P&P: RR 412 Version No: 1.1 Effective Date: 11/04/2014	IRB RELIANCE	Supercedes: CPHS Policies and Procedures 05/02/2014

1. BACKGROUND

Human subjects research must be conducted in accordance with ethical principles and various regulatory and institutional requirements. Paramount among these requirements is receipt of approval from an Institutional Review Board (IRB) appointed to protect human subjects before initiation of research. However, as human subjects research becomes an increasingly collaborative activity where researchers from multiple institutions work together towards the same aim, this has prompted further consideration of institutional approval policies.

2. POLICY

The University of California at Berkeley (UCB) Human Research Protection Program (HRPP) acknowledges the challenge of multiple IRB reviews and allows for, in some circumstances, reliance on its IRB review by other institutions, or UCB's reliance on another institution's IRB review, for multi-site research as outlined in this policy. UCB HRPP's primary objective is to protect the rights, safety, and welfare of research subjects while concurrently providing effective and efficient review and/or reliance of review for researchers.

Specific Requirements

2.1 Collaboration Within the University of California System

2.1.1 Collaborative human subjects research interventions or interactions, research with obtained coded or identifiable samples, or research with de-identified samples subject to FDA oversight occurring at two or more University of California (UC) sites may utilize the UC Memorandum of Understanding (MOU) that allows UC researchers to rely on one UC campus for IRB review.

2.1.2 All those engaged in human subjects research using the MOU must meet the requirements and conditions for use of the MOU.

2.1.3 All IRB and exempt review of research under the MOU will follow all federal and state regulations, UC policies, and the institutional policies of the IRB of record (i.e., the IRB of the reviewing institution) regarding human subjects research.

2.1.4 All non-exempt research must have an approved informed consent document or approved waiver of elements of consent or documentation; however, the reviewing institution's IRB will allow revisions to this document to reflect local requirements of the relying institution (e.g., phone number for local researcher).

2.1.5 The Director of the UCB Office for Protection of Human Subjects (OPHS) is authorized to accept or decline review or reliance.

2.1.6 Each site must ensure that local conflicts of interest review, biosafety review, radiation safety review, and other compliance-related reviews and approvals are secured as applicable.

2.1.7 Renewal of research conducted under the UC MOU must be reviewed based on the reviewing IRB's campus policies.

2.2 Collaboration Outside of the University of California System

2.2.1 Investigators engaged in collaborative human subjects research outside of the UC system may request UCB to be the IRB of record or ask that UCB researchers be permitted to rely on another institution's IRB review for both sites.

2.2.2 All those engaged in human subjects research using a reliance must follow their institution's requirements for training in human subjects protection. If UCB is the IRB of record, the PI must describe the human subjects protection training for non-UCB personnel within the collaboration section of eProtocol, or if the relying institution does not provide training, the UCB PI must provide a training outline and describe how PI will train the collaborators.

2.2.3 All research under a reliance will follow all applicable federal and state regulations and institutional policies of the IRB of record regarding human subjects research.

2.2.4 All non-exempt research must have an approved informed consent document or approved waiver of elements of consent or documentation, and if required by the IRB of record, provide consent document(s) for exempt research.

2.2.5 Each site must ensure that local review of conflicts of interest, biosafety review, radiation safety review, and other compliance-related reviews and approvals are secured as applicable.

2.2.6 UCB researchers may have additional requirements when collaborating with institutions that apply the federal regulations to all research regardless of funding source or that have less flexibility in their institutional policies than UCB.

2.2.7 UCB or the relying institution will cooperate with the IRB of record regarding review of noncompliance and serious adverse events and/or unanticipated problems involving risk to participants or others.

2.2.8 UCB uses the OHRP Inter-Institutional Agreement template document that follows the terms of our Federalwide Assurance for the Protection of Human Subjects (FWA) for studies that are subject to federal oversight, greater than minimal risk, FDA-regulated, or seeking a Certificate of Confidentiality. The template document is not necessary for studies that do not meet the above criteria.

2.2.9 The Director of OPHS has the authority to decline review or reliance.

2.3 Collaboration With Non-UC Individual Investigators

2.3.1 UCB researchers collaborating with individual investigators who are engaged in the human subjects research but are not affiliated with an institution which has an FWA and/or an internal IRB may use UCB as the IRB of record. UCB requires the use of an Individual Investigator Agreement for studies that are subject to federal oversight, greater than minimal risk, FDA-regulated, or seeking a Certificate of Confidentiality.

2.3.2 UCB requires that such non-UCB affiliated investigators are adequately trained and described in the collaboration section of the eProtocol application, and may require that specific training be taken and passed before UCB agrees to be the IRB of record for an individual investigator.

2.3.3 By signing an Individual Investigator Agreement, the non-UC investigator agrees to CPHS policies.

3. SCOPE

3.1 Generally, UCB will serve as the IRB of record or rely on another IRB for any academic institution in the United States that has a Federalwide Assurance with the Office for Human Research Protections and has its own institution-based IRB. For other types of institutions or collaborative partners, the OPHS Director under the Institutional Official (IO)'s delegation has authority to determine when UCB will serve as the IRB of record or rely on another institution's IRB review.

3.2 UCB evaluates each study reliance request on a case-by-case basis when determining if UCB will rely or be the IRB of record.

3.3 These requirements and procedures apply to all UCB investigators and research staff, and as appropriate, others involved in UCB human subjects research.

3.4 The FDA requires researchers to submit clinical investigations (e.g., devices, drugs, and biologics) to an institutional review committee which has been established in accordance with regulations of the Secretary of the Department of Health and Human Services to supervise clinical testing of drugs, devices, or biologics in the facilities where the proposed clinical testing is to be conducted.

4. RESPONSIBILITY

The Institutional Official (IO) has delegated to the Director of OPHS the responsibility for ensuring that human subjects research receives IRB review following relevant federal and state regulations and institutional policies.

The Principal Investigator (PI) at each institution has the responsibility to ensure that research is conducted according to the approved protocol and to oversee qualified personnel at his/her site. The PI from the IRB of record has responsibility over all sites and personnel, regardless of the location of the research. The PI at the reviewing site is also responsible for

facilitating proper documentation of any reliance of UCB or another IRB review. OPHS maintains a copy of any pertinent documentation.

The UCB PI collaborating with an individual investigator has the responsibility to ensure that the collaborator is fully informed on his/her responsibilities and obligations relative to his/her role in the approved protocol, and that the collaborator follows the approved protocol. Any deviations made by the collaborator must be promptly reported to the IRB per policy RR 408: Unanticipated Problems and Adverse Events.

5. PROCESS OVERVIEW

The UCB IO, the Vice Chancellor of Research, has authority for deciding when to review research for another institution and when to rely on another institution's review. The Human Protections Administrator on UCB's FWA, the Director of OPHS, has been delegated with this authority.

UCB will base its determination upon the following:

- Whether the other HRPP meets UCB standards for conducting ethical human subjects research and appropriate IRB review.
- Who the prime awardee is for funded research, how monies are distributed, and the type of funding (federal versus non-federal).
- The location(s) where recruitment, consent, and procedures or activities occur.
- The presence of a Principal Investigator who can provide oversight of research activities and where the PI's primary appointment resides.
- Which IRB has appropriate expertise to review the research.
- Institutional nature of the collaborating institution (i.e., academic, community hospital, independent research center, etc.).
- History of experience working with the other institution and/or the investigators engaged in the research.
- Appropriateness of the human research training/training plan for the non-UCB collaborators relying on UCB CPHS review.

5.1 Collaboration Within the University of California System When UCB Reviews

5.1.1 For multi-site research occurring at two or more of the 10 UC campuses (Berkeley, Davis, Irvine, Los Angeles, Merced, Riverside, San Diego, San Francisco, Santa Barbara, and Santa Cruz) or the Lawrence Berkeley National Laboratory (LBNL), researchers must use the online UC Reliance Registry to document IRB review and approval under the MOU. Any new requests, continuing reviews, and amendments must be submitted through the registry, along with appropriate submission to the reviewing IRB site.

5.1.2 Individuals involved in the design, conduct, or reporting of research must provide proof of training in human subjects research protection, which can be satisfied through the completion and passing of the pertinent biomedical or social and behavioral human research course of the Collaborative Institutional Training Initiative (CITI).

5.1.3 UCB will generally be the IRB of record if UCB is the prime awardee of a grant or if UCB is the main research site where recruitment and research activities occur (upon discretion of the OPHS Director).

5.1.4 In addition to the online registry, researchers must also complete a UCB eProtocol application for submission. Once the research is approved, the UCB Principal Investigator is responsible for oversight at all research sites and should report events from any site to UCB's IRB.

5.1.5 When CPHS/OPHS is the IRB of record, UCB will review all initial and continuing reviews, amendments, unanticipated problems involving risk to participants or others (e.g., serious adverse events), and non-compliance. UCB has the authority to suspend or terminate the research.

5.1.6 OPHS will keep a copy of all IRB records relating to the research and will provide relying campuses specific documentation pertaining to the protocol and/or its review as requested.

5.2 Collaboration Within the University of California System When UCB Relies

5.2.1 Individuals involved in the design, conduct, or reporting of research must provide proof of training in human subjects research protection, which can be satisfied through the completion and passing of the pertinent biomedical or social and behavioral human research course of the Collaborative Institutional Training Initiative (CITI).

5.2.2 Researchers must submit a protocol to the campus providing IRB review along with a copy of the registration application.

5.2.3 UCB CPHS/OPHS will report any events or possible noncompliance to the reviewing IRB.

5.2.4 UCB investigator completes the CPHS Reliance Application Cover Sheet and the Financial Conflict of Interest form and submits to OPHS.

5.3 Collaboration Outside of the University of California System

5.3.1 The OPHS Director may approve requests for other institutions to rely on UCB for IRB review or for UCB to rely on another institution's IRB. Contact OPHS staff for further guidance on making such a request.

5.3.2 OPHS will help the investigator with the process whether UCB is the IRB of record or the relying institution. OPHS will obtain the UCB IO signature for IIAs; the investigator is responsible for obtaining the appropriate signatures from the other institution; however OPHS staff may assist in the process.

5.3.3 If UCB is the IRB of record, the PI must submit an eProtocol application to CPHS/OPHS for review. This can be done concurrently with obtaining signatures for any required IIAs, but final approval of the protocol will not be issued until the IIA document is complete (if applicable). By signing an Inter-Institutional Agreement, the relying institution agrees to CPHS policies.

5. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56

45 CFR 46

Belmont Report

OHRP IRB Guidebook

OHRP Guidance on Engagement of Institutions in Human Subjects Research

University of California System Memorandum of Understanding (dated May 2012)

CITI - UC Berkeley Information Page