

SOP: IRB Reliance When UC Davis Relies on an External IRB

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1 PURPOSE

- 1.1 This procedure establishes the process for relying on an external IRB for review of human subject research in which UC Davis is engaged.
 - 1.1.1 IRB Administration receives notice that UC Davis is being asked to rely on external IRB.
 - 1.1.2 The procedure ends when the research subject to IRB review is completed and/or closed, or the written agreement establishing the relationship of reliance is otherwise terminated under its terms and conditions.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 Administrative Updates
- 2.2 Added information relating to 21 CFR 50.24 review and reports of unanticipated problems involving risks to subjects or others and serious or continuing non-compliance.
- 2.3 Added that PIs should contact the UC Davis IRB for changes that affect local context. Specified that master reliance agreements will be maintained in an electronic archive. Administrative updates.
- 2.4 Removed review of exception from informed consent by biomedical Chair/Vice Chair.

3 POLICY

- 3.1 Circumstances arise in which an investigator at UC Davis may rely on an external IRB for review and oversight of human subject research in which UC Davis is engaged.
- 3.2 UC Davis will cede IRB review only to IRBs that are accredited by a recognized accrediting organization or otherwise have a process for ensuring compliance with ethical principles, applicable law and guidance.
- 3.3 The UC Davis IRB must approve the reliance and sign a reliance agreement before UC Davis faculty, employees or students can engage in human subject research under the oversight of an external IRB.
- 3.4 The UC Davis IRB must conduct an institutional review of human subject research that includes an exception to the requirement for informed consent under 21 CFR 50.24 before ceding.

4 RESPONSIBILITIES:

- 4.1 UC Davis IRB staff members, Principal Investigators, Independent Investigators, and IRB Chairs and members carry out these procedures.

5. PROCEDURES

- 5.1 IRB staff members will review inquiries for reliance on external IRBs for review of human subject research:
 - 5.1.1 If the human subject research is minimal risk, the staff member may agree to external review subject to a signed IRB Reliance Agreement.
 - 5.1.2 If the human subject research is greater than minimal risk and the reviewing IRB is accredited by AAHRPP or equivalent body, the staff member may agree to external review subject to a signed IRB Reliance Agreement.
 - 5.1.3 If the human subject research is greater than minimal risk and the reviewing IRB is not accredited by AAHRPP or an equivalent body, the Director or Associate Director may agree to external review subject to a signed IRB Reliance Agreement from the external IRB and existence of a process for ensuring ethical and compliant review.
- 5.2 IRB staff members will review the IRB Reliance Agreement provided by the external IRB.
 - 5.2.1. UC Davis and the reviewing IRB will take maximum advantage of other existing reliance agreements. Existing master reliance agreements will be retained in an electronic archive of reliance documentation. If the human subject research is subject to an existing agreement such as the NCI IRB, Neuronext or SMART IRB agreement, go to Section 5.3.
 - 5.2.2. If the reviewing IRB provides its template agreement, the IRB staff member will review the document using [HRP-334 WORKSHEET: Reliance Agreement](#). The IRB staff member will work with the external IRB to create an acceptable agreement. Once the document is

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acceptable, IRB staff will forward the worksheet and agreement to the UC Davis IRB Director or Associate Director.

- 5.2.3. The UC Davis IRB Director or Associate Director will review the agreement and notify staff if any issues are identified. Once the agreement is acceptable to the Director or Associate Director, the Institutional Official or designee will sign the agreement and return it to the appropriate staff member.
- 5.2.4. The IRB staff member will return the fully executed agreement to the external IRB with a copy to the UC Davis Investigator and will include the following contingency in the correspondence:
UC Davis must administratively review and acknowledge the protocol, consent document and approval letter before UC Davis faculty, staff and students are engaged in human subject research reviewed by an external IRB.
- 5.2.5. A copy of the Reliance Agreement will be retained with the initial IRB project submission materials.
- 5.3 The Investigator or research staff will submit a new project to the UC Davis IRB via the electronic submission system.
- 5.4 IRB Staff will review the New Project using [HRP-442 CHECKLIST: External IRB review of Human Subject Research](#). If the submission is complete and acceptable, IRB Staff will acknowledge the submission.
- 5.5 Following acknowledgement, Investigators are required to submit only the following to the UC Davis IRB:
 - 5.5.1. Modifications that involve a new exception from the informed consent process under 21 CFR 50.24;
 - 5.5.2. New reports of local events that are unanticipated problems involving risks to subjects or others, or meet the UC Davis definition of Serious or Continuing non-compliance;
 - 5.5.3. Change in UC Davis PI;
 - 5.5.4. Change in funding source; and
 - 5.5.5. Notification of study closure.
- 5.6 Investigators should contact the UC Davis IRB when there is a change in research that impacts UC Davis local context approval. Examples include, but are not limited to:
 - 5.6.1. Addition of Prisoners as research subjects;
 - 5.6.2. Request for new or change to an existing waiver of HIPAA Authorization where UC Davis is serving as the Privacy Board; or
 - 5.6.3. Change to UCD required consent language.
- 5.7 IRB Staff who are designated reviewers will review reports of unanticipated problems involving risks to subjects or others, and serious or continuing non-compliance and will:
 - 5.7.1. Work with the Principal Investigator to develop an adequate corrective and preventive action plan;
 - 5.7.2. Work with the reviewing IRB to develop a report to institutional officials and regulatory agencies;
 - 5.7.3. Obtain consultations with the Institutional Official, UC Health Compliance, an IRB Chair, or UC Davis Counsel, when applicable.

6. MATERIALS

- 6.1 WORKSHEET: Reliance Agreement (HRP-334)
- 6.2 CHECKLIST: External IRB review of UC Davis Human Subject Research (HRP-442)