

P&P: GA 102 Version No: 1.6 Effective Date: 5/1/2015	TRAINING AND EDUCATION	Supercedes: CPHS Policies and Procedures 5/5/2014
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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 detailed training in the regulations, guidelines, ethics, and policies applicable to human subjects research. Likewise, principal investigators, post docs, research staff, students and volunteer research staff must be knowledgeable about the policies and regulations that protect individuals who participate as subjects in 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 the 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.
- 1.1.7 Any UCB academic senate faculty member submitting his/her first protocol as PI to CPHS on or after 5/1/2014 must complete the UC Berkeley-affiliated online Collaborative Institutional Training Initiative (CITI) human subjects research basic training course – biomedical or social-behavioral – most germane to the type of research s/he will be conducting. Academic senate faculty who have previously submitted protocols as a principal investigator and received CPHS approval are strongly encouraged to take the appropriate CITI course as above or the respective refresher course, but are in effect “grandfathered” as exempt from this general training requirement. However, some exceptions exist, e.g., funding agencies may require specific training to meet their requirements for receipt of funding. See 1.1.8, 1.1.9 and 1.1.11 for exceptions to 1.1.7.
- 1.1.8 In accord with the specific federal funding policies, UCB PIs (including all academic senate faculty) and non-student key personnel who are funded by either (1) the National Institutes of Health (NIH) or (2) the Department of Defense (DoD) and/or a DoD-related units (e.g. Army, Navy, Air Force) are required to meet the funding agency’s initial education and IRB training requirements before a protocol can be approved (or re-approved, if up for renewal) and before funding is released. These two agencies require initial training and, in certain circumstances, refresher training. Researchers can meet the requirement by completing and passing the UC Berkeley-provided CITI online human research course most germane to their area of research (i.e., biomedical or social-behavioral). Academic senate faculty who have previously submitted protocols as a principal investigator and received CPHS approval may meet the NIH Human Subjects Education and Training requirement by taking the NIH online course Protecting Human Research Participants dated March 1, 2008 or later.
- 1.1.9. All UCB research personnel, including faculty exempt under 1.1.7 above, who are collaborating with other UC institutions and want to use the UC System Memorandum of Understanding (either to have UCB review or to rely on another UC institution’s review) must complete and pass the CITI online human research course most germane to their area of study (i.e., biomedical or social-behavioral) prior to completing the Reliance Registry process. Note: If the multi-campus UC study is NIH- or DoD-funded, academic senate research personnel (only) may substitute the relevant funding agency’s online training for the required UCB CITI online training course.
- 1.1.10 All other UCB human subjects research personnel (e.g., adjunct or visiting faculty, staff, undergraduate or graduate students, visiting or post-doctoral scholars etc.) engaged in human subjects research must complete and pass the CITI online human research course for UCB that is most germane to their area of research (i.e., biomedical or social-behavioral) prior to being added to an

approved protocol and engaging in human subjects research. Non-UCB engaged personnel whose human subjects research activities are reviewed by UCB must also complete and pass the CITI online human research course or have human subjects research protection training provided by the UCB researchers as outlined in the eProtocol application.

- 1.1.11 All UCB investigators who are engaged in FDA-regulated research must complete and pass the online biomedical course sequence of the basic human subjects research CITI course prior to the FDA-regulated study receiving IRB approval.

1.2 Documentation

- 1.2.1 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.
- 1.2.2 OPHS maintains records of CITI training completed since September 1, 2005. OPHS may accept documentation of comparable CITI training obtained at other institutions at the discretion of the Director of OPHS. Investigators must maintain documentation of any other human subjects training obtained (e.g. NIH online training) for their records. Within eProtocol submissions, investigators must provide training completion dates on the personnel information page and provide copies of the training certificates in the attachment section.

2. SCOPE

These policies and procedures apply to all UCB IRB members, investigators and research staff, OPHS staff, and as appropriate, others involved in the oversight or conduct of human subjects research.

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 serves as the CITI Coordinator for the UCB HRPP.

The IRB Chair and/or Vice Chair(s) 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 or on an as-needed basis.

The Principal Investigator (PI) must ensure that s/he completes training as required per this policy and inform his/her research staff of the need for training as appropriate.

The PI must ensure that non-UCB affiliated volunteer research staff complete and pass CITI online training, and ensure that said individuals' roles are described in the protocol and documentation of their CITI completion uploaded with the protocol. In the event that non-UCB affiliated volunteer research staff do not have access to a computer and/or the internet, the PI may request that CPHS approve an alternative means of training and the PI must document alternative training for said research staff.

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 in regard to conflicts of interest and confidentiality issues dealing with his/her service on the IRB. The new member will also receive practical training as to 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.
- The new IRB member will attend a meeting of the IRB as an observer, in order to meet colleagues and observe the review process.
- A new Institutional Official (IO), IRB Chair, or Human Protections Administrator (HPA) must complete the Office of Human Research Protections (OHRP) Assurance Training Modules as soon as possible after assuming his/her responsibilities. Likewise, these individuals must complete any training as required for FWA Addendums 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 Collaborative Institutional Training Initiative (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.

The new IRB member will not be added to UCB's IRB roster with OHRP until s/he has completed the Orientation and Training session and online CITI IRB Member training,

provided the documentation required (e.g. curriculum vitae, training certificate), and attended at least one CPHS meeting as a guest/observer.

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.
- At least once a year, a mini-refresher training course will 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 Investigator 101 CD ROM training program; reading materials such as *Protecting Study Volunteers in Research; Institutional Review Board Member Handbook; Institutional Review Board: Management and Function*; and IRB-related periodicals such as *IRB: Ethics and Human Research*.
- 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 101 or 250, IRB Administrator 101, 201 and/or 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).

- Other 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).
- 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 IO and the Assistant Vice Chancellor for Research Administration and Compliance (AVC-RAC) should complete the Office of Human Research Protections Assurance Training Modules.
- The Director must complete the Office of Human Research Protections Assurance Training Modules.
- The Director will 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 Federal Wide Assurance.

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

UC Berkeley Investigators

- Investigators who are requesting funding from NIH must meet the NIH Human Subjects Education and Training requirement by completing and passing the UC Berkeley-provided CITI online human research course most germane to their area of research (i.e., biomedical or social-behavioral). Academic senate faculty who have previously submitted protocols as a principal investigator and received CPHS approval may meet the requirement by taking the online course *Protecting Human Research Participants* dated March 1, 2008 or later and certify to the Sponsored Projects Office that they have met the NIH requirement. (See 1.1.9 above)
- Investigators who are requesting funding from DoD (or its sub-units) must meet the DoD Human Subjects Education and Training requirement. Continuing education recertification will be required to document that refresher training has been done as required by the funding agency. (See 1.1.9 above)
- All UCB academic senate faculty members submitting their first protocol as PI to CPHS on or after May 1, 2014 must complete the Collaborative Institutional Training Initiative

(CITI) online human subjects training modules most germane to the type of research they will be conducting prior to their protocol being approved. Academic senate faculty who have previously submitted protocols are strongly encouraged to take the basic CITI course or the refresher course, but are in effect “grandfathered” as exempt from this requirement. (See 1.1.7 and 1.1.8 above for details)

- Non-faculty senate and adjunct faculty, undergraduate and graduate students, staff, and visiting or post-doctoral scholars engaged in human subjects research must complete and pass the CITI online training human research course most germane to the type of research project they will be engaged in (i.e., biomedical or social-behavioral) and submit documentation to CPHS of completion with their application materials along with providing completion dates on the personnel information page.
- Non-UCB engaged personnel whose human subjects research activities are reviewed by UCB must either complete and pass the CITI online training human research course most germane to the type of research project they will be engaged in (i.e., biomedical or social-behavioral) or the UCB researchers must describe a human subjects research protection training plan in their eProtocol application for these personnel and have materials and documentation of training available to OPHS upon request.
- All UCB researchers including academic senate faculty who want to use the UC System Memorandum of Understanding to have UCB serve as the reviewing campus or rely on another UC institution’s IRB review must complete and pass the CITI online human research course most germane to their area of study (i.e., biomedical or social-behavioral). Alternatively, if the study is NIH-funded, the principal investigator and academic senate key personnel may substitute documentation of NIH online training (*Protecting Human Research Participants*) for the CITI online training program (per 1.1.9 above).
- All UCB investigators who are engaged in FDA-regulated research must complete and pass the online biomedical course sequence of the CITI prior to the FDA-regulated study receiving IRB approval.

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