SOP: IRB Reliance When UC Davis Relies on an External IRB				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-058	09/17/2018	C Gates	C. Kiel	1 of 2

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 through a submission, telephone call, email message or other business communication.

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.

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 IRB's 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 receive and administratively review the protocol, consent document(s) and approval documents in order to accept the approval of an external IRB, and before UC Davis faculty, employees and students can engage in human subject research under external IRB oversight.

3.5 The UC Davis IRB must review waivers of consent, waivers of documentation of consent and waiver of HIPAA authorization before any such waivers are used to conduct human subject research under external IRB oversight.

3.6 The UC Davis IRB must review protocols that include an exception to the requirement for informed consent under 21 CFR 50.24.

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. If the human subject research is subject to an existing agreement such as the NCI IRB, Neuronext or Petal 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 WORKSHEET: Reliance Agreement. The IRB staff member work with the external IRB to create an acceptable agreement. Once the document is acceptable, IRB staff will forward the worksheet and agreement to the UC Davis IRB 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 in the following contingency in the correspondence:
UC Davis must administratively review the protocol, consent document and other approval documents 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 1) in an electronic archive of reliance documentation and 2) with the initial IRB project submission materials (initial IRBNet project submission).

5.3 The Investigator or research staff will submit a new project to the UC Davis IRB via IRBNet and will complete the Initial Review Application for reliances. The package will include the approved protocol, consent document, local ancillary approvals, and, when applicable, the Reliance Agreement and other approval documents.

5.4 IRB Staff will review the approved documents using CHECKLIST: External IRB review of Human Subject Research. If the submission is complete and acceptable, IRB Staff will acknowledge the submission with an acknowledgement Letter.

5.5 A Chair of a bio-medical committee will review all research involving an exception to the informed consent process under 21 CFR 50.24 to determine whether the exception is acceptable from an institutional standpoint.

5.6 Following acknowledgement, Investigators are required to submit only the following to the UC Davis IRB:

5.6.1. Modifications that involve a new exception from the informed consent process under 21 CFR 50.24;

5.6.2. 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;

5.6.3. Change in UC Davis PI; and

5.6.4. Notification of study closure.

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)