P&P: GA 102b Version No: 2.0 Effective Date: 10/10/2022	TRAINING AND EDUCATION FOR INVESTIGATORS	Supercedes: CPHS Policies and Procedures 2/1/2021

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, principal investigators, post docs, research staff, students, volunteer research staff, and collaborators who are engaged in human subjects research 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 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 before 5/1/2014 are strongly encouraged to take the appropriate CITI course as above or the respective refresher course, but are exempt from this general training requirement as legacy PIs. However, some exceptions exist, e.g., funding agencies may require specific training to meet their requirements for receipt of funding. See 1.1.3 and 1.1.5 below for exceptions to 1.1.1.

1.1.2 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, alternatively, meet the NIH Human Subjects Education and Training requirement if they've completed the 2008 NIH online course Protecting Human Research Participants before 1/1/2021, or by completing the Human Research Protection Training offered by the HHS Office for Human Research Protections

(OHRP). All lessons must be completed in order to fulfill the training requirement.

1.1.3 All UCB research personnel, including faculty exempt under 1.1.1 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- funded, academic senate research personnel (only) may substitute the relevant funding agency's online training for the required UCB CITI online training course.

1.1.4 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 receive appropriate training. If available, non-UCB engaged personnel must complete and pass the CITI online human research course hosted by their home institution or by UCB (an affiliate CalNet is required). If the non-UCB engaged personnel are unable to access CITI training (e.g. no access to internet, computer, etc.) UCB researchers must provide human subjects research protection training for the non-UCB personnel they have outlined in the eProtocol application. UCB researchers are encouraged to use the PowerPoint "Working with Research Study Participants: An Overview" when providing training. The Human Research Protection Training offered by the HHS Office for Human Research Protections (OHRP) may also be used, and all online lessons must be completed in order to fulfill the training requirement.

1.1.5 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.

1.1.6 All UCB investigators who are engaged in human subjects research involving an NIH-funded clinical trial must complete and pass Good Clinical Practices (GCP) training through CITI in the area of study most germane to the research. GCP training should be refreshed at least every three years in order to stay up to date with regulations, standards, and guidelines.

1.1.7 All UCB investigators who are engaged in human subjects research involving the use of protected health information (PHI) are subject to the requirements of the HIPAA Privacy Rule and must complete and pass the Health Privacy(HIPAA) course through CITI .

1.1.8 Non-UCB engaged personnel must also complete the above-referenced training requirements, when applicable, which may require a CalNet affiliate account to access the above-referenced courses in CITI.

1.2 Documentation

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, OHRP training, etc.) for their records.

2. SCOPE

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

3. RESPONSIBILITY

The OPHS Director serves as the CITI Coordinator for the UCB HRPP.

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. In the event that non-UCB affiliated volunteer research staff do not have access to a computer and/or the internet, or access to the CITI program website, the PI (or other UCB researchers named in the protocol) may provide human subjects research protection training for said non-UCB affiliated research staff.

4. PROCESS OVERVIEW

PIs must complete required training, given the research context and funding, in a timely manner so as to prevent any delay in CPHS review and approval. PIs must also ensure that all research personnel are appropriately trained. OPHS staff will assist PIs in verifying CITI online training when a new protocol has been submitted for review, or when an approved protocol has been amended to add additional researchers.

5. APPLICABLE REGULATIONS AND GUIDELINES

- 21 CFR 56.107
- 45 CFR 46.107
- Belmont Report
- OHRP IRB Guidebook
- [Department of Defense Directive](#)

- NIH NOTICE: OD-00-039 Required Education in the Protection of Human Research Participants
- NIH NOTICE: NOT-OD-16-148 Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials
- Institutional Review Board Member Handbook by Amdur
- University of California System Memorandum of Understanding (dated May 2012)
- CITI - UC Berkeley Information Page
- UCB CPHS Guidance on HIPAA and Human Subjects Research