Policy on IRB Reliance

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I. Background
UC Santa Cruz researchers commonly collaborate with investigators outside of UCSC. The Office of Human Research Protections of The Department of Health and Human Services allows multiple institutions to “enter into a joint review arrangement, rely upon the review of another qualified Institutional Review Board (IRB), or make similar arrangements for avoiding duplication of effort” (45 CFR 46.114). This process of reliance avoids duplicative reviews, while still requiring both parties to comply with human subjects research regulations. When conducting collaborative research, UC Santa Cruz reviews requests for UCSC to either review for or rely on another institution to help streamline research and alleviate unnecessary investigator burden.

II. Definitions
a. IRB Authorization Agreement (IAA)/Inter-Institutional Authorization (IIA): a written agreement between two collaborating institutions that allows one institution to review on behalf of the other, while establishing responsibilities for both institutions.
b. IRB of Record: The IRB that reviews and approves the research for both institutions.
c. Reviewing Institution: The institution that conducts IRB review for both parties.
d. Relying Institution: The institution that cedes IRB review to the reviewing institution.

III. Deciding which IRB Reviews
The IRB of record for collaborative research is determined by the Institutional Official (IO), the Vice Chancellor of Research (VCR), with support from the IRB administrative office based on several factors such as:
   a. Who claims to be the “lead Principal Investigator (PI)”;
   b. Who the prime awardee of a grant is; Whether the research is paid for by UCSC funds or funds administered by UCSC;
   c. Whether UCSC students will use the research to complete UCSC degree requirements;
   d. Whether UCSC students will be used as subjects;
   e. Where the human research activities occur;
   f. The compliance makeup of the IRB of record (e.g., factors such as Federalwide Assurance with OHRP, adherence to federal regulations, state laws, and robust institutional policies and procedures, etc.);
   g. Expertise regarding the human research procedures; and
h. Requirements of the funding agency (e.g., NIH for multi-site research will select the IRB of record)

IV. **Decision to Review or Rely**
The decision on whether UCSC will review on behalf of or rely upon another institution is left up to the VCR with consultation from the Office of Research Compliance Administration (ORCA). Note that the collaborating institution must be an established entity that complies with federal regulations and, unless an exception is approved by the VCR, holds a Federalwide Assurance with the Office of Human Research Protections. Their Principal Investigator is responsible for oversight of the research at their institution and following the approved protocol, and the institution must have an established human subjects protection training program or investigators must take online UCSC human research training via the Collaborative Institutional Training Initiative (CITI).

V. **Procedures-UCSC Reviews (non-University of California collaborator)**
   a. UCSC PI submits an IRB application listing the collaborating institution and all investigators who will be engaged in human subjects research from both institutions,
   b. UCSC PI provides a summary of what human research activities will be conducted by investigators at each institution.
   c. UCSC PI provides verification of human research training for all UCSC research personnel, the collaborating PI, and either all collaborating researchers individually or a statement from the collaborating PI that all researchers at their institution will complete training before beginning work on the project.
   d. UCSC PI informs ORCA of any federal funding for the project and ORCA performs the required grant congruency check, if applicable.
   e. UCSC PI informs ORCA of any use of human tissues/fluids/cells subject to review by the Biosafety Committee.
   f. The relying institution informs ORCA of any procedures required by the collaborating institution to manage a collaborating investigator’s conflict of interest.
   g. ORCA will review request; if accepted, ORCA will send an IAA form for the relying institution to complete and sign.
   h. The UCSC IO will review and sign off on the IAA.
   i. ORCA will send the signed IAA to the UCSC PI. Activities may not begin until both the IIA and the IRB approval are complete.

VI. **Procedures-UCSC Reviews (University of California collaborator)**
a. UCSC PI submits an IRB application listing the collaborating institution and all investigators who will be engaged in human subjects research from both institutions.
b. UCSC PI provides a summary of what human research activities will be conducted by investigators at each institution.
c. UCSC PI provides verification of human research training for all UCSC research personnel.
d. UCSC PI informs ORCA of any federal funding for the project and ORCA performs the required grant congruency check, if applicable.
e. The relying institution informs ORCA of any procedures required by the collaborating institution to manage a collaborating investigator’s conflict of interest.
f. UCSC PI starts a Reliance Registry request in the UC MOU online registry.
g. ORCA will review request once the reviewing and relying PIs completed all of the required information; if accepted, ORCA will approve the reliance and the PIs will be notified. Activities may not begin until both the registry reliance is approved and the IRB approval is complete.

VII. Procedures-UCSC Relies (non-University of California collaborator)

a. UCSC PI completes a Relying PI application.
b. UCSC PI provides a summary of what human research activities will be conducted by UCSC investigators.
c. UCSC PI provides verification of human research training for all UCSC research personnel.
d. UCSC PI informs ORCA of any federal funding for the project and ORCA performs the required grant congruency check, if applicable.
e. UCSC PI informs ORCA of any use of human tissues/fluids/cells subject to review by the Biosafety Committee.
f. ORCA will review request; if accepted, ORCA will receive the reviewing institution’s IAA with their IO’s signature.
g. The UCSC IO will review and sign off on the IAA.
h. ORCA will send the signed IAA to the UCSC PI. Activities may not begin until both the IIA and the IRB approval are complete.

VIII. Procedures-UCSC Relies (University of California collaborator)

a. UCSC PI completes a relying PI application.
b. UCSC PI provides a summary of what human research activities will be conducted by UCSC investigators.
c. UCSC PI provides verification of human research training for all UCSC research personnel.
d. UCSC PI informs ORCA of any federal funding for the project and ORCA performs the required grant congruency check, if applicable.
e. Collaborating PI starts a Reliance Registry request in the UC MOU online registry.
f. ORCA will review request once the reviewing and relying PIs complete all of the required information; if accepted, ORCA will approve the reliance and the PIs will be notified. Activities may not begin until both the registry reliance is approved and the IRB approval is complete.

IX. Investigator Responsibilities
The Principal Investigators at each institution must oversee the research to ensure compliance with the approved protocol. The Reviewing PI must make sure all relying sites have current approved materials. This includes any approved amendments to the protocol. Each sites’ PI must be responsible for any ancillary reviews, including conflicts of interest and addition of personnel at their own sites and assured human subjects training. Each site must still report to their respective IRB any unanticipated problems involving risks to subjects or others and noncompliance. The Reviewing IRB is responsible for any reporting to federal agencies.

X. References
21 CFR 56.114, 45 CFR 46.114, OHRP Correspondence: Use of a Centralized Institutional Review Board (IRB), University of California System Memorandum of Understanding