly.
☐ Yes ☐ No ☐ NA	Reports of deviations from the investigational plan. The investigator notifies the sponsor and the reviewing IRB of any deviation from the investigational plan to protect the life or physical well-being of a subject in an emergency. Such notice is given as soon as possible, but in no event later than 5 working days after the emergency occurred. Except in such an emergency, prior approval by the sponsor is required for changes in or deviations from a plan, and if these changes or deviations may affect the scientific soundness of the plan or the rights, safety, or welfare of human subjects, FDA and IRB is required.
☐ Yes ☐ No ☐ NA	Reports of use of the device without informed consent. If the investigator uses a device without obtaining informed consent, the investigator reports such use to the sponsor and the reviewing IRB within 5 working days after the use occurs.
☐ Yes ☐ No ☐ NA	Final report. The investigator, within 3 months after termination or completion of the investigation or the investigator's part of the investigation, submits a final report to the sponsor and the reviewing IRB.

8. Document Retention

Response	Requirement
☐ Yes ☐ No ☐ NA	In accordance with UC Office of the President policy, research records must be retained for 10 years after the end of the calendar year in which the research is completed unless otherwise specified in the award agreement. If research involves the investigation of FDA regulated products: Information/biospecimens must be retained for two years after an approved marketing application. If approval is not received, the information/biospecimens will be kept for 2 years after the investigation is discontinued and the FDA is notified per FDA sponsor requirements. Refer to the following sections.

9. Document Retention (IND studies)

Response	Requirement
☐ Yes ☐ No ☐ NA	An investigator retains records required to be maintained under this part for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified.

10. Document Retention (IDE studies)

Response	Requirement
☐ Yes ☐ No ☐ NA	An investigator or sponsor shall maintain the records required by this subpart during the investigation and for a period of 2 years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol.

11. Informed Consent Disclosures

Both the informed consent discussion and the written informed consent form and any other written information to be provided to subjects includes explanations of the following:

Informed Consent Requirement	Response
Required (*Can be omitted if there are none.)	☐ The form begins with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research. This part of the informed

	consent must be organized and presented in a way that facilitates comprehension. (**NA if research is subject to Pre-2018 Requirements) NA:** ☐ ☐ The study involves research. ☐ The purposes of the research. ☐ The expected duration of the subject's participation. ☐ The procedures to be followed. ☐ Identification of any procedures, which are experimental.* ☐ Any reasonably foreseeable risks or discomforts to the subject.* ☐ Any benefits to the subject or to others, which may reasonably be expected from the research.* ☐ Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.* ☐ The extent, if any, to which confidentiality of records identifying the subject will be maintained.* ☐ How to contact the research team for questions, concerns, or complaints about the research. ☐ How to contact someone independent of the research team for questions, concerns, or complaints about the research; questions about the subjects' rights; to obtain information; or to offer input. ☐ Whom to contact in the event of a research-related injury to the subject. ☐ Participation is voluntary. ☐ Refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled. ☐ The subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. ☐ One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens: ☐ A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the LAR, if this might be a possibility; or ☐ A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies. (**NA if research is subject to Pre-2018 Requirements) NA:** ☐
Required for More than	☐ Whether any compensation is available if injury occurs and, if so, what it consists of,

<u>Minimal Risk</u> Research	or where further information may be obtained. ☐ Whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
Required for Clinical Trials that Follow ICH-GCP	☐ The approval of the IRB. ☐ The trial's investigational product(s) and probability for random assignment to each treatment, if applicable. ☐ What is expected of the participants. ☐ When applicable, the reasonably foreseeable risks or inconveniences to the participant's partner, to an embryo, fetus, or nursing infant. ☐ When applicable, the reasonably expected benefits to the participant's partner or to an embryo, fetus, or nursing infant. ☐ When there is no intended clinical benefit to the participant, the participant should be made aware of this. ☐ The process by which the participant's data will be handled, including in the event of withdrawal or discontinuation of participation in accordance with regulatory requirements. ☐ That by agreeing to participate in the trial, the participant or their legally authorized representative allows direct access to source records, based on the understanding that the confidentiality of the participant's medical record will be safeguarded. This access is limited for the purpose of viewing trial activities and/or reviewing or verifying data and records by the regulatory authority(ies) and the sponsor's representative, for example, monitor(s), or auditor(s), and in accordance with applicable regulatory requirements, the IRB/IEC(s). ☐ If the results of the trial are published, the participant's identity will remain confidential. The trial may be registered on publicly accessible and recognized databases, per applicable regulatory requirements. ☐ Trial results and information on the participant's actual treatment, if appropriate, will be made available to them should they desire it.
Required for FDA-Regulated Research	☐ The possibility that the Food and Drug Administration may inspect the records. ☐ The data collected on the subject to the point of withdrawal remains part of the study database and may not be removed. ☐ The investigator should ask a subject who is withdrawing whether the subject wishes to provide further data collection from routine medical care. ☐ For controlled drug or device trials (except Phase I drug trials) and pediatric device surveillance trials: "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."
Additional: (Include when	☐ The particular treatment or procedure may involve risks to the subject, which are

appropriate.)	currently unforeseeable. ☐ If the subject is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable. ☐ Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent. ☐ Any additional costs to the subject that may result from participation in the research. ☐ The consequences of a subject's decision to withdraw from the research. ☐ Procedures for orderly termination of participation by the subject. ☐ Significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation will be provided to the subject. ☐ Approximate number of subjects involved in the study. ☐ Amount and schedule of all payments. ☐ A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit. (**NA if research is subject to Pre-2018 Requirements)** ☐ A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions. (**NA if research is subject to Pre-2018 Requirements)** ☐ For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.,* sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen). (NA if research is subject to Pre-2018 Requirements) ☐ Any additional information which should be given to subjects when in the IRB's judgement the information would meaningfully add to the protection of the rights and welfare of subjects.[ii] ☐ When the study involves genetic testing, a statement that outlines the protections afforded to the subject under the Genetic Information Nondiscrimination Act (GINA).

12. Study Conduct (IND studies)

Response	Study Conduct Category
☐ Yes ☐ No ☐ NA	Investigators are responsible for the control of drugs under investigation.
☐ Yes ☐ No ☐ NA	Investigators administer the drug only to subjects under their personal supervision or under the supervision of a sub-investigator responsible to the investigator.
☐ Yes ☐ No ☐ NA	Investigators do not supply the investigational drug to any person not authorized to receive it.

13. Study Conduct (IDE studies)

Response	Study Conduct Category
☐ Yes ☐ No ☐ NA	Investigators permit an investigational device to be used only with subjects under the investigator's supervision.
☐ Yes ☐ No ☐ NA	Investigators do not supply an investigational device to any person not authorized to receive it.
☐ Yes ☐ No ☐ NA	Upon completion or termination of a clinical investigation or the investigator's part of an, or at the sponsor's investigation request, investigators return to the sponsor any remaining supply of the device or otherwise dispose of the device as the sponsor directs.
☐ Yes ☐ No ☐ NA	If the investigation is terminated, suspended, discontinued, or completed, investigators return the unused supplies of the drug to the sponsor, or otherwise provide for disposition of the unused supplies of the drug as authorized by the sponsor.
☐ Yes ☐ No ☐ NA	If an investigational drug is subject to the Controlled Substances Act, investigators take adequate precautions, including storage of the investigational drug in a securely locked, substantially constructed cabinet, or other securely locked, substantially constructed enclosure, access to which is limited, to prevent theft or diversion of the substance into illegal channels of distribution.
	Investigators prepare and submit the following reports to the sponsor:
☐ Yes ☐ No ☐ NA	Any unanticipated adverse device effect occurring during an investigation. (Within 5 working days.)
☐ Yes ☐ No ☐ NA	Withdrawal of approval by the reviewing IRB of the investigator's part of an investigation. (Within 5 working days.)
☐ Yes ☐ No ☐ NA	Progress reports on the investigation. (At least yearly.)
☐ Yes ☐ No ☐ NA	Any deviation from the investigational plan to protect the life or physical well-being of a subject in an emergency. (As soon as possible, but in no event later than 5 working days after the emergency occurred.)
☐ Yes ☐ No ☐ NA	Use of a device without obtaining informed consent (within 5 working days after the use occurs).
☐ Yes ☐ No ☐ NA	A final report. (Within 3 months after termination or completion of the investigation or the investigator's part of the investigation.)
	Investigators prepare and submit the following reports to the IRB:
☐ Yes ☐ No ☐ NA	Any unanticipated adverse device effect occurring during an investigation. (As soon as possible, but in no event later than 10 working days after first learning of the effect.)
☐ Yes ☐ No ☐ NA	Progress reports on the investigation. (At least yearly.)

☐ Yes ☐ No ☐ NA	Any deviation from the investigational plan to protect the life or physical well-being of a subject in an emergency. (As soon as possible, but in no event later than 5 working days after the emergency occurred.)
☐ Yes ☐ No ☐ NA	Use of a device without obtaining informed consent (within 5 working days after the use occurs).
☐ Yes ☐ No ☐ NA	A final report (within 3 months after termination or completion of the investigation or the investigator's part of the investigation).
	Investigators prepare and submit the following reports to the study monitor:
☐ Yes ☐ No ☐ NA	Progress reports on the investigation. (At least yearly.)

14. IND Sponsor-Investigator Requirements

Response	Requirement
☐ Yes ☐ No ☐ NA	The investigator submits a completed Form FDA 3454 attesting to the absence of financial interests and arrangements for all participating clinical investigators.
☐ Yes ☐ No ☐ NA	For any participating clinical investigator for whom the investigator does not submit a completed Form FDA 3454, the investigator submits a completed Form FDA 3455 (Disclosure Statement).
☐ Yes ☐ No ☐ NA	The investigator maintains on file information pertaining to the financial interests of clinical investigators for 2 years after the date of approval of the application.
☐ Yes ☐ No ☐ NA	The investigator selects qualified investigators.
☐ Yes ☐ No ☐ NA	The investigator provides participating investigators with the information they need to conduct an investigation properly.
☐ Yes ☐ No ☐ NA	The investigator ensures that the investigation(s) is conducted in accordance with the general investigational plan and protocols contained in the IND.
☐ Yes ☐ No ☐ NA	The investigator maintains an effective IND with respect to the investigations.
☐ Yes ☐ No ☐ NA	The investigator ensures that FDA is promptly informed of significant new adverse effects or risks with respect to the drug.
☐ Yes ☐ No ☐ NA	The investigator ensures that all participating investigators are promptly informed of significant new adverse effects or risks with respect to the drug.
☐ Yes ☐ No ☐ NA	The investigator selects only investigators qualified by training and experience as appropriate experts to investigate the drug.
☐ Yes ☐ No ☐ NA	The investigator ships investigational new drugs only to investigators participating in the investigation.
☐ Yes ☐ No ☐ NA	Before permitting an investigator to begin participation in an investigation, the

	investigator obtains the following:
☐ Yes ☐ No ☐ NA	A signed investigator statement (Form FDA-1572).
☐ Yes ☐ No ☐ NA	A curriculum vitae or other statement of qualifications of the investigator showing the education, training, and experience that qualifies the investigator as an expert in the clinical investigation of the drug for the use under investigation.
☐ Yes ☐ No ☐ NA	Sufficient accurate financial information to allow the investigator to submit complete and accurate certification or disclosure statements.
☐ Yes ☐ No ☐ NA	The investigator selects a monitor qualified by training and experience to monitor the progress of the investigation.
☐ Yes ☐ No ☐ NA	The investigator provides each participating clinical investigator an investigator brochure.
☐ Yes ☐ No ☐ NA	The investigator ensures, as the overall investigation proceeds, that each participating investigator is informed of new observations discovered by or reported to the investigator on the drug, particularly with respect to adverse effects and safe use.
☐ Yes ☐ No ☐ NA	The investigator monitors the progress of all clinical investigations being conducted under the IND.
☐ Yes ☐ No ☐ NA	If the investigator discovers that an investigator is not complying with the signed agreement (Form FDA-1572), the general investigational plan, or other applicable requirements; the investigator promptly either secures compliance or discontinues shipment of the investigational new drug to the investigator and ends the investigator's participation in the investigation.
☐ Yes ☐ No ☐ NA	If the investigator's participation in the investigation is ended, the investigator ensures that the investigator dispose of or returns the investigational drug and notifies the FDA.
☐ Yes ☐ No ☐ NA	The investigator reviews and evaluates the evidence relating to the safety and effectiveness of the drug as it is obtained from the investigator(s).
☐ Yes ☐ No ☐ NA	If the investigator determines that the investigational drug presents an unreasonable and significant risk to subjects, the investigator:
☐ Yes ☐ No ☐ NA	Ensures discontinuation of those investigations that present the risk.
☐ Yes ☐ No ☐ NA	Notifies the FDA, all institutional review boards, and all investigators who have at any time participated in the investigation of the discontinuance.
☐ Yes ☐ No ☐ NA	Ensures the disposition of all stocks of the drug outstanding.
☐ Yes ☐ No ☐ NA	Furnishes the FDA with a full report of the investigator's actions.
☐ Yes ☐ No ☐ NA	The investigator maintains adequate records showing the receipt, shipment, or other disposition of the investigational drug, including, as appropriate, the name of the investigator to whom the drug is shipped, and the date, quantity, and batch or code

	mark of each such shipment.
☐ Yes ☐ No ☐ NA	The investigator retains these records and reports for 2 years after a marketing application is approved for the drug; or, if an application is not approved for the drug, until 2 years after shipment and delivery of the drug for investigational use is discontinued and FDA has been so notified.
☐ Yes ☐ No ☐ NA	The investigator retains reserve samples of any test article and reference standard identified in and used in any bioequivalence or bioavailability studies and release the reserve samples to the FDA upon request.
☐ Yes ☐ No ☐ NA	The investigator retains each reserve sample for a period of at least 5 years following the date on which the application or supplemental application is approved, or, if such application or supplemental application is not approved, at least 5 years following the date of completion of the bioavailability study.
☐ Yes ☐ No ☐ NA	The investigator permits, upon request from any properly authorized officer or employee of the Food and Drug Administration, at reasonable times, such officer or employee to have access to and copy and verify any records and reports relating to a clinical investigation being conducted under the IND.
☐ Yes ☐ No ☐ NA	The investigator submits, upon written request by the FDA, the records or reports (or copies of them) to the FDA.
☐ Yes ☐ No ☐ NA	The investigator discontinues shipments of the drug to any investigator who has failed to maintain or make available records or reports of the investigation as required.
	If an investigational new drug is a substance listed in any schedule of the Controlled Substances Act (21 U.S.C. 801; 21 CFR part 1308), the investigator ensures:
☐ Yes ☐ No ☐ NA	Upon the request of a properly authorized employee of the Drug Enforcement Administration of the Department of Justice, all records concerning shipment, delivery, receipt, and disposition of the drug, which are required to be kept be made available by the investigator to whom the request is made, for inspection and copying.
☐ Yes ☐ No ☐ NA	That adequate precautions are taken, including storage of the investigational drug in a securely locked, substantially constructed cabinet, or other securely locked, substantially constructed enclosure, access to which is limited, to prevent theft or diversion of the substance into illegal channels of distribution.
☐ Yes ☐ No ☐ NA	The investigator ensures the return of all unused supplies of the investigational drug from each individual investigator whose participation in the investigation is discontinued or terminated.

15. Significant Risk IDE Sponsor-Investigator Requirements

Response	Requirement

☐ Yes ☐ No ☐ NA	The investigator ensures that no part of the investigation begins until the IRB and FDA have both approved the application or supplemental application.
☐ Yes ☐ No ☐ NA	The investigator selects other investigators qualified by training and experience to investigate the device.
☐ Yes ☐ No ☐ NA	The investigator selects monitors qualified by training and experience to monitor the investigational study in accordance with the IDE and other applicable FDA regulations.
☐ Yes ☐ No ☐ NA	The investigator ships investigational devices only to qualified investigators participating in the investigation.
☐ Yes ☐ No ☐ NA	The investigator obtains a signed agreement from each participating investigator that includes:
☐ Yes ☐ No ☐ NA	The participating investigator's curriculum vitae,
☐ Yes ☐ No ☐ NA	A statement of the participating investigator's relevant experience, including the dates, location, extent, and type of experience, where applicable,
☐ Yes ☐ No ☐ NA	An explanation of the circumstances that led to termination of a study if the participating investigator was involved in an investigation or other research that was terminated,
☐ Yes ☐ No ☐ NA	A statement of the participating investigator's commitment to: • Conduct the investigation in accordance with the agreement, the investigational plan, the IDE and other applicable FDA regulations, and conditions of approval imposed by the reviewing IRB or FDA, • Supervise all testing of the device involving human subjects, and • Ensure that the requirements for obtaining informed consent are met.
☐ Yes ☐ No ☐ NA	The investigator maintains sufficient accurate financial disclosure information to submit a complete and accurate certification or disclosure statement as required under 21 CFR 54, Financial Disclosure by Clinical Investigators.
☐ Yes ☐ No ☐ NA	The investigator obtains a commitment from clinical investigators to promptly update this information if any relevant changes occur during the course of the investigation and for one year following completion of the study. (The financial certification or disclosure is submitted in the PMA or Premarket Notification 510(k) application. It should not be submitted in the IDE application.)
☐ Yes ☐ No ☐ NA	The investigator supplies all participating investigators with copies of the investigational plan and a report of prior investigations of the device.
☐ Yes ☐ No ☐ NA	Securing Compliance: If the investigator discovers that a participating investigator is not complying with the signed agreement, the investigational plan, the IDE requirements, any other applicable FDA regulations, or any conditions of approval imposed by the reviewing IRB or FDA, the investigator promptly either secures compliance, or discontinues shipments of the device to the investigator and

	terminates the investigator's participation in the investigation. A sponsor must also require that the investigator dispose of or return the device, unless this action would jeopardize the rights, safety, or welfare of a subject.
☐ Yes ☐ No ☐ NA	Unanticipated Adverse Device Effects: The investigator immediately conducts an evaluation of any unanticipated adverse device effect. An investigator who determines that an unanticipated adverse device effect presents an unreasonable risk to subjects terminates all investigations or parts of the investigations presenting that risk as soon as possible. Termination must occur no later than 5 working days after the sponsor makes this determination and no later than 15 working days after the sponsor first received notice of the effect.
☐ Yes ☐ No ☐ NA	Resumption of Terminated Studies: For significant risk device investigations, an investigator may not resume a terminated investigation without IRB and FDA approval.
	The investigator must maintain accurate and complete records relating to the investigation. These records include:
☐ Yes ☐ No ☐ NA	All correspondence including required reports,
☐ Yes ☐ No ☐ NA	Records of receipt, use or disposition of a device that relate to: • The type and quantity of the device, the dates of its receipt, and the batch number or code mark. • The names of all persons who received, used, or disposed of each device. • Why and how many units of the device have been returned to the sponsor, repaired, or otherwise disposed of.
☐ Yes ☐ No ☐ NA	Signed investigator agreements including financial disclosure information,
☐ Yes ☐ No ☐ NA	Records concerning complaints and adverse device effects whether anticipated or not,
☐ Yes ☐ No ☐ NA	Any other records that FDA requires to be maintained by regulation or by specific requirement for a category of investigation or a particular investigation.
	The investigator provides the following reports in a timely manner to FDA, the IRBs, and/or the investigators.
☐ Yes ☐ No ☐ NA	Unanticipated Adverse Device Effects
☐ Yes ☐ No ☐ NA	Withdrawal of IRB Approval
☐ Yes ☐ No ☐ NA	Withdrawal of FDA Approval
☐ Yes ☐ No ☐ NA	Current list of Investigators
☐ Yes ☐ No ☐ NA	Progress Reports
☐ Yes ☐ No ☐ NA	Recalls and Device Disposition

☐ Yes ☐ No ☐ NA	Final Report
☐ Yes ☐ No ☐ NA	Informed consent
☐ Yes ☐ No ☐ NA	Significant Risk Device Determination
☐ Yes ☐ No ☐ NA	Other Reports
☐ Yes ☐ No ☐ NA	The investigational device or its immediate package bears a label with the following information: • The name and place of business of the manufacturer, packer, or distributor; • The quantity of contents, if appropriate; and • The statement, "CAUTION Investigational device. Limited by Federal (or United States) law to investigational use."
☐ Yes ☐ No ☐ NA	The label describes all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and precautions.
☐ Yes ☐ No ☐ NA	The labeling of an investigational device does not contain any false or misleading statements nor imply that the device is safe or effective for the purposes being investigated.
☐ Yes ☐ No ☐ NA	The investigator provides detailed information on device labeling in the investigational protocol. This information may vary depending on the device and the nature of the study. Product labeling should be sufficient to ensure stability of the test article for the duration of the study (storage requirements, calibration procedures), bear sufficient directions for proper administration, and detail procedures to follow in the event of patient injury.
☐ Yes ☐ No ☐ NA	The investigator, or any person acting for or on behalf of the investigator does not: • Promote or test market an investigational device, until after FDA has approved the device for commercial distribution. • Commercialize an investigational device by charging the subjects or investigators a higher price than that necessary to recover costs of manufacture, research, development, and handling. • Unduly prolong an investigation. If data developed by the investigation indicate that premarket approval (PMA) cannot be justified, the sponsor must promptly terminate the investigation. • Represent that an investigational device is safe or effective.
☐ Yes ☐ No ☐ NA	Advertisements have been reviewed and approved by the IRB to assure that they are not unduly coercive and do not promise a certainty of cure beyond what is outlined in the consent and the protocol. No claims are made, either explicitly or implicitly, that the device is safe or effective for the purposes under investigation, or that the test article is known to be equivalent or superior to any other device.

16. Abbreviated IDE Sponsor-Investigator Requirements

Response	Requirement
☐ Yes ☐ No ☐ NA	The device is labeled with the name and place of business of the manufacturer. *21 CFR §812.2(b)(1)(i)*
☐ Yes ☐ No ☐ NA	The device is labeled with the following statement: "CAUTION-Investigational device. Limited by Federal (or United States) law to investigational use." *21 CFR §812.2(b)(1)(i)*
☐ Yes ☐ No ☐ NA	The labeling describes all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and precautions. *21 CFR §812.2(b)(1)(i)*
☐ Yes ☐ No ☐ NA	The investigator has obtained IRB review and approval of the research. *21 CFR §812.2(b)(1)(ii)*
☐ Yes ☐ No ☐ NA	The protocol includes a brief explanation of why the device is not a significant risk device. *21 CFR §812.2(b)(1)(ii)*
☐ Yes ☐ No ☐ NA	The IRB has determined that the device is not a significant risk device. *21 CFR §812.2(b)(1)(ii)*
☐ Yes ☐ No ☐ NA	The IRB has documented that determination in the minutes along with the IRB's rationale for making that determination. *FDA Information Sheets for IRBs*
☐ Yes ☐ No ☐ NA	The investigator has obtained informed consent of each subject in accordance with 21 CFR §50. *21 CFR §812.2(b)(1)(iii).*
☐ Yes ☐ No ☐ NA	Unless waived by the IRB, the investigator has documented informed consent of each subject in accordance with 21 CFR §50. *21 CFR §812.2(b)(1)(iii).*
☐ Yes ☐ No ☐ NA	The investigator monitors the investigation for compliance. *21 CFR §812.2(b)(1)(iv)*
☐ Yes ☐ No ☐ NA	The investigator immediately conducted an evaluation of any unanticipated adverse device effect. *21 CFR §812.2(b)(1)(iv)*
☐ Yes ☐ No ☐ NA	If the investigator determined whether each unanticipated adverse device effect presented an unreasonable risk to subjects. *21 CFR §812.2(b)(1)(iv)*
☐ Yes ☐ No ☐ NA	If the investigator terminated all investigations or parts of investigations presenting that risk as soon as possible, not later than 5 working days after making this determination. *21 CFR §812.2(b)(1)(iv)*
☐ Yes ☐ No ☐ NA	If the investigator determined whether each unanticipated adverse device effect presented an unreasonable risk to subjects, the investigator has to terminate all investigations or parts of investigations presenting that risk as soon as possible, not later than 5 working days after the investigator makes this determination. *21 CFR §812.2(b)(1)(iv)*
☐ Yes ☐ No ☐ NA	**The investigator maintains the following records consolidated in one location and available for FDA inspection and copying: *21 CFR §812.2(b)(1)(v)-(vi)***
☐ Yes ☐ No	A statement of the extent to which the good manufacturing practice regulation in part 820 will be followed in manufacturing the device. *21 CFR §812.140(b)(4)*

	(v)
☐ Yes ☐ No	The name and intended use of the device and the objectives of the investigation. *21 CFR §812.140(b)(4)(i)*
☐ Yes ☐ No	A brief explanation of why the device is not a significant risk device. *21 CFR §812.140(b)(4)(ii)*
☐ Yes ☐ No	The name and address of each investigator. *21 CFR §812.140(b)(4)(iii)*
☐ Yes ☐ No	The name and address of each IRB that has reviewed the investigation. *21 CFR §812.140(b)(4)(iv)*
☐ Yes ☐ No	Records concerning adverse device effects (whether anticipated or unanticipated) and complaints. *21 CFR §812.140(b)(5)*
☐ Yes ☐ No	Records of each subject's case history and exposure to the device. 21 CFR §812.140(a)(3)(i)
☐ Yes ☐ No	Case report forms and supporting data. 21 CFR §812.140(a)(3)(i)
☐ Yes ☐ No	Signed and dated consent forms. 21 CFR §812.140(a)(3)(i)
☐ Yes ☐ No	Medical records including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes. 21 CFR §812.140(a)(3)(i)
☐ Yes ☐ No	Documents evidencing informed consent. 21 CFR §812.140(a)(3)(i)
☐ Yes ☐ No ☐ NA	For any use of a device by the investigator without informed consent, any written concurrence of a licensed physician and a brief description of the circumstances justifying the failure to obtain informed consent. 21 CFR §812.140(a)(3)(i)
☐ Yes ☐ No	Documentation that informed consent was obtained prior to participation in the study. 21 CFR §812.140(a)(3)(i)
☐ Yes ☐ No	**The investigator makes the following reports to FDA: *21 CFR §812.2(b)(1)(v)***
☐ Yes ☐ No ☐ NA	Unanticipated adverse device effects. An evaluation of an unanticipated adverse device effect under §812.46(b) was reported to FDA and the IRB within 10 working days after the sponsor first receives notice of the effect. Thereafter the investigator submitted additional reports concerning the effect as FDA requested. *21 CFR §812.140(a)(1); 21 CFR §812.150(b)(1)*
☐ Yes ☐ No ☐ NA	Withdrawal of IRB approval. The investigator notified FDA of any withdrawal of approval of an investigation or a part of an investigation by the IRB within 5 working days after receipt of the withdrawal of approval. *21 CFR §812.140(a)(2); 21 CFR §812.150(b)(2)*

☐ Yes ☐ No ☐ NA	Withdrawal of FDA approval. The investigator notified the IRB and participating investigators of any withdrawal of FDA approval of the investigation, and did so within 5 working days after receipt of notice of the withdrawal of approval. *21 CFR §812.150(b)(3)*
☐ Yes ☐ No ☐ NA	Progress reports. At regular intervals, and at least yearly, the investigator submitted progress reports to the monitor and the IRB. *21 CFR §812.140(a)(3); 21 CFR §812.150(b)(5)*
☐ Yes ☐ No ☐ NA	Recall and device disposition. The investigator notified FDA and the IRB of any return, repair, or disposal of any units of a device. Such notice occurred within 30 working days after the request was made and stated why the request was made. *21 CFR §812.150(b)(6)*
☐ Yes ☐ No ☐ NA	The investigator submitted a final report to the IRB within 6 months after termination or completion. *21 CFR §812.150(b)(7)*
☐ Yes ☐ No ☐ NA	Informed consent. The investigator submitted to FDA and the IRB a copy of any use of a device without obtaining informed consent, within 5 working days of receipt of notice of such use. *21 CFR §812.140(a)(5); 21 CFR §812.150(b)(8)*
☐ Yes ☐ No ☐ NA	Significant risk device determinations. If the IRB determined that a device was a significant risk device, the investigator submitted to FDA a report of the IRB's determination within 5 working days after first learning of the IRB's determination. *21 CFR §812.150(b)(9)*
☐ Yes ☐ No ☐ NA	Other. The investigator, upon request by the IRB or FDA, provided accurate, complete, and current information about any aspect of the investigation. *21 CFR §812.150(b)(10)*
☐ Yes ☐ No	**The investigator does not:**
☐ Yes ☐ No	Promote or test market the device. *21 CFR §812.7(a)*
☐ Yes ☐ No	Commercialize the device by charging the subjects a price larger than that necessary to recover costs of manufacture, research, development, and handling. *21 CFR §812.7(b)*
☐ Yes ☐ No	Unduly prolong an investigation. *21 CFR §812.7(c)*
☐ Yes ☐ No	Represent that an investigational device is safe or effective. *21 CFR §812.7(d)*

Clinical Trials Case History (complete for each subject)

Basic Information	Study and Subject Details
Principal Investigator	Click or tap here to enter text.
Protocol Name	Click or tap here to enter text.
Subject Code	Click or tap here to enter text.
Name of Person Completing Worksheet	Click or tap here to enter text.
Date Completed	Click or tap here to enter text.

1. Subject selection

Response	Requirement
☐ Yes ☐ No ☐ NA	There is a completed eligibility worksheet.
☐ Yes ☐ No ☐ NA	The eligibility criteria worksheet includes dated signature/initials of the person obtaining the information.

2. Consent

Response	Requirement
☐ Yes ☐ No ☐ NA	For subjects who did not meet eligibility (e.g. screen-failures), identifiable information was destroyed or authorization obtained to keep subject information.
☐ Yes ☐ No ☐ NA	Original copies of all consent forms signed by subjects are on file.
☐ Yes ☐ No ☐ NA	There is a current consent form on file.
☐ Yes ☐ No ☐ NA	All previous consent forms are on file.
☐ Yes ☐ No ☐ NA	Valid IRB-approved consent forms were used.
☐ Yes ☐ No ☐ NA	The consent forms on file are the *original* signed and dated version (not a photocopy).
☐ Yes ☐ No ☐ NA	All pages of the consent forms are on file for each subject.
☐ Yes ☐ No ☐ NA	All yes/no or similar options on the consent forms are completed/initialed.
☐ Yes ☐ No ☐ NA	Consent forms are free of any handwritten changes/corrections.
☐ Yes ☐ No ☐ NA	The subject signed his/her own consent forms. (Exceptions: IRB-approved surrogate or parental consent)
☐ Yes ☐ No ☐ NA	The subject received a copy of the signed and dated consent form.
☐ Yes ☐ No ☐ NA	The subject's receipt of a copy of the signed and dated consent form is documented.

3. Prompt Reporting Requirements

Response	Requirement
☐ Yes ☐ No ☐ NA	All prompt reporting requirements have been fulfilled.

4. Data Collection Source Documents

☐ Yes ☐ No ☐ NA	Data collection complete/accurate for each subject. (e.g. no blank fields/missing data)
☐ Yes ☐ No ☐ NA	Source documentation is available to support data entry.
☐ Yes ☐ No ☐ NA	The source documentation/CRF for each subject includes dated signature/initials of the person obtaining the information for each subject.
☐ Yes ☐ No ☐ NA	Changes/cross-outs, additional comments (if any) in subject files routinely initialed and dated.
☐ Yes ☐ No ☐ NA	For any changes/cross-outs being made, the original entry is still legible. (e.g. use of white-out or pencil erased entries is not acceptable)

[i] 21 CFR 56.109 (b): (b) An IRB shall require that information given to subjects as part of informed consent is in accordance with 50.25. The IRB may require that information, in addition to that specifically mentioned in 50.25, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

[ii] 21 CFR 56.109 (b): (b) An IRB shall require that information given to subjects as part of informed consent is in accordance with 50.25. The IRB may require that information, in addition to that specifically mentioned in 50.25, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

WORKSHEET: Minutes Quality Improvement Assessment[i]

The purpose of this worksheet is to allow individuals to conduct a quality improvement self-assessment of IRB minutes.

Minutes Information

Minutes Information	Response
IRB Committee	Click or tap here to enter text.
Meeting Date with link	Click or tap here to enter text.
Name of Person Completing Worksheet	Click or tap here to enter text.
Date Completed	Click or tap here to enter text.

1. General Minutes Requirements

Response	Requirement
☐ Yes ☐ No	Does the "Attendance Table" record each voting member (regular members and alternates) present at the meeting at any time?
☐ Yes ☐ No	Does the "Attendance Table" record any member in attendance who did not vote at any time?
☐ Yes ☐ No	Does the "Attendance Table" record each member's name?
☐ Yes ☐ No	Does the "Attendance Table" record which members were chairs or vice chairs?
☐ Yes ☐ No	Does the "Attendance Table" record each member's status as an unaffiliated member or affiliated member? [ii]
☐ Yes ☐ No	Does the "Attendance Table" record each member's status as a scientific member or non-scientific member?
☐ Yes ☐ No	When a member is a representative of vulnerable population, does the "Attendance Table" record that member's representative capacity? (Prisoners, children, adults with impaired decision-making capacity)
☐ Yes ☐ No ☐ NA	Does the "Attendance Table" record for each alternate member the name of IRB member for whom alternate is substituting.
☐ Yes ☐ No	Does the "Attendance Table" record whether any members were present by teleconference and if so indicate them by name?
☐ Yes ☐ No	Do the minutes record the total number of members present on the current IRB roster excluding alternate IRB members?
☐ Yes ☐ No	Do the minutes correctly record the number of members required for a quorum? (Divide the number of members by two and select the next whole number. For example, if there are 10 IRB members on the roster, then 10/2 = 5 and the next whole number is 6. If there 11 IRB members on the roster, then 11/2=5.5 and the next whole number is 6.)
☐ Yes ☐ No	Do the minutes indicate whether members present by teleconference received all pertinent material before the meeting and were able to actively and equally participate in all discussions?
☐ Yes ☐ No	Do the minutes record the meeting start time?
☐ Yes ☐ No	Do the minutes record the meeting end time?

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☐ Yes ☐ No	Do the minutes record a summary of each business item that was discussed? (such as compliance reports, policy issues, admin issues, COI and reporting of expedited reviews)
☐ Yes ☐ No	A statement that when a protocol is approved, the criteria for approval found in regulations 45 CFR 46.111 and if applicable, 21 CFR 56.111, were discussed and that the protocol was approved based on the criteria.

2. Requirements for Each Protocol Reviewed

Response	Requirement
☐ Yes ☐ No	Do the minutes record a protocol ID?
☐ Yes ☐ No	Do the minutes record a protocol title?
☐ Yes ☐ No	Do the minutes record an investigator's name?
☐ Yes ☐ No	Do the minutes record a type of review as either initial review, continuing review, or review of modifications to previously approved research?
☐ Yes ☐ No	A quorum was present during the individual protocol review.
☐ Yes ☐ No ☐ NA	If the minutes record a consultant report, does it summarize the key information provided the consultant. (NA if there were no consultant reports)
☐ Yes ☐ No	Do the minutes record controverted issues (when the IRB members express a difference of opinion among themselves) or indicate "None"?
☐ Yes ☐ No ☐ NA	If the minutes record controverted issues, does what is recorded qualify as a "Controverted Issue" and "Resolution"? (NA if there were no controverted issues)
☐ Yes ☐ No ☐ NA	If the minutes record controverted issues, does the information sufficiently describe the controverted issue? (NA if there were no controverted issues)
☐ Yes ☐ No ☐ NA	If the minutes record controverted issues, does the Controverted Issue include a resolution or a statement that there was no resolution? (NA if there were no controverted issues)
☐ Yes ☐ No	Do the minutes record a motion as one of the following: Approved, Modifications Required to Secure Approval, Deferred, Disapproved?
☐ Yes ☐ No ☐ NA	For initial or continuing review do the minutes record the period of approval for the motion?
☐ Yes ☐ No ☐ NA	Do the minutes record the vote as the number of members for, against, abstaining, absent, or recused?
☐ Yes ☐ No ☐ NA	Do the minutes list the full names of IRB members who were absent or recused?
☐ Yes ☐ No ☐ NA	If both a regular IRB member and the alternate IRB member are present at the meeting do the minutes record the vote of just one? (NA if both a regular IRB member and the alternate IRB member were not present at the meeting)
☐ Yes ☐ No ☐ NA	If both a regular IRB member and the alternate IRB member are present at the meeting do the minutes indicate which voted? (NA if both a regular IRB member and the alternate IRB member were not present at the meeting)
☐ Yes ☐ No	Is the sum total of the number of members for, against, abstaining, absent, or recused constant among votes and equal to the number of people listed in the attendance table?
☐ Yes ☐ No	Do minutes document the level of risk determined by the convened IRB as either Minimal Risk or more than Minimal Risk?
☐ Yes ☐ No ☐ NA	If the research involves the use of: • Waiver or alteration of consent, • Waiver of written documentation of consent, • Short form Consent, • Waiver of HIPAA,

	• Children, • Pregnant women or fetuses / neonates, • Neonates of uncertain viability or non-viable neonates, • Prisoners, • Adults with impaired decision-making capacity do the minutes include one or more of the “Possible Contingencies for Determination and Protocol Specific Findings” tables in HRP-501 - TEMPLATE - MINUTES? (NA if no research requiring documented findings was reviewed)
☐ Yes ☐ No ☐ NA	If the research involves use of: • Humanitarian use device (HUD), • Significant risk or non-significant risk devices, • FDA non-significant risk device determinations • IDE exempt devices, • Devices not under clinical investigation, • Investigational Drugs (IND or IND exempt), • Use of placebo / sham, do the minutes include one or more of the “Possible Contingencies for Determination and Protocol Specific Findings” tables in HRP-501 - TEMPLATE - MINUTES? (NA if no research requiring documented findings was reviewed)
☐ Yes ☐ No ☐ NA	If the IRB determined the Level of review or Privacy / Confidentiality and required an NIH Certificate of Confidentiality, do the minutes include one or more of the “Possible Contingencies for Determination and Protocol Specific Findings” statements in HRP-501 - TEMPLATE - MINUTES? (NA if no research requiring documented findings was reviewed)
☐ Yes ☐ No ☐ NA	For Continuing Reviews, Special Populations and Determinations applicable to News & Renewals were documented in the minutes?
☐ Yes ☐ No ☐ NA	If the minutes include one of more of the “Determination/Protocol Specific Findings” tables, is the table completed? (NA if no research requiring documented findings was reviewed)
☐ Yes ☐ No ☐ NA	Do minutes justify any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent document? (NA if a DHHS-approved sample consent form was not reviewed)
☐ Yes ☐ No ☐ NA	Do minutes document the rationale for a significant/non-significant device determination? (NA if abbreviated IDE devices were not reviewed.)
☐ Yes ☐ No ☐ NA	Do minutes document modifications required to secure approval? (NA if there were no modifications required to secure approval)
☐ Yes ☐ No ☐ NA	When minutes document modifications required to secure approval does the “Recommended Changes and Reasons” section include a reason (basis) for each modification? (NA if there were no modifications required to secure approval)
☐ Yes ☐ No ☐ NA	When minutes document modifications required to secure approval, does the “Recommended changes and reasons” describe the required modifications in such a way that an IRB staff member can determine whether an investigator has made the required changes without judging whether a change meets the regulatory criteria for approval? Note: modifications required to secure approval must have specific defined changes required by the committee. (NA if there were no modifications required to secure approval)
☐ Yes ☐ No ☐ NA	If a protocol was deferred, do the minutes indicate this and provide the reason for tabling? (NA if there were no deferred protocols)
☐ Yes ☐ No ☐ NA	If a protocol was deferred or disapproved do the minute document the reasons? (NA if there were no deferred or disapproved protocols)
☐ Yes ☐ No ☐ NA	If a protocol was deferred do the minutes document recommended changes? (NA if there were no deferred or disapproved protocols)

☐ Yes ☐ No ☐ NA	If a protocol was previously deferred and re-reviewed at the current meeting, do the minutes include the relevant “Possible Contingencies for Determination and Protocol Specific Findings” statement in HRP-501 - TEMPLATE - MINUTES?

3. Requirements for Each Problem Reviewed (☐ NA if no problems were reviewed)

Response	Requirement
☐ Yes ☐ No	Do the minutes describe the problem?
☐ Yes ☐ No	Do the minutes describe whether the problem was serious or continuing non-compliance, an Unanticipated Problem Involving Risks to Subjects or Others, or a Suspension of IRB Approval or Termination of IRB Approval?
☐ Yes ☐ No ☐ NA	Do the minutes record a protocol ID? (NA if there was no specific protocol involved)
☐ Yes ☐ No ☐ NA	Do the minutes record a protocol title? (NA if there was no specific protocol involved)
☐ Yes ☐ No ☐ NA	Do the minutes record an investigator name? (NA if there was no specific investigator involved)
☐ Yes ☐ No	Do the minutes record controverted issues (when the IRB members express a difference of opinion among themselves) and their resolution or indicate “None”?
☐ Yes ☐ No	If the minutes record controverted issues, does what is recorded qualify as a “Controverted Issue” and “Resolution”?
☐ Yes ☐ No ☐ NA	If the minutes record controverted issues does the information sufficiently describe the controverted issue? (NA if there were no controverted issues)
☐ Yes ☐ No ☐ NA	If the minutes record controverted issues does the “Controverted Issue” include a resolution or a statement that there was no resolution? (NA if there were no controverted issues)
☐ Yes ☐ No	Do the minutes document the motion?
☐ Yes ☐ No	Do the minutes record the vote as the number of members for, against, abstaining, absent, or recused?
☐ Yes ☐ No ☐ NA	Do the minutes list the names of IRB members who were absent or recused?
☐ Yes ☐ No ☐ NA	If both a regular IRB member and the alternate IRB member are present at the meeting do the minutes record the vote of just one? (NA if both a regular IRB member and the alternate IRB member were not present at the meeting)
☐ Yes ☐ No ☐ NA	If both a regular IRB member and the alternate IRB member are present at the meeting do the minutes indicate which voted? (NA if both a regular IRB member and the alternate IRB member were not present at the meeting)
☐ Yes ☐ No	Is the sum total of the number of members for, against, abstaining, absent, or recused constant among votes and equal to the number of people listed in the attendance table?

4. EQUIP QA Recommendations (For general observations and recommendations that are not protocol specific):

Click or tap here to enter text.

5. Minutes Findings (minutes require revisions):

Click or tap here to enter text.

6. Protocol Specific Findings (approval letter/ZOT IRB required revisions):

Click or tap here to enter text.

7. Minutes Efficiency (per SOP HRP 043 – minutes approval should be within 2 business days)

Indicate the number of days between the meeting and the finalization of the minutes: Click or tap here to enter text.

---

[i] Minutes of IRB Guidance: Both the HHS regulations at 45 CFR 46.115(a)(2) and the FDA regulations at 21 CFR 56.115(a)(2) specifically require that an institution, or when appropriate, an IRB, prepare and maintain adequate documentation of IRB activities, including minutes in sufficient detail to show attendance at the meetings, actions taken by the IRB, the vote on these actions, including the number of members voting for, against, and abstaining, the basis for requiring changes in or disapproving research; and written summary of the discussion of controverted issues and their resolution.

[ii] For ease of review, OHRP and FDA recommend that attendance information be listed at the beginning of the minutes and include the full name and representative capacity (e.g., scientist, nonscientist, unaffiliated) of each IRB member present at the convened meeting.

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PI WORKSHEET: HIPAA Waiver of Authorization

This worksheet is required for the following submission types when research involves a waiver of HIPAA authorization: Exempt research that requires IRB review, Expedited research, or Full Committee research.

The purpose of this worksheet is to provide support for individuals conducting reviews of research involving a waiver of HIPAA authorization. Waivers and alterations of HIPAA authorization are reviewed and approved by either convened or expedited review procedures of the IRB or Privacy Board.[i] The PI completes this worksheet to document determinations required by the regulations along with protocol specific findings justifying those determinations. For more information, visit: Protected Health Information (HIPAA).

Attach this worksheet to the "Local Site Documents" section of the ZOT IRB application.

1. SUBMISSION INFORMATION

1.1 Basic Information:
1.1.1 IRB Study Number[1]: Click or tap here to enter text.
1.1.2 Short Title: Click or tap here to enter text.

2. SCOPE (Check all that apply.)

☐ (Partial) Waiver of HIPAA authorization for recruitment
☐ Waiver of HIPAA authorization for conduct of study

3. DOCUMENTATION OF WAIVER APPROVAL (Check if "Yes." All must be checked.)

☐ The description of the PHI for which use or access is included in the protocol narrative and is necessary for the research.

☐ The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements: (Check if "Yes." All must be checked.)
- ☐ An adequate plan to protect the identifiers from improper use and disclosure.
- ☐ An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.
- ☐ Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information for which an authorization or opportunity to agree or object is not required by 45 CFR 164.512.

[1] The IRB study number is generated when the submission is created in ZOT IRB. Please enter the number prior to final submission to the IRB.

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Specify if any entities outside the UCI study team (e.g., contract research organization, sponsor) will access, use, or disclose a research subject's PHI and explain why the entity need PHI to conduct the study.

Click or tap here to enter text.

☐ The research could **NOT** practicably[ii] be conducted without the waiver or alteration. (Check if "Yes". One must be checked.)

- ☐ Only minimal contact information will be obtained for recruitment purposes and prescreening medical records is necessary to identify potential eligible subjects.
- ☐ It would not be feasible to individually contact the large numbers of potential subjects in the study
- ☐ It would not be possible to locate many of the individuals whose records would be used for the study
- ☐ Many of the individuals, whose records would be used for the study, are now deceased
- ☐ Requiring HIPAA authorization may introduce systemic bias into the information
- ☐ The risk of contacting the subjects to obtain HIPAA authorization is greater than the risk of the study procedures
- ☐ Other, provide scientifically and ethically justifiable rationale.

Click or tap here to enter text.

☐ The research could **NOT** practicably be conducted without access to and use of the protected health information.

[i] 45 CFR §164.512(i)

[ii] Practicably means capable of being done; it should not be determined by considerations of convenience, cost, or speed.

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PI WORKSHEET: International Research

This worksheet is required for the following submission types when research involves research conducted outside the United States: Exempt research that requires IRB review, Expedited research, or Full Committee research.

The purpose of this worksheet is to provide support for IRB members or the Designated Reviewer when research involves research conducted outside the United States (US) or with participants located outside the US. The PI completes this worksheet to document determinations required by the institution along with protocol specific findings justifying those determinations.

Answer all questions succinctly using non-technical language as much as possible.

- If a question is not applicable to the research, state "N/A".
- If a question is not answered, the IRB does not know if the question was overlooked. This will result in unnecessary "back and forth" for clarification.

Attach this worksheet to the "Local Site Documents" section of the ZOT IRB application.

Use a separate worksheet for each international research location.

1. SUBMISSION INFORMATION

1.1 Basic Information:

1.1.1 IRB Study Number[1]: Click or tap here to enter text.

1.1.2 Short Title: Click or tap here to enter text.

2. COUNTRY INFORMATION

2.1 Country: Specify name of countries and locations where research will be performed.

Click or tap here to enter text.

2.2 International Regulations: Select all that apply and address the required action, as applicable.

☐ General Data Protection Regulation: European Union (EU) / European Economic Area (EEA), United Kingdom (UK), Iceland, Liechtenstein, or Norway

- Action Required: Insert the Consent Language: General Data Protection Regulation (GDPR) into the consent document.

☐ Personal Information Protection Law: China

- Action Required: Insert the Consent Language: China's Personal Information Protection Law (PIPL) into the consent document.

☐ Office of Foreign Assets Control (OFAC) sanctioned countries, individuals and/or entities

- Action Required: Research cannot begin until a license is obtained from Export Controls. *This process can take several months*.

☐ Other: Specify and provide web address of the regulation.

[1] The IRB study number is generated when the submission is created in ZOT IRB. Please enter the number prior to final submission to the IRB.

Click or tap here to enter text.

2.3 Ethics Committee: Specify if the international location has an Institutional Review Board (IRB) or an equivalent ethics committee.

- Action Required: IRB/ethics committee approval letter for the research or a letter from them waiving the requirement for their review.

Click or tap here to enter text.

2.4 Cultural Norms:

2.4.1 Explain how the cultural norms differ compared with U.S. culture in respect to research autonomy, consent, recruitment, confidentiality, etc.

2.4.2 Include an explanation of the cultural sensitivities that will be required to conduct this study; consider current events (include additional documentation if necessary).

Click or tap here to enter text.

2.5 Community Invitation: Specify if UCI researchers have been invited into the community and why.

Click or tap here to enter text.

3. STUDY TEAM QUALIFICATIONS

3.1 Qualifications of UCI Study Team:

3.1.1 Describe researcher qualifications (e.g., relevant coursework, past experience, training) to conduct human subjects research in an international setting.

3.1.2 Specify if researchers speak/read/write the language of the potential participants. If researchers cannot, explain how recruitment, the informed consent discussion and data collection will take place.

3.1.3 Explain how the researcher(s) have knowledge of local community attitudes to mitigate the cultural norms and remain in compliance with U.S. regulations for research.

Click or tap here to enter text.

3.2 UCI Oversight: Describe how UCI researchers (including medical faculty, as applicable) will actively oversee the research project, including supervision of the research team (e.g., the Principal Investigator will hold bi-weekly video meetings with the study team to review research data, answer questions, etc.)

Click or tap here to enter text.

3.3 Onsite: Specify who will be physically present at the research site, their role in the research, and how long they intend to be present at the location.

Click or tap here to enter text.

4. RESEARCH ACTIVITIES

4.1 Engagement: Specify whether the international investigator and/or an international site is engaged in human subjects research activities (e.g., interact with participants; have access to identifiable information) and their level of engagement.

Click or tap here to enter text.

4.2 Medical Records: If the research involves access to participant medical records, explain whether the country has regulations that protect access to medical records for research purposes (i.e. HIPAA in the U.S) and explain how the researchers will adhere to the country's requirements.

Click or tap here to enter text.

4.3 Therapeutic Research: If the research is therapeutic (i.e. medical, psychological, physical, etc.), describe what provisions have been made to provide continued access to the therapeutic intervention after completion of the study.

Click or tap here to enter text.

4.4 Clinical Care: If the research involves clinical care, please address the following:

4.4.1 Describe how the research may address an important scientific question regarding the host community/ country. If applicable, describe how the proposal is responsive to local health needs of the host community/country.

4.4.2 Describe both the standard of care in the US and the available standard of care/alternatives in the host community/country.

4.4.3 If UCI medical students/residents are performing clinical procedures, clarify if it is within the guides of what they would be allowed to do as a medical student/resident.

4.4.4 Describe how any incidental findings will be handled, including who will confirm the findings and how results will be conveyed to the participant.

4.4.5 In some countries, the type and level of clinical care provided to participants may not be available to them outside of the research context.

4.4.5.1 Describe how the research team will minimize the likelihood participants will believe mistakenly that the purpose of the research is solely to provide treatment rather than to contribute to scientific knowledge.

4.4.5.1.1 Clarify whether there has been an effort to secure continued access for all participants to needed experimental interventions that have been proven effective at the conclusion of the project.

4.4.5.1.2 Explain whether, if proven effective, the procedures will be available to the country population.

4.4.5.1.3 If procedures are available to the country, describe any pre-negotiations among sponsors, host country officials, and other appropriate parties aimed at making interventions available after the research. If procedures will not be available to the country, explain why.

Click or tap here to enter text.

4.5 Access to Study Data: Describe any arrangements that will be in place for the study data to be available to the participant population at the conclusion of the study.

Click or tap here to enter text.

PI WORKSHEET: Right to Try

The purpose of this worksheet is to provide support for intended for treatment with an investigational drug or biologic under the provisions of Right to Try (RTT) and to provide support the Committee reviewing such uses. This worksheet is to be used when overseeing such uses. For more information visit: Right to Try - Unapproved Drugs or Biologics.

Attach this protocol to the "Basic Study Information" section of the ZOT IRB application. Other supplemental documentation (i.e. consent, other) can be attached in "Local Site Documents".

1. SUBMISSION INFORMATION

1.1 Basic Information:
1.1.1 IRB Study Number[1]: Click or tap here to enter text.
1.1.2 Short Title: Click or tap here to enter text.

2. TREATING PHYSICIAN CHECKLIST

Confirm the following as part of preparing for Right to Try at UC Irvine:

2.1 Drug Applicability Criteria: (Check if "Yes." All must be checked.)
☐ The investigational drug or biologic has successfully completed a Phase I clinical trial.
☐ The drug or biologic is under investigation in a clinical trial.
☐ The drug or biologic is actively being developed/produced by the manufacturer OR not placed on clinical hold.

2.2 Patient Criteria: (Check if "Yes." All must be checked.)
☐ The patient has an *immediately* life-threatening disease or condition (a stage of disease in which there is a reasonable likelihood that death will occur in a matter of months).

Provide specific findings justifying this determination. Click or tap here to enter text.

☐ The patient has exhausted all other approved treatment options currently approved by the Food and Drug Administration (FDA).

Describe why other FDA approved treatment options are not viable. Click or tap here to enter text.

☐ The patient has not been accepted to participate in the nearest clinical trial to his or her home for the immediately life-threatening disease within one week of completion of the clinical trial application process, or, in the treating physician's medical judgment, it is unreasonable for the patient to participate in that clinical trial due to the patient's current condition and stage of disease.

[1] The IRB study number is generated when the submission is created in ZOT IRB. Please enter the number prior to final submission to the IRB.

2.3 Gather the Following Documents. Seek and Obtain IRB Approval:
☐ Draft a consent document using HRP-498 - CONSENT - Right to Try.
☐ Review and sign Treating Physician Attestation. See section 6 of the form.
☐ Submit documentation to the IRB through the ZOT IRB application.
☐ Secure signature on the Consulting Physician Attestation before treatment begins. See section 7 of the form.
☐ Notify UCI Chief Medical Officer of RTT request.

2.4 Other Treating Physician Responsibilities:
☐ Consult with Clinical Trials Team in Sponsored Projects Administration to determine whether an agreement is necessary with the sponsor/manufacturer.
☐ All cancer-related patient care must undergo Tumor Board review. To submit a study for review, download the application. Email the completed application to CancerCenter_Committees@hs.uci.edu
☐ Consult with Research Revenue Integrity (RRI) to determine billing implications.
    ☐ Register the patient in OnCore, as determined by RRI.
☐ Consult with Investigational Drug Services pharmacy to determine drug requirements.
☐ Ensure patient understands financial and health care considerations outlined in consent form.
☐ Treating physician will not be compensated directly by the manufacturer.

2.5 Provide the Following Within 30 Days of Beginning of Treatment:
☐ Provide the following to IRB@research.uci.edu. Indicate "Right to Try Follow Up" in the subject line. *Do not include patient identifiable information or Protected Health Information (PHI).*
☐ Provide a copy of the signed attestation.
☐ Provide the following status as required for UCI HRP reporting to the State Department of Public Health, the Medical Board of California, and the Osteopathic Medical Board of California:
    ☐ The duration of the treatment.
    ☐ The costs of the treatment paid by eligible patients.
    ☐ The success or failure of the investigational drug, biological product, or device in treating the immediately life-threatening disease or condition from which the patient suffers.
    ☐ Any adverse event for each investigational drug, biological product, or device.

3. TREATMENT PLAN

3.1 Treatment Plan: Specify the treatment plan including the dosage (as applicable) and duration of treatment. Do not include patient identifiable data nor protective health information (PHI).

☐ ***This is included in a separate treatment plan attached.***

Click or tap here to enter text.

3.2 Safety, Monitoring, and Data: Describe provisions for safety, monitoring and collecting data.

Click or tap here to enter text.

4. CONSENT PROCESS

4.1 Consent criteria (Check if "Yes". All must be checked.)
☐ Informed consent will be sought from the patient or the patient's Legally Authorized Representative (LAR) when the patient lacks the capacity to consent and attested to by the patient's primary physician and the uninvolved consulting physician.
☐ If non-UCI covered components will access PHI, HIPAA Research Authorization will be obtained. Attach the HIPAA Form.

☐ If this study includes a non-English-speaking patient, the English version of the consent materials will be translated for non-English speaking participant or their LAR.

5. FINANCIAL CONSIDERATIONS FOR PATIENTS

5.1 Patient Cost: State the cost of the treatment. In the case that the sponsor may cover costs, specify what the patient will be charged.

Click or tap here to enter text.

6. TREATING PHYSICIAN ATTESTATION

As the Treating Physician of the Patient, I have:

1. Confirmed that the investigational drug or biologic:
   a. Is not yet approved by the U.S. FDA for any use;
   b. Has completed Phase 1 trials;
   c. Remains under investigation by the FDA (i.e., an NDA or BLA has been filed with the FDA, or remains under investigation in a clinical trial); and is
   d. Actively being developed/produced by manufacturer or not placed on clinical hold.
2. Examined the Patient and his/her relevant medical records and determined the Patient's diagnosis and prognosis.
3. Verified that the Patient is an Eligible Patient as described below and is competent, acting voluntarily.
   "Eligible Patient" is a person who meets all of the following conditions:
   a. Has an immediately life-threatening disease or condition, where immediate means that the Patient is in a stage of disease in which there is a reasonable likelihood death will occur in a matter of months.
   b. Has considered all other treatment options currently approved by the FDA.
   c. Has not been accepted to participate in the nearest clinical trial to his/her home for the immediately life-threatening disease or condition within one week of completion of the clinical trial application process; or in my medical judgment, it is unreasonable for the patient to participate in that clinical trial due to the patient's current condition and stage of disease; and
4. As the Patient's treating physician, I recommend that the Patient receive the investigational drug or biologic. I acknowledge that I am in good standing with all applicable licensing organizations.
5. I will not be compensated directly by the manufacturer.
6. A Consulting Physician has completed the Consulting Physician Attestation Form.
7. Prior to providing treatment, I will confirm that the Patient:
   a. Has given written informed consent for the use of the investigational drug or biologic, using the RTT Consent Form; or, if s/he lacks the capacity to consent, her/his legally authorized representative has given written informed consent on her/his behalf. NOTE: The consent document and treatment protocol must be prospectively approved by the UCI IRB.
   b. Has received documentation attesting that the Patient meets the requirements of California Health and Safety Code Article 4.5 Right to Try Act 111548.1(b).

_____
Name of Treating Physician

_____ _____
Signature of Treating Physician **Date**

7. CONSULTING PHYSICIAN ATTESTATION

As I the Consulting Physician, I have:

1. Examined the Patient and his/her relevant medical records.
2. Confirmed the Treating Physician's diagnosis and prognosis.
3. Verified that the Patient is Eligible as described below and is competent, acting voluntarily.
   "Eligible Patient" is a person who meets all of the following conditions:
      a. Has an immediately life-threatening disease or condition, where immediate means that the Patient is in a stage of disease in which there is a reasonable likelihood that death will occur in a matter of months.
   b. Has considered all other treatment options currently approved by the FDA.
   c. Has not been accepted to participate in the nearest clinical trial to his/her home for the immediately life-threatening disease or condition within one week of completion of the clinical trial application process; or in the treating physician's medical judgment, it is unreasonable for the patient to participate in that clinical trial due to the patient's current condition and stage of disease
   d. Has received a recommendation from the Treating Physician for the use of investigational drug or biological product; and
      e. As the Consulting Physician, I recommend that the Patient receive the investigational drug or biologic
4. Prior to providing treatment, I will confirm that the Patient:
   a. Has given written informed consent for the use of the investigational drug or biological product; or, if s/he lacks the capacity to consent, her/his legally authorized representative has given written informed consent on her/his behalf. NOTE: The consent document and treatment protocol must be prospectively approved by the UCI IRB.
   b. Has received documentation from the Treating Physician attesting that the patient meets the requirements of California Health and Safety Code Article 4.5 Right to Try Act 111548.1(b).

_____

Name of Consulting Physician

_____ _____

Signature of Consulting Physician **Date**

WORKSHEET: Information Practices Act

The purpose of this worksheet is to provide support for IRB members or the Designated Reviewers when research involves the use of personal information from University of California offices.

REQUIREMENTS FOR DISCLOSURE (All of the following criteria must be met.)

☐ The researcher has provided a plan sufficient to protect personal information from improper use and disclosures, including sufficient administrative, physical, and technical safeguards to protect personal information from reasonable anticipated threats to the security or confidentiality of the information. **Documented in the 'Risk/Benefit Assessment' and 'Privacy and Confidentiality' sections of the Protocol Narrative.**

☐ The researcher has provided a sufficient plan to destroy or return all personal information as soon as it is no longer needed for the research project, unless the researcher has demonstrated an ongoing need for the personal information for the research project and has provided a long-term plan sufficient to protect the confidentiality of that information. **Documented in the 'Privacy and Confidentiality' and 'Information and Biopecimen Sharing' sections of the Protocol Narrative.**

☐ The researcher has provided sufficient written assurances that the personal information will not be reused or disclosed to any other person or entity, or used in any manner, not approved in the research protocol, except as required by law or for authorized oversight of the research project. **Documented in the 'Privacy and Confidentiality' and 'Information and Biospecimen Sharing' sections of the Protocol Narrative.**

☐ The requested personal information is needed to conduct the research. **Documented in the 'Privacy and Confidentiality' section of the Protocol Narrative.**

☐ The personal information to be released is not more than the minimum necessary to conduct the research. **Documented in the 'Privacy and Confidentiality' section of the Protocol Narrative.**

☐ Social security numbers are not released if other unique codes (not derived from the social security numbers) can practicably be utilized to conduct the research. **Documented in the 'Privacy and Confidentiality' section of the Protocol Narrative.**

PI WORKSHEET: New Study Submission – No Reliance

Please use this checklist to help prepare for your IRB submission in ZOT IRB:

☐	The Principal Investigator (PI) is eligible to serve as a PI at UCI either on their own or with a Faculty Advisor. Refer to the University of California Systemwide Contract and Grant Manual (Subchapter 1-500) for more information.
☐	The PI and Study Team review the Investigator's Manual. The Investigator's Manual specifies expectations for conducting human subject research at UCI.
☐	The PI and Study Team review the Human Research Protection Program Plan to understand the human subject program at UCI, what constitutes human subject research and importantly, IRB submission types that may be self-determined.
☐	The PI and Study Team can locate the HRP Toolkit. All pertinent IRB submission materials, above referenced guides and HRPP standard operating materials may be found within the HRP Toolkit.
☐	Access the HRP Toolkit. Complete the applicable version of the Protocol Narrative that corresponds to your study type.
☐	**When completing the Protocol Narrative:** Ensure all activities / procedures involving subjects are explained in a step-by-step, consistent manner.
☐	Recruitment and selection of participants must be equitable. Exclusions are scientifically justified.
☐	Be mindful of additional considerations and protections for vulnerable populations. Complete the applicable PI Worksheets as found in the HRP Toolkit and as prompted by selections made in the Protocol Narrative. PI Worksheets are required to address special populations and help the Institutional Review Board (IRB) to confirm applicable subparts of the federal regulations.
☐	Reasonable risks and potential benefits to participants and society are explained adequately.
☐	For Greater than minimal risk research, a data and safety monitoring plan has been developed.
☐	The consent form addresses areas required by federal regulations and is written at the eighth- grade level or lower language when possible. Refer to the HRP Toolkit for all consent templates.
☐	Complete any assent, consent and recruitment documents as found in the HRP Toolkit. Use the Protocol Narrative as a guide to determine which documents are needed.
☐	If creation, use, or disclosure of Protected Health Information is applicable: Indicate whether subjects will sign a written HIPAA research authorization If a waiver of HIPAA Authorization is requested, ensure the research meets the criteria. Remember! Complete the applicable PI Worksheets as found in the HRP Toolkit and as prompted by selections made in the Protocol Narrative. If HIPAA Research Authorization applies, when the study is IRB approved, ensure that the HIPAA Research Authorization is attached to the IRB approved consent form.
☐	Gather the completed Word documents. Initiate the new study in the ZOT IRB SmartForm.
☐	**When completing the SmartForm in ZOT IRB:** Ensure the Brief Description of the study is concise and addresses all aspects of the study in language understandable to a non-scientist reviewer.

☐	When completing the Study Team section, keep the following points in mind: List only those as necessary per the Research Team Table. Use the Template – UCI Research Team Log to track study team outside of ZOT IRB. If collaborators at UCI need read only access to the protocol, they may be added to the Guest List in the main study space. Refer to this HRP Listserv for more information on this process. Refer to the same HRP Listserv for enabling the PI Proxy. All Study Team members listed formally in ZOT IRB must complete the applicable CITI training.
☐	Include all drugs and devices required by the protocol. If using an experimental drug or device, or using a marketed product off-label, provide the IND / IDE number or confirm IND/IDE exempt criteria. If marketed (on-label) drugs or devices will be used as part of research procedures (not as part of standard clinical care), list the products and their marketing status under drug or medical devices in the protocol application. Use discretion for those drugs or devices that are well known or understood (e.g., standard MRI, Tylenol, etc.).
☐	Non-standard questionnaires are provided.
☐	All applicable approvals for other committee reviews have been obtained or are in process.
☐	If research will be funded by an external sponsor (grant, contract, or gift), contact Sponsored Projects.
☐	If research will take place off-site, or data or materials, will be shared between institutions, proper documentation (permission letter, Federalwide Assurance for off-site entity, off-site research agreement, data use agreement (DUA), material transfer agreement (MTA), etc.) has been obtained or is in progress. Wanda Seang handles all DUA related inquiries or referrals for non-Industry organizations. The Clinical Trial Team handles human subject data agreements with industry. When transferring tangible research material to an organization, please contact UCI Beall Applied Innovation.
☐	Review the IRB approval letter. Understand what is required to conduct human subject research at UCI. Refer back to the Human Research Protection Program Plan and the Investigator's Manual throughout the research, as needed.
☐	Refer to Documentation for Sponsors in the HRP Toolkit for information that may be helpful for sponsors or publishers.

SOP: Establishing Reliance Agreements

1 PURPOSE

1.1 The purpose of this process is to execute Authorization Agreements with other institutions and agreements with individuals for reliance for non-exempt human research.

1.2 This process begins when an institution/organization or collaborating independent investigator or collaborating institutional investigator at a non-assured institution has been identified for a potential Authorization Agreement.

1.3 This process ends when an Institutional Profile has been established or an Individual Investigator Agreement (IIA) has been executed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Summary of Changes:

2.1.1 Revised tite to 'Establishing Reliance Agreements'.

2.1.2 Under 5.1.2.4, removed instruction to file HRP-815 - FORM - Institutional Profile, as is duplicative with instructions in HRP-802 - SOP - Institutional Profile Management.

2.1.3 In 5.2, revised "unaffiliated individual or individual affiliated with an organization that does not have an FWA" to "Collaborating Individual Investigator or Collaborating Institutional Investigator', consistent with OHRP guidance and the terms defined in HRP-001.

2.1.4 Removed HRP-815 from the References section.

2.2 Reason for Change: HRP Toolkit version 5.4 released December 2025.

2.3 Prior Version: 09/01/2025.

3 POLICY

3.1 HRP-101 - Human Research Protection Program Plan details the criteria for reviewing for or relying on other institutions/organizations or reviewing for unaffiliated individuals.

3.2 An institution or individual must be engaged in non-exempt Human Research as determined by using HRP-311 - WORKSHEET - Engagement Determination for IRB reliance to occur.

3.3 The institution may leverage an existing Institutional Profile to collect information requested in the Institutional Profile SmartForm. For example, Institutional Profiles created for IREx or the SMART IRB platform are acceptable.

3.4 The institution may leverage the SMART IRB agreement or the local UCI Institutional Authorization Agreement to establish reliance.

3.5 Where this institution serves as the reviewing institution every effort will be made to promote the use of SMART IRB agreement. A LOA is required between both institutions.

3.6 This institution does allow an unaffiliated individual or individual affiliated with an organization that does not have an Federalwide Assurance (FWA) to request reliance on this institution’s FWA and IRB via an IIA.

3.7 This institution leverages the local IIA to establish reliance.

4 RESPONSIBILITIES

4.1 The Reliance Coordinator or IRB staff generally carry out these procedures. The IO/OO or HRPP Director may also participate in reliance determinations.

5 PROCEDURE

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5.1 If the request is for IRB reliance on or by an institution, determine whether the criteria for reviewing for or relying on other institutions/organizations are met:

5.1.1 Review HRP-101 - Human Research Protection Program Plan to determine if basic criteria are met.

5.1.1.1 If the criteria have not been met, do not execute an Authorization Agreement. Prepare HRP-856 – LETTER – Decline Reliance on an External IRB, or HRP- 850 - LETTER - Decline to Serve and send to the other institution/organization.

5.1.1.2 If the request is for your institution to rely on another institution's IRB, use HRP-832 - PI WORKSHEET - Considerations for Relying on an External IRB to inform your determination of whether your institution will rely on another institution's IRB.

5.1.1.3 If an institution is requesting to rely on your institution's IRB, use HRP-833 - PI WORKSHEET - Considerations for Serving as the Reviewing IRB to inform your determination of whether your institution's IRB will serve as the sIRB.

5.1.2 If the criteria have been met, for an institution/organization, execute an Authorization Agreement with that institution/organization. (Use of the SMART IRB Agreement is documented via a letter of acknowledgement (SMART LOA) or use of their Online Reliance System on a study specific basis.)

5.1.2.1 Indicate in the Authorization Agreement the conditions under which you serve as the IRB of record for that institution/organization.

5.1.2.2 Indicate in the Authorization Agreement the conditions under which that institution/organization will serve as the IRB of record for you.

5.1.2.3 Include the following in the Authorization Agreement, or as (an) addendum(s):

5.1.2.3.1 When UCI is reviewing IRB and the authorization agreement is not SMART, include a communication plan. Use HRP-830 - WORKSHEET - Communication and Responsibilities to create a communication plan.

5.1.2.3.2 Consent form instructions, including instructions for the institution/organization to provide local contact information and details regarding compensation for research-related injuries.

5.1.2.3.3 Recruitment material instructions.

5.1.2.3.4 New information reporting instructions.

5.1.2.3.5 Required terms.

5.1.2.3.6 Negotiable terms.

5.1.2.3.7 The process for adding participating sites or additional research to existing Authorization Agreement (if this is a master agreement).

5.1.2.3.8 Relevant tribal, state, or non-US laws, regulations, or policies, such as age of majority, circumstances that affect the age of consent, who can serve as a Legally Authorized Representative, and other information that may not be identified elsewhere in the Authorization Agreement.

5.1.2.4 Use HRP-802 - SOP - Management of Institutional Profiles to record the collected information in the Institutional Profile SmartForm.

5.1.3 If the criteria within HRP-832- PI WORKSHEET - Considerations for Relying on an External IRB or HRP-833- PI WORKSHEET - Considerations for Serving as the Reviewing IRB have not been met, do not execute an Authorization Agreement. Prepare HRP-856 – LETTER – Decline Reliance on an External IRB, or HRP-850 - LETTER – Decline to Serve and send to the other institution/organization.

5.2 If the request is for a Collaborating Individual Investigator or Collaborating Institutional Investigator to rely on your institution, determine whether the criteria have been met:

5.2.1 Confirm the individual does not need their institution to obtain its own FWA (e.g., they are the prime awardee, or routinely conduct human subjects research).[i]

5.2.2 Review HRP-101 - Human Research Protection Program Plan to determine if basic criteria are met.

5.2.2.1 If the criteria have not been met, do not execute an IIA. Prepare HRP-850 - LETTER – Decline to Serve and send to this institution's study team.

5.2.2.2 If the criteria have been met, execute IIA with the individual.

5.2.2.3 Upload the finalized IIA under "Other Attachments" in the study application.

6 MATERIALS

6.1 HRP-021 - SOP - Pre-Review

6.2 HRP-101 - Human Research Protection Program Plan

6.3 HRP-802 - SOP - Management of Institutional Profiles

6.4 HRP-830 - WORKSHEET - Communication and Responsibilities

6.5 HRP-832 - PI WORKSHEET - Considerations for Relying on an External IRB

6.6 HRP-833 - PI WORKSHEET - Considerations for Serving as the Reviewing IRB

6.7 HRP-850 - LETTER - Decline to Serve

6.8 HRP-856 - LETTER - Decline Reliance on an External IRB

6.9 HRP-861 - WORKBOOK - Institutional Profiles

6.10 Reliance Agreement Templates (IIA, IAA, SMART LOA): Available on HRP Toolkit

7 REFERENCES

7.1 Single IRB Exception Determinations: https://www.hhs.gov/ohrp/regulations-and-policy/single-irb-exception-determinations/index.html

7.2 SMART IRB Agreement: https://smartirb.org/agreement/

7.3 OHRP Authorization Agreement template: https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/forms/irb-authorization-agreement/index.html

7.4 Extending an FWA to Cover Collaborating Investigators (2005): https://www.hhs.gov/ohrp/regulations-and-policy/guidance/extension-of-institutional-fwa-via-individual-investigator-agreement/index.html

[i] Extending an FWA to Cover Collaborating Investigators (2005) | HHS.gov: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/extension-of-institutional-fwa-via-individual-investigator-agreement/index.html

SOP: Institutional Profile Management

1 PURPOSE

1.1 The purpose of this process is to manage Institutional Profiles.

1.2 This process begins when this institution receives new or updated information from another institution/organization that impacts the content of the Institutional Profile.

1.3 This process ends when updated information has been communicated to appropriate parties.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 Any substantive changes to an Institutional Profile may result in an amended Authorization Agreement. Any non-substantive changes, e.g., contact information updates, do not require an amended Authorization Agreement.

3.2 The institution may leverage an existing Institutional Profile to collect information requested in the Institutional Profile SmartForm. For example, Institutional Profiles created for IREx or the SMART IRB platform are acceptable.

4 RESPONSIBILITIES

4.1 The Reliance Coordinator or IRB staff generally carries out these procedures.

5 PROCEDURE

5.1 If no Institutional Profile exists for a site for which this institution is being asked to serve as the single IRB, or an IRB on which this institution is being asked to rely, update the Institutional Profile SmartForm with information about the external institution/organization.

5.1.1 Gather this information from any of the following sources:

5.1.1.1 SMART IRB Agreement online Profile

5.1.1.2 IREx Online Profile

5.1.1.3 Information included in the IRB Authorization Agreement (IAA)

5.1.1.4 Direct communication with the Human Research Protection Program (HRPP) of the external institution/organization

5.1.1.4.1 HRP-815 - FORM Institutional Profile can be used to collect this information

5.2 If a relying site or reviewing IRB provides updated information for an existing Institutional Profile, update the Institutional Profile SmartForm with the information.

5.3 If an amended Authorization Agreement is needed, file the updated HRP-815 - FORM - Institutional Profile with the amended Authorization Agreement.

5.4 Determine whether the updates impact any existing studies. If so, develop a plan for how to address the impact.

5.5 Communicate these updates and any plans to address impacts to appropriate parties as needed.

6 MATERIALS

6.1 HRP-815 - FORM - Institutional Profile

7 REFERENCES

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7.1 None

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SOP: External IRB Post-Review

1 PURPOSE

1.1 The purpose of this process is to conduct post-review for submissions where this institution is being asked to rely on an external IRB.

1.2 This process begins when a request to rely oversight has been submitted and pre-review has been completed.

1.3 This process ends when all correspondence related to IRB determinations and actions have been sent and additional tasks have been completed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY

3.1 None.

4 RESPONSIBILITIES

4.1 The Reliance Coordinator or IRB staff generally carries out these procedures.

5 PROCEDURE

5.1 For studies where IRB oversight has been ceded to an external IRB:

5.1.1 Execute the “Record sIRB Decision” activity and complete the Smartform with the information in the external IRB approval letter. Upload the external IRB determination letter in the designated space for “External IRB Approval Letter” if not already attached under “Other Attachments” in the study application.

5.1.2 Execute the “Finalize Documents” activity if necessary.

5.1.3 Execute the “Prepare Letter” activity to generate and edit HRP-857 - LETTER - Acknowledge External IRB.

5.1.4 Execute the “Send Letter” activity.

6 MATERIALS

6.1 HRP-857 - LETTER - Acknowledge External IRB

7 REFERENCES

7.1 None

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SOP: External IRB Updates

1 PURPOSE

1.1 The purpose of this process is to ensure that the relying institution is made aware of updates approved by the external IRB or when the local investigator makes changes at the site level.

1.2 This process begins when the local site investigator submits newly approved materials from the external IRB or when the local investigator submits local site changes.

1.3 This process ends when an external IRB submission has been updated.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Summary of Changes: Revised Policy statements to direct the submission of reportable events as RNI (instead of via Update Study Details), with corresponding removal of section 5.2.5-5.2.8.

2.2 Reason for Change: HRP Toolkit version 5.4 released December 2025.

2.3 Prior Version: 09/01/2025.

3 POLICY

3.1 An investigator relying on an external IRB must update the site record with changes approved by the external IRB, including providing notification of Continuing Review approval, by the external IRB, using the “Update Study Details” activity.

3.2 If changes are made at the local site that affect institutional requirements (including changes to personnel, conflicts of interest, funding, HIPAA, or changes to institutionally required consent language) on an external IRB study, the investigator must update the site record using the “Create Site Modification” activity.

3.3 The site record must be updated with any reportable new information occurring locally that is determined by the external IRB to be Serious Non-Compliance, Continuing Non-Compliance, or an Unanticipated Problem Involving Risks to Subjects or Others, using the “Report New Information” activity.

4 RESPONSIBILITIES

4.1 The Reliance Coordinator or IRB staff generally carry out these procedures.

5 PROCEDURE

5.1 If the item includes updates to the local site information (Site Modification for study team members or other parts of the site), review the updates using HRP-830 - WORKSHEET - Communication and Responsibilities.

5.1.1 If the item is a personnel change, ensure the personnel are qualified and have required training.

5.1.2 If the item is a change to a conflict of interest management plan, follow HRP-055 – SOP - IRB Review of Financial Conflicts of Interest.

5.1.3 If the item is a change to HIPAA authorization waivers or alterations and the local site is serving as the Privacy Board, review and document the appropriate waivers using HRP-441-WORKSHEET for HIPAA Waiver of Authorization.

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5.1.4 If the item is a change triggering an ancillary review, execute the Manage Ancillary Review activity and assign the appropriate ancillary review organization or individual as outlined in HRP-309 - WORKSHEET - Ancillary Review Matrix.

5.2 If the item was determined to be Serious Non-Compliance or Continuing Non-Compliance or an Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO) that occurred locally:

5.2.1 If the external IRB has not notified the local IRB of the event, contact the external IRB, request additional information and documentation as needed, and confirm reporting requirements as described in the reliance agreement terms.

5.2.2 Notify the IO/OO of the event.

5.2.3 Consult with the HRPP Director or designee to determine whether any additional actions are needed, including local review of the event.

5.2.3.1 Follow HRP-024 - SOP - New Information to review the event.

5.2.3.2 In coordination with the HRPP Director or designee, notify other local departmental offices as appropriate (i.e., department leadership, deans, privacy, quality, or risk management).

5.2.4 Respond to the external IRB with any edits requested to any applicable reporting requirement letter(s) or file the report with any appropriate agency(ies) in accordance with oversight requirements outlined in the Authorization Agreement terms.

5.3 If the item is an update to the overall study (Update to Study Details for funding, study scope, or study related documents and template), review the updates in accordance with the roles and responsibilities of your institution as outlined in the Authorization Agreement or HRP-830 - WORKSHEET - Communication and Responsibilities.

5.3.1 The institutional policy requires that the IRB Coordinator or IRB staff execute the “Finalize Updates” activity in the system:

5.3.1.1 Review the updates and if they are satisfactory, determine if the changes require an update to the sIRB Decision:

5.3.1.1.1 If yes, execute the “Edit sIRB Decision” activity and complete the SmartForm, indicating whether documents need to be finalized or a letter needs to be sent.

5.3.1.1.2 If applicable, execute the “Finalize Documents” activity and then the “Send Letter” activity to send HRP-859 - TEMPLATE LETTER - Acknowledge External IRB Update.

5.3.1.1.3 If no, no further action is necessary.

5.3.1.2 If the item includes other updates and are not satisfactory:

5.3.1.2.1 Contact the investigator by posting a comment in the submission workspace with requested changes. Instruct the investigator to edit the submission.

5.3.1.2.2 When the investigator edits the submission, confirm that the requested changes were made.

5.3.1.3 Review the updates and if they are satisfactory, determine if the changes require an update to the sIRB Decision:

5.3.1.3.1 If yes, execute the “Edit sIRB Decision” activity and complete the SmartForm, indicating whether documents need to be finalized or a letter needs to be sent.

5.3.1.3.2 If applicable, execute the “Finalize Documents” activity and then the “Send Letter” activity to send HRP-859 - TEMPLATE LETTER - Acknowledge External IRB Update.

5.3.1.3.3 If no, no further action is necessary.

6 MATERIALS

6.1 HRP- 024 - SOP - New Information

6.2 HRP-055 - SOP - IRB Review of Financial Conflicts of Interest

6.3 HRP-309 - WORKSHEET - Ancillary Review Matrix

6.4 HRP-441- PI WORKSHEET - HIPAA Waiver of Authorization

6.5 HRP-830 - WORKSHEET - Communication and Responsibilities

6.6 HRP-859 - LETTER - Acknowledge External IRB Update

7 REFERENCES

7.1 None.

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SOP: Review Request to Rely on an External IRB

1 PURPOSE

1.1 This procedure establishes the process to ensure the criteria for this Institution to rely on an external IRB for review and oversight of non-exempt human research have been met.

1.2 This process begins when a study team submits a request to rely on an external IRB.

1.3 This process ends when the request to rely on an external IRB has been approved or declined.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 The IO/OO or their designee has the authority to determine what IRBs the Institution will rely upon, as well as approve and rescind authorization agreements for IRBs.

3.2 Reliance on an external IRB requires an Authorization Agreement and an active local Institutional Profile, as well as a local review for compliance with local policies of the Institution.

4 RESPONSIBILITIES

4.1 The Reliance Coordinator or IRB staff carry out these procedures.

5 PROCEDURE

5.1 Click on the Institutional Profile area in IRB system and determine if the external IRB has an active profile.

5.1.1 If there is an active profile and the IRB is not required to approve each individual request to rely for this external IRB (e.g. NCI CIRB), go to Section 5.2.2.

5.1.2 If there is not an active profile OR the IRB is required to approve each individual request to rely for this external IRB, proceed to next section.

5.2 Using HRP-832 - PI WORKSHEET - Criteria for Relying on an External IRB, determine if the study is eligible to rely on an external IRB of record.

5.2.1 If the study does not meet the criteria for reliance on an external IRB:

5.2.1.1 Execute the Confirm Reliance activity.

5.2.1.2 Indicate NO to the question #3 “Confirm reliance on the single IRB of record?”

5.2.1.2.1 Manually prepare and send HRP-856- Reliance Determination Decline to Rely to communicate the determination to the Investigator.

5.2.1.2.2 If the Investigator chooses to submit a response to the IRB regarding the determination, proceed with step 5.1 above.

5.2.2 If the study is eligible to rely on an external IRB of record:

5.2.2.1 Determine if a valid authorization agreement is part of the Institutional Profile.

5.2.2.1.1 If not, follow HRP-801 - SOP - Establishing Reliance Agreements to create a new authorization agreement.

5.2.2.2 Confirm that all local requirements and ancillary reviews are complete.

5.2.2.2.1 Human Subjects Training is complete.

5.2.2.2.2 Conflict of Interest management plan is in place when applicable and will be provided to IRB of Record.

5.2.2.2.3 Written consent to be used at this institution includes institutionally required language where applicable.

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5.2.2.2.4 HIPAA Authorization language is provided as separate document to be used at this institution when applicable to the study.

5.2.2.2.5 Refer to the Institutional Profile or authorization agreement to determine institutional responsibilities.

5.2.2.2.6 Use HRP-441 PI WORKSHEET - HIPAA Waiver of Authorization when applicable and this institution will serve as Privacy Board.

5.2.2.2.7 Use HRP-064 -SOP- NIH GDS Institutional Certification and HRP-332 PI WORKSHEET NIH GDS Institutional Certification when applicable and this institution is responsible for certification.

5.2.2.2.8 All relevant local ancillary review requirements have been met or are in progress in accordance with HRP-309 - WORKSHEET - Ancillary Review.

5.2.2.3 If any institutional requirements are not met, execute the “Request Pre-Review Clarification” activity from the investigator.

5.2.2.4 Offer the investigator the opportunity to update the submission.

5.2.2.5 Execute the Confirm Reliance Activity:

5.2.2.5.1 Indicate YES or NO to the question “Confirm reliance on the single IRB of record?”

5.2.2.5.2 If you indicated YES and the investigator does not yet have external IRB approved documents, and your institution requires these be provided, leave the study in “Pending sIRB Review” state and wait for the Investigator to log a comment with IRB approved documents. Communicate this requirement to the Investigator.

5.2.2.5.3 Draft and upload HRP-852 - LETTER - Permission to Rely on an External IRB, as needed (e.g., if documentation is required to be submitted to the external IRB).

5.2.2.5.4 If you indicated NO, see instructions above for when the study does not meet the criteria for reliance on an external IRB.

5.2.2.6 If the investigator already uploaded external IRB approved documents for this site (e.g., NCI CIRB), execute the “Record sIRB Decision” activity and complete any information required by the local IRB.

5.2.2.6.1 Indicate NO to the question “Do you need to finalize documents or send a letter” unless finalizing documents and/or sending a letter is required. This moves the study to the Review Complete state.

5.2.2.6.2 Indicate YES if finalizing documents and/or sending a letter is required. This will move the study to the Post Review state.

5.2.2.7 Refer to HRP-804 - SOP - External IRB Post-Review.

6 MATERIALS

6.1 HRP-064 -SOP- NIH GDS Institutional Certification
6.2 HRP-309 - WORKSHEET - Ancillary Review Matrix
6.3 HRP-332 - WORKSHEET - NIH GDS Institutional Certification
6.4 HRP-441 - WORKSHEET - HIPAA Waiver of Authorization
6.5 HRP-801 - SOP - Establishing Reliance Agreements
6.6 HRP-804 - SOP - External IRB Post-Review
6.7 HRP-815 - FORM - Institutional Profile
6.8 HRP-832 - PI WORKSHEET - Considerations for Ceding IRB Review
6.9 HRP-852 - LETTER - Permission to Rely on External IRB
6.10 HRP-857 - LETTER - Acknowledge External IRB
6.11 HRP-856 - LETTER - Decline Reliance on an External IRB

6.12 HRP-859 - LETTER - Acknowledge External IRB Update
6.13 HRP-861 - WORKBOOK - Institutional Profiles

7 REFERENCES

7.1 SMART IRB Agreement: https://smartirb.org/agreement/
7.2 OHRP Authorization Agreement template: https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/forms/irb-authorization-agreement/index.html

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PI WORKSHEET: Considerations for Relying on an External IRB Review

This worksheet is required for the following submission types when research involves a request to rely on an external IRB: Expedited research or Full Committee research.

The purpose of this worksheet is to provide considerations that the institution may evaluate when considering requests to outsource review to a commercial IRB or to require a pSite's IRB to serve as sIRB. For more information, visit: UCI is the Relying IRB.

Answer all questions succinctly using non-technical language as much as possible.

- If a question is not applicable to the research, state "N/A".
- If a question is not answered, the IRB does not know if the question was overlooked. This will result in unnecessary "back and forth" for clarification.

Attach this protocol to the "Basic Study Information" section of the ZOT IRB application. Other supplemental documentation (i.e. consent, recruitment, other) can be attached in "Local Site Documents".

1. STUDY OVERVIEW

1.1 Basic Information:

1.1.1 IRB Study Number[1]: Click or tap here to enter text.
1.1.2 Short Title: Click or tap here to enter text.

2. SINGLE IRB REVIEW CRITERIA

2.1 Eligibility Criteria: The following are circumstances in which UCI may rely on an external IRB for review of a multisite study or collaboration. (Check if "Yes." All must be checked.)

☐ The study is determined to involve Human Research.
☐ UCI is engaged in the research activities.
☐ The study is not determined to be Exempt.[i]
☐ The external IRB and performance sites are in the United States.
☐ The external IRB maintains an OHRP-approved Federalwide Assurance (FWA).
☐ At least one of the following is true (Check if "Yes". Check all that apply.)

- ☐ The study is federally funded (PI anticipates NIH or federal funding) cooperative research that meets the following criteria.
  - ☐ More than single IRB review is **not** required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe).
  - ☐ Federal department or agency has **not** determined that the use of a single IRB is not appropriate for the particular context.

- ☐ The study is FDA-regulated cooperative research that meets the following criteria.

[1] The IRB study number is generated when the submission is created in ZOT IRB. Please enter the number prior to final submission to the IRB.

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☐ More than single IRB review is **not** required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe).
☐ Research does **not** involve a highly specialized FDA-regulated medical product for which unique, localized expertise is required (*Rare*).
☐ Research does **not** involve drugs that are exempt from the requirements for an IND application under § 312.2(b).
☐ Research does **not** involve medical devices that meet the abbreviated requirements under § 812.2(b) or that meets the requirements for exempted investigations under § 812.2(c).
☐ Research is **not** an investigator initiated/authored clinical investigation or ☐ Research is an investigator initiated/authored clinical investigation conducted under a UC cancer consortium.
☐ **Not** expanded access, compassionate use, or right to try.

☐ The study is other cooperative research (not federally funded, not FDA-regulated) that meets the following criteria.
☐ Research does not involve any HHS or FDA exceptions for cooperative research.
☐ UCI has a master service agreement with the external IRB or the SMART IRB agreement v3.0 is used.
☐ External IRB has one of the following quality assurance (QA) mechanisms.
☐ The external IRB is AAHRPP accredited.
☐ The external IRB is CARE-Q certified.
☐ The external IRB is actively seeking accreditation / certification, explain.

Click or tap here to enter text.

☐ [IRB staff to confirm] A UCI director has reviewed the external IRB's human research protection program plan and policies to confirm, at minimum, that their program has a quality assurance program and is otherwise appropriate to serve as the Reviewing IRB.

2.2 IRB Agreement: Indicate which IRB agreement applies.
☐ Advarra IRB
☐ National Cancer Institute Central Institutional Review Board (NCI CIRB)
☐ SMART IRB (CHOC, MHS, NEALs, StrokeNet, UC). The External IRB must be a Participating Institution that has signed v3.0 of the SMART IRB Agreement.
☐ Indicate the communication platform that will be used.
☐ SMART IRB Online Reliance System. Provide the ORS tracking number (optional).

Click or tap here to enter text.

☐ IRB Reliance Exchange (IREx)
☐ SMART IRB Letter of Acknowledgement (LOA). Attach the External IRB's version of the LOA.
☐ Western Copernicus Group IRB (WCG)

3. CONSIDERATIONS TO RELY ON A COMMERCIAL IRB

☐ ***This section is not applicable.***

3.1 Study Characteristics: The following characteristics of the study will be evaluated to determine whether to rely on a Commercial IRB (e.g., Advarra, WCG, etc.). (At least one of the following considerations should be true.)

☐ The project is commercially sponsored research.
☐ The UCI is the lead site of a Multi-Site Study and the institution has elected to use a commercial IRB for the review of the study.
☐ Other relevant considerations.

Click or tap here to enter text.

4. [IRB STAFF TO CONFIRM] GENERAL CONSIDERATIONS FOR RELYING ON AN OTHER (NON-COMMERCIAL) IRB

☐ ***This section is not applicable.***

4.1 Study Characteristics: The following are additional considerations for evaluating the institution's willingness to rely on an institution with a valid OHRP-approved Federalwide Assurance (FWA). (At least one of the following considerations should be true.)
☐ Single IRB review is mandatory.
☐ The reviewing IRB has sufficient expertise and experience reviewing and overseeing research of similar nature to the proposed study.
☐ The external IRB has sufficient expertise with certain features of the protocol or the participant population that may pose special concerns (e.g., recruitment of socially or economically disenfranchised populations, local cultural mores, or unique clinical circumstances).
☐ Whether relying on an external IRB review could create or mitigate unique institutional risks, such as conflicts of interest.
☐ Implications for the institution of the decision, including:
    ☐ analysis of lost research opportunities (i.e., unwillingness of a sponsor or funder to allow local);
    ☐ the additional administrative time and costs associated with establishing authorization agreements.
☐ Resources needed by the study team to learn and adhere to the policies and procedures of the reviewing IRB.

5. PARTICIPANTS

5.1 Participant Populations: Participant Populations: Select all that apply.
☐ Adults
☐ Adults not able to consent for themselves (e.g., cognitively impaired or medically incapacitated)
☐ Pregnant individuals/fetuses
☐ Neonates
☐ Prisoners
☐ Children (minors)
☐ American Indian or Alaska native tribes
☐ UCI inpatients or outpatients
☐ UCI students/staff/faculty

5.2 UCI Interaction/intervene: Specify whether the UCI study team will interact or intervene with participants.
☐ Yes
☐ No, UCI will not be recruiting own subset of subjects. Instead, UCI will be accessing identifiable data/records/biospecimens for analysis only.
☐ No, describe/explain.

Click or tap here to enter text.

5.3 Number of Individuals Pre-screened: If subject eligibility is verified prior to recruitment/consent, address the following for each participant group (e.g., experimental vs control).

3.5.1 Specify the number of individuals prescreened prior to recruitment/consent.

3.5.2 Explain how the pre-screen number was determined (e.g., cohort discovery, anticipated rate of screen failure).

Click or tap here to enter text.

5.4 Number of Participants Consented: Provide the max number of individuals consented for each participant group (e.g., experimental vs control). If applicable, include screen failures and withdrawals.

Click or tap here to enter text.

5.5 Expected/Target Number of Participants: Provide the expected/targeted number of participants needed to complete the study.

Click or tap here to enter text.

5.6 Multi-site Number: If applicable, specify total number of subjects across all sites (UCI & other sites).

Click or tap here to enter text.

6. PRE-SCREENING INDIVIDUALS PRIOR TO CONSENT

☐ ***This section is not applicable. Participants are consented prior to screening activities.***

6.1 Source of Eligibility Information: Select all that apply and address the required action, as applicable.

- IMPORTANT! All activities involving health data must adhere to the standards set forth by the UCI Health Data Governance Committee (HDGC) for requesting and managing health data. Access to health data is facilitated through data stewards identified by the HDGC.

☐ Center for Clinical Research Pre-screening and Recruitment Protocol IRB# 414

☐ Chao Family Comprehensive Cancer Center Chart Screening Protocol IRB# 20096837

☐ Direct access to UCI Health medical records: Explain why an HDGC Data Steward cannot be utilized.

- Action Required: A partial waiver of HIPAA authorization is required. Attach PI WORKSHEET - HIPAA Waiver of Authorization.

☐ HDGC Data Steward/Honest Broker: Center for Artificial Intelligence in Diagnostic Medicine (CAIDM) IRB# 20184417

- Action Required: A partial waiver of HIPAA authorization is required. Attach PI WORKSHEET - HIPAA Waiver of Authorization.

☐ HDGC Data Steward/Honest Broker: Experimental Tissue Resource (ETR) IRB# 20128716.

- Action Required: A partial waiver of HIPAA authorization is required. Attach PI WORKSHEET - HIPAA Waiver of Authorization.

☐ HDGC Data Steward/Honest Broker: UCI Health Enterprise Data & Analytics (EDA) IRB# 20128757

- Action Required: A partial waiver of HIPAA authorization is required. Attach PI WORKSHEET - HIPAA Waiver of Authorization.

☐ IRB approved research: Specify the UCI IRB number or attach the IRB approved consent form that documents the sharing of information.

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☐ Oral or written communication with the prospective participant or Legally Authorized Representative (LAR) (i.e. self-report of medical information; medical records will not be screened)
- Action Required: Attach a screening script that adheres to Recruitment Requirements and includes:
  - a description of the information that will be obtained,
  - the reasons for performing the screening, and
  - statement that if the individual is not eligible their identifiable information will not be used for research purposes and will be destroyed at the earliest opportunity consistent with conduct of the research.

☐ Student records: Specify the type of records.
- Action Required: Attach a Letter of Permission from the local school/district confirming the use of student records and compliance with the Family Educational Rights and Privacy Act (FERPA). When accessing UCI student records, attach a letter from the UCI Registrar FERPA Analyst.

☐ Other: Specify the types of records/biospecimens and explain how the study team will obtain the records. Specify whether the information/biospecimen was originally collected for research purposes. If so, attach the IRB approved consent form that documents the sharing of information.

Click or tap here to enter text.

6.2 Screening Variables: Provide a complete list of ALL data points/variables/information that will be collected/recorded. Information collected/recorded from medical/student records must be limited to the contact information unless justified otherwise. Eligible participants should be recruited for the study.

☐ ***This is included in a separate document attached. Include page and line item on protocol.***

Click or tap here to enter text.

7. RECRUITING PARTICIPANTS

☐ ***This section is not applicable. The study does not involve human interaction/communication.***

7.1 Recruitment Methods: Select all that apply and address the required action, as applicable.
☐ Center for Clinical Research (CCR) Find a Trial web page
☐ CCR Chart Pre-Screening and Recruitment Protocol IRB# 414
☐ Chao Family Comprehensive Cancer Center Chart Screening Protocol IRB# 20096837
☐ Clinicaltrials.gov (Note: Clinicaltrials.gov statement must be included in consent documents)
☐ Colleagues provide participants with information about the research and how to contact investigators
- Action Required: When a treating physician screens patient medical records outside of clinical care (i.e. solely for research purposes), a partial waiver of HIPAA authorization is required. Attach PI WORKSHEET - HIPAA Waiver of Authorization.

☐ Colleagues seek or obtain the participants' permission for investigators to contact them
- Action Required: When a treating physician obtains verbal permission from a patient to disclose their name and contact information to the study team, a partial waiver of HIPAA authorization is required. Attach PI WORKSHEET - HIPAA Waiver of Authorization.

☐ Colleagues, who are treating physicians, will send UCI IRB approved recruitment letter to their patients
- Action Required: Attach the recruitment letter to be signed by the treating physician.

☐ Email/Postal Mail/Phone: Specify how contact information will be obtained.
- Action Required: Attach the recruitment material/script.

☐ Flyers/Brochures: Specify where recruitment will be posted and whether the location is public (open access) or private (controlled access).
- Action Required: Attach the recruitment material.

☐ Individual/Group/Class Presentation: Specify where recruitment will be posted and whether the location is public or private.
- Action Required: Attach the recruitment material.

☐ Newspaper/Radio/Television: Specify where recruitment will be posted.
- Action Required: Attach the recruitment material.

☐ Online/Social Media: Specify where recruitment will be posted and whether the location is public or private.
- Action Required: Attach the recruitment material.

☐ Study team will approach students, employees, patients, economically, educationally, or cognitively disadvantaged
- Action Required: Attach recruitment and consent documents that reflect an individual's decision to participate in research will not affect their relationship with UCI, how their doctor cares for them as a patient or their care at UC Health in general and/or how their instructor grades their performance in the course.

☐ Study team will contact potential participants who have given prior permission to be contacted for research studies: Specify how permission was granted and documented.
☐ UCI IRB approved participant screening protocol: Specify IRB number(s).
☐ UCI Participant Pool: Specify pool(s).
☐ Other: Describe recruitment methods. Specify where recruitment will be posted. Specify where recruitment will be posted and whether the location is public or private.
- Action Required: Attach the recruitment material.

Click or tap here to enter text.

Click or tap here to enter text.

8. INFORMED CONSENT

8.1 Consent Methods: Select all that apply and address the required action, as applicable.
☐ Electronic signed consent [participant or Legally Authorized Representative (LAR)], parental permission, or assent (child or adult unable to consent). For FDA-regulated clinical investigations, specify how the process is 21 CFR 11 compliant.
- Action Required: Attach the following (as applicable):
  - consent and/or assent form,
  - informational materials, including any videos and web-based presentations, which the subject will receive and view during the electronic process, and
  - any optional questions or methods used to gauge subject comprehension of key study elements.

☐ Paper-based signed consent (participant or LAR), parental permission, or assent (child or adult unable to consent)
- Action Required: Attach the consent and/or assent form.

☐ Verbal/implied consent and/or parental permission
- Action Required: Attach the Study Information Sheet.

☐ Verbal/implied assent (child or adult unable to consent)
- Action Required: Attach the assent script.

☐ Consent materials will be translated for non-English speaking participants or their LAR
☐ Short Form Consent
☐ No consent or parental permission

☐ No assent (child or adult unable to consent)
☐ Emergency exception to informed consent

8.2 Consent/Assent Process Description:

8.2.1 Provide a breakdown of the groups (as applicable) and consent/assent procedures for each.
8.2.2 Describe the type of setting(s) in which the consent/assent process will be conducted – if the setting is not private, describe the measures to protect confidentiality.
8.2.3 Describe the measures that will be taken to provide prospective research participants (their parent or LAR) with sufficient opportunity to consider participating in the study.
8.2.4 Specify the length of time participants are given to decide whether they wish to participate in the study.
8.2.5 Explain how the study team will assess whether participants understand the information conveyed during the consent process.

Click or tap here to enter text.

8.3 Non-English-Speaking Participants:

8.3.1 Specify the qualifications of the person translating the consent (i.e. language fluency).
8.3.2 Indicate how the participants or their LAR will be consented in their language.
☐ A member of the study team is fluent in the language that will be used for communication, and that study team member will be available during emergencies. Provide their qualifications to serve in this capacity (i.e. language fluency) in the Study Team section in the ZOT IRB form.
☐ 24-hour translation service with sufficient medical expertise to discuss the research in this study.
☐ Other: Describe/explain
8.3.3 If applicable, address the following regarding the use of short form:
8.3.3.1 Specify the languages that will utilize short form.
8.3.3.2 Explain why short form consent is necessary for the research study. If enrollment of certain language speaking participants is not expected due to the disease or condition being studied and the anticipated study enrollment, please include study specific justification.
8.3.3.3 Explain who will be performing the oral translation of the English-approved consent form. Specify the credentials, experience, and expertise of the individual(s) performing the translation.

Click or tap here to enter text.

9. HIPAA AUTHORIZATION

☐ ***This section is not applicable.***

9.1 Information related to health or mental health care: Select all that apply.
☐ Derived from a medical or clinical record
☐ Derived from observation of clinical care
☐ Created or collected as part of health or mental health care
☐ Used to make healthcare or mental healthcare decisions and/or provided to other healthcare professionals
☐ Research information will be entered into the participants' medical or clinical record

9.2 HIPAA Authorization: Select all that apply and address the required action, as applicable.
☐ Signed HIPAA authorization (participant or Legally Authorized Representative)
- Action Required: Attach the UCI HIPAA Research Authorization

☐ Partial waiver of HIPAA authorization for screening and recruitment purposes
- Action Required: Attach the PI WORKSHEET - HIPAA Waiver of Authorization

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☐ Total waiver of HIPAA authorization
- Action Required: Attach the PI WORKSHEET - HIPAA Waiver of Authorization

10. STUDY INFORMATION AND BIOSPECIMENS SOURCES OTHER THAN THE PARTICIPANT (SECONDARY DATA ANALYSIS)

☐ ***This section is not applicable.***

10.1 Information/Biospecimen Source: This should reflect the portion of the research that gathers information or biospecimens from sources other than the participant. Select all that apply and address the required action, as applicable.
- IMPORTANT! All activities involving health data must adhere to the standards set forth by the UCI Health Data Governance Committee (HDGC) for requesting and managing health data. Access to health data is facilitated through data stewards identified by the HDGC.

☐ Access to medical records from another institution (not UCI): Institutions' healthcare authorization for release of health information will be used or a waiver for release of health information will be granted from the institution.

☐ Direct access to medical records from UCI Health: Explain why an HDGC Data Steward cannot be utilized.
- Action Required: Attach the UCI HIPAA Research Authorization as applicable.

☐ HDGC Data Steward/Honest Broker: Center for Artificial Intelligence in Diagnostic Medicine (CAIDM) IRB# 20184417
- Action Required: A partial waiver of HIPAA authorization is required. Attach PI WORKSHEET - HIPAA Waiver of Authorization.

☐ HDGC Data Steward/Honest Broker: Experimental Tissue Resource (ETR) IRB# 20128716
- Action Required: A partial waiver of HIPAA authorization is required. Attach PI WORKSHEET - HIPAA Waiver of Authorization.

☐ HDGC Data Steward/Honest Broker: UCI Health Enterprise Data & Analytics (EDA) IRB# 20128757
- Action Required: A partial waiver of HIPAA authorization is required. Attach PI WORKSHEET - HIPAA Waiver of Authorization.

☐ IRB approved research: Specify the UCI IRB number or attach the IRB approved consent form that documents the sharing of information.

☐ Stored identifiable biospecimen(s): Specify clinic or operating room.
- IMPORTANT! Except for biospecimens specifically listed as exempt in UCI Health Anatomical Pathology/Surgical Pathology - Procedure Number: S-23 or biospecimens obtained from Dermatopathology, retain evidence of Pathology clearance from Dr. Robert Edwards (redwards@uci.edu) or Delia Tifrea (dtifrea@hs.uci.edu).

☐ Student records: Specify the type of records.
- Action Required: Attach a Letter of Permission from the local school/district confirming the use of student records and compliance with the Family Educational Rights and Privacy Act (FERPA). When accessing UCI student records, attach a letter from the UCI Registrar FERPA Analyst.

☐ Other: Specify the types of records/biospecimens and explain how the study team will obtain the records. Specify whether the information/biospecimen was originally collected for research purposes. If so, attach the IRB approved consent form that documents the sharing of information.

Click or tap here to enter text.

10.2 Information Variables:

10.2.1 Specify the date-range of the information used for the project (e.g. January 2002 to January 2020)

10.2.2 Provide a complete list of ALL information points, variables, and/or information that will be collected/recorded (i.e. data abstraction form) from sources other than the participant (e.g., medical records).

10.2.3 When utilizing UCI Health Enterprise Data & Analytics services (e.g., pre-screening, information pull), specify timeframes for each eligibility factor, as applicable. For diagnoses, procedures, and laboratory tests, provide standard codes whenever possible.

☐ ***This is included in a separate scientific protocol attached. Include page and line item on protocol.***

Click or tap here to enter text.

11. PRIVACY AND CONFIDENTIALITY

11.1 Information: Indicate the personally identifiable information collected or retained for information analysis, recruitment, consenting and/or compensation. Select all that apply.

☐ Not applicable
☐ Names
☐ All elements of dates that are directly related to an individual: birth date, admission date, discharge date, death date, and all ages over 89
☐ All geographic subdivisions smaller than a state: street address, city, county, precinct, ZIP code, and geocodes
☐ Telephone numbers
☐ Email address
☐ Social Security number
☐ Health plan beneficiary numbers
☐ Medical record number
☐ Account numbers
☐ Vehicle identifier and serial numbers: license plate
☐ Web URLS
☐ IP addresses
☐ Biometric Identifiers: finger and voice prints
☐ Full-face photographs and any comparable images
☐ Any other unique identifier (does not include a code assigned by the investigator to identify the information)

11.2 Social Security Number: Explain why social security numbers are necessary, how they will be used, how they will be protected, and how long they will be retained. Social security numbers should not be used if other unique codes (not derived from the social security numbers) can practicably be utilized to conduct the research.

Click or tap here to enter text.

11.3 Personal Information: If University of California office records (e.g., medical, employment, student applications, etc.) are disclosed to the research team, indicate whether the records include personal information. Select all that apply.

☐ Not Applicable
☐ Identifiable information as indicated above
☐ Physical description
☐ Education
☐ Financial matters
☐ Medical history
☐ Employment history
☐ Statements made by, or attributed to, the individual
☐ Other, describe/explain.

Click or tap here to enter text.

11.4 Identifiable/Personal Information Rationale:

11.4.1 Explain why the identifiable and/or personal information indicated in the prior sections are needed to conduct the research.

11.4.2 Explain why the identifiable and/or personal information indicated in the prior sections are not more than the minimum necessary to conduct the research.

Click or tap here to enter text.

11.5 Information/Biospecimen Storage: Review How to Protect Research Data to complete this section.

- Consider housing research data in a managed **on-premise or enterprise-approved** cloud environment (e.g., UCI's Secure Research Environment (SRE), Campus Research Storage Pool (CRSP), Microsoft OneDrive).
- Review Research Environment Mapping to determine whether the storage location requires consultation. For example, consultation with the UCI Health Security Team would be required to store Protected Health Information (PHI) in a PI managed environment (laptop, desktop, workstation, etc).
- PHI or any other restricted UCI Health data must not be entered/stored into external (non-UCI) consumer environments unless they are explicitly approved for institutional use (see BFB-IS-3: Electronic Information Security).

11.5.1 Classify the research data into one of the four protection levels. Contact your Administrative Unit Information Security Lead for assistance.

☐ Level 1/P1 (published research)
☐ Level 2/P2 (draft or unpublished research papers, research using publicly available data, de-identified research or patient data, etc.)
☐ Level 3/P3 (student records, UCI personnel records, etc.)
☐ Level 4/P4 (personally identifiable information, protected health information (PHI), patient records, etc.)

11.5.2 Indicate the storage environment(s)/location.

☐ Biospecimens will be stored in a locked lab/refrigerator/freezer with limited access by authorized personnel: Specify location.
☐ Paper records will be stored physically in a locked area with limited access by authorized personnel: Specify location.
☐ Protected Virtual Computing Environment (PVCE): Data disclosed by UCI Health Enterprise Data & Analytics (EDA) is deposited in a study-specific storage area in the PVCE.
☐ UCI/Enterprise cloud-based storage: Specify environment.
☐ Other: Describe/explain

11.5.3 For storage environments that require consultation, indicate who provided a security assessment. Maintain documentation of the security assessment in the research records.

☐ Not Applicable: Acceptable environment on mapping chart
☐ Chief Information Security Officer
☐ Health Security Team: Submit through HSServiceNow for a UCI Health data Security Risk Assessment (SRA)
☐ Systemwide Security Team
☐ Technical Unit Information Security Lead
☐ Other: Describe/explain

Click or tap here to enter text.

11.6 Information/Biospecimen Transport: If participant identifiers be transported or maintained on portable devices (e.g., laptop, smartphone, external hard drive, etc.), address the following:

11.6.1 Specify the device/method of transportation.
11.6.2 Explain why transporting or maintaining participant identifiers on portable devices is necessary.

Click or tap here to enter text.

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11.7 Information/Biospecimen Retention: Indicate how long research information/biospecimens will be retained.

☐ In accordance with UCOP policy, information/biospecimens will be retained for 10 years after the end of the calendar year in which the research is completed, unless otherwise specified in the award agreement.
☐ In addition, if the research involves the investigation of FDA regulated products, information/biospecimens will be retained for two years after an approved marketing application. If approval is not received, the information/biospecimens will be kept for 2 years after the investigation is discontinued and the FDA is notified per FDA sponsor requirements.
☐ This research includes the potential for future secondary research using information/biospecimens which will be stored and maintained indefinitely.
☐ Other, describe/explain.

Click or tap here to enter text.

12. INFORMATION AND BIOSPECIMEN SHARING

☐ ***This section is not applicable.***

All appropriate data use and/or materials transfer agreements will be finalized before sharing.

- When third parties are provided access to health data, they must adhere to the contracting guidelines set forth by the UCI Health Data Governance Committee (HDGC).
- When transferring data to a non-profit, contact Wanda Seang, Ancillary Agreements Officer, at wandas@uci.edu.
- When transferring data to a for profit entity for clinical research, contact or-ctcontracts@uci.edu.
- When transferring data to a for-profit, contact the Industry Contract Officer assigned to your department.
- When transferring tangible research material to an organization, contact MaterialTransfer@uci.edu.

12.1 Multi-Site/Center Information Sharing: Indicate what information relevant to the protection of human participants will be recorded and shared between the participating sites. Select all that apply.

☐ Not applicable
☐ Adverse Events
☐ Information on Safety Monitoring
☐ Interim Findings
☐ Modifications to the protocol or consent document(s)
☐ Unanticipated Problems to Participants or Others
☐ Other: Describe/explain information impacting risks

Click or tap here to enter text.

12.2 Sharing Within Scope:

12.2.1 Specify if information/biospecimens are shared with collaborators (i.e., researchers not covered under the UCI IRB), for purposes within the scope of the current project.
12.2.2 Specify the collaborator and explain why they need access to the information/biospecimens.
12.2.3 Specify whether identifiable or de-identified (participants cannot be identified by other researcher) data will be shared.
12.2.4 Provide a complete list of all identifiers to be shared and provide rationale.

Click or tap here to enter text.

12.3 Future Contact with Participants: If there is a plan to retain participant contact information to recruit them for future research, address the following:

12.3.1 Describe the purpose of the future contact.

12.3.2 Specify whether use of the contact information will be limited to the UCI study team.

12.3.2.1 If applicable, describe who else could be provided with the contact information and criteria for approving requests.

Click or tap here to enter text.

12.4 Future/Secondary Research: If information/biospecimens be shared, used again, or stored for undefined future research purposes beyond the aims/scope written in the current protocol (i.e. secondary research), address the following:

12.4.1 Specify who will establish and manage the biorepository/registry/database.

12.4.2 If biorepository/registry/database is managed by the UCI study team, address the following:

12.4.2.1 Specify who on the UCI study team will manage the biorepository/registry/database (i.e., person responsible for receiving requests, stripping identifiers, distributing information/biospecimens).

12.4.2.2 Describe the procedures to release information/biospecimens, including the process to request a release, approvals required for release and who can obtain information/biospecimens.

12.4.2.3 Provide the physical location where the information/biospecimens will be stored (i.e. building and room number, indicate if freezer is involved, etc.).

12.4.2.4 Describe the security plan for the biorepository/registry/database. Include, if there are automated backup security systems to monitor storage equipment, including a backup power source in the event of a freezer failure or other emergency.

12.4.3 Specify what information/biospecimens will be included in the biorepository/registry/database.

12.4.4 Provide a complete list of all information/biospecimens to be shared with researchers and provide the rationale.

12.4.5 Describe the broadest possible future uses, including limitations or restrictions (if any) on future uses or users.

Click or tap here to enter text.

[i] For a HHS funded or supported, non-exempt collaborative research study involving human subjects, any site that is engaged must rely on the sIRB for review. If the research as a whole is non-exempt and an institution is engaged in the research (even if their portion of the research is exempt), then the institution must rely on the sIRB. *(Correspondence with OHRP, September 27, 2022)*.

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PI WORKSHEET: Considerations for Serving as the Reviewing IRB

This worksheet is required for the following submission types: Exempt research that requires IRB review (PI with dual affiliation only), Expedited research, or Full Committee research.

The purpose of this worksheet is to provide information on considerations that the institution will evaluate when considering requests for the UCI's IRB to serve as the Reviewing IRB for multi-site or collaborative research. For more information, visit: UCI is the Reviewing IRB.

Answer all questions succinctly using non-technical language as much as possible.

- If a question is not applicable to the research, state "N/A".
- If a question is not answered, the IRB does not know if the question was overlooked. This will result in unnecessary "back and forth" for clarification.

For an Institutional Agreement: After initial IRB approval has been granted for the UCI site, add the external site using the "Manage Participating Sites" feature. Attach this worksheet in second step of the process when the status is "Awaiting Site Materials".

For an Individual Investigator Agreement: Attach this worksheet to "External Study Team Members for UCI" of the ZOT IRB application.

Use a separate worksheet for each external entity.

1. SUBMISSION INFORMATION

1.1 Basic Information:

1.1.1 IRB Study Number[1]: Click or tap here to enter text.
1.1.2 Short Title: Click or tap here to enter text.

2. SINGLE IRB REVIEW INFORMATION

2.1 Eligibility Criteria: The following are circumstances in which UCI may serve as the Reviewing IRB for a multisite study or collaboration. (Check if "Yes." All must be checked.)

☐ The study is determined to involve Human Research.
☐ The external site or collaborator is engaged in the research activities.
☐ The study is not Exempt[i] or ☐ if Exempt, the UCI PI has a dual affiliation with the external site.
☐ The external site or collaborator is in the United States.
☐ At least one of the following is true (Check if "Yes". Check all that apply.)
    ☐ The study is federally funded (PI anticipates NIH or federal funding) cooperative research that meets the following criteria.
        ☐ More than single IRB review is **not** required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe).

[1] The IRB study number is generated when the submission is created in ZOT IRB. Please enter the number prior to final submission to the IRB.

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☐ Federal department or agency has **not** determined that the use of a single IRB is not appropriate for the particular context.

☐ The study is other cooperative research (not federally funded) that meets the following criteria.
- ☐ Research meets the above federal funding criteria for cooperative research.
- ☐ SMART IRB agreement v3.0 is used (preferred) or an Institutional Authorization Agreement will be established.
- ☐ External IRB (or site) has one of the following quality assurance (QA) mechanisms to monitor the human subject research activity at the site.
  - ☐ The external IRB is AAHRPP accredited.
  - ☐ The external IRB is CARE-Q certified.
  - ☐ The external IRB is actively seeking accreditation / certification; explain.

Explain: Click or tap here to enter text.

  - ☐ The external IRB has a QA mechanism; explain.

Explain: Click or tap here to enter text.

  - ☐ [IRB staff to confirm] A UCI director has reviewed the external IRB's human research protection program plan and policies to confirm, at minimum, that their program has a quality assurance program and is otherwise appropriate to serve as the Relying IRB.

☐ The study involves a collaboration with an individual investigator.

2.2 Reviewing IRB Rationale: Provide the rationale for UCI to serve as the Reviewing IRB.

☐ UCI study team is engaged in human research at the external site.
- ☐ The site does **not** have an IRB, and it requests that UCI serve as the Reviewing IRB.
- ☐ The site has an IRB; however, it requests that UCI serve as the Reviewing IRB.

Explain: Click or tap here to enter text.

☐ External collaborator is engaged in human research, and they request that UCI serve as the Reviewing IRB. (Select which option applies.)
- ☐ The collaborator is an individual investigator who is not affiliated with a site and does not have an IRB. They request that UCI serve as the Reviewing IRB. Attach the Individual Investigator Agreement (IIA).
- ☐ The collaborator is at a site that does **not** have an IRB. The site requests that UCI serve as the Reviewing IRB.

Explain: Click or tap here to enter text.

- ☐ The collaborator is at a site that has an IRB. The site requests that UCI serve as the Reviewing IRB.

Explain: Click or tap here to enter text.

2.3 HIPAA Privacy Board: Specify if medical records from the external site are accessed, used, or created and whether the site has a privacy board.

☐ Yes, the research involves medical records from the site.
- ☐ The site will serve as its own privacy board.
- ☐ The site does **not** have a privacy board, and the site requests that UCI serve as its privacy board.
- ☐ The site has a privacy board; however, the site requests that UCI serve as its privacy board (rare).

Explain: Click or tap here to enter text.

☐ No, the research does not involve medical records from the site.

2.4 Reliance Agreement: Specify if the site participates in SMART IRB v3.0.
☐ Not applicable, individual investigator.
☐ Yes. Indicate and attach the appropriate agreement letter.
- ☐ SMART IRB Letter of Acknowledgement - Research Does Not Involve Access to Medical Records
- ☐ SMART IRB Letter of Acknowledgement - Research Involves Access to Medical Records

☐ No. Indicate and attach the appropriate agreement letter.
- ☐ Institutional Authorization Agreement (IAA) - UCI is IRB of Record
- ☐ Institutional Authorization Agreement (IAA) - UCI is IRB of Record & HIPAA Board

3. EXTERNAL INVESTIGATOR INFORMATION

3.1 External Investigator Information: Provide the following information.
3.1.1 Investigator's name, title, and degrees.
3.1.2 Investigator's Department.
3.1.3 Investigator's email and phone number.
3.1.4 List the research activities or procedures to be performed by the investigator.
3.1.5 Specify the investigator's relevant qualifications (training, experience) to perform research activities.

Click or tap here to enter text.

3.2 External Study Team: Does the investigator have a study team at their site?
☐ Yes. List the research activities or procedures to be performed by the study team.

Click or tap here to enter text.

☐ No

3.3 Conflict of interest (COI): Does the external investigator or their study team have a financial conflict of interest (COI)?
☐ Yes. Specify and attach the external institution's COI management plan.

Click or tap here to enter text.

☐ No

3.4 Communication: Describe how the external investigators will be provided with a copy of the UCI IRB approved study documentation (i.e. protocol, recruitment, consent, etc.) throughout the duration of the study.

Click or tap here to enter text.

4. SITE INFORMATION

4.1 Site Information:

4.1.1 Specify, name, type and location.

4.1.2 For sites outside of California, specify if there are any applicable state or local laws, regulations, or policies that are relevant to the research.

4.1.3 Specify if any ancillary committee approvals (e.g., RSC, IBC) are required at the site and attach their approvals.

Click or tap here to enter text.

5. STUDY CONSIDERATIONS FOR SERVING AS THE REVIEWING IRB FOR OTHER INSTITUTIONS

UCI will evaluate on a case-by-case basis serving as the Reviewing IRB. The following characteristics of the study will be evaluated to determine whether UCI and the study team can adequately support and oversee the research.

☐ Complexity of protocol/risk level of study.

Comments: Click or tap here to enter text.

☐ Number, type and location of participating sites.

Comments: Click or tap here to enter text.

☐ UCI study team is adequately resourced and prepared to facilitate the multi-site study.

Comments: Click or tap here to enter text.

☐ Participating site(s) are adequately resourced and prepared to participate in the multi-site study.

Comments: Click or tap here to enter text.

☐ FDA regulated research activities are included in the study.

1. Specify the resources available at each external site to treat emergencies resulting from study-related procedures.
2. Describe how will the drugs/agents used in the study be managed at the external site.
3. Specify the name and title of the pharmacist/responsible person for the drugs/agents at the external site and how they are provided with a current copy of the protocol.

Comments: Click or tap here to enter text.

4. [IRB STAFF TO CONFIRM] ADDITIONAL CONSIDERATIONS FOR SERVING A REVIEWING IRB

The following are additional considerations for evaluating the UCI's ability to serve as the Reviewing IRB for a multisite study.

☐ The UCI IRB has sufficient expertise and resources to conduct the IRB review.

☐ The UCI HRPP has sufficient expertise and resources to establish and manage multiple participating sites.

☐ The UCI HRPP Stakeholders (Sponsored Projects Administration, Quality Assurance Program, etc.) have adequate resources to support or monitor the research activities.

☐ Ability for UCI to comply with the relevant local context considerations of the participating site(s).

☐ Preference to outsource Reviewing IRB function to an external IRB.

☐ Other relevant considerations (e.g., vulnerable populations, conflicts of interest, costs, etc.).

7. [IRB STAFF TO CONFIRM] ADDITIONAL CONSIDERATIONS FOR SERVING AS REVIEWING IRB FOR A DOD INSTITUTION

The following are additional considerations for evaluating the UCI's ability to serve as the Reviewing IRB for a DOD institution (DoDI 3216.02 section 3.5).

☐ UCI has a current federal assurance of compliance.
☐ UCI's IRB is registered in accordance with Subpart E of 45 CFR 46.
☐ There is a process for the DOD institution to review the protocol to ensure all applicable local and DOD requirements are addressed in the protocol.
☐ UCI's IRB will apply the DOD requirements specified in DoDI 3216.02, including but not limited to non-DOD institutional responsibilities defined under DoDI 3216.02 section 3.6(b).
☐ If the research constitutes classified human participant research, the COHRP must approve the reliance agreement.

8. [IRB STAFF TO CONFIRM] ADDITIONAL CONSIDERATIONS FOR SERVING AS REVIEWING IRB FOR VA RESEARCH

The following are additional considerations for evaluating the UCI's ability to serve as the Reviewing IRB for VA research.

☐ UCI's IRB must meet all the IRB requirements described in 38 CFR Part 16.
☐ When the IRB of Record is directly operated and supported by a non-VA entity, the policies and procedures related to the review of VA research by the non-VA entity must be consistent with VHA Directive 1200.05, 1005.01, and all requirements applicable to VA research.
☐ VAs may rely upon the VHA Central Office IRB (VA Central IRB), an IRB of another VA facility, the IRB(s) of a medical or dental school, or the IRB of another federal agency. A VA facility may also use an IRB for multi-site protocols that has been specifically designated by ORD as an IRB that may serve as a multi-site IRB for VA facilities.
☐ A VA will permit the use of a commercial IRB as an IRB of Record if it has been specifically designated by ORD as a commercial IRB that may serve as an IRB for cooperative research.
☐ A Memorandum of Understanding (MOU) or Authorizing Agreement has been established and signed.
☐ The institution's IRB must hold current IRB registrations with FDA/OHRP and provide updates to membership as required by VHA Handbook 1058.03 and the institution has a current federal assurance of compliance.

[i] For a HHS funded or supported, non-exempt collaborative research study involving human subjects, any site that is engaged must rely on the sIRB for review. If the research as a whole is non-exempt and an institution is engaged in the research (even if their portion of the research is exempt), then the institution must rely on the sIRB. *(Correspondence with OHRP, September 27, 2022)*.

Letter of Acknowledgement (LOA)
Research Does NOT Involve Access to Medical Records

This form documents that University of California, Irvine (UCI) will serve as Reviewing Institutional Review Board (IRB) for the research noted below; and the following Relying Institution has agreed to cede IRB review to UCI. Flexible implementation applies.

IRB Review will be ceded under the **SMART IRB Agreement Version 3.0**. Questions regarding this reliance arrangement should be directed to SMART IRB institutional Points of Contact (POC).

Relying Institution Information	
Relying Investigator Name:	
Relying Investigator Phone:	
Relying Investigator E-mail:	
Relying Institution:	

Reviewing Institution Information	
Reviewing Institution:	University of California, Irvine (UCI)
UCI Principal Investigator (PI) Name:	
UCI IRB Protocol #:	
UCI Study Title:	

This reliance arrangement is effective on the date that the last official signs and may be terminated by either party at any time. If the arrangement is terminated prior to the completion of the research, the Relying Institution will need to obtain alternative IRB review.

SMART IRB encourages use and distribution of this content. If you extract any language, please cite SMART IRB as follows, "This information was obtained from "Letter of Acknowledgment" as part of SMART IRB, which is funded in whole or in part with Federal funds from the National Center for Advancing Translational Sciences, National Institutes of Health, Department of Health and Human Services, under Contract No. 75N950C00008.

Reviewing Institution Designee	**Signature:** ***(Signature to be obtained by IRB staff)*** **Name:** **Title:** **Date:**
Relying Institution POC/Designee	**Signature:** **Name:** **Title:** **Date:**

Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, through grant number 3UL1TR002541-01S1.

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"This information was obtained from [doc name] as part of SMART IRB, which is funded by the NIH National Center for Advancing

Flexible Implementation Applies

1. Standard Operating Procedures:
Reviewing IRB SOPs Will Apply
The Participating Institutions will follow the Reviewing IRB SOPs with respect to the identified research.

2. HIPAA Determinations and Actions:
The Ceded Research does not fall under HIPAA Privacy Rule, OR Relying Institution is NOT a HIPAA Covered Entity.
No HIPAA determinations or actions are required for Relying Institution to use/disclose PHI.

3. Conflicts of Interest:
Relying Institution Will Perform Conflict of Interest Analyses Under Their Policies
The Relying Institution will perform their own analyses under their relevant policy with respect to disclosure and management of their Research Personnel's conflicts of interest in connection with the identified research. The Relying Institution's resulting determinations, prohibitions, management plans, and any updates will be provided to the Reviewing IRB. Note that the Reviewing IRB has the right to impose additional prohibitions or conflict management requirements.

4. For-Cause Audits:
Relying Institution Will Conduct Any IRB-Initiated, For-Cause Audits or Investigations
The Reviewing IRB will request Relying Institution conduct any IRB-initiated audits or investigations of matters relating to the Ceded Review of the identified research.

5. IRB Notifications (of Decisions, Changes, Lapses in Approval, Problems, Noncompliance)
Reviewing IRB Will Provide Notifications Through Another Party
The Reviewing IRB will provide notifications through the UCI PI to the Overall PI, Site Investigator(s), and Relying Institution(s) of decisions, changes, lapses in approval, problems, and non-compliance.

6. IRB-Initiated External Reporting:
Reviewing IRB Will Draft and Submit Reports to External Recipients
The Reviewing IRB will draft and submit to external parties (e.g., regulatory agencies, other oversight authorities) any reports of unanticipated problems, serious or continuing noncompliance, and suspension or termination of IRB approval that the IRB determines are required in connection with the identified research. Note that the Relying Institution have the right to review/ comment on the draft report(s) and to make/submit their own report(s) in addition to the Reviewing IRB's report(s).

7. Congruence of Federal Grant Applications/Contract Proposals:
Another Party Will Review Congruence
The Reviewing IRB will delegate responsibility for review of the congruence of any federal grant application(s) or contract proposal(s) supporting the identified research to the UCI PI.

8. Financial Agreements:
Reviewing IRB/Institution Will Not Charge Relying Institution for Review Costs
The Relying Institution will not be responsible for financial support of the costs of review of the identified research. The Reviewing IRB may charge the sponsor or other third parties for those costs.

9. Quality Assurance/Quality Improvement ("QA/QI" Function or Program):
[Delete the option that does not apply]
Program Access Required – Relying Institution Has an IRB or is an Independent IRB Organization
Each Participating Institution must have or have access to a human subjects research QA/QI program or service (or an alternate means of monitoring) that can conduct and report to that institution the results of for-cause and not-for-cause audits of the institution's and its Research Personnel's compliance with human subjects protections and other relevant requirements.

Program Access Not Required – Relying Institution Does Not Have an IRB or is Not an Independent IRB Organization
Participating Institutions engaged in or conducting the identified research are not required to have or have access to a human subjects' research QA/QI program or service.

10. Insurance:
[Delete the option that does not apply]
Insurance Required – Non-Public Participating Institution
Each Non-Public Participating Institution must maintain insurance coverage of sufficient type(s) and in reasonable amount(s) to cover its activities with respect to the identified research, including coverage of its IRB/IRB members when acting as a Reviewing IRB. Participating Institutions may request from one another an insurance certificate or equivalent documentation of the relevant coverage (including any sponsor-provided coverage).

Insurance Not Required – Public Participating Institution
Participating Institutions are not required to maintain insurance coverage to cover activities with respect to the identified research.

Relying Investigator Certifications

(1) I understand that individuals are engaged in human research whenever: (a) an individual intervenes or interacts with human subjects for research purposes; or (b) the individual obtains identifiable private information about human subjects for research purposes.

(2) I accept responsibility for safeguarding the rights and welfare of each research subject I interact with on this project, and I understand that the subject's rights and welfare must at all times come before the goals and requirements of the research.

(3) I will maintain evidence of human research educational training at my institution for myself and my study team, or I / they will complete the UCI Human Research Protections educational training and maintain evidence of completion prior to initiating research covered under this Agreement.

(4) I will conduct the research as approved by the UCI IRB and I will not make any changes in the research without prior UCI IRB review and approval, except where necessary to eliminate apparent immediate hazards to participants.

(5) I will report immediately to the UCI IRB any unfavorable occurrence or any unanticipated problems involving risks to participants or others in research covered under this Agreement.

(6) If I am responsible for enrolling subjects, I will obtain, document, and maintain records of informed consent for each such subject or each subject's legally authorized representative following the methods described in the approved study. Upon conclusion of the study, these records will be transferred to the UCI PI for appropriate maintenance and storage.

(7) I will promptly report to the UCI PI, IRB, or institutional official listed above any noncompliance with the standards or requirements reference in this Agreement, whether by the Investigator, any co-investigators, research staff, or others, regardless of fault or intent.

(8) I will abide by all determinations of the UCI IRB and provide all information requested by the UCI IRB or the UCI PI in a timely manner.

(9) I will provide the names of any individuals engaged in the research who are working under my direction to the UCI IRB.

(10) I will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this agreement.

(11) I will abide by all determinations of the UCI IRB designated under the above FWA and will accept the final authority and decisions of the UCI IRB, including but not limited to directives to terminate participation in designated research activities.

Relying Investigator
Signature: **Title:** **Date:**

Letter of Acknowledgement (LOA)
Research Involves Access to Medical Records

This form documents that University of California, Irvine (UCI) will serve as Reviewing Institutional Review Board (IRB) for the research noted below; and the following Relying Institution has agreed to cede IRB review to UCI. Flexible implementation applies.

IRB Review will be ceded under the **SMART IRB Agreement Version 3.0**. Questions regarding this reliance arrangement should be directed to SMART IRB institutional Points of Contact (POC).

Relying Institution Information	
Relying Investigator Name:	
Relying Investigator Phone:	
Relying Investigator E-mail:	
Relying Institution:	

Reviewing Institution Information	
Reviewing Institution:	University of California, Irvine (UCI)
UCI Principal Investigator (PI) Name:	
UCI IRB Protocol #:	
UCI Study Title:	

This reliance arrangement is effective on the date that the last official signs and may be terminated by either party at any time. If the arrangement is terminated prior to the completion of the research, the Relying Institution will need to obtain alternative IRB review.

SMART IRB encourages use and distribution of this content. If you extract any language, please cite SMART IRB as follows, "This information was obtained from "Letter of Acknowledgment" as part of SMART IRB, which is funded in whole or in part with Federal funds from the National Center for Advancing Translational Sciences, National Institutes of Health, Department of Health and Human Services, under Contract No. 75N950C00008.

Reviewing Institution Designee	**Signature:** ***(Signature to be obtained by IRB staff)*** **Name:** **Title:** **Date:**
Relying Institution POC/Designee	**Signature:** **Name:** **Title:** **Date:**

Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, through grant number 3UL1TR002541-01S1.

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"This information was obtained from [doc name] as part of SMART IRB, which is funded by the NIH National Center for Advancing

Flexible Implementation Applies

1. Standard Operating Procedures:
Reviewing IRB SOPs Will Apply
The Participating Institutions will follow the Reviewing IRB SOPs with respect to the identified research.

2. HIPAA Determinations and Actions:
[Delete the option that does not apply]
Relying Institution or 3rd Party Will Provide Determination
The Relying Institution or a third party named by Relying Institution will make any HIPAA determinations or perform any HIPAA Actions in connection with the research.

Reviewing IRB Will Provide Determination (Rare at UCI)
The Reviewing IRB will review in accordance with 45CFR164.512(i)(1)(i) and (i)(2) a request for HIPAA Waiver/Alteration of Authorization in Connection with the Research. Each institution will retain their own Privacy reporting responsibilities should a breach of privacy occur.

3. HIPAA Authorization Language and Consent Forms:
[Delete the option that does not apply. Remove the entire prompt if a waiver of authorization is requested.]
Relying Institution Will Provide Reviewing IRB with Separate HIPAA Authorization
The Reviewing IRB is under no obligation to ensure HIPAA Authorization language meet the requirements of 45 CFR 164.508(b) and (c).

Reviewing IRB Will Provide Separate HIPAA Authorization Form (Rare at UCI)
Reviewing IRB will provide separate HIPAA authorization form on behalf of the Relying Institution meeting the requirements of 45 CFR 164.508(b) and (c) as necessary to permit the use and disclosure of PHI. UCI makes no guarantee that the template is appropriate for use at the Relying Institution. By UCI providing this template, and as a condition of this agreement, the Relying Institution accepts all responsibility and liability for evaluating the adequacy of such template for the Relying Institution's own needs.

4. Conflicts of Interest:
Relying Institution Will Perform Conflict of Interest Analyses Under Their Policies
The Relying Institution will perform their own analyses under their relevant policy with respect to disclosure and management of their Research Personnel's conflicts of interest in connection with the identified research. The Relying Institution's resulting determinations, prohibitions, management plans, and any updates will be provided to the Reviewing IRB. Note that the Reviewing IRB has the right to impose additional prohibitions or conflict management requirements.

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The Reviewing IRB will provide notifications through the UCI PI to the Overall PI, Site Investigator(s), and Relying Institution(s) of decisions, changes, lapses in approval, problems, and non-compliance.

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Reviewing IRB Will Draft and Submit Reports to External Recipients
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Another Party Will Review Congruence
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9. Financial Agreements:
Reviewing IRB/Institution Will Not Charge Relying Institution for Review Costs
The Relying Institution will not be responsible for financial support of the costs of review of the identified research. The Reviewing IRB may charge the sponsor or other third parties for those costs.

10. Quality Assurance/Quality Improvement ("QA/QI" Function or Program):
[Delete the option that does not apply]
Program Access Not Required – Relying Institution Does Not Have an IRB or is Not an Independent IRB Organization
Participating Institutions engaged in or conducting the identified research are not required to have or have access to a human subjects' research QA/QI program or service.

Program Access Required – Relying Institution Has an IRB or is an Independent IRB Organization
Each Participating Institution must have or have access to a human subjects research QA/QI program or service (or an alternate means of monitoring) that can conduct and report to that institution the results of for-cause and not-for-cause audits of the institution's and its Research Personnel's compliance with human subjects protections and other relevant requirements.

11. Insurance:
[Delete the option that does not apply]
Insurance Required – Non-Public Participating Institution
Each Non-Public Participating Institution must maintain insurance coverage of sufficient type(s) and in reasonable amount(s) to cover its activities with respect to the identified research, including coverage of its IRB/IRB members when acting as a Reviewing IRB. Participating Institutions may request from one another an insurance certificate or equivalent documentation of the relevant coverage (including any sponsor-provided coverage).

Insurance Not Required – Public Participating Institution
Participating Institutions are not required to maintain insurance coverage to cover activities with respect to the identified research.

Relying Investigator Certifications

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(3) I will maintain evidence of human research educational training at my institution for myself and my study team, or I / they will complete the UCI Human Research Protections educational training and maintain evidence of completion prior to initiating research covered under this Agreement.

(4) I will conduct the research as approved by the UCI IRB and I will not make any changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to participants.

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(8) I will abide by all determinations of the UCI IRB and provide all information requested by the UCI IRB or the UCI PI in a timely manner.

(9) I will provide the names of any individuals engaged in the research who are working under my direction to the UCI IRB.

(10) I will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this agreement.

(11) I will abide by all determinations of the UCI IRB designated under the above FWA and will accept the final authority and decisions of the UCI IRB, including but not limited to directives to terminate participation in designated research activities.

Relying Investigator
Signature: **Title:** **Date:**

Institutional Authorization Agreement (IAA)
Research Does NOT Involve Access to Medical Records

Relying Institution Information	
Relying Investigator Name:	
Relying Investigator Phone:	
Relying Investigator E-mail:	
Relying Institution:	
Institution Address:	
Federalwide Assurance (FWA) #:	

Reviewing Institution Information	
Reviewing Institution:	University of California, Irvine (UCI)
IRB Registration #:	A: 00000393, B: 00000394, C: 00000395
UCI FWA #:	00004071
UCI Principal Investigator (PI) Name:	
UCI IRB Protocol #:	
UCI Study Title:	

The UCI Institutional Review Board (IRB) will serve as the IRB of record for research covered under this agreement; it will review the research as specified above, consistent with the requirements of 45 CFR 46 and 21 CFR 50, 56, 312, and 812, as applicable. The UCI IRB will follow written procedures for reporting its findings and actions to appropriate officials at the institution specified above. Relevant minutes of IRB meetings will be made available to the institution specified above, upon request. The institution specified above relying on the UCI IRB remains responsible for ensuring compliance with UCI IRB's determinations and with the Terms of its OHRP-approved FWA, and all other applicable laws and regulations related to the conduct of research covered under this agreement. This document must be kept on file by both parties and provided to OHRP upon request.

This Agreement is effective on the date that the last official signs and may be terminated by either party at any time. If the Agreement is terminated prior to the completion of the research, the institution specified above will need to obtain alternative IRB review.

Authorized Official for Relying Institution		Authorized Official for UCI
Signature: **Title:** **Date:**		**Signature:** ***(Signature to be obtained by UCI IRB Staff)*** **Title:** **Date:**

Communication and Responsibilities

1. Standard Operating Procedures:
Reviewing IRB SOPs Will Apply
The Participating Institutions will follow the Reviewing IRB SOPs with respect to the identified research.

2. HIPAA Determinations and Actions:
The Ceded Research does not fall under HIPAA Privacy Rule, OR Relying Institution is NOT a HIPAA Covered Entity.
No HIPAA determinations or actions are required for Relying Institution to use/disclose PHI.

3. Conflicts of Interest:
Relying Institution Will Perform Conflict of Interest Analyses Under Their Policies
The Relying Institution will perform their own analyses under their relevant policy with respect to disclosure and management of their Research Personnel's conflicts of interest in connection with the identified research. The Relying Institution's resulting determinations, prohibitions, management plans, and any updates will be provided to the Reviewing IRB. Note that the Reviewing IRB has the right to impose additional prohibitions or conflict management requirements.

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Relying Institution Will Conduct Any IRB-Initiated, For-Cause Audits or Investigations
The Reviewing IRB will request Relying Institution conduct any IRB-initiated audits or investigations of matters relating to the Ceded Review of the identified research.

5. IRB Notifications (of Decisions, Changes, Lapses in Approval, Problems, Noncompliance):
Reviewing IRB Will Provide Notifications Through Another Party
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7. Congruence of Federal Grant Applications/Contract Proposals:
Another Party Will Review Congruence
The Reviewing IRB will delegate responsibility for review of the congruence of any federal grant application(s) or contract proposal(s) supporting the identified research to the UCI PI.

8. Financial Agreements:
Reviewing IRB/Institution Will Not Charge Relying Institution for Review Costs
The Relying Institution will not be responsible for financial support of the costs of review of the identified research. The Reviewing IRB may charge the sponsor or other third parties for those costs.

9. Quality Assurance/Quality Improvement ("QA/QI" Function or Program):
[Delete the option that does not apply]
Program Access Not Required – Relying Institution Does Not Have an IRB or is Not an Independent IRB Organization
Participating Institutions engaged in or conducting the identified research are not required to have or have access to a human subjects' research QA/QI program or service.

Program Access Required – Relying Institution Has an IRB or is an Independent IRB Organization

Each Participating Institution must have or have access to a human subjects research QA/QI program or service (or an alternate means of monitoring) that can conduct and report to that institution the results of for-cause and not-for-cause audits of the institution's and its Research Personnel's compliance with human subjects protections and other relevant requirements.

10. Insurance:

[Delete the option that does not apply]

Insurance Required – Non-Public Participating Institution

Each Non-Public Participating Institution must maintain insurance coverage of sufficient type(s) and in reasonable amount(s) to cover its activities with respect to the identified research, including coverage of its IRB/IRB members when acting as a Reviewing IRB. Participating Institutions may request from one another an insurance certificate or equivalent documentation of the relevant coverage (including any sponsor-provided coverage).

Insurance Not Required – Public Participating Institution

Participating Institutions are not required to maintain insurance coverage to cover activities with respect to the identified research.

Relying Investigator Certifications

(1) I understand that individuals are engaged in human research whenever: (a) an individual intervenes or interacts with human subjects for research purposes; or (b) the individual obtains identifiable private information about human subjects for research purposes.

(2) I accept responsibility for safeguarding the rights and welfare of each research subject I interact with on this project, and I understand that the subject's rights and welfare must at all times come before the goals and requirements of the research.

(3) I will maintain evidence of human research educational training at my institution for myself and my study team, or I / they will complete the UCI Human Research Protections educational training and maintain evidence of completion prior to initiating research covered under this Agreement.

(4) I will conduct the research as approved by the UCI IRB and I will not make any changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to participants.

(5) I will report immediately to the UCI IRB any unfavorable occurrence or any unanticipated problems involving risks to participants or others in research covered under this Agreement.

(6) If I am responsible for enrolling subjects, I will obtain, document, and maintain records of informed consent for each such subject or each subject's legally authorized representative following the methods described in the approved study. Upon conclusion of the study, these records will be transferred to the UCI PI for appropriate maintenance and storage.

(7) I will promptly report to the UCI PI, IRB, or institutional official listed above any noncompliance with the standards or requirements reference in this Agreement, whether by the Investigator, any co-investigators, research staff, or others, regardless of fault or intent.

(8) I will abide by all determinations of the UCI IRB and provide all information requested by the UCI IRB or the UCI PI in a timely manner.

(9) I will provide the names of any individuals engaged in the research who are working under my direction to the UCI IRB.

(10) I will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this agreement.

(11) I will abide by all determinations of the UCI IRB designated under the above FWA and will accept the final authority and decisions of the UCI IRB, including but not limited to directives to terminate participation in designated research activities.

Relying Investigator
Signature: **Title:** **Date:**

Institutional Authorization Agreement (IAA)
Research Involves Access to Medical Records

Relying Institution Information	
Relying Investigator Name:	
Relying Investigator Phone:	
Relying Investigator E-mail:	
Relying Institution:	
Institution Address:	
Federalwide Assurance (FWA) #:	

Reviewing Institution Information	
Reviewing Institution:	University of California, Irvine (UCI)
IRB Registration #:	A: 00000393, B: 00000394, C: 00000395
UCI FWA #:	00004071
UCI Principal Investigator (PI) Name:	
UCI IRB Protocol #	
UCI Study Title:	

UCI IRB will serve as the IRB of record for research covered under this agreement; it will review the research as specified above, consistent with the requirements of 45 CFR 46 and 21 CFR 50, 56, 312, and 812, as applicable. The UCI IRB will follow written procedures for reporting its findings and actions to appropriate officials at the institution specified above. Relevant minutes of IRB meetings will be made available to the institution specified above, upon request. The institution specified above relying on the UCI IRB remains responsible for ensuring compliance with UCI IRB's determinations and with the Terms of its OHRP-approved FWA, and all other applicable laws and regulations related to the conduct of research covered under this agreement. This document must be kept on file by both parties and provided to OHRP upon request.

This Agreement is effective on the date that the last official signs and may be terminated by either party at any time. If the Agreement is terminated prior to the completion of the research, the institution specified above will need to obtain alternative IRB review.

Authorized Official for Relying Institution		Authorized Official for UCI
Signature: **Title:** **Date:**		**Signature:** ***(Signature to be obtained by UCI IRB Staff)*** **Title:** **Date:**

Communication and Responsibilities

1. **Standard Operating Procedures:**
   Reviewing IRB SOPs Will Apply
   The Participating Institutions will follow the Reviewing IRB SOPs with respect to the identified research.

2. **HIPAA Determinations and Actions:**
   [Delete the option that does not apply]
   Relying Institution or 3rd Party Will Provide Determination
   The Relying Institution or a third party named by Relying Institution will make any HIPAA determinations or perform any HIPAA Actions in connection with the research.

   Reviewing IRB Will Provide Determination (Rare at UCI)
   The Reviewing IRB will review in accordance with 45CFR164.512(i)(1)(i) and (i)(2) a request for HIPAA Waiver/Alteration of Authorization in Connection with the Research. Each institution will retain their own Privacy reporting responsibilities should a breach of privacy occur.

3. **HIPAA Authorization Language and Consent Forms:**
   [Delete the option that does not apply. Remove the entire prompt if a waiver of authorization is requested.]
   Relying Institution Will Provide Reviewing IRB with Separate HIPAA Authorization
   The Reviewing IRB is under no obligation to ensure HIPAA Authorization language meet the requirements of 45 CFR 164.508(b) and (c).

   Reviewing IRB Will Provide Separate HIPAA Authorization Form (Rare at UCI)
   Reviewing IRB will provide separate HIPAA authorization form on behalf of the Relying Institution meeting the requirements of 45 CFR 164.508(b) and (c) as necessary to permit the use and disclosure of PHI. UCI makes no guarantee that the template is appropriate for use at the Relying Institution. By UCI providing this template, and as a condition of this agreement, the Relying Institution accepts all responsibility and liability for evaluating the adequacy of such template for the Relying Institution's own needs.

4. **Conflicts of Interest:**
   Relying Institution Will Perform Conflict of Interest Analyses Under Their Policies
   The Relying Institution will perform their own analyses under their relevant policy with respect to disclosure and management of their Research Personnel's conflicts of interest in connection with the identified research. The Relying Institution's resulting determinations, prohibitions, management plans, and any updates will be provided to the Reviewing IRB. Note that the Reviewing IRB has the right to impose additional prohibitions or conflict management requirements.

5. **For-Cause Audits:**
   Relying Institution Will Conduct Any IRB-Initiated, For-Cause Audits or Investigations
   The Reviewing IRB will request Relying Institution conduct any IRB-initiated audits or investigations of matters relating to the Ceded Review of the identified research.

6. **IRB Notifications (of Decisions, Changes, Lapses in Approval, Problems, Noncompliance):**
   Reviewing IRB Will Provide Notifications Through Another Party
   The Reviewing IRB will provide notifications through the UCI PI to the Overall PI, Site Investigator(s), and Relying Institution(s) of decisions, changes, lapses in approval, problems, and non-compliance.

7. **IRB-Initiated External Reporting:**
   Reviewing IRB Will Draft and Submit Reports to External Recipients
   The Reviewing IRB will draft and submit to external parties (e.g., regulatory agencies, other oversight authorities) any reports of unanticipated problems, serious or continuing noncompliance, and suspension or termination of IRB approval that the IRB determines are required in connection with the identified research. Note that the Relying Institution have the right to review/ comment on the draft report(s) and to make/submit their own report(s) in addition to the Reviewing IRB's report(s).

8. **Congruence of Federal Grant Applications/Contract Proposals:**

Another Party Will Review Congruence
The Reviewing IRB will delegate responsibility for review of the congruence of any federal grant application(s) or contract proposal(s) supporting the identified research to the UCI PI.

9. Financial Agreements:
Reviewing IRB/Institution Will Not Charge Relying Institution for Review Costs
The Relying Institution will not be responsible for financial support of the costs of review of the identified research. The Reviewing IRB may charge the sponsor or other third parties for those costs.

10. Quality Assurance/Quality Improvement ("QA/QI" Function or Program):
[Delete the option that does not apply]
Program Access Not Required – Relying Institution Does Not Have an IRB or is Not an Independent IRB Organization
Participating Institutions engaged in or conducting the identified research are not required to have or have access to a human subjects' research QA/QI program or service.

Program Access Required – Relying Institution Has an IRB or is an Independent IRB Organization
Each Participating Institution must have or have access to a human subjects research QA/QI program or service (or an alternate means of monitoring) that can conduct and report to that institution the results of for-cause and not-for-cause audits of the institution's and its Research Personnel's compliance with human subjects protections and other relevant requirements.

11. Insurance:
[Delete the option that does not apply]
Insurance Required – Non-Public Participating Institution
Each Non-Public Participating Institution must maintain insurance coverage of sufficient type(s) and in reasonable amount(s) to cover its activities with respect to the identified research, including coverage of its IRB/IRB members when acting as a Reviewing IRB. Participating Institutions may request from one another an insurance certificate or equivalent documentation of the relevant coverage (including any sponsor-provided coverage).

Insurance Not Required – Public Participating Institution
Participating Institutions are not required to maintain insurance coverage to cover activities with respect to the identified research.

Relying Investigator Certifications

(1) I understand that individuals are engaged in human research whenever: (a) an individual intervenes or interacts with human subjects for research purposes; or (b) the individual obtains identifiable private information about human subjects for research purposes.

(2) I accept responsibility for safeguarding the rights and welfare of each research subject I interact with on this project, and I understand that the subject's rights and welfare must at all times come before the goals and requirements of the research.

(3) I will provide evidence of human research educational training at my institution for myself and my study team, or I / they will complete the UCI Human Research Protections educational training and maintain evidence of completion prior to initiating research covered under this Agreement.

(4) I will conduct the research as approved by the UCI IRB and I will not make any changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to participants.

(5) I will report immediately to the UC PI any unfavorable occurrence or any unanticipated problems involving risks to participants or others in research covered under this Agreement.

(6) If I am responsible for enrolling subjects, I will obtain, document, and maintain records of informed consent for each such subject or each subject's legally authorized representative following the methods described in the approved study. Upon conclusion of the study, these records will be transferred to the UCI PI for appropriate maintenance and storage.

(7) I will promptly report to the UCI PI, IRB, or institutional official listed above any noncompliance with the standards or requirements reference in this Agreement, whether by the Investigator, any co-investigators, research staff, or others, regardless of fault or intent.

(8) I will abide by all determinations of the UCI IRB and provide all information requested by the UCI IRB or the UCI PI in a timely manner.

(9) I will provide the names of any individuals engaged in the research who are working under my direction to the IRB.

(10) I will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this agreement.

(11) I will abide by all determinations of the UCI IRB designated under the above FWA and will accept the final authority and decisions of the UCI IRB, including but not limited to directives to terminate participation in designated research activities.

Relying Investigator
Signature:
Title:
Date:

Individual Investigator Agreement (IIA)

Relying Investigator Information	
Relying Investigator Name:	
Relying Investigator Phone:	
Relying Investigator E-mail:	
Relying Investigator Role on Project:	

Reviewing Institution Information	
Reviewing Institution:	University of California, Irvine (UCI)
IRB Registration #:	A: 00000393, B: 00000394, C: 00000395
UCI FWA #:	00004071
UCI Principal Investigator (PI) Name:	
UCI IRB Protocol #:	
UCI Study Title:	

The UCI Institutional Review Board (IRB) will serve as the IRB of record for research covered under this agreement; it will review the research as specified above, consistent with the requirements of 45 CFR 46 and 21 CFR 50, 56, 312, and 812, as applicable. The Relying Investigator is responsible for ensuring compliance with UCI IRB's determinations and with the Terms of its OHRP-approved FWA, and all other applicable laws and regulations related to the conduct of research covered under this agreement. This document must be kept on file by both parties and provided to OHRP upon request.

This Agreement is effective on the date that the official signs and may be terminated by either party at any time. If the Agreement is terminated prior to the completion of the research, the Relying Investigator will need to obtain alternative IRB review.

Authorized Official for UCI
Signature: *(Signature to be obtained by UCI IRB Staff)* **Title:** **Date:**

Relying Investigator Certifications

(1) I understand that individuals are engaged in human research whenever: (a) an individual intervenes or interacts with human subjects for research purposes; or (b) the individual obtains identifiable private information about human subjects for research purposes.

(2) I accept responsibility for safeguarding the rights and welfare of each research subject I interact with on this project, and I understand that the subject's rights and welfare must at all times come before the goals and requirements of the research.

(3) I will complete the UCI Human Research Protections educational training and provide evidence of completion prior to initiating research covered under this Agreement.

(4) I will conduct the research as approved by the UCI IRB and I will not make any changes in the research without prior UCI IRB review and approval, except where necessary to eliminate apparent immediate hazards to participants.

(5) I will report immediately to the UCI PI any unfavorable occurrence or any unanticipated problems involving risks to participants or others in research covered under this Agreement.

(6) If I am responsible for enrolling subjects, I will obtain, document, and maintain records of informed consent for each such subject or each subject's legally authorized representative following the methods described in the approved study. Upon conclusion of the study, these records will be transferred to the UCI PI for appropriate maintenance and storage.

(7) I will promptly report to the UCI PI, UCI IRB, or the institutional official listed above any noncompliance with the standards or requirements reference in this Agreement, regardless of fault or intent.

(8) I will abide by all determinations of the UCI IRB and provide all information requested by the UCI IRB or the UCI PI in a timely manner.

(9) I will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this agreement.

(10) I will abide by all determinations of the IRB designated under the above FWA and will accept the final authority and decisions of the UCI IRB, including but not limited to directives to terminate participation in designated research activities.

Relying Investigator
Signature: **Title:** **Date:**