

P&P: CO 602 Version No: 1.1 Effective Date: 10/1/2009	INTRA-INSTITUTIONAL COMMUNICATION	Supersedes: CPHS Policies and Procedures 11/1/2007
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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.

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. Attached to the annual report will be copies of the approved prior year's CPHS minutes.

The Director communicates with the IO on an as needed basis for regulatory documentation (e.g. Inter-Institutional Agreements). 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 (face to face, email, facsimile 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. CLEB formulates and recommends campus policy on laboratory and environmental safety aspects of teaching and research programs involving biohazards and potentially biohazardous materials in accordance with applicable local, State and Federal regulations and established policies. OPHS staff facilitate regulatory compliance by requesting information about Biological Use Authorization (BUA) from investigators; and, by providing periodic summary reports of human subject research protocols using or collecting biological materials from subjects to the Biosafety Officer.

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 Animal Care and Use Committee by forwarding a copy of the CPHS application to the ACUC office. The ACUC will make a determination about whether the use of animals in the study protocol is covered by an ACUC protocol and notify the IRB if appropriate. The IRB will take the ACUC 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 Radiation Safety Committee (RSC)

All proposals to administer radioactive material to humans or ionizing radiation for research purposes from sources external to the body must have radiation use authority (RUA) and IRB approval. The RUA process involves the Office of Environment, Health & Safety to review the final protocol and obtain the required approvals from a subcommittee of the Radiation Safety Committee (RSC) comprising the Radiation Safety Officer (RSO), members of the RSC and the IRB, and a medical professional knowledgeable about the biological effects of radiation. Administration of radiation or radioactive materials to human subjects may not be performed without both up-to-date CPHS approval and a current RUA

Upon identification of an affirmative response to the use of radioactive or ionizing radiation the Director of OPHS (or his/her designee) and the RSO will communicate as per their standard operating procedures for intra-office communication. The IRB will take the RSC determination into account when making a decision to require changes to the protocol and/or informed consent forms; and, approve or deny the application for the human subjects research. The IRB will notify the RSO of changes, if any, it makes as a result of its consideration of the RSC's recommendations. The RSO will issue the RUA when informed that there are no changes or the changes are acceptable to the RSC Chair.

1.2.4 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) and the Laser Safety Officer will communicate as per their SOP for intra-office communication. 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.

1.2.5 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.

1.2.6 Conflict of Interest (COI) Committee

The OPHS Director is responsible for coordinating communication between the COI Committee, COI Administrative Staff and the IRB for research protocols that indicate a potential financial conflict of interest as identified on the CPHS Checklist for Financial Conflict of Interest – Human Subject Studies. When a positive (yes) response is noted on the Checklist, OPHS staff either notify the COI Administrator to review an electronic (eProtocol) submission or they prepare a hard copy packet consisting of the CPHS Application Coversheet (copy), COI Checklist (original) and a copy of the Protocol Narrative. The Director maintains a log of COI submissions and a copy of the COI Checklist is kept in the protocol file.

The IRB does not approve an application nor make a determination of exemption until notified by the COI Committee that there is: 1) no substantive financial conflict of interest present; or, 2) the conflict is being managed and the COI Committee's management plan may necessitate revision or modification of the consent form prior to final IRB approval of the protocol or a determination of exemption by the IRB.

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 research administrators communicate directly with OPHS to confirm IRB approvals before SPO releases funding. OPHS staff also carbon copy IRB approval and administrative closure letters to a designated SPO email address if the project is externally funded through SPO.

SPO and the IRB through OPHS coordinate on the review and comparison of Department of Health and Human Services (DHHS) funded human subjects research as per RR 411 – Grant Protocol Review.

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. In addition, the Graduate Division is copied on all IRB determinations of exemption, findings of “not human subjects research” or approval letters involving graduate students as lead investigators or key personnel on a protocol.

1.2.10 Departmental or Unit Liaison

The OPHS Director (or designee) will serve as a liaison for departmental or unit pre-IRB submission review processes and facilitate communication between the IRB and/or OPHS and supporting components campus-wide.

1.2.11 Industry Alliances Office (IAO)

The OPHS Director is responsible for coordinating communication between the staff of the IAO and the IRB involving protocols with industry sponsorship. In addition, the IAO is copied (Cc’ed) on 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 IRB Manager 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 IRB Manager (or his or her designee) with the appropriate entity, depending on the issue in question. Specific, detailed standard operating procedures are followed for each different unit with which there is frequent, regular communication.