Policy & Procedure Training in the Responsible Use of Human Subjects in Research	Effective Date	02/01/2026
	Revision Date	01/2026
	Revision No.	3.0

I. PURPOSE & SCOPE

In order to fulfill the directive of the Human Subjects Committee (HSC) to safeguard the rights, privacy, safety, and welfare of research subjects throughout the Berkeley Lab research community and to comply with DOE Order 443.1C.Chg1, this document sets forth the requirements and procedures for completing training in human subjects' protection at Lawrence Berkeley National Laboratory (Berkeley Lab). This policy applies to all personnel conducting human subjects research (HSR) under the oversight of the HSC as the Reviewing IRB, as well as HSC members.

II. REVISION HISTORY

Date	Version No.	Change	Reference Section(s)
08/2021	1.0	New Procedure Drafted	Not Applicable
01/2026	2.0	Updated to meet DOE Order 443.1C.chg1 and adopt new formatting	All

III. POLICY

Per DOE Order 443.1C.chg1, researchers who submit studies to the DOE central and DOE site IRBs, including the HSC at Berkeley Lab, and members of these IRBs must complete initial and periodic refresher training in human subjects' protection. It is the policy of the HSC that all personnel conducting or reviewing human subjects research at or for the Berkeley Lab complete an appropriate training no less than once every 3 years in the subject area that meets their role.

A. Qualifying Training Courses

1. Training completed through CITI Program that are specific to human subjects protections typically satisfy the course requirements. Currently accepted courses include:
   a) The following courses completed under the institutional affiliation "Other DOE"
      (1) Biomedical Research Basic/Refresher Course - for researchers collecting biological or medical data from participants through direct interaction or intervention.
      (2) Social & Behavioral Research Basic/Refresher Course - for researchers collecting social/behavioral data from participants through direct interaction or intervention.
      (3) Other Key Staff Basic/Refresher Course – this abbreviated course is for engaged researchers working only with data and having no direct interaction with

participants.

(4) IRB Members – a basic course required for both voting and alternate members of the Human Subjects Committee, and recommended for non-voting members. The HSC Chair and IO are additionally recommended to complete the courses specific to their roles.

b) The following courses completed under the institutional affiliation "Department of Energy"

(1) Biomedical Research Basic/Refresher

(2) Social & Behavioral Research Basic/Refresher

(3) Biomedical Data or Specimens Only Research

(4) IRB Members

2. Foundational training offered by the Office for Human Research Protections (OHRP) is a free option that is accepted as a minimum requirement.
   a) All research staff are required to complete Lessons 1 through 4 in order to meet the minimum requirements.
   b) HSC members and Chairs must complete Lessons 1 through 5 to meet the minimum requirements. Additional review of the scenarios in Considerations for Reviewing Human Subjects Research are recommended, and may be presented to the full committee as continuing education.
   c) Responsible personnel who are conducting informed consent discussions may additionally be required to complete the OHRP-hosted Participant-Centered Informed Consent Training, at the discretion of the HSC.
3. Other courses can be evaluated for equivalency by the HARC Office on a case-by-case basis. Examples of acceptable training courses may include, but are not limited to, CITI training in human subjects protections under another institutional license or institutionally-hosted equivalent training.

B. Additional Considerations

1. Researchers who submit studies to the central DOE IRBs and members of the central DOE IRBs must additionally complete DOE-specific training that includes a module on recognizing and addressing bias in the design, review, and conduct of HSR. See Current Central DOE training information.
2. Access to the CITIprogram courses through the institutional affiliation "Department of Energy" is available for Berkeley Lab employees, affiliates, subcontractors, and collaborators. Specific directions for how to navigate this resource are available at the HSC Training website - https://commons.lbl.gov/spaces/harc/pages/93095498/Training+in+the+Responsible+Conduct+of+Human+Subjects+Research.

IV. PROCEDURES

A. Documentation of up-to-date training is required to be submitted to the HARC Office for all personnel listed as study staff on a human subjects protocol under the oversight of the HSC. Documentation can be in the form of any Certificates of Completion or Completion Report (certificate/report) that includes the date of completion, and can be submitted in any of the following ways:

1. Email the certificate of completion or completion report to HARC@lbl.gov
2. Include the certificate/report as an attachment when submitting the HARP Account Request Form.
3. Upload the completion certificate/report into an HSC-approved location, as determined by the HARC Office.

B. The HSC reviews training at the time of initial and continuing review of human subjects protocols for all engaged personnel covered under the Berkeley Lab Federalwide Assurance (e.g. employees, affiliates, and individual investigators covered under an Individual Investigator Agreement).

1. For all HSR protocols housed within the HARP system, training completion dates and documentation should be uploaded into the Researcher Profile by HARC staff.
2. When HSR protocols are housed outside of the HARP system, the HSC must be given access to verified training documentation in order to ensure all personnel are in compliance, such as by uploading documentation into an HSC-approved location.
3. For collaborative projects, Berkeley Lab requires the relying institution to maintain their own proof of training for all engaged investigators. These records must be made available to the HSC upon request.

C. **Equivalency Review**: Personnel who have previously completed training in human subjects protections can submit the course curriculum and the corresponding proof of completion to the HARC Office via email to HARC@lbl.gov. Course content will be reviewed for equivalency to the basic elements in the currently approved training. The investigator will be informed via email of the results of the review, and approved training will then be documented in the same manner established above.

V. ROLES & RESPONSIBILITIES

Role	Responsibility
Protocol Lead Investigator	The PLI on the study is responsible for completing training as required per this policy and for ensuring all staff are up-to-date on training, as appropriate.
Study Personnel	All personnel are responsible for completing training as required per this policy and submitting documentation.

Role	Responsibility
HSC Committee Members	All members are responsible for completing training as required per this policy. During review, members are responsible for ensuring that protocol personnel have met training requirements.
HARC Staff	Administrative staff are responsible for uploading the proof of completion, and facilitating these procedures.

VI. AUTHORITIES AND REFERENCES

Title	Web Link (as of 01/2026)	Description	Type
10 CFR Part 745	https://www.ecfr.gov/current/title-10/chapter-III/part-745	The Common Rule regulations - Dept of Energy version	Regulatory Auth…
DOE Order 443.1C.chg.1 - Protection of Human Research Subjects (or current version)	https://www.directives.doe.gov/directives-documents/400-series/0443.1-border-c-chg1-ltdchg	Dept of Energy Order applicable to research performed by or through LBNL. Contractor Requirements Document is incorporated into Contract 31.	Regulatory Auth…
45 CFR 46	https://www.ecfr.gov/current/title-45/part-46	The Common Rule regulations - HHS	Regulatory Auth…
21 CFR Parts 50 & 56	https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-50 https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-56	Food & Drug Administration (FDA) regulations governing human subjects research and IRB requirements for FDA-regulated products.	Regulatory Auth…
UC-DOE Prime Contract	https://www.ucop.edu/laboratory-management/contracts/lbnl/index.html	UC-DOE Prime Contract for the management and operation of Lawrence Berkeley National Laboratory (LBNL).	Source Require…
The Belmont Report	https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html	Foundational document outlining core ethical principles and guidelines for research involving human subjects.	Source Require…
UCOP Policy for Protection of Human Subjects in Research	https://policy.ucop.edu/doc/2500499/ProtectHumanSubject	Governing policy for the University of California system, applicable to research performed by LBNL.	Source Require…
Berkeley Lab's Federalwide Assurance for	https://commons.lbl.gov/download/attachments/93095490/FWA%208-16-2021.pdf?version=1&modificationDate=1629153435063&api=v2	Current version of FWA on file with the Office for Human Research Protections (OHRP)	Source Require…

Protection of Human Subjects			
PUB-3000 Chapter 22 03.02.002.001	https://ehs.lbl.gov/resource/esh-manual-pub-3000/ch22/	Overview of standards for Research with Human and Animal Subjects	Source Require…
OHRP Foundational Training	https://www.hhs.gov/ohrp/education-and-outreach/human-research-protection-training/human-research-protection-foundational-training/index.html	Free training in human subjects protections curated and hosted by OHRP.	Reference Mate…
Human Subjects Committee Charter	https://commons.lbl.gov/download/attachments/93095490/LBNL%20HSC%20Charter%202021%20FINAL.pdf?version=1&modificationDate=1633976726304&api=v2	Charter establishing HSC composition and high level processes.	Implementing D…
HSC Website	https://commons.lbl.gov/display/harc/Human+Subjects+Committee	Website for the Human Subjects Committee that holds extensive resources.	Reference Mate…