Policy on Human Research Protections Program Oversight
Date of Last Revision: 9/20/2019; 4/19/2021

I. Background
   (a) The UC Santa Cruz (UCSC) 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 UCSC. The Office of Research Compliance Administration (ORCA) provides administrative support to the IRB and assists researchers in navigating federal, state and University policies regarding human subjects research and. 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 the Department of Health and Human Services (DHHS). Through the assurance of compliance, an institution commits to DHHS 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 (OHRP)
   (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 the name of the institution, Human Protections Administrator, or Institutional Official.
   (b) The UCSC Chancellor delegates human subjects research authority to the VCR who serves as UCSC’s IO. The IO provides oversight of the Human Research Protection
Institutional Review Board

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 DHHS regulations (45 CFR 46, including all Subparts) to research involving human participants that is funded by any Common Rule department or agency. Commensurate protections are in place for all other human subject research conducted at or under the jurisdiction of UCSC. See UCSC IRB Policy on Regulatory Flexibility. To find funding agencies to which the regulations apply see Common Rule Departments and Agencies and HHS Agencies & Offices.

(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 subjects.

(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 DHHS must be registered with DHHS.

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

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

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

(a) 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. ORCA administratively supports investigators and the IRB, makes determinations regarding exemption from IRB review, facilitates IRB review of human subjects research and IRB meetings, and provides regulatory support to the UCSC research community.

(b) The ORCA Director oversees ORCA staff and overall unit operations.

(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 policies and procedures. Policies are to be reviewed and updated periodically, no less than every 7 years. If policies are not followed, investigators may need to report noncompliance. See UCSC IRB 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 a reliance agreement, through which the non-UCSC institution’s IRB agrees to "rely" on the UCSC IRB’s review of the proposed human subjects research.

(b) UCSC IRB primarily reviews social, behavioral, and educational research (SBER). The IRB currently does not review FDA regulated research (UCSC has an agreement with commercial IRB vendor Western IRB for investigators 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 research 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.
(m) The IO may also suspend or terminate research. See UCSC IRB Policy on Suspension and Termination.
(n) 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) An sIRB is mandated for some multi-site research as follows:
   (1) As required by DHHS regulations (45 CFR 46.114), all research funded by any Common Rule department or agency. To find funding agencies to which the regulations apply see Common Rule Departments and Agencies and HHS Agencies & Offices.
   (2) If required by the study sponsor.
(c) If Lead PI is at UCSC and UCSC is expected to be Lead Site of a study involving a clinical trial (as defined above) or FDA-regulated research, 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 UCSC IRB Policy on Collaborative Research.
(e) UCSC will ensure compliance with other institutional regulatory requirements such as Conflict of Interest, Human Stem Cell Research Oversight (hSCRO) Committee (reviewed by the 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. When necessary, failure to do so may result in non-compliance.

(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 a reliance 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 a human subjects research study, ORCA and/or the COIC must determine whether the interest could appear to compromise the investigators objectivity on a study.

(c) ORCA and/or the COIC must review the interest before the study receives IRB approved or an exempt determination. The IRB reviews the COIC actions/management plan to ensure they are incorporated into the application for review of proposed human subject research and related consent document(s), and may accept the safeguards as written, determine additional steps are necessary, or make revisions.

X. Office of Sponsored Projects

(a) The Office of Sponsored Projects (OSP) verifies with ORCA that extramural funding is included in the application for review of proposed human subject research before releasing funds. PIs are responsible for notifying OSP of any human subjects research studies that have associated extramural funding, and notifying the IRB/ORCA of any extramural funding associated with human subjects research studies (This includes
reporting any new funding obtained during the course of an IRB-approved/exempt certified human subjects research studies. Sponsors/funding agencies expect the PI to ensure that the scope of work described in a funding proposal is congruent with that described in the application for review of proposed human subject research, and may ask to see documentation of IRB approval/certification of exemption and/or the human subjects research study.

XI. Institutional Biosafety Committee
(a) Any research activity involving biological 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 studies for proper acquisition, handling, transfer, and disposal of potentially hazardous or regulated biological materials.
(c) While not required for IRB approval/exempt determination, IBC approval is required prior to conducting research activities involving biological materials potentially containing human pathogens.
(d) Instructions for submission and review of research activities involving materials potentially containing human pathogens can be found at UCSC EH&S Biosafety.

XII. Human Stem Cell Research
(a) UCSC research activities involving human stem cells 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 UC San Francisco (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 Memorandum of Understanding (MOU). More information can be found at UCSF GESCR - Human Stem Cell Research.
(c) While not required for IRB approval/exempt determination, GESCR approval is required prior to conducting research activities involving human stem cells.
(d) Instructions for submission and review of research activities involving human stem cells can be found at Conducting Human Stem Cell Research at UCSC.

XIII. Other Approvals
(a) Research involving human subjects 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 activities involving human subjects. Investigators should be sure to check with other pertinent offices before beginning any research activities involving human subjects.
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