Policy on IRB Reliance

Effective date: 9/20/2019

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): a written agreement between two collaborating institutions that allows one institution’s IRB to review on behalf of the other’s, while establishing responsibilities for both institutions.
b. Inter-Institutional Authorization Agreement (IIAA): a written agreement between UCSC and an independent investigator who is not affiliated with any qualified IRB, which allows UCSC to review on behalf of the investigator and establishes investigator responsibilities.
c. IRB of Record: The IRB that reviews and approves the research for both institutions (or for UCSC and one or more independent investigators).
d. Reviewing Institution: The institution that conducts IRB review for both parties.
e. Relying Institution: The institution that cedes IRB review to the reviewing institution.
f. 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).

III. Deciding which IRB Reviews
Which IRB will serve as the IRB of record for a given collaborative research project is decided by the IO in agreement with the other institution’s corresponding official and in consultation with the Office of Research Compliance Administration (ORCA). This decision is based on several factors including (but not limited to):
   a. Who claims to be the “lead Principal Investigator (PI)”;
b. Who the prime awardee of a grant is;
c. Whether the research is paid for by UCSC funds or funds administered by UCSC;
d. Whether UCSC students will use the research to complete UCSC degree requirements;
e. Whether UCSC students will be used as subjects;
f. Where the human research activities occur;
g. The compliance makeup of the IRB of record (e.g., adherence to US federal regulations and state laws where the research is being conducted, robust institutional policies and procedures, etc.);
h. Expertise regarding the human research procedures; and
i. Requirements of the funding agency (e.g., NIH will select the IRB of record for multi-site research)

IV. Decision to Review or Rely
Whether UCSC is willing to review on behalf of another institution or rely on another institution’s review is decided by the IO in consultation with ORCA. The collaborating institution must be an institution that complies with federal regulations and, unless an exception is approved by the IO, holds a Federalwide Assurance with the Office of Human Research Protections. The collaborating PI is responsible for overseeing the research at their institution and following the approved protocol. The institution must have an established human subjects protection training program or else investigators must take UCSC human research training online via the Collaborative Institutional Training Initiative (CITI).

V. Procedures-UCSC Reviews for a non-University of California institution or individual collaborator
a. UCSC PI submits an IRB application listing the collaborating institution(s), if applicable, and all investigators who will be engaged in human subjects research, including independent investigators.
b. UCSC PI submits a Request to Review Research for Another IRB and/or Request to Review Research for an Independent Investigator form, as applicable. These forms require the following information:
   a. a summary of what human research activities will be conducted by investigators at each external institution, or by the independent investigator;
   b. verification of human research training for all UCSC research personnel and the collaborating PI or independent investigator. With regard to other collaborating investigators, the UCSC PI either
      i. provides verification of human subjects training for all collaborating researchers individually; or
ii. affirms on the Request to Review form that the collaborating PI requires all researchers at their institution to complete their institution’s required human subjects training before beginning work on the project;

c. if UCSC is the prime recipient of an award from a 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), UCSC PI submits IRB approvals or exempt determinations from all collaborating sites;

d. any use of human tissues/fluids/cells subject to review by the Biosafety Committee and authorizations obtained to date; and

e. any procedures required by the collaborating institution to manage a collaborating investigator’s conflict of interest. For independent investigators, UCSC PI submits an IRB Financial Interest Disclosure form and ORCA or the COI Committee will follow up with any investigator with interests to disclose.

f. ORCA reviews the Request to Review and if reliance conditions are met, ORCA drafts a UCSC IAA or IIA form (as applicable) with UCSC IRB and study information and sends it to the relying institution/independent investigator to complete and sign.

g. The UCSC IO will review and sign off on the IAA/IIAA.

h. ORCA will send the executed IAA/IIAA to the UCSC PI. Activities may not begin until the IAA/IIAA is executed and the IRB protocol is approved.

VI. Procedures-UCSC Reviews for a University of California institution

a. UCSC PI submits an IRB application listing the collaborating institution(s) and all investigators who will be engaged in human subjects research from all institutions.

b. UCSC PI submits a Request to Review Research for Another IRB form. This form requires the following information:
   i. a summary of what human research activities will be conducted by investigators at each external institution;
   ii. verification of human research training for all UCSC research personnel;
   iii. if UCSC is the prime recipient of an award from a 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), UCSC PI submits IRB approvals or exempt determinations from all collaborating sites; and
   iv. any procedures required by the collaborating institution to manage a collaborating investigator’s conflict of interest.
c. UCSC PI creates a reliance record for this study in the UC MOU online Reliance Registry.

d. ORCA reviews the Request to Review and if reliance conditions are met, ORCA will approve the reliance upon approving the IRB protocol or making an exempt determination. PIs at all UC collaborating institutions will be notified automatically by the Registry. Activities may not begin until both the reliance is approved in the Registry and the IRB protocol or exempt determination is approved.

VII. Procedures-UCSC Relies on a non-University of California institution
a. UCSC PI submits a Request to Rely on Another IRB’s Review form and IRB Financial Interest Disclosure form. The Request to Rely form requires the following information:
   1. a summary of what human research activities will be conducted by UCSC investigators;
   2. verification of human research training for all UCSC research personnel;
   3. notice of whether UCSC is the prime recipient of an award from a 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) in which all human subjects activities will be carried out by employees or agents of another institution(s);
   4. whether the research is regulated by the Food and Drug Administration (FDA) and, if required by FDA, verification of additional FDA training for UCSC personnel; and
   5. any use of human tissues/fluids/cells subject to review by the Biosafety Committee and authorizations obtained to date.

b. ORCA reviews the Request to Review and if reliance conditions are met, ORCA will forward the reviewing institution’s IAA with their IO’s signature to the UCSC IO.

c. The UCSC IO will review and sign off on the IAA.

d. ORCA will send the signed IAA to the UCSC PI. Activities may not begin until both the IAA is executed and the IRB protocol or exempt determination is approved.

VIII. Procedures-UCSC Relies on a University of California institution
a. UCSC PI submits a Request to Rely on Another IRB’s Review form and IRB Financial Interest Disclosure form. The Request to Rely form requires the following information:
1. a summary of what human research activities will be conducted by UCSC investigators;
2. verification of human research training for all UCSC research personnel;
3. notice of whether UCSC is the prime recipient of an award from a 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) in which all human subjects activities will be carried out by employees or agents of another institution(s);
4. whether the research is regulated by the Food and Drug Administration (FDA) and, if required by FDA, verification of additional FDA training for UCSC personnel; and

b. Reviewing PI creates a reliance record for this study in the UC MOU online Reliance Registry.
c. UCSC PI responds to prompts from the Registry.
d. ORCA reviews the Request to Rely and if reliance conditions are met, ORCA will approve the reliance when prompted by the Registry. PIs at all UC collaborating institutions will be notified automatically by the Registry. Activities may not begin until both the reliance is approved in the Registry.

IX. SMART IRB Registration
a. The UCSC PI and ORCA will use the SMART IRB online registration system in lieu of the IAA form any time a collaborating institution requires it or when UCSC is the IRB of record on a multisite NIH funded study.
b. UCSC PI completes the same internal forms described above according to the circumstances – i.e. Request to Rely on Another IRB’s Review, Request to Review for Another IRB, Request to Review for Independent Investigator, and/or IRB Financial Interest Disclosure.
c. ORCA reviews the applicable request forms, ORCA will approve the reliance in SMART IRB as soon as reliance conditions are met and, if applicable, the IRB protocol is approved or the research is determined exempt.

X. 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 access to current approved materials, including approved amendments to the protocol. Each relying PI is responsible for their own respective ancillary reviews, including conflicts of interest, and for ensuring that new personnel at their own sites complete human subjects training and are added by IRB-approved amendment request before beginning work on the project. A reliance agreement does not change the responsibility of each PI to report to their respective IRB any unanticipated problems involving risks to
subjects or others, or noncompliance. The Reviewing IRB is responsible for any reporting to federal agencies.

XI. References
   a. 45 CFR 46.114
   b. OHRP Correspondence: Use of a Centralized Institutional Review Board (IRB)
   c. University of California System Memorandum of Understanding