Policy Number: 1
Title: Institutional Commitment and IRB Authority
Date of Last Revision: 01/29/09; 08/19/10; 05/24/11; 06/18/12; 05/01/13; 01/12/15; 01/28/15; 05/01/16; 08/01/16, 02/14/17, 06/07/17, 08/24/17, 11/27/18, 02/25/19; 01/05/22; 03/09/22

Policy:
The University of California, Irvine (UCI) commits to upholding its Assurance and to registering its boards with the Office for Human Research Protections (OHRP). UCI supports review by one Institutional Review Board for multi-site clinical trials and collaborative research (single IRB review or sIRB).

A. UCI agrees to uphold the ethical principles of the *Belmont Report.*
B. UCI will apply OHRP regulations (45 CFR 46, including all Subparts) to all federally-funded proposed research involving human participants. Commensurate protections are in place for all other human subject research conducted at or under the jurisdiction of UCI.
C. UCI agrees to apply additional regulations such as, the U.S. Food and Drug Administration (FDA) Human Subject Regulations (21 CFR 50, 56, 312 and 812) and the Health Insurance Portability and Accountability Act of 1996 (HIPAA), when applicable, to research involving human participants.
D. Clinical trials 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 practices and the applicable regulatory requirements.
E. Safeguarding the rights and welfare of human participants in research and other research activities is a general Institutional policy delegated by the Chancellor through the Vice Chancellor for Research. The Vice Chancellor for Research is the Institutional Official (IO). The IO is responsible to exercise appropriate administrative oversight to assure that UCI's policies and procedures designed for protecting the rights and welfare of human participants are effectively applied in compliance with its Assurance.

I. **IRB Registration**
A. Through a Federalwide Assurance (FWA), an institution commits to the Department of Health and Human Services (HHS) that it will comply with the requirements in the HHS Protection of Human Subjects regulations at 45 CFR part 46. The Federalwide Assurance (FWA) is the only type of assurance currently accepted and approved by OHRP.
B. UCI's FWA is 00004071. The FWA is maintained electronically and is available on the UCI Human Research Protection Program's (HRP) website: https://research.uci.edu/human-research-protections/.
C. Human subjects research that takes place under the legal name of UCI (The Regents of the University of California as described in Article IX,

Section 9 of the California Constitution (University of California, Irvine)) are covered under UCI's FWA and subject to HRP policies and procedures.

D. UCI's faculty, staff, and students, which comprise its schools, departments, divisions, institutes and facilities, are subject to the FWA and subject to HRP policies and procedures. This includes any research for which an Assurance or another formal agreement (e.g., MOU) identifies UCI's Institutional Review Board (IRB) as the IRB of record.

E. IRBs are operated by IRB Organizations (IORGS). UCI's IORG is 0000236.

F. IORGs allow for registration of IRBs. The individual UCI IRB registration numbers are:
   1. IRB A: 00000393
   2. IRB B: 00000394
   3. IRB C: 00000395
   4. IRB E: 00008624
   5. IRB WB: 00011147

G. A list of IRB members is available from the main UCI Human Research Protections website.

H. IRB Registration is effective for three years. Updates are required as specified through the IORG website. As an example, IRB registration must be updated within 90 days after changes occur regarding the contact person who provided the IRB registration information and/or the IRB chairperson.

II. Structure of the Human Research Protections Unit

A. The UCI Office of Research Administration (ORA) is an administrative unit of the Office of Research. Research Protections (RP) and Sponsored Projects are divisions of OR. Human Research Protections (HRP) is a unit within Research Protections. HRP facilitates and promotes the ethical involvement of human subjects in research by providing administrative support to the IRBs, and consultative services to Investigators and their research staff. The UCI HRP staff facilitates the IRB review and approval of human subjects research in accordance with applicable federal and state regulations, and UC/UCI policies and procedures.

B. The Director of HRP has operational and HRP personnel management responsibilities. The Director reports to the Associate Vice Chancellor for Research Administration. The Assistant Director of HRP is part of the management team that supports the operational goals of the unit.

III. Structure of the Institutional Review Board

A. The IRB Committees are official University Regulatory Committees. The IRB Committees serve UCI as a whole, rather than a particular school or department, and any institution for which UCI's IRB is designated as the IRB of record in an Assurance filed with OHRP with a corresponding MOU.

A. UCI's Assurance presently designates five (5) OHRP-registered IRB Committees. Designation of additional IRB Committees under the Assurance requires prior notification of and approval by OHRP.
   1. Three Committees review biomedical research studies that are designed primarily to increase the scientific base of information about

normal or abnormal physiology and development, and studies intended to evaluate the safety, efficacy, and usefulness of drugs, biologics, devices, medical products, procedures or interventions.

2. One Committee reviews social and behavioral sciences studies that are designed primarily to contribute to behavioral, educational, psychological, and social science knowledge.
3. One Committee primarily reviews matters of alleged non-compliance related to human subject research conducted by a UC Irvine personnel. This committee may also review unanticipated problem reports that involve matters of potential non-compliance and transactional items when needed to support ongoing research.

IV. Responsibilities of the IRB to Provide Oversight in accordance with the Federalwide Assurance

A. Approval by the IRB is required prior to the initiation of all human subjects research.

B. Except for research exempted or waived in accordance with 45 CFR 46.101(b) or 45 CFR 101(i), all federally human subjects research will be reviewed, prospectively approved, and, subject to continuing oversight and review at least annually by the IRB.

C. The IRB has the authority to:

1. Approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.
2. Require that information given to subjects as part of informed consent is in accordance with 45 CFR 46.116 and 21 CFR 50.25. The IRB may require that information, in addition to that specifically mentioned in 45 CFR 46.116, be given to the subjects when the information would meaningfully add to the protection of the rights and welfare of subjects.
3. Require documentation of informed consent or waive documentation in accordance with 45 CFR 46.117 and 21 CFR 50.27.
4. Grant permission for the use of surrogate consent, in accordance with California Health and Safety Code 24178.
5. Observe or have a third party observe the consent process and the research.
6. Suspend, place restrictions on, or terminate approval of research activities that are not being conducted in accordance with applicable federal regulations, state statutes, and/or UC/UCI policies and procedures, or that has been associated with unanticipated problems involving risk to subjects or others.

D. Federally funded human subject research that qualifies as Exempt research in accordance with 45 CFR 46.104, will be reviewed by an experienced HRP staff member or IRB Chair to confirm exempt status and registered for three years.

E. Exempt confirmation may be made by additional, various mechanisms at UCI. See Policy # 12.

F. UCI Exempt research activities are subject to the same subject protections and ethical standards as outlined in *The Belmont Report*. All exempt research is subject to applicable UCI and UCI IRB policies and procedures.

G. Research reviewed and approved by the IRB may be subject to review and disapproval by officials of UCI, or any institution for which the UCI IRB is designated as the IRB of record in accordance with an Assurance or a signed MOU or IRB Authorization Agreement with the UCI. However, if the UCI IRB does not grant IRB approval or suspends or terminates IRB approval, these decisions may not be overturned anyone at a higher level.

V. Single IRB Review of Multi-Site Clinical Trials and Cooperative Research

A. UCI supports the use of a single Institutional Review Board (sIRB) for multi-site research to enhance and streamline the IRB review process. sIRB eliminates duplicative IRB review thereby minimizing unnecessary administrative burdens and systemic inefficiencies while assuring human subjects protections. Other institutional regulatory requirements such as Conflict of Interest, Radiation Safety, Human Stem Cell Research Oversight and Institutional Biosafety must reviewed and approved at UCI.

B. UCI IRB can serve as the IRB of Record for an external site engaged in non-exempt research as well as cede IRB review to a non-UCI IRB. To ensure that appropriate regulatory requirements are addressed as part of the IRB review process, typically, international sites are excluded from these agreements.

C. When the UCI IRB serves as the IRB of Record it is accepting the responsibility of oversight of the conduct of the research for a particular study site.

D. The terms and responsibilities of the IRB of record, the ceding Institution are documented in an IRB Authorization Agreement for a single protocol or a Memorandum of Understanding (MOU) or IRB Master Agreement for multiple research cooperative agreement. Agreements may include UCI serving as the Privacy Board for institutions that do not have such a committee.

E. UCI IRB currently has several reciprocal Master Agreements whereby any institution signed on the agreement may serve as the IRB of Record. See HRPP Policy # 4.

VI. Transferring IRB Oversight / Continuity

A. To prevent lapses in human subject protection, it is generally preferred that the same IRB retain oversight responsibility throughout the conduct of a study, if possible. That said, sometimes transfers to another IRB for subsequent review and oversight is desired or necessary (e.g., sponsor request, workload redistribution – temporary or permanent, unexpected, adverse events such as natural disaster).

B. When transferring IRB oversight, the original IRB works closely with the clinical investigator, the receiving IRB, and the sponsor, as appropriate, throughout the transfer process to assures continuous IRB oversight with no lapse in either IRB approval or the protection of human subjects, and with minimal disruption of research activities.

C. The breadth and duration of the IRB transfer process may vary depending on the reason for the transfer, the entities involved, and the number and type of studies being transferred.

D. When transferring ongoing research to another IRB, UCI will assure that the terms and responsibilities of the Reviewing IRB and UCI as the ceding institution are documented in an IRB Master Agreement.

E. In general, the IRB transfer process involves:
   1. Identifying the studies to be transferred;
   2. Ensuring the availability and retention of pertinent research records;
   3. Establishing an effective date for transfer of oversight, including IRB records, for the clinical investigation(s) and other types of studies;
   4. Receiving IRB conducts a review of the studies (new or continuing review), as appropriate, before it accepts responsibility for the studies;
   5. Confirming or establishing the date for the next continuing review;
   6. Determining whether the consent form needs to be revised;
   7. Notifying the Original IRB, the investigator, and sponsor; and
   8. Updating IRB registration information, as applicable

References:

45 CFR 46
21 CFR 50 and 56, 312, 812
45 CFR 160 and 164
California Health and Safety Code Sections 24170-24179.5
Declaration of Helsinki
NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research
University Policy on Protection of Human Subjects in Research (issued September 2, 1981)
UCI Office of Research Continuity Plan – March 2014
UCI Research Policy for the Protections of Human Subjects in Research
The Belmont Report

Procedure Number: 1.A
Title: Procedure for Institutional Oversight of Assurance

Procedure:
This procedure outlines the UCI Institutional Review Board responsibilities in maintaining the UCI Federalwide Assurance.

I. **Lead Researcher (LR) Responsibilities;**
- A. Obtains the appropriate knowledge regarding human subjects protections, ethics, federal regulations, training, and monitoring to conduct his/her proposed research,
- B. Assures that the research team is adequately trained and knowledgeable regarding human subjects protections, ethical considerations, and Federal regulations applicable to the proposed research,
- C. Complies with the training, monitoring, and human research guidance as outlined in the Assurance and IRB policies and procedures,
- D. Assures that when UCI is ceding IRB review, the study or clinical trial is registered with UCI IRB,
- E. Complies with the determinations and requirements of the IRB of record and follows the policies of the IRB of record,
- F. Reports Unanticipated Problems involving Risks to Subjects or Others, and potential Serious Noncompliance or Continuing Noncompliance instances to the IRB of record and to UCI IRB when UCI is ceding review

II. **Department Chair Responsibilities;**
- A. The IRB relies on the Department Chair or Organized Lead Unit Director to help assess the new human subject protocol and provide an assurance to the following points:
  1. The Lead Researcher (and Faculty Sponsor) is competent to perform (and supervise) the study,
  2. 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),
  3. There are adequate resources and funds available to support the performance of this research.

III. **Institutional Official (IO) Responsibilities;**
- A. Allocates the Office of Research budget,
- B. Ensure that the Human Research Protections unit and the IRB has sufficient resources, including IRBs appropriate for the volume and types of human research to be reviewed, so that reviews are accomplished in a thorough and timely manner,
- C. Speak for and legally commit the institution to adherence to the requirements of the federal regulations regarding the involvement of human subjects in biomedical and social-behavioral research,

D. Assures institutional compliance with the Assurance, federal regulations, state statutes, and UC/UCI policies and procedures,
E. Appoints and may remove IRB Chairs, Vice Chairs and IRB Members for service on the UCI IRBs,
F. Review and sign federal assurances and addenda,
G. Ensures ongoing authority and autonomy of the IRBs to perform their function,
H. Provides adequate resources for maintenance of human subject protection at UCI, including HRP staff, facilities, resources and equipment,
I. Reports to the Executive Vice Chancellor, communicates with the Vice Chancellor, the Vice Chancellor for Health Affairs, the Deans of the Schools and other campus officials regarding human subjects protection issues,
J. Suspends or terminates IRB approval of research,
K. Disapproves research approved by the IRB

IV. **Associate Vice Chancellor for Research Administration (AVCRA) for Research Responsibilities;**
A. Oversees and manages the activities of the OR to promote responsible and ethical conduct in research and to ensure cooperation among individuals and offices that support research and other sponsored activities,
B. Creates the Human Research Protection Program budget,
C. Reviews and authorizes sIRB MOUs,
D. Appoints IRB Chairs, Vice Chairs and IRB Members for service on the UCI IRBs

V. **IRB Committee Responsibilities;**
A. Reviews all human subjects research activities and document its findings regarding ethical considerations, scientific merit in regard to the risk/benefit profile, adherence to federal regulations, state statutes, and IRB policies and procedures,
B. Reviews and monitors ongoing research for adherence to the federal regulations, state statutes, and IRB policies and procedures,
C. Has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. The IRB's action of suspension or termination shall be reported promptly to the investigators, appropriate institutional officers, and the Secretary of HHS,
D. When UCI is ceding IRB review, the IRB subcommittee (or designee) may confirm the appropriateness of ceding research that involves greater than minimal risk

VI. **Director of Research Protections Responsibilities;**
A. Assures that UCI’s Federalwide Assurance and IRB registration is updated or renewed as required.
B. Assures that UCI maintains standard policies and procedures (SOPPs) reflecting the current practices of the IRB in conducting reviews and approvals under its Assurance.

1. These policies and procedures will be maintained and kept current by UCI's Human Research Protections staff. The SOPPs will be re-reviewed at least every three years. All revision dates will be listed under the revision date section for each policy and procedure.
2. As appropriate, procedures are developed and revised by the Human Research Protections' Director or designee. Changes in policy are to be discussed and confirmed by the IRB Chairs, the Associate Vice Chancellor for Research, and the Human Research Protections Management. Changes are provided at the Research Protections Working Group.
3. All procedures are to be approved by the Director of Human Research Protections.

C. Oversees program implementation and management and communicates to the IO or his/her designee any human research protections issues that are likely to present risks or other concerns to the institution,

D. Coordinates, on behalf of the IRB, prompt reporting to the IO and to governmental oversight entities of unanticipated problems involving risks to subjects or others, serious or continuing non-compliance with Federal regulations or IRB requirements, and suspension or termination of IRB approval,

E. Maintains, as the official institutional record, all documents pertaining to UCI's Assurance and compliance activity,

F. Overall responsibility for management and supervision of all HRP personnel,

G. Reviews and negotiates sIRB agreements (IAAs and MOUs). The Director or designee has the authority to sign IAAs (single protocol agreements),

H. Appoints (or designee) IRB Chairs, Vice Chairs and IRB Members for service on the UCI IRBs

VII. Annually, the budget for the IRB and the HRP will be reviewed by the Vice Chancellor for Research, the Associate Vice Chancellor for Research Adinistration and the Director of Human Research Protections and modified as necessary to accommodate the volume and type of research reviewed, space, facilities and staff.