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The HRP policy and procedure glossary is an alphabetized listing of specialized terms with their meanings. This glossary will assist the reader to understand new or uncommon vocabulary and specialized terms used in the UCI HRP Policies and Procedures.

1. **Administrative Hold:** An action initiated by the Researcher in response to an IRB request to place specific research activities on hold temporarily pending additional information.
2. **Administrative Review**: The purpose of an Administrative Review is to determine whether the allegation of regulatory non-compliance can be substantiated and whether it requires further review by a regulatory oversight committee. An Administrative Review is initiated when an allegation is received from an individual; it is deemed by the Office of the VCR or the Chair of a regulatory oversight committee that a review is necessary, or when informal or formal monitoring activities reveal potential regulatory non-compliance.
3. **Adverse Event (AE)**: An untoward or undesirable experience associated with research.
4. **Advertising:** A public announcement usually by a printed notice or voice or data broadcast that describes a research study including contact information. Typically this is used for recruitment purposes for a research study.
5. **Anonymous Data:** Information that was previously recorded or collected without any of the 18 identifiers as defined by HIPAA, and no code is assigned which would allow data to be traced to an individual.
6. **Assent:** An individual's affirmative agreement to participate in research obtained in conjunction with permission from the individual's parents or legally authorized representative. Mere failure to object should not, absent affirmative agreement, be construed as assent.
7. **Assurance:** A contract or agreement that establishes standards for human subjects research as approved by the Office for Human Research Protections (OHRP).
8. **Belmont Report**: A statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1978.
9. **Benefit**: A valued or desired outcome; an advantage.
10. **Bonus Payment:** Compensation tied to the rate or timing of recruitment. Examples of bonus payments include but are not limited to the following: The sponsor announces that the highest enrolling site in the nation will receive a $10,000 bonus; The sponsor offers to pay an additional $10,000 to any site that enrolls five participants within a week; The sponsor offers to pay an additional $10,000 to any site that fulfills its recruitment target by the end of the month; The sponsor offers to pay an additional $1,000 for any subject who agrees to enroll within one day of initial contact.
11. **Certificate of Confidentiality**: An advance grant of confidentiality issued by the NIH that provides protection against compulsory disclosure, such as a subpoena, for research data in studies that involve data collection about sensitive issues (such as illegal behavior, alcohol or drug use, or sexual practices or preferences) that require protection of confidentiality beyond preventing accidental disclosures.
12. **Child**: Person who has 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. In California, the individual that meets this definition is a person under 18 years of age.

13. **Children:** According to Federal regulations children are "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." According to California law, the legal age of consent is 18 years of age.
14. **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.
15. **Clinical Research Finance Assessment (CRFA)**: An office established by the UCI HealthSystems to fulfill regulatory requirements from the federal Office of the Inspector General, the University of California (UC) Corporate Compliance Program and the Joint Commission on Accreditation of Healthcare Organizations. The CRFA is responsible for ensuring proper registration and billing practices for all human subjects receiving clinical care while enrolled in clinical investigations.
16. **Clinical Trials Protocol Review and Monitoring Committee (CTPRMC):** A Committee required by Institutions receiving funding from the National Cancer Institute (NCI) for a comprehensive Cancer Center. The CTPRMC is charged with reviewing human research studies that involve patients with cancer, participants at risk for cancer, or research involving a specific cancer focus.
17. **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.
18. **Cognitively Impaired:** Having a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorder), an organic impairment (e.g., dementia) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including individuals under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and individuals with severely disabling physical handicaps, may also have diminished ability to make decisions in their best interest.
19. **Compensation for injury:** Payment or medical care provided to participants injured in research; this does not refer to payment (remuneration) for participation in research.
20. **Competent**: Term used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice.
21. **Confidentiality**: Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.
22. **Conflict of Interest:** A situation where an investigator's or IRB member's outside financial interest(s) or obligation(s) bias or has the potential to bias a research project.
23. **Conflict of Interest Oversight Committee (COIOC)**: A Committee mandated by State, Federal and University requirements. The COIOC is charged with ensuring that an investigator's personal interest in, or commitment to, entities outside the University's purview does not compromise or appear to compromise his/her objectivity in performing a research project, in mentoring students involved in a research project or in reporting the results of a research project conducted under the aegis of the UC. COIOC recommends action to the Vice Chancellor for Research (VCR).
24. **Continuing Non-compliance**: A pattern of noncompliance 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.

25. **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.
26. **Cooperative Research:** (45 CFR 46.114 (a)): Cooperative research projects are those projects covered by this policy that involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy.
27. **Coordinating Center:** An institution, department, or center, which agrees to be responsible for the conduct, administrative, or coordinating functions of a multi-center research project.
28. **Covered Entity:** A health plan, a health care clearinghouse, or a health care provider who transmits health information and is therefore subject to the HIPAA regulations. For the purpose of this policy, the University of California is a hybrid Covered Entity with both covered and non-covered functions. All UC covered entities constitute a single health care component (SHCC). Research at the University of California is not a covered function under the HIPAA Privacy Rule. UC's employees/workforce members, when acting solely in their capacity as researchers, are not considered a part of the SHCC. When a UC researcher is also a health care provider or a member of a medical center's workforce, the Privacy Rule applies to the researcher's activities; thus the UC researcher must comply with all requirements of the Privacy Rule.
29. **DHHS:** The Department of Health and Human Services.
30. **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.
31. **Data and Safety Monitoring**: A plan to oversee the implementation of a study protocol for compliance monitoring.
32. **Data and Safety Monitoring Board/Committee (DSMB or DSMC)**: A formally appointed independent group consisting of at least three (3) 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.
33. **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.
34. **Data Use Agreement:** 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:
    a. Not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law;
    b. Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the data use agreement;
    c. 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;
    d. 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
    e. Not identify the information or contact the individuals.

35. **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:
    a. The code is not derived from or related to the information about the individual;
    b. The code could not be translated to identify the individual; and
    c. The covered entity (as described above) does not use or disclose the code for other purposes or disclose the mechanism for re-identification.
36. **Department of Health and Human Services (DHHS):** The United States government's agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves.
37. **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).
38. **Directed Audit**: These audits are conducted by the IRB Compliance Team to assess the Investigator's compliance with federal regulations, state and local laws, and UCI IRB policies and procedures. These audits of IRB approved research studies are in response to identified concern(s). Concerns may be identified by an IRB Committee, an external source (e.g. OHRP, FDA or Sponsor), or an internal source (e.g. participant, family member, or Institutional personnel).
39. **Disclosable Financial Interests**:
    a. Ownership interest, stock, stock options, or other financial interest related to the research, unless it meets all four tests:
        1. Less than $10,000 when aggregated for the immediate family and
        2. Publicly traded on a stock exchange and
        3. Value will not be affected by the outcome of the research and
        4. Less than 5% interest in any one single entity.
    b. Compensation related to the research, including salary, consultant payments, honoraria, royalty payments, dividends, loans, or any other payments or consideration with value, including payments made to the University Health Sciences Compensation Plan, unless it meets both of the following tests:
        1. Less than $10,000 in the past year when aggregated for the immediate family and the
        2. Amount will not be affected by the outcome of the research.
    c. Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright or licensing agreement.
    d. Board or executive relationship (e.g., director, officer, partner, or trustee) related to the research, regardless of compensation.
40. **Dissent:** An individual's negative expressions, verbal and/or non-verbal, that they object to participation in the research or research activities.
41. **Emergency Research:** Research conducted in participants who are in a life-threatening or emergent situation, where available treatments are unproven or unsatisfactory, and 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.
42. **Emergency Treatment IDE:** A mechanism through the FDA for providing eligible participants with investigational devices for the treatment of an immediate serious or life-threatening illness for which there are no satisfactory alternatives.
43. **Emergency Treatment IND:** A mechanism through the FDA for providing eligible participants with investigational drugs, agents, or biologics for the treatment of an immediate serious or life-

threatening illness for which there are no satisfactory alternatives.

44. **Emergency Use:** The use of an investigational drug, agent, biologic, or device with a human subject in an immediate serious life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval.
45. **Engaged in Human Subjects Research**: An individual is "engaged" when they will interact with living individuals and/or will have access to subject identifiable records or data for the purposes of study performance. For more specific information on the definition of engagement, including examples of engagement and non-engagement, review OHRP's Guidance document.
46. **Exempt Review:** Studies determined by the IRB to meet the exempt criteria as defined by the Federal regulations.
47. **Expedited Review:** Studies determined by the IRB to meet the expedited criteria as defined by the Federal regulations.
48. **Expired Study:** When continuing review of the research does not occur prior to the end of the approval period specified by the IRB, IRB approval expires automatically. The study expires on the date specified on the approval letter and the informed consent document. No research activities can occur after the expiration date.
49. **External Adverse Events**: From the perspective of a UCI investigator engaged in a multi-center clinical trial, external adverse events are those adverse events experienced by subjects enrolled by investigators at other institutions engaged in the clinical trial (not under UCI IRB authority).
50. **FDA:** The DHHS Food and Drug Administration. The FDA oversees the safety of foods, drugs, devices, biologics and cosmetics for human use, and enforces DHHS regulations (21 CFR Parts 50 and 56) for the protection of human subjects and the general standards for the composition, operation, and responsibility of an Institutional Review Board (IRB) that reviews clinical investigations.
51. **Federalwide Assurance:** A contract or agreement that formalizes the institution's commitment to protect human subjects as approved by the Office for Human Research Protections (OHRP). The Federal Policy for the Protection of Human Subjects requires that each institution "engaged" in Federally-supported human subject research file an "Assurance" of protection for human subjects. The requirement to file an Assurance includes both "awardee" and collaborating "performance site" institutions. Per Federal Policy, awardees and their collaborating institutions become "engaged" in human subject research whenever their employees or agents (i) intervene or interact with living individuals for research purposes; or (ii) obtain, release, or access individually identifiable private information for research purposes.
52. **Fetus**: The product of conception from implantation until delivery.
53. **Finalize:** A term used to describe the point where consent is obtained from the subject. If a signed consent form is required the subject and researcher sign the form. If signed consent is not required the researcher obtains oral agreement to participate. A researcher that finalizes the consent process orients the subject to the study, answers any questions and signs the consent form, when applicable.
54. **Finder's Fee:** 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.
55. **Food and Drug Administration (FDA)**: The FDA is the federal oversight agency responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

56. **Guardian**: An individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care. In California, guardians are considered legally authorized representatives.
57. **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.
58. **Health Insurance Portability and Accountability Act (HIPAA) Research Tutorial**: An internet-based tutorial developed by the University of California (UC) designed for researchers involved with accessing, creating or disclosing Protected (Personal) Health Information (PHI). All Lead Researchers and research personnel who access, create or disclose PHI are required to complete the tutorial.
59. **Human Fetal Tissue**: Tissue or cells obtained from a dead embryo or fetus after a spontaneous or induced abortion, or after a stillbirth.
60. **Human Research Tutorial:** An internet-based module on the protection of human participants in research. UCI offers two versions of the Basic Human Research Training course through the Collaborative Institutional Training Initiative (CITI): one for Biomedical Investigators and one for Social & Behavioral Investigators. Individuals choose the course that best matches their research activities. A CITI Refresher course is required every 5 years to ensure ongoing education about human research protections. There are also two versions of the refresher course.
    All Lead Researchers and research personnel with direct intervention or interaction with participants or access to private, identifiable data are required to complete the tutorial.
61. **Human Subject:** A living individual about whom a Investigator conducting research obtains data through intervention or interaction with an individual or identifiable private information; or an individual who is or becomes a participant 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. **Intervention:** Includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subjects' environment that are performed for research purposes.
    b. **Interaction:** Includes communication or interpersonal contact between an Investigator or his/her research staff and the research participant or their private identifiable information.
    c. **Private Information:** Includes information about behavior that occurs in a setting in which an individual can reasonably expect that no observation or recording is taking place. It includes information, which has been provided for specific purposes by an individual, and the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable in order to be considered information to constitute research involving human participants. This may include identifiable private information obtained from a primary participant about a third party.
62. **Human Subject Research:** Any research or clinical investigation that involves human subjects.
63. **Human Subjects Radiation Committee (HSRC):** The HSRC, part of the Radiation Safety Division of Environmental Health and Services (EH&S), must approve all research protocols that involve radiation exposure (from x-rays or radio nuclides) to human subjects from routine diagnostic or therapeutic procedures used in a supporting role and which the subject would not otherwise receive as a part of their medical care.
64. **Humanitarian Device Exemption (HDE)**: Exemptions granted by the FDA in which the manufacturer is not required to provide the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose prior to marketing. HDE allows for the device to be used in clinical treatment as well as clinical investigation.
65. **Humanitarian Use Device (HUD)**: A device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4,000 individuals per year in the United States.
66. **IRB**: Institutional Review Board established in accord with DHHS and FDA regulations.

67. **IRB Approval/Registration:** The determination of the IRB that the human subjects research has been reviewed and may be conducted by or for UCI within the constraints set forth by the IRB and by other institutional and Federal requirements.
68. **IRB Committee Member:** An individual serving as an IRB Committee Member including Chairs, the IRB, alternates or expert consultants regardless of voting privileges.
69. **IRB of Record:** 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 OHRP. A Memorandum of Understanding is required, designating the relationship, for UCI to serve as the IRB of Record.
70. **IRB Reliance Agreement:** **A** formal, written document that provides a mechanism for an institution engaged in research to delegate IRB review to an IRB of another institution. Institutions may use different descriptive terms, (e.g., reliance agreement, cooperative agreement, IRB authorization agreement (IAA), or memorandum of understanding (MOU)). Agreements may cover single studies, categories of studies, or all human subjects research under an organization's Federalwide Assurance (FWA).
71. **Immediate Family Member:** Spouse, domestic partner, or child.
72. **Industry-Supported:** When a commercial entity contributes to the design or conduct of the study (as evidenced by a sponsor's protocol, sponsor's identification number and/or Investigator's brochure); coordinates the study as a multi-center trial; reimburses UCI or a UCI Investigator for costs associated with conducting the trial; or will have access to, or will publish or present the data gained from conducting the trial.
73. **Informal Resolution**: Oversight of minor or sporadic non-compliance incident by the IRB Chair or Committee. Informal resolution is typically approved by the IRB Chair and is reported to IRB members at monthly convened meeting.
74. **Informed Consent:** An individual's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure.
75. **Institutional Biosafety Committee (IBC):** A Committee required by Institutions receiving funding from the National Institutes of Health (NIH) for research involving recombinant DNA molecules. It is further charged with reviewing and approving research conducted with microorganisms pathogenic to humans, plants, or animals. The IBC also provides guidance on the proper acquisition, handling, transfer, and disposal of potentially hazardous or regulated biological materials.
76. **Institutional Official (IO)**: The individual who has the authority to sign the institution's Assurances, making a commitment on behalf of the institution that federal regulations and policies with be followed.
77. **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.
78. **Interaction**: Communication or interpersonal contact between investigator and subject.
79. **Internal Adverse Events**: From the perspective of a UCI investigator engaged in a multi-center clinical trial, *internal adverse events* are those adverse events experienced by subjects enrolled by the UCI investigator(s) (under UCI IRB authority). In the context of a single-site study, all adverse events would be considered *internal adverse events.*
80. **Intervention:** Both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
81. **Investigational Agent:** A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial. This includes products with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, products used for an unapproved indication, or products used to gain further information about an approved use.
82. **Investigational Device:** Any healthcare product that does not achieve its primary intended purposes

by chemical action or by being metabolized. A medical device that is the subject of a clinical study designed to evaluate the effectiveness and/or safety of the device. Investigational use also includes clinical evaluation of certain modifications or new intended uses of legally marketed devices.

83. **Investigational Device Exemption (IDE):** A FDA approved IDE permits a device that otherwise would be required to comply with a performance standard or to have pre-market approval to be shipped lawfully for the purpose of conducting investigations of that device.
84. **Investigational Drugs/Investigational Biologics:** A new drug or biologic that is used in a clinical investigation. The term investigational biologic also includes a biological product that is used in vitro for diagnostic purposes. Investigational drugs or biologics may include:
    a. Products that are not generally recognized as being safe and effective for any use under the conditions prescribed, recommended, or suggested by the FDA; or
    b. Products already approved by the FDA as safe and effective for specific indications that are being studied for new indications (or doses, strengths, or frequency).
85. **Investigational New Drug (IND):** FDA permission that a new drug, agent, or biologic may be used in humans prior to FDA review of clinical data that demonstrates a particular product is safe and effective for a specific use. The FDA permission is evidenced by the assignment of an IND number by the FDA or the granting of an IND exemption.
86. **Investigational Drug Service (IDS):** The IDS is a division of the UCIMC Pharmacy Department that must be consulted prior to study initiation regarding the proper storage, handling, and dispensing of investigational drugs, agents, and biologics to assure compliance with all IDS policies and procedures, as well as institutional, State, Federal (FDA) and Joint Commission on Accreditation of Hospital Organizations (JCAHO) requirements.
87. **Key Personnel**: Personnel considered of primary importance to the successful conduct of a research project. The term usually applies to the senior members of the project staff; however, sponsors may have differing definitions of Key Personnel. Key personnel are typically individuals who are involved in the design and conduct of the study, determining subject eligibility, performing data collection, interpreting and/or analyzing subject identifiable records or data; and authors on presentations or manuscripts related to the research.
88. **Lead Researcher**: The person with primary responsibility for meeting all ethical, scientific, and regulatory requirements for the conduct of a UCI research study, whether or not acting as the Principal Investigator (PI) for the award that funds the study.
89. **Legal Guardian:** An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.
90. **Legally Authorized Representative (LAR):** A person authorized either by California statute or by court appointment to make legal decisions on behalf of another person. In human subjects research, 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.
91. **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.
92. **Local Research Context:** Knowledge of the institution and community environment in which human research will be conducted.
93. **Memorandum of Understanding (MOU):** A formal agreement between UC Irvine and another institution that identifies the UCI Institutional Review Board as the IRB of record for a specific protocol or a specific type of research or vice versa.
94. **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 lives of the general population* or during the performance of routine physical or psychological examinations or tests.

95. **Minimal Risk for Prisoners:** 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 examinations of healthy persons.
96. **Minimum Necessary Standard:** The least information reasonably necessary to accomplish the intended purpose of the use, disclosure, or request of PHI.
97. **Minor**: Person who has 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. In California, the legal age is 18 years old.
98. **Minor modification:** A proposed change in research related activities that does not significantly affect an assessment of the risks and benefits of the study and does not substantially change the specific aims or design of the study.
99. **Minor Non-compliance**: An action or omission taken by an Investigator that is administrative in nature that does not compromise the rights and welfare of a participant. Example – reporting an unanticipated problem one day late or failure to date a consent form.
100. **Modification:** Any change to an IRB-approved study protocol regardless of the level of review it receives initially.
101. **Neonate**: A newborn.
102. **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.
103. **Non-Human Subjects Research**: Any activity determined by the IRB to not represent "Human Subjects Research."
104. **Non-Significant Risk (NSR) Device Study:** A study of a device that does not meet the definition for a significant risk device and does not present a potential for serious risk to the health, safety, or welfare of participants.
105. **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.
106. **Not Less Than Once Per Year:** All approved research projects, with the exception of exempt research, must receive IRB continuing review at a minimum of once every 365 days, per Federal regulations. There are no exceptions or grace periods allowed.
107. **Office for Human Research Protections (OHRP):** The office under the Department of Health and Human Services responsible for implementing DHHS regulations (45 CFR 46) governing biomedical and behavioral/social science research involving human subjects.
108. **Offsite Location:** Occurring outside of UCI owned, operated, or leased facilities (including international sites). For purposes of research oversight, private facilities located on UCI land are considered offsite locations.
109. **Offsite Locations Engaged in Research:** An offsite location is "engaged" in human subjects research when its employees or agents 1) intervene or interact with living individuals for research purposes, or 2) obtain individually identifiable private information for research purposes. Further, an offsite location is considered to be "engaged" in human subjects research when it receives Federal funds to support the research.
110. **On-going Monitoring**: Monitoring of the informed consent process or IRB-approved research to ensure compliance with federal regulations, state and local laws, and UCI IRB policies and procedures as well as adherence to the study protocol and reporting of study related activities.
111. **Parent:** A child's biological or adoptive parent. In California, parents are considered legally authorized representatives.
112. **Performance Site:** A site where human subjects research is performed.

113. **Performance Site(s) Engaged in Research:** A performance site becomes "engaged" in human subjects research when its employees or agents 1) intervene or interact with living individuals for research purposes, or 2) obtain individually identifiable private information for research purposes. Further, a performance site is considered to be "engaged" in human subjects research when it receives a direct Federal award to support the research.

114. **Performance Sites Not Engaged in Research:** A performance site is "not engaged" in human subjects research if its employees or agents do not 1) intervene or interact with living individuals for research purposes; or 2) obtain individually identifiable private information for research purposes. If a UCI Investigator or his/her staff, including site personnel contracted by UCI, performs all research related activities as well as screening, recruiting, or consenting at the performance site, the performance site would be considered "not engaged" in research, unless the non-UCI performance site releases identifiable private information to UCI Investigators without first obtaining participants' permission.

115. **Periodic Compliance Review**: Assessments at UCI conducted by other internal entities (e.g., UCI HealthSystems Compliance Office, Internal Audit Services) of IRB-approved studies or of departments involved in the conduct of human subjects research. These reviews evaluate proper execution and accurate documentation of an IRB-approved research project as well as adherence to federal regulations, state and local law, and IRB policies and procedures.

116. **Permission:** The agreement of parent(s) or guardian(s) to the participation of their child or ward in research.

117. **Placebo**: A chemically inert substance given in the guise of medicine for its psychologically suggestive effect; used in controlled clinical trials to determine whether improvement and side effects may reflect imagination or anticipation rather than actual potency of a drug.

118. **Placebo- controlled study**: A study where one arm of the study involves the use of a placebo for comparing with the treatment condition(s). Participants are usually randomly assigned to treatment conditions.

119. **Placebo washout period**: A period in a clinical investigation during which participants receive only a placebo prior to the initiation of the study.

120. **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.

121. **Preparatory to Research:** Any action taken in assessing the research question or hypothesis, such as accessing medical records, querying of databases for any type of individually identifiable health information, or any activity where PHI is accessed to prepare a research protocol.

122. **Principal Investigator**: The scientist or scholar responsible for the conduct of research or other activity, described in a proposal for an award. The Principal Investigator is responsible for all programmatic and administrative aspects of a project or program. The scientist or scholar with primary responsibility for the scientific, technical and administrative conduct of a funded research project.

123. **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. Probation and parole are treated the same and are usually NOT considered as incarceration. Ankle bracelets/in home restrictions are considered as incarceration. Mental and substance abuse facilities are considered incarceration if someone is mandated to attend in lieu of jail or prison; however, an individual in such a facility is NOT considered incarcerated if they voluntarily commit themselves.

124. **Privacy**: Control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

125. **Privacy Rule**: The Privacy Rule is a nickname for DHHS' regulation, "Standards for Privacy of Individually Identifiable Health Information," applicable to entities covered by the Health Insurance Portability and Accountability Act (HIPAA). The privacy provisions of HIPAA apply to health information created or maintained by health care providers who engage in certain electronic transactions, health plans, and health care clearinghouses. The DHHS Office for Civil Rights (OCR) is responsible for implementing and enforcing the Privacy Rule, effective April 14, 2003.
126. **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 which the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.
127. **Prospective:** Research utilizing human participants' specimens/data that will be collected after the research is approved by the IRB.
128. **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.
129. **Protocol Deviation:** Accidental or unintentional changes to, or non-compliance with the research protocol that *does not* increase risk or decrease benefit or; does not have a significant effect on the subject's rights, safety or welfare; and/or on the integrity of the data. Deviations may result from the action of the participant, researcher, or research staff.
130. **Protocol Violation**: Accidental or unintentional changes to, or non-compliance with the IRB approved protocol without prior sponsor and IRB approval. Violations generally increase risk or decrease benefit, affect the subject's rights, safety, or welfare, and/or affect the integrity of the data.
131. **Quality Assurance Reviews:** Quality Assurance reviews are performed by the HRP Teams to verify that the electronic database is consistent with the IRB paper files and the paper files are collated in accordance with IRB policy and procedure.
132. **Radioactive Drug Research Committee (RDRC):** A UC Irvine committee responsible for the review and approval of research protocols involving human research participants and radioactive drug exposure.
133. **Recruitment:** Seeking individuals to enroll or participate in a research project.
134. **Regulatory Committee Review**: A Regulatory Committee Review is initiated after a completed Administrative Review suggests that an incident of non-compliance appears to have occurred and when informal resolution was not achieved or when informal resolution is achieved but the Investigator has been determined to have engaged in a pattern of disregard for research regulations, policies or procedures. Regulatory Committee Reviews may be conducted by full committees or by subcommittees charged by the IRB Chairs. Whenever possible, the result of a Regulatory Committee Review will be informal resolution.
135. **Related**: An event is considered related if it is at least *possibly related to the research* (i.e., there is a reasonable possibility that the adverse event, experience or problem may have been caused by the procedures involved in the research).
136. **Relatedness**:
    a. **Related** - An event that in the judgment of the researcher is definitely caused by the research activities or definitely affected the rights and welfare of the participants. A related event/problem has a strong temporal relationship and an alternative cause is unlikely.
    b. **Probably related** - An event that in the judgment of the researcher is likely caused by the research activities or likely affected the rights and welfare of the participants. The event has a timely relationship to the research and follows a known pattern of response, but a potential alternative cause may be present.
    c. **Possibly related** - An event that in the judgment of the researcher is possibly caused by the

research activities or that possibly affected the rights and welfare of the participants. The event has a timely relationship to the research; however no known pattern of response exists, and an alternative cause seems more likely, or there is significant uncertainty about the cause of the event.

d. **Unrelated**- An event that in the judgment of the researcher is known and is in no way caused by any aspect of research activities or in no way affected the rights and welfare of the participants. If there is any uncertainty regarding causality of the event then the event must be assessed as possibly related to the research.

137. **Repository:** A storage site or mechanism by which identifiable human tissue, blood, genetic material or data are stored or archived for research by multiple Investigators or multiple research projects.
138. **Research:** Any systematic investigation (including research development, testing and evaluation) designed to develop or contribute to generalizable knowledge.
139. **Research Health Information (RHI):** Individually identifiable health information that is or has been collected solely for the purposes of research.
140. **Research Payments:** Cash and non-cash payments for reimbursement of time and expenses associated with participation in research activities.
141. **Research Personnel:** The Lead Researcher and all individuals responsible for the design or conduct of the study (including collaborators and colleagues at other institutions, engaged in human subjects research).
142. **Research Protections (RP)**: Division of OR responsible for managing the University's programs for research compliance, specifically: human subjects research protections, animal care and use, and research involving human stem cells. This includes providing administrative support to UCI's IRB Committees, the Institutional Animal Care and Use Committee (IACUC), and the Human Stem Cell Research Oversight (hSCRO) Committee, and the Radioactive Drug Research Committee (RDRC).
143. **Research-Related Cost**: Those costs generated specifically as a result of the subject's participation in a research project and which would not otherwise have been generated in the course of the subject's routine and customary health care.
144. **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.
145. **Retrospective:** Research utilizing human participants' specimens/data that were previously collected (e.g., on the shelf) before the research was approved by the IRB.
146. **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.
147. **Risk**: The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk."
148. **Risk-Potential Benefit Profile**: An evaluation of the risks and potential benefits that have occurred during the course of the study**.**
149. **Sanction**: A punitive action designed to secure compliance with Federal regulations, UC and/or UCI IRB Policy, or the determinations or requirements of the UCI IRB by imposing a penalty. Sanctions are imposed in cases where cooperation from the Researcher does not occur or when it is determined that subjects or the Institution has been placed at risk.
150. **Safety Report (SR)**: Alerts issued by the FDA or the study sponsor to inform all researchers using the

same pharmacological compound about serious adverse events or reactions that have occurred in patients/participants.

151. **Scientific Review:** To approve human subjects research, the IRB must determine that research subjects are treated ethically and equitably and that research design minimizes risks to subjects. Moreover, scientific review assures that the research has scientific validity, feasibility; statistical relevance and potential benefit to the participant and/or to society. The IRB will utilize the expertise of the biostatisticians in the Biostatistics, Epidemiology, & Research Design (BERD) unit of the Institute for Clinical and Translational Science *(*ICTS) to review the methodological and statistical information for specific types of research (e.g. UCI investigator authored, biomedical or clinical research, greater than minimal risk and no prior peer review, non-cancer related research or as required by the IRB), prior to IRB review.

152. **Serious:** An event is "serious" if it involves harm to one or more persons (who may or may not be participants), or required intervention to prevent one or more persons from experiencing harm.

153. **Serious Adverse Event (SAE)**: Any adverse event temporally associated with the subject's participation in research that meets any of the following criteria: results in death; is life-threatening (places the subject at immediate risk of death from the event as it occurs); requires inpatient hospitalization or prolongation of existing hospitalization; results in a persistent or significant disability/incapacity; results in a congenital anomaly/birth defect; or any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

154. **Serious 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 that has a significant adverse impact either on the rights or welfare of participants or on the integrity of the data.

155. **Short Form Consent:** A written informed consent document that summarizes the required elements of informed consent to be presented orally to the participant or his or her legally authorized representative.

156. **Significant Modification:** A proposed change in research related activities that significantly affects an assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study.

157. **Significant Risk (SR) Device Study:** A study of a device that presents a potential for serious risk to the health, safety, or welfare of a participant and 1) is intended as an implant; 2) is used in supporting or sustaining human life; or otherwise prevents impairment of human health; 3) is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; or 4) otherwise presents a potential for serious risk to the health, safety, or welfare of a participant.

158. **Sponsor-Imposed Suspension**: A determination from the sponsor of the study to place specific research activities on hold. This determination may be made for interim data analysis; inadequate drug availability; in response to a Data Safety Monitoring Board (DSMB) report/recommendation; or a pre-planned stopping point.

159. **Sponsor Investigator**: A *Sponsor-Investigator* is an individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug or device is administered or dispensed. The term does not include any person other than an individual.

160. **Sponsored Projects (SP)**: Division of OR responsible for reviewing, endorsing and submitting proposals to extramural sponsors for research, training and public service projects. Other institutional responsibilities include: negotiating and accepting awards on behalf of The Regents; drafting, negotiating and executing subcontracts; ensuring institutional compliance with applicable Federal and State regulations, sponsor policy and University policy; representing the campus and The Regents when interacting with sponsors; coordinating pre-award and post-award actions that require either institutional or sponsor prior approval; resolving problems related to sponsored projects; and

reviewing UCI consultant agreements. Funding for human subjects research (e.g., grant, contract) will not be finalized without prior IRB review and approval.

161. **Sporadic Non-compliance**: A random action or omission taken by an Investigator that does not compromise the rights and welfare of a participant yet indicates a lack of knowledge about Federal regulations, UCI Policy, UCI IRB Policy, or determinations or requirements of the UCI IRB.
162. **Standard of Care Costs**: Those costs generated in the course of the subject's routine and customary health care.
163. **State Death Data Records:** State of California issued death certificates and indices containing personal identifying information. The state of California requires IRB review of studies using California issued death records.
164. **Surrogate Decision-Maker:** In the case of an incompetent individual, or an individual who lacks decision-making capacity, the individual's surrogate decision-maker is designated in order of preference per California Health and Safety Code -Section 24178.
165. **Suspension**: An action initiated by the IRB to stop some or all research procedures pending future action by the IRB or by the Investigator or his/her research personnel.
166. **Termination**: An action initiated by the IRB to stop permanently some or all research procedures.
167. **Test Article:** Any drug (including a biological product), medical device, food additive, color additive, electronic product, or any other article intended for human use subject to regulation under the Federal Food, Drug, and Cosmetic Act.
168. **Third-party:** Any person or vendor (external to the University) who receives payment for providing research-related services and/or products.
169. **Treatment IDE**: A mechanism through the FDA for providing eligible participants with investigational devices for the treatment of a serious or life-threatening illness for which there are no satisfactory alternatives.
170. **Treatment Withholding Phase**: A period in a clinical investigation where the participants receive no active treatment.
171. **UCI-Affiliated Institutions**: Offsite locations that have formal agreements in place with UCI that allow the offsite location to conduct regulatory committee (i.e., IRB) review for research proposed solely to occur on their premises. Institutions that currently have agreements in place with UCI include Fairview Developmental Center, Kaiser Permanente Medical Care Program (Southern California component sites only), and Metropolitan State Hospital.
172. **UCI Facilities:** Facilities owned, operated, or leased by UCI including UCI campus, UCIMC, and any space rented to the University.
173. **UCI Personnel:** UCI students, staff, and faculty (including part-time, emeritus, and volunteer faculty), or any other agents of UCI.
174. **UCI Resources:** Funds, facilities, employee time, equipment, supplies, services, and non-public information.
175. **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.
176. **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.

177. **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 to participants or others associated with a device that relates to the rights, safety, or welfare of participants.

178. **Unexpected**: An event is unexpected when its specificity and severity are not accurately reflected in the informed consent document

179. **Unexpected Adverse Event**: Any adverse event occurring in one or more subjects in a research protocol, the nature, severity, or frequency of which is not consistent with either:
    a. the known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in (a) the protocol, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document, and (b) other relevant sources of information, such as product labeling and package inserts; or
    b. the expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.

180. **University duties**: Responsibilities assigned by the University or tasks performed to meet expectations of one's employment, affiliation, appointment, or academic program.

181. **Viable (as it pertains to the neonate)**: Being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration. If a neonate is viable then it may be included in research only to the extent permitted and in accordance with the requirements for research involving children

182. **Violation***:* Accidental or unintentional change to, or non-compliance with the IRB approved protocol without prior sponsor and IRB approval. Violations generally increase risk or decrease benefit, affects the participant's rights, safety, and welfare, or the integrity of the data. *This definition may not match the PI's or Sponsor's definition.* Examples: failure to obtain valid informed consent; failure to conduct research procedures related to primary aim of study; accidental distribution of incorrect study medication.

183. **Ward:** A child who is placed in the legal custody of the State or other agency, institution, or entity, consistent with applicable Federal, State, or local law.

184. **Witness**: Individual who signs and dates the consent form attesting that the requirements for informed consent have been satisfied; that consent is voluntary and freely given by the subject, guardian, or surrogate, without any element of force, fraud, deceit, duress, coercion, or undue influence. The witness should be an adult who is not a member of the study team (i.e., is not listed on the protocol narrative).