| P&P: GA 102a<br>Version No: 1.8<br>Effective Date: 7/18/2023 | TRAINING AND EDUCATION FOR IRB MEMBERS & OPHS STAFF | Supercedes: CPHS Policies and Procedures 8/8/2017 |
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## 1. POLICY

The UC Berkeley Human Research Protection Program (HRPP) recognizes the important role of training and education to fulfill its mandate to protect the rights, safety, and welfare of research subjects in a consistent manner throughout the University of California, Berkeley research community. Therefore, IRB members, OPHS staff, and others charged with responsibility for reviewing, approving, and overseeing human subjects research must receive training in the regulations, guidelines, ethics, and policies applicable to human subjects research.

### Specific Requirements

### 1.1 Training

1.1.1 Management-level OPHS staff and members of any IRB who are overseeing research on human subjects, as defined in 45 CFR 46.102(f) and/or 21 CFR 56.102(e), that is managed by, funded by, or taking place in an entity under the jurisdiction of the Regents of the University of California, Berkeley will receive initial and ongoing training regarding the responsible review and oversight of research and the Committee for Protection of Human Subjects policies and procedures.

1.1.2 The Director of the Office for Protection of Human Subjects (OPHS), with endorsement of the Institutional Official (IO) or his/her designee, establishes the educational and training requirements for IRB members and OPHS staff who review biomedical and social-behavioral research involving human subjects at this institution and who perform related administrative duties. Initial and ongoing training is provided and documented by this institution through the Director and/or Assistant Director.

1.1.3 Members of the IRB will participate in initial and continuing training in areas germane to their responsibilities, and as required by specific funding agencies for UC Berkeley's receipt of funding or for the review of FDA-regulated protocols.

1.1.4 Chairs will receive additional training in areas germane to their specific responsibilities.

1.1.5 OPHS staff will receive initial and continuing training in the areas germane to their responsibilities, including all OPHS standard operating procedures (e.g., eProtocol Manual and the CPHS Policies and Procedures).

1.1.6 IRB members and OPHS staff will be encouraged to attend workshops and other educational opportunities focused on IRB functions. UC Berkeley will support

such activities to the extent possible and as appropriate to the level of responsibilities of members and staff.

### 1.2 Documentation

Training and continuing education shall be documented and added to the records of the IRB as described in these policies and procedures. Copies of training documentation for the IO, CPHS Chairs, and OPHS staff will be kept by the Director of OPHS.

## 2. SCOPE

These policies and procedures apply to all UCB IRB members and OPHS staff.

## 3. RESPONSIBILITY

The OPHS Director is responsible for oversight (development, conduct, and support) of all relevant training programs for IRB members, OPHS staff, and as appropriate, others involved in the oversight or conduct of human subjects research. The Director (or designee) serves as the CITI Coordinator for the UCB HRPP.

The IRB Chair and/or Vice Chair(s) may participate in the initial orientation and training of new IRB members as well as refresher training for all IRB members.

The Director, in collaboration with the OPHS Assistant Director, is responsible for developing, implementing, and documenting educational programs for IRB members and staff.

The OPHS staff is responsible for receiving training reports (documentation) from investigators and maintaining these completed CITI training records.

The OPHS Director and/or staff (as assigned) are responsible for providing face-to-face consultation, workshops, and presentations to investigators per request, time permitting, or on an as-needed basis.

## 4. PROCESS OVERVIEW

**New IRB Members**

- New IRB members are required to attend an Orientation and Training session hosted by the IRB Chair (or his/her designee). This session is developed and implemented by the IRB Chair and Director of OPHS, with assistance from other OPHS staff. Topics discussed include the role and responsibilities of being an IRB member, as well as the expectations of the position, particularly regarding conflicts of interest and confidentiality issues dealing with his/her service on the IRB. The new member will also receive practical training in how to review and present IRB submissions to the full board.

- A member of the OPHS staff will also notify the new IRB member of CPHS meeting dates and provide instruction as needed on how to access member materials online.
- Incoming new IRB members are encouraged to attend a meeting of the IRB as an observer prior to their formal appointment to meet future colleagues, gain context for their training, and observe the review process and ensuing discussions.
- A new Institutional Official (IO), IRB Chair, or Human Protections Administrator (HPA) should complete appropriate online training as available through CITI and any training as required for FWA Addenda for the Department of Defense (DoD).
- As part of their CITI training, all IRB members should read the Belmont Report.
- New IRB members are required to complete the initial CITI online training program module for IRB Members. Completion of other modules is optional.
- Additional one-on-one training for IRB members is provided as needed by the Director, Assistant Director, or IRB Analysts.
- New IRB Chairs, Vice Chairs, and designated IRB reviewers receive training for their additional responsibilities pertaining to expedited reviews.

**Continuing Education of IRB Members**

- IRB members periodically receive information to supplement or supplant existing information that is available on the CPHS web site.
- IRB members are encouraged to attend human subjects-related conferences, seminars, and workshops on and off campus. Institutional support may be available to support expenses related to attending off-campus educational events.
- IRB members may be emailed online resources (or links to resources) on timely topics, new regulations, and/or guidelines from agencies and task forces or commissions.
- Continuing IRB members are encouraged to complete additional CITI training modules and/or the refresher modules as appropriate.
- Mini-refresher training courses may be presented to IRB members by the OPHS Director (or designee).
- As needed, time will be set aside at IRB meetings to provide information and education on topics germane to current issues the IRB must consider. These topics are presented by various internal and external IRB experts including OPHS staff members.
- One-on-one training is provided as needed by the Director or Assistant Director.
- The Vice Chancellor for Research and/or the Assistant Vice Chancellor for Research Administration and Compliance may support the attendance of the IRB Chair or Vice Chairs at PRIM&R IRB training sessions, or related pre-conference workshops, as well as other national/regional meetings.

**OPHS Staff Members**

- The Assistant Director and other OPHS staff are required to complete one basic human subjects training course, the online CITI group designated for OPHS Staff, and may complete others such as the NIH training program *Protecting Human Research*

*Participants*. In addition, completion of the DoD online training modules is required along with an every-three-years refresher course.

- Full-time OPHS staff are also required to complete HIPAA training and other training as required by the institution as a condition of employment.
- Optional supplemental training is available through the books and periodicals in the OPHS library.
- OPHS staff are encouraged to participate in video or satellite teleconferences, webinars and online learning activities, and to read the IRB Forum listserv discussions.
- The Assistant Director and IRB Administrators are expected to attend IRB Administrator 101 or 201 and other similar events sponsored by professional organizations and oversight agencies. Depending on the unit budget, attendance will be supported at one or more human subjects research-related conferences (regional and/or national) annually or as needed for development and maintenance of expertise in human subjects protections (e.g., Certified IRB Professional (CIP) certification).
- OPHS staff members will be expected to attend conferences and workshops as pertinent to their job responsibilities or as needed for development and maintenance of expertise in human subjects protections (e.g., CIP Certification), depending on the unit budget.
- OPHS staff will participate in educational training activities hosted by the Director (or his/her designee) for staff development and training.
- All OPHS staff members are expected to be familiar with the CPHS Policies & Procedures, the OPHS office procedures, and the UCB CPHS website.
- All OPHS staff are required to read the Belmont Report.

**Other Administrators Associated with Oversight of Human Subjects Research**

- The Director should attend human subjects research-related conferences (regional and/or national) annually or as needed to facilitate the management and growth of the UCB Human Research Protection Program (HRPP), and for professional development and maintenance of expertise in human subjects protections.
- The IO, IRB Chairs, and Director must also complete initial and refresher training as may be required by agencies for UCB to receive funding and/or finalize an addendum to the institution's Federalwide Assurance.

The Director will also participate in many of the educational activities outlined for IRB members and OPHS Staff members.

## 5. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.107

45 CFR 46.107

Belmont Report

OHRP IRB Guidebook

Department of Defense Directive

http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf

NIH NOTICE: OD-00-039 Required Education in the Protection of Human Research Participants

Institutional Review Board Member Handbook by Amdur

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

CITI - UC Berkeley Information Page