Policy on Human Subjects Research Program Oversight

Effective date: 9/20/2019

I. Background
The UC Santa Cruz Institutional Review Board (IRB) is charged with protecting the rights and welfare of human subjects in research conducted by UCSC personnel. The IRB has responsibility for review of research involving human subjects conducted at or sponsored by UC Santa Cruz. The Office of Research Compliance Administration (ORCA) assists researchers in navigating federal, state and University policies regarding human subjects research and provides administrative support to the IRB. This policy outlines UCSC’s assurance with the federal government and authority for oversight of human subjects research under the auspices of UCSC.

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

b. **Federalwide Assurance (FWA):** An assurance of compliance is a written document submitted by an institution (not an Institutional Review Board) that is engaged in non-exempt human subjects research conducted or supported by HHS. Through the assurance of compliance, an institution commits to HHS that it will comply with the requirements set forth in the regulations for the protection of human subjects at 45 CFR part 46. The Federalwide Assurance is the only type of assurance of compliance accepted and approved by the Office of Human Research Protections.

c. **Institutional Official (IO):** 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. At UCSC, this is the Vice Chancellor of Research (VCR).

d. **Reviewing IRB:** The “IRB of record” to which authority for IRB review and oversight has been ceded by another participating institution for an instance of research under a reliance agreement.

III. Federalwide Assurance (FWA)

a. UCSC has a Federalwide Assurance (FWA) with OHRP under #FWA00002797; the assurance is kept electronically in ORCA and available upon request. It must be renewed every five years, or within 90 days of a triggering change including, but not limited to, a change to name of institution, Human Protections Administrator, or Institutional Official).
b. The UCSC Chancellor delegates human subjects research authority to the Vice Chancellor of Research who serves as UCSC’s IO. The IO provides oversight of the Human Research Protection Program (HRPP) to follow UCSC’s assurance, federal and state regulations, and UC and UCSC policies and procedures.

c. Human subjects research conducted at UCSC campus is subject to the FWA and this policy.

d. All UCSC faculty, staff, and students engaged in human subjects research are subject to the FWA and this policy, whether or not UCSC IRB is the Reviewing IRB.

e. UCSC agrees to uphold the ethical principles outlined in the Belmont Report, as follows:

   Respect for Persons: Recognition of the personal dignity and autonomy of individuals and special protection of those persons with diminished autonomy;

   Beneficence: Obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risk of harm; and

   Justice: Fairness in the distribution of research benefits and burdens.

f. UCSC will apply Department of Health and Human Services (HHS) regulations (45 CFR 46, including all Subparts) to research involving human participants that is funded by any Common Rule department or agency (see https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html and https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html). Commensurate protections are in place for all other human subject research conducted at or under the jurisdiction of UCSC. See Policy on Regulatory Flexibility.

g. UCSC agrees to apply additional regulations such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA), when applicable, to research involving human participants.

h. 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.

IV. IRB Registration
a. UCSC’s IRB is registered with DHHS in compliance with 45 CFR part 46, Subpart E. Each IRB that is designated by an institution under an assurance of compliance approved for federalwide use by OHRP under 45 CFR part
46.103(a) and that reviews research involving human subjects conducted or supported by HHS must be registered with HHS.

b. UCSC’s IRB organization number is IORG0000158 and the IRB registration number is IRB00000266.

c. The registration must be updated every 3 years, or within 90 days of change of IRB chairperson or contact person by the ORCA Director or their designee.

V. Office of Research Compliance Administration (ORCA) and Office of Research

a. The Office of Research Compliance Administration (ORCA) is an administrative unit within the Office of Research. ORCA ensures human subjects research is conducted ethically and consistent with federal and state regulations and with UC and UCSC policies. They administratively support researchers and the IRB, facilitate exempt and IRB review of human subjects research and IRB meetings, and provide regulatory support to the research community.

b. ORCA’s Director oversees ORCA staff and overall operations for the unit.

c. The ORCA Director or their designee establishes UCSC IRB policies and procedures with input from IRB members and ORCA staff, and oversees the preparation, revision, approval and maintenance of all relevant written procedures. Policies are to be reviewed and updated periodically, no less than every 7 years. If policies are not followed, researchers may need to report noncompliance. See Policy on Noncompliance.

d. The ORCA Director reports to the Assistant VCR, who reports to the IO.

e. The IO allocates the HRPP budget to ensure sufficient resources.

f. The IO appoints IRB members and may remove members.

g. The IO determines whether to review for or rely on another IRB.

h. The IO establishes the IRB and affords them independence to conduct their work.

i. The IO may further review and disapprove research approved by the IRB.

j. ORCA notifies the IO of IRB findings and actions by providing IRB meeting minutes to the IO and discusses any concerns or questions with the IO.

VI. UCSC Institutional Review Board

a. The IRB Committee is an official University regulatory committee and serves the entire UCSC research community, rather than any particular school or department, and is empowered by the IO. The UCSC IRB also serves as Reviewing IRB for any institution for which that institution and UCSC agree to enter into an Institutional Authorization Agreement.

b. UCSC IRB primarily reviews social, behavioral, and educational research. They currently do not review FDA regulated research (UCSC has an
agreement with commercial IRB vendor Western IRB for researchers wishing to conduct research with investigational drugs, devices, or biologics).

c. All human subjects research must be either approved by the IRB or determined exempt before any human subjects activities occur.

d. The IRB has the authority to: approve, require modifications to (to secure approval), or disapprove all research activities covered by this policy.

e. The IRB monitors ongoing research and reviews changes to research.

f. The IRB shall require that information given to subjects as part of informed consent is in accordance with 45 CFR 46.116. 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.

g. The IRB shall require documentation of informed consent or waive documentation in accordance with 45 CFR 46.

h. The IRB grants permission for the use of surrogate consent, in accordance with California Health and Safety Code 24178.

i. The IRB may observe or have a third party observe the consent process and the research.

j. The IRB can 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/UCSC policies and procedures, or that has been associated with unanticipated problems involving risk to subjects or others.

k. Studies which qualify as exempt shall be reviewed by ORCA staff, in consultation with the Chair as needed, with the exception of Limited IRB review which requires an expedited IRB member reviewer. Exempt research must follow the ethical principles outlined in the Belmont Report and UCSC policies.

l. The IO may disapprove research approved by the IRB, but no one may overturn disapprovals, suspensions, or termination actions made by the IRB. The IO may also suspend or terminate research. See Policy on Suspension and Termination.

m. The IRB relies on ORCA for administrative support and regulatory guidance.

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

a. UCSC supports the use of a single Institutional Review Board (sIRB) for multi-site research to enhance and streamline the IRB review process.

b. A sIRB is mandated for some multi-site research as follows:
   1. Between the effective date of this policy and 1/20/2020, all NIH-sponsored human subjects research.
   2. Beginning on 1/20/2020, all research funded by any Common Rule department or agency (see https://www.hhs.gov/about/agencies/hhs-

3. If required by the sponsor.
   c. If Lead PI is at UCSC and UCSC is expected to be Lead Site, the PI will need to use Western IRB as the Reviewing IRB.
   d. When sIRB is not mandated, UCSC may serve as reviewing IRB for multi-site research subject to IO approval (see Policy on IRB Reliance).
   e. UCSC will ensure compliance with other institutional regulatory requirements such as Conflict of Interest, Human Stem Cell Research Oversight (reviewed by UCSF on UCSC’s behalf through an MOU), and Institutional Biosafety.

VIII. Transferring IRB Oversight / Continuity
   a. Transfer to another IRB for subsequent review and approval due to unforeseen issues may be necessary (e.g., sponsor request, workload redistribution – temporary or permanent, natural disasters, etc.).
   b. The source IRB works closely with the principal investigator (PI), the destination IRB, and the sponsor, as appropriate, throughout the transfer process to assure continuous IRB oversight with no lapse in either IRB approval or the protection of human subjects, and with minimal disruption to research activities.
   c. The period 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, terms and responsibilities of the Reviewing IRB at the ceding institution are documented in an IRB Authorization 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.

IX. Conflicts of Interest in Human Subjects Research
a. UCSC's Conflict of Interest Committee (COIC) reviews outside financial interests of investigators based on applicable federal or state regulations. The COIC will recommend actions to the IRB and to the IO.
b. For significant financial interests related to human subjects research, ORCA and/or the COIC must determine whether the interest could appear to compromise their objectivity on a project.
c. ORCA and/or the COIC must review the interest before the IRB research is approved. The IRB reviews the COIC actions/management plan to ensure they are incorporated into the consent document and study application, and may accept the safeguards as written, determine additional steps are necessary, or make revisions.

X. Office of Sponsored Projects
The Office of Sponsored Projects verifies with ORCA that extramural funding is listed on IRB protocols before releasing funds. PIs are responsible for notifying OSP of any IRB protocols associated with any funding, and notifying the IRB of any funding associated with IRB protocols (new funding must be reported via protocol amendment request). Sponsors expect the PI to ensure that the scope of work described in the grant proposal is congruent with that described in the IRB protocol and may ask to see the IRB approved study.

XI. Institutional Biosafety Committee
a. Any research activity involving materials potentially containing human pathogens (e.g. human specimens, human blood, saliva, fingernails, etc.) must be approved, either by the Biosafety Officer or by the UCSC Institutional Biosafety Committee (IBC).
b. The IBC reviews protocols for proper acquisition, handling, transfer, and disposal of potentially hazardous or regulated biological materials.
c. IBC approval is required prior to IRB approval.

XII. Human Stem Cell Research
a. UCSC activities involving any human stem cell research shall be conducted in accordance with the applicable federal, state and funding agency regulations, including any restrictions on the use of federal funds for such research under the NIH Stem Cell Guidelines.
b. The UCSF Human Gamete, Embryo, and Stem Cell Research Committee (GESCR) functions as the Stem Cell Research Oversight (SCRO) Committee for the UCSC campus through a MOU. Instructions are on UCSC’s Stem Cell website.
c. GESCR approval is required prior to IRB approval.

XIII. Other Approvals
Research may be subject to other review processes in addition to those listed in this policy, such as permissions to gain access to data (UCSC student data) or populations (students in various school districts). Other approvals may be needed, in addition to IRB approval, in order to carry out research and researchers should check with other pertinent offices before starting research.

XIV. References
   a. UC Irvine policy Institutional Commitment and IRB Authority
   b. UC Irvine policy IRB Committees Relationship to Other University Committees
   c. Stanford University HRPP Policy Manual
   d. OHRP Assurance Process FAQ
   e. SACHRP Committee Recommendations
   f. SMART IRB Glossary
   g. NIH clinical trial definition
   h. 45 CFR 46, Including Subpart E
   i. The Belmont Report