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Training in the Responsible Use of Human Subjects in Research	Document No.:	HSC-2021-001
	Effective Date:	September 1, 2021
	Revision Date:	
	Revision No.:	
	Approval:	HSC Approved August 27, 2021

A. Purpose

This document sets forth the requirements and procedures for completing training in human subjects protection for individuals engaged in conduct or review of human subjects research at Lawrence Berkeley National Laboratory (Berkeley Lab).

B. Persons Affected

- All personnel conducting human subjects research for or as a part of BERKELEY LAB. (Including contractors, collaborators, and staff)
- Human Subjects Committee members, including alternates.

C. Exceptions

In the case of a study being covered as a part of the UC Reliance Registry, there is a Memorandum of Understanding (MOU) in place that states, "All participating campuses agree to accept one another's trainings". Therefore, if the study in question includes a Notice of Intent to Rely (NOITR) as a part of the UC Reliance Registry, the training for personnel from the relying or reviewing institution will be accepted as required by their home institution.

D. Policy Statement

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 as a requirement to ensure more consistent and documented training of those involved in human subjects research and/or the review of such research at Berkeley Lab, all individuals conducting or reviewing research in a Berkeley Lab study must take the research-appropriate course on the Collaborative Institutional Training Initiative (CITI) Program's website.

1) Training Requirements

a. As of September 1, 2021, the HSC requires that all study personnel conducting human subjects research at or for the Berkeley Lab complete the appropriate CITI training no less than once every 3 years, choosing from those courses listed under Human Subjects Research:

i. Biomedical Research Basic/Refresher Course

ii. Social & Behavioral Research Basic/Refresher Course

iii. Other Key Staff Basic/Refresher Course

b. Alternatively, all personnel who have previously completed an equivalent training can submit their corresponding proof of completion for determination from HARC staff of fulfilling the requirement. Examples of acceptable training courses include, but are not limited to, CITI training in Good Clinical Practices, Human Subjects Protections, or Responsible Conduct of Research.

c. All HSC members, including alternates, are required to complete the IRB Members Basic/Refresher course no less than every 3 years, with initial training being completed within the first 3 months of appointment to the committee.

d. The Chair of the HSC is required to complete the IRB Chair Basic/Refresher course, in addition to the IRB member course, no less than every 3 years.

2) Procedures

a. To complete the required trainings as a part of the Berkeley Lab research community, individuals must register at citiprogram.org with an Organization Affiliation of "Other DOE".

b. If an individual already has a CITI profile from a previous organization, they can "add an affiliation" on the My Courses Homepage using "Other DOE" as the new organization.

c. Once in the Select Curriculum page, the applicable training should be selected under Question 1 Human Subjects Research.

d. Once the required modules have been completed, the proof of completion can be downloaded by selecting the View-Print-Share Record button.

e. Completion Certificates or Completion Reports can be sent to HARC staff for upload to the HARP profile for the individual.

E. Roles & Responsibilities

Role	Responsibility
Protocol Lead Investigator	The PLI on the study is responsible for completing training as required per this policy and for informing their staff of the need for training as appropriate.
Study Personnel	All personnel are responsible for completing training as required per this policy and submitting documentation.
HSC Committee Members	All members are responsible for completing training as required per this policy. Additionally, during review members are responsible for ensuring that protocol personnel have training documented that meets the requirements of this policy.
HARC Staff	Administrative staff are responsible for uploading the proof of completion for all persons into their profile within the electronic protocol system.

F. Definitions/Acronyms

a. **Research:** A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition and do not fall under one of the exclusions at 45 CFR 46.102(l)(1)-(4) constitute research for purposes of this policy whether or not they are conducted or supported under a program which is considered research for other purposes.

   i. **Systematic Investigation:** a study or examination involving a methodical procedure or plan.

   ii. **Generalizable knowledge:** The information is expected to expand the knowledge base of a scientific discipline or other scholarly field of study and yield one or both of the following:

   - Results that are applicable to a larger population beyond the site of data collection or the specific subjects studied. OR
   - Results that are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study.
   - Usually includes results shared at conferences and public forums, included in abstracts, or published in journals or other literature, outside the institution.

b. **Human subject:** A living individual about whom an investigator (whether professional or student) conducting research: (1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies or analyzes the information or biospecimens; or (2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. In clinical research, a subject is someone who becomes a participant in research, either as a recipient of the test article or as a control.

   i. **Intervention** includes both physical procedures by which data or biospecimens are gathered (e.*g.*, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

   ii. **Interaction** includes communication or interpersonal contact between investigator and subject.

c. **HARC:** The Human and Animal Regulatory Committees office. Operated as a part of the EH&S division, staff are responsible for the administration of the Human Subjects Committee, Animal Welfare and Research Committee, and the Radioactive Drug Research Committee.

d. **HARP:** The Human/Animal Research Protocol Management System. The system housing online "smart" forms that lead all Berkeley Lab researchers through protocol application, renewal, amendment, and adverse/unexpected event reporting processes.

e. **Protocol Lead Investigator:** The researcher with primary responsibility for conducting human subjects research under a specific protocol.

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G. Recordkeeping Requirements

All documentation of completed trainings will be maintained through the upload of completion reports or certificates to the Researcher Profile within the HARP system.

H. Implementing Documents

Document Number	Document Title	Type
N/A	Human Subjects Committee	Website
N/A	Human/Animal Research Protocol Management System	Website

I. Contact Information

Human and Animal Regulatory Committees Office
HARC@lbl.gov
(510) 486-5399

J. Revision History

Date	Revision	By whom	Revision Description	Section(s) affected	Change Type