

P&P: CO 602 Version No: 1.2 Effective Date: 1/21/2019	INTRA-INSTITUTIONAL COMMUNICATION	Supersedes: CPHS Policies and Procedures 10/1/2009
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1. POLICY

The efficiency and effectiveness of the IRB is supported by contact with other entities and individuals within the University of California Berkeley. The Vice Chancellor for Research and/or the Assistant Vice Chancellor for Research Administration and Compliance may establish additional reporting relationships between the Office for the Protection of Human Subjects (OPHS), designated IRBs and other officials or committees as deemed appropriate. A designated IRB may require that proposed research be reviewed by other institutional committees or the relevant committees of collaborating institutions.

1.1 Specific Policies

1.1 Communication with specific individuals

1.1.1 Institutional Official (IO)

The IO of UC Berkeley receives an Annual Report from the Committee for the Protection of Human Subjects (CPHS) authored by the IRB Chair(s) and the Director of the OPHS. The Director communicates with the IO on an as needed basis for regulatory documentation. The IRB Chair and Director communicate with the IO (or his/her designee) as needed on other IRB business. The Assistant Vice Chancellor for Research Administration and Compliance communicates regularly with the IO about the IRB and OPHS business during standing meetings.

1.1.2 Investigators

OPHS staff communicate directly with investigators through one-on-one consultations (e.g. face-to-face, email, or by phone) in advising and in the pre-reviewing process. However, all revisions and clarifications communicated on behalf of the IRB are done so in writing.

Investigators may be invited to a convened IRB meeting if the IRB Chair believes that their presence may facilitate the review and discussion of their protocol. Occasionally with very complex protocols, an IRB member or sub-committee of IRB members may meet with an investigator to help him or her better understand the Committee's concerns and work with the investigator to find acceptable solutions. The IRB will notify investigators in writing of its decision to approve or disapprove a proposed research protocol and/or modification.

1.2 Communication with specific entities

1.2.1 Institutional Biosafety Committee (IBC)

The Biosafety Program provides compliance assistance, technical information, and training to assist UC Berkeley faculty and staff in meeting the requirements of local, State and Federal regulations and established policies for the possession, use or transport

of biohazards and potentially biohazardous materials. The Committee for Laboratory & Environmental Biosafety (CLEB) functions as the Institutional Biosafety Committee. OPHS staff facilitate regulatory compliance by requesting information about Biological Use Authorization (BUA) from investigators; and, by the OPHS Director serving on CLEB as a member.

1.2.2 Animal Care and Use Committee (ACUC)

For a research protocol that involves the use of human and animal subjects, an OPHS staff member will notify the office for Animal Care and Use by forwarding a copy of the CPHS application to the ACUC office. The OACU Director (or his/her designee) will make a determination about whether the use of animals in the study protocol is covered by an ACUC protocol and notify the OPHS analyst as appropriate. The IRB will take the ACUC/OACU determination into account when making a decision to approve or deny the application if animal subject use is integral to the human subjects research protocol.

1.2.3 Non-ionizing Radiation Safety (Laser) Committee

The University of California at Berkeley Laser Safety Program is intended to provide staff, researchers, students and visitors with a safe laser use environment. All Class 3a, 3b, and 4 lasers on the campus must be registered with the UC Berkeley Non-Ionizing Radiation Safety Program. The Office of Environment, Health & Safety administers this program for the UC Berkeley Non-Ionizing Radiation Safety Committee (NIRSC). The campus Laser Safety Officer (LSO) is responsible for implementation of the Non-Ionizing Radiation Safety program.

Upon identification of an affirmative response to the use of lasers in human subjects research the Director of OPHS (or his/her designee) is responsible for coordinating communication between the Laser Safety Officer and the IRB for research involving both committees.

The IRB will take the NIRSC determination into account when making a decision to require changes to the protocol; and, approve or deny the application for the human subjects research.

1.2.4 Research Integrity Officer

If an issue comes to the attention of the IRB, the IRB Chair, or the Director of OPHS which may require the involvement of the Research Integrity Officer (RIO) as per UCB policy; then, the Chair of the IRB is responsible for reporting and communicating in writing to the RIO the nature of the concerns. The RIO is responsible for investigating any issues or concerns and communicating the final outcome to the IRB Chair and Director should the findings have a potential impact on the investigator's conduct of human subjects research.

1.2.5 Conflict of Interest (COI) Committee

When a positive (yes) response is noted on the Potential Financial Conflict of Interest page in an eProtocol application, the investigator must fill out the Human Subjects

Financial Conflict of Interest Form and add the completed form to the Attachments section of their eProtocol application. The reviewing OPHS staff member is responsible for ensuring that the appropriate COI-related language is included in the consent form per guidance from the COI Office.:

The IRB does not approve an application until appropriate COI-related language is included in the study's consent form(s).

1.2.7 Sponsored Projects Office

Sponsored Projects Office (SPO) is a partnership of staff responsible to Assistant Vice Chancellor for Research Administration and Compliance (AVC-RAC). The SPO staff are responsible for Contract and Grant proposal review, awards negotiation and management, and controls grant administration and compliance. SPO and OPHS work collaboratively to ensure regulatory compliance as it pertains to the external funding of research. Individual contracts and grants officers (CGOs) communicate directly with OPHS to confirm IRB approvals before SPO releases funding.

1.2.8 Stem Cell Research Oversight (SCRO) Committee

The Assistant Vice Chancellor for Research Administration and Compliance and the Director of OPHS serve as members of the SCRO. The OPHS Director is responsible for coordinating communication between the SCRO and the IRB for research involving both committees.

1.2.9 Graduate Division

The OPHS Director is responsible for coordinating communication between the Dean of the Graduate School, the Graduate Division staff and the IRB involving policies regarding graduate student investigators.

1.2.10 Industry Alliances Office (IAO)

The OPHS Director is responsible for coordinating communication between the staff of the IAO and OPHS involving protocols with industry sponsorship. In addition, the IAO is informed of all IRB determinations of exemption, findings of “not human subjects research” or approval letters involving industry sponsorship of a protocol.

2. SCOPE

These policies and procedures apply to all human subjects research submitted to the IRB.

3. RESPONSIBILITY

The OPHS Director and/or OPHS Assistant Director is responsible for overseeing all IRB and OPHS communications.

4. PROCESS OVERVIEW

Contact with the intra-institutional entity will be initiated by the OPHS Director or designee with the appropriate entity, depending on the issue in question.