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1 PURPOSE

- 1.1 This procedure establishes the process for reviewing research on behalf of another institution. The process begins when:
 - 1.1.1 IRB Administration receives notice that another institution intends to rely on UC Davis IRB either through a submission, telephone call or other business communication.
 - 1.1.2 The process ends when the study 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 Minor administrative changes. Updates to reliance procedures.

3 POLICY

- 3.1 Circumstances arise in which an individual who is not a University/Affiliate investigator may wish to use the UC Davis IRB for review and oversight of their non-exempt human subject research or to rely on the UC Davis IRB for oversight of non-exempt human subject research.
- 3.2 An *Independent Investigator* is one whose home institution does not have an IRB or is not affiliated with an institution.
- 3.3 An *External Investigator* is one whose home institution has an IRB.
- 3.4 The UC Davis IRB will review studies for an Independent Investigator only when that investigator is involved in research being conducted by a collaborating UC Davis investigator.
- 3.5 External Investigators include researchers engaged in or collaborating on research projects for which the UC Davis investigator is the lead researcher or is responsible for the overall conduct of the research. When a UC Davis Investigator is the lead researcher, the University prefers the External Investigator's institution cede review to the UC Davis IRB.
- 3.6 Human subject research may not commence at the Independent Investigator's or the External Investigator's site until the responsibilities specified herein are met.

4 RESPONSIBILITIES:

- 4.1 IRB staff members, Principal Investigators, Independent Investigators, and IRB members carry out these procedures when the IRB is reviewing for an Independent Investigator.
- 4.2 IRB staff members, Principal Investigators, External Investigators, External Institutions and IRB members carry out these procedures when the IRB is reviewing for an External Investigator.

5. PROCEDURES WHEN THE RELIANCE IS FOR AN INDEPENDENT INVESTIGATOR

- 5.1 IRB staff members provide to the Independent Investigator a copy of the UC Davis Authorization Agreement for Independent Investigators and Attachment 1. These documents may be provided to the UC Davis PI or his/her staff who will forward it to the Independent Investigator.
- 5.2 Upon receipt of the agreement and Attachment 1, IRB staff will administratively review the documents to see if they are complete and return them for completion if clarification is needed.
- 5.3 When complete documents are received, IRB staff will forward the agreement to the UC Davis IRB Director or Associate Director.
- 5.4 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.
- 5.5 The IRB staff member will return the fully executed agreement to the Independent Investigator.
- 5.6 A copy of the signed agreement will be retained by IRB Administration in an electronic archive.
- 5.7 If the Independent Investigator is a Principal Investigator, they must register with IRBNet and the Principal Investigator at UC Davis must share the project with the Independent Investigator. If the Independent Investigator is considered research staff of the Principal Investigator at UC Davis, he/she does not need to register with IRBNet.
- 5.8 If the Independent Investigator is a Principal Investigator, the Independent Investigator is responsible for submitting Attachment 1 and any other site specific documents for review.
- 5.9 The IRB will review the investigator credentials and resources. This review can be conducted as a

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minor revision to previously approved research if the reliance submission is submitted as a separate amendment.

- 5.10 If the Independent Investigator is a Principal Investigator, the IRB will send letters, notices and approval documents to the Independent Investigator through IRBNet.

6. PROCEDURES WHEN RELIANCE IS FOR AN EXTERNAL INVESTIGATOR

- 6.1 Principal Investigators should contact the UC Davis IRB as soon as possible if a decision is made to use the UC Davis IRB as the single IRB for a multi-site project.
- 6.2 If the project is funded by DHHS, the Principal Investigator must include the direct cost of IRB review in the research budget.
- 6.3 Check to see if an IRB Reliance Agreement already exists and use applicable, existing agreements whenever feasible:
 - 6.3.1 If the External Investigator is from a University of California (UC) campus, consider using the UC Reliance Registry for registering the site with the External Institution.
 - 6.3.2 If the External Investigator's Institution is part of IRBChoice, SMART IRB or another IRB UC Davis has a Reliance agreement with, consider using the existing agreement and platform for registering the study with the external Institution.
 - 6.3.3 Follow the SOPs of the chosen reliance for collection of study documents and distribution of approval notifications and documents.
- 6.4 If no IRB Authorization Agreement exists, send the UC Davis IRB Authorization Agreement, the UC Davis Site Submission Form and any other documents that will facilitate reaching an agreement quickly to the Relying IRB and the External Investigator.
- 6.5 The External Investigator must complete the Site Submission Form.
- 6.6 Upon receipt of the agreement and Site Submission Form, IRB staff will administratively review the documents to see if they are complete and return them for completion or clarification as needed.
- 6.7 When complete documents are received, IRB staff will forward the agreement to the UC Davis IRB Director or Associate Director.
- 6.8 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.
- 6.9 The IRB staff member will return the fully executed agreement to the Relying IRB.
- 6.10 A copy of the signed agreement will be maintained by the IRB in an electronic archive.
- 6.11 An External Investigator who is a Principal Investigator must register with IRBNet and the Principal Investigator at UC Davis must share the project with the External Investigator.
- 6.12 IRB Staff will create a submission in IRBNet to upload the Site Submission Form and any site specific documents that need approval.
- 6.13 The IRB will review the investigator credentials and resources. This review can be conducted as a minor revision to previously approved research if the submission is submitted as a separate amendment.
- 6.14 If the External Investigator is a Principal Investigator, the IRB will send letters, notices and approval documents to the External Investigator through IRBNet.

7. REFERENCES

- 7.1 None