RELIANCE AGREEMENTS FOR NON-UCB COLLABORATIONS

This guidance document is intended for UC Berkeley investigators planning to conduct collaborative research, involving researchers outside of UC Berkeley. (Note: This guidance document does not apply to projects utilizing a commercial IRB, which involves different requirements/instructions.) Should you need additional assistance, please contact OPHS at irb_reliance@berkeley.edu.

Table of Contents:

A. Introduction

Collaborative research projects are studies that involve more than one institution *engaged* in human subjects research. In the conduct of collaborative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with pertinent federal regulations, state regulations, and institutional policies. For collaborative research projects, institutions may choose to rely upon the review of another Institutional Review Board (IRB) to avoid duplication of effort. Reliance agreements for institutions or individual investigators may be executed upon the request of the investigator, the Committee for Protection of Human Subjects (CPHS)/Office for Protection of Human Subjects (OPHS), or the collaborating institution to document IRB review and engagement in human subjects research.

B. Definitions

1. **Engagement:** The Office for Human Research Protections (OHRP) considers an institution "*engaged*" in non-exempt human subjects research when its employees or agents, for the purposes of a research project, obtain:

   a. An award through a grant, contract, or cooperative agreement directly from HHS for the non-exempt human subjects research, even where all activities involving human subjects are carried out by employees or agents of another institution;
   b. Data about the subjects of the research through intervention or interaction with them;
   c. Identifiable private information about the subjects of the research; or
   d. The informed consent of human subjects for the research.

   CPHS and OPHS base their determinations of *engagement* on the *OHRP Guidance on Engagement of*

Institutions in Human Subjects Research. CPHS/OPHS considers UCB *engaged* in human subjects research when a UCB researcher initiates a human subjects research study or UCB receives a grant, contract, or cooperative agreement from a funding agency (e.g., National Institutes of Health, National Science Foundation, Department of Defense) to conduct human subjects research. In such instances, UCB will still be considered *engaged* in human subjects research even if all activities involving human subjects are carried out by another entity (e.g., contractors, enumerators, collaborators), and that entity only provides de-identified data to the UCB researchers. See CPHS Guidelines on Engagement in Human Subjects Research for additional information.

2. **Individual Investigator:** An individual who is not otherwise an employee/agent of UCB (e.g., faculty, staff, or student) and is not acting as an employee of any institution with respect to his/her involvement in the research being conducted with UCB.

3. **Reliance Agreement - Individual Investigator:**

   a. Single Individual Investigator. Documentation of an individual investigator's reliance on CPHS' review, when the investigator is engaged in human subjects research under the direction/supervision of a UCB Principal Investigator (PI). This agreement is signed by:

      - The Institutional Official of UCB, or his/her/their designee; and
      - The collaborating individual investigator.

   b. Multiple Individual Investigators. Documentation of multiple individual investigators' reliance on CPHS' review, when the investigators are engaged in the same human subjects research project under the direction/supervision of a UCB Principal Investigator (PI). This agreement is signed by:

      - The Institutional Official of UCB, or his/her/their designee; and
      - The UCB Principal Investigator (PI).

4. **Reliance Agreement - Institution:** Documentation of an institution's reliance on an external IRB's review of a research study. A reliance agreement may be signed by:

   a. The Institutional Official of University of California, Berkeley (UCB), or his/her/their designee; and
   b. The Institutional Official of the collaborating institution, or his/her/their designee.

5. **Relying Institution/IRB:** The entity that is relying on an external IRB's review of a research study. In many cases, the relying institution will have an FWA and an internal IRB (i.e., the relying IRB).

6. **Relying PI:** The individual serving as the PI at the relying institution.

7. **Relying Investigators:** Researchers who are working under the supervision of the relying PI or individual investigators who are conducting research under the purview of CPHS.

8. **Reviewing Institution/IRB:** The entity conducting the review of a research study on behalf of another entity. The term **IRB of Record** is deemed to be synonymous with reviewing IRB.

9. **Reviewing PI:** The individual serving as the PI at the reviewing institution.

C. IRB Reliance for Collaborative Research

1. ***Criteria for Voluntary Reliances (i.e., collaborative projects not subject to sIRB requirements)***

CPHS may agree to serve as the reviewing IRB if the research meets all of the criteria below:

a. Generally, non-UCB researchers (i.e. relying) do not have a potential financial Conflict of Interest associated with the research (for an exception to this standard, investigators should contact irb_reliance@berkeley.edu for guidance; such requests will be reviewed on a case-by-case basis); and
b. The relying entity is in agreement with CPHS Policies and Procedures, including Exempt Category 70 (if applicable). It is the relying entity's responsibility to ensure they understand and agree with CPHS Policies and Procedures.

UCB may agree to rely on another IRB if the research meets all of the criteria below:

a. Generally, UCB researchers do not have a potential financial Conflict of Interest associated with the research (for an exception to this standard, investigators should contact irb_reliance@berkeley.edu for guidance; such requests will be reviewed on a case-by-case basis);
b. The reviewing institution holds an active Federalwide Assurance (FWA);
c. A human subjects protocol has been submitted for IRB review at the Reviewing Institution; and
d. The study does not use a UCB subject pool (e.g., RPP, SONA, etc).

2. ***Requesting a Reliance***

Collaborating investigators may either obtain separate IRB reviews or obtain review from a single IRB. In certain circumstances, single IRB (sIRB) review is required. UCB researchers who are interested in an IRB reliance must consult with OPHS staff by submitting the appropriate reliance request form to irb_reliance@berkeley.edu. Reliance requests and execution of reliance agreements for institutions or individual investigators are subject to approval of the OPHS Director. Determinations will be based on Part 5 (Process Overview) of the IRB Reliance Policy.

If the reliance request is declined, then each entity shall seek separate IRB reviews for their respective involvement in human subjects research.

3. ***Executing an Agreement***

Reliance agreements for institutions and individual investigators should be executed to document an IRB reliance when the research is *non-exempt* or if a documented agreement is requested by the CPHS/OPHS, the investigator, and/or the collaborating institution.

D. When CPHS Is the Reviewing IRB: Investigator Responsibilities

1. ***UCB Reviewing PI***
In addition to standard UCB PI responsibilities, when CPHS is the reviewing IRB, the UCB PI is responsible for the items outlined below.

a. *Training:* Following CPHS Education and Training requirements.

b. *Agreements*: Obtaining required signatures from the relying institution(s) and/or the individual investigator(s), when a signed agreement will be executed.

c. *Protocol submissions*: Ensuring that the research activities to be conducted by relying investigators are described in a research protocol submitted to and approved by CPHS prior to implementation.

d. *Coordination and dissemination of study materials:* Communicating with all relying investigators to ensure necessary and required coordination of any research activities. This includes disseminating the most recent approved version of the protocol, consent document(s), and study materials to relying investigators.

e. *Reporting*: Submitting reports of unanticipated problems involving risks to subjects or others, serious adverse events, deviations, and/or non-compliance to CPHS on behalf of the relying investigators.

2. ***Non-UCB Relying PI and Investigators***

Responsibilities of non-UCB collaborating investigators, who are relying on CPHS review, are outlined below.

a. *Training:* Following CPHS Education and Training requirements.

b. *Compliance:* Complying with CPHS Policy and Procedures, federal and state regulations, and if applicable, also complying with the relying institution's policies and procedures.

c. *Conducting research:* Conducting research according to the protocol approved by CPHS. The relying investigators should not implement any revisions or changes to the protocol without prior approval from CPHS, except where necessary to eliminate immediate hazard(s) to research subjects. Necessary changes to the research should be communicated to the reviewing PI. The reviewing PI is responsible for handling the IRB amendment submission to the reviewing IRB.

E. When CPHS Is the Relying IRB: Investigator Responsibilities

1. ***UCB Relying PI and Investigators***

Responsibilities of UCB researchers when relying on an external IRB are outlined below.

a. *Training:* Following CPHS Education and Training requirements.

b. *Agreements*: Obtaining required signatures from the reviewing institution, when a signed reliance agreement will be executed.

c. *Conducting Research:* Conducting research according to the approved protocol and ensuring that the planned research activities are approved by the reviewing IRB prior to implementation. The relying investigators should not implement any revisions or changes to the protocol without prior approval from reviewing IRB, except where necessary to eliminate immediate hazard(s) to research subjects. Necessary changes should be reported to the reviewing PI. The reviewing PI is responsible for handling the IRB amendment submission to the reviewing IRB.

d. *Compliance:* Complying with CPHS Policies and Procedures and the reviewing IRB's policies and procedures, in addition to federal, state, and local regulations.

e. *Reporting*: Reporting unanticipated problems involving risks to subjects or others, serious adverse events, deviations, non-compliance, and suspension/termination to the reviewing PI, who is responsible for reporting to the reviewing IRB.

f. *Other compliance-related reviews*: Ensuring other required compliance-related reviews and/or training at UCB (e.g., radiation safety, laser safety, biosafety) are completed.