



Policy & Procedure HSC Membership	Effective Date	02/01/2026
	Revision Date	01/2026
	Revision No.	1.0

I. PURPOSE & SCOPE

This document establishes the requirements and expectations for members of the Human Subjects Committee (HSC), the Institutional Review Board for Berkeley Lab. The composition of the committee, member standards and responsibilities, and processes of member appointment are all detailed below.

II. REVISION HISTORY

Date	Revision No.	Change	Reference Section(s)
10/2021		New Procedure Drafted	Not Applicable
02/2026	1.0	Reformatted, standardized terminology and requirements in line with approved Charter.	All

III. POLICY

A. Committee Composition

The HSC shall be composed as defined in the Committee’s Charter. This includes at least 5 members, including one member from each of the following categories; scientific, non-scientific, and unaffiliated. For the review of FDA-regulated studies, reviewers should include a physician. Should outside consultation be conducted, it should be reviewed by the HSC and included in the protocol discussion. There is no limit on the number of alternate members.

B. Member Appointments

Each member is appointed for a term of up to three years and there is no limit to the number of terms a member may serve. Extension letters should be provided to clarify the new term’s expiration. Terms will be staggered whenever possible to minimize disruption of Committee functions.

Members may be designated as regular members or alternate members. Alternate members will only vote in the absence of their designated regular members, which is defined in their appointment letter or in the roster. All members may be designated by the Chair as having the experience and training necessary to review applications eligible for expedited review processes.



Ex-officio members are non-voting Subject Matter Experts (SME) who are not required to attend meetings regularly. Instead, these members will be called upon when specific needs arise for SME input on a protocol.

C. Maintaining Confidentiality

Service on the HSC includes the review of documents that contain personal, confidential and proprietary information. Members of the HSC are responsible for maintaining all committee proceedings and documents in strict confidence. Such information may not be used for any purpose other than the HSC review and should not be disclosed to anyone outside of the HSC unless permission is granted in writing by the Institutional Official for Human Subjects Protection.

IV. ROLES & RESPONSIBILITIES

Role	Responsibility
Scientific Member	Members whose training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline should be considered a scientist. Scientific members are expected to review assigned applications, as well as contribute to the evaluation of a research project on its scientific merits and standards of practice. These members are able to advise the HSC if additional expertise in a scientific area is required to assess if a research project adequately protects the rights and welfare of subjects.
Non-scientific Member	Members whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline should be considered a nonscientist. Non-scientific members are expected to provide input on matters germane to their individual knowledge, expertise and experience, professional and otherwise. Nonscientific members advise the HSC if additional expertise in a nonscientific area is required to assess if the research project adequately protects the rights and welfare of subjects.
Unaffiliated Member	Non-affiliated members are expected to provide input regarding their individual knowledge about the local community and be willing to discuss issues and research from that perspective. Must not have a direct affiliation (employee, contractor, student in a fellowship, volunteer at the institution, or business related to the IRB, and must not have an immediate family member who is affiliated with the institution).



HSC Chair	<p>In addition to scientific member responsibilities listed above, the Chairperson;</p> <ul style="list-style-type: none"> ● Reviews all applications presented to the HSC and communicates with other reviewers, as needed, so that important issues or concerns are resolved or identified prior to the convened HSC meeting. ● Directs the proceedings and discussion of convened HSC meetings ● Administers convened HSC decisions with assistance from HARC ● Serves as the primary liaison and authorized signatory for all formal committee communications, including recommendations to the IO and warning letters to researchers. ● Designates reviewers as eligible for the expedited review process as mandated by federal regulations 45 CFR 46.110(b) and 21 CFR 56.110(b). ● Consults with the HARC Office on NHR determination requests, when needed. ● Gives input on HSC matters whenever necessary, particularly in the case of questions fielded by the HARC office. ● Attends the HSWG meeting with the Department of Energy HSPP ● Stays up-to-date on regulatory guidelines and IRB issues through attendance at conferences and trainings as applicable ● Ensure the maintenance of a complete membership roster as required by 45 CFR 46, in conjunction with HARC
Primary Reviewer	<p>Primary reviewers are assigned a study based on their particular expertise in relation to the study. The primary review is expected to present a brief oral summary of the application at the beginning of the committee discussion and then to provide detailed comments about the protocol, and consent forms, if appropriate (typically requests for additional information or revisions). The primary will recommend a committee action.</p>
Secondary Reviewer	<p>A secondary reviewer is also assigned as backup and to provide additional comments and sometimes to provide comments in a particular area of expertise (e.g. non-scientist review of consent forms). These comments can be entered electronically in HARP or via email, either before or after the meeting, or provided verbally during the meeting. The secondary reviewer will also recommend a committee action.</p>
Institutional Official	<ul style="list-style-type: none"> ● Supports the HSC in their authority and decisions ● Completes initial and continuing education in the protection of human subjects. ● Ensures sufficient resources and institutional support for the human subjects protection program ● When necessary, assists the HSC by appointing investigative committees or committee members and by assuring that suspended research projects are shut down pending such investigation.



Berkeley Lab HARC Office	Responsible for facilitating all required communications, documentation, and administrative support for the reporting process as the staff supporting the HSPP. A Compliance Specialist from HARC will be a voting member of the HSC, with a primary role as SME on regulatory issues during protocol review.
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V. Procedures

A. Membership Appointment

Membership shall be discussed among committee members at least once each year as a part of annual self-assessment activities. Areas to review may include upcoming vacancies, term expirations, reappointments, and identification of areas where additional expertise may be needed. Recommendations shall be forwarded to the IO, who, in consultation with Lab management, shall assist in identifying candidates to fill the committee. Unexpected vacancies shall be addressed in a similar manner when they occur.

Members of the HSC may be nominated by the HSC or recommended by members of the Laboratory community. Before submitting a candidate, the recommender shall confirm that the candidate is willing to serve. Candidates will submit resumes to and be evaluated by the HSC, considering factors noted in the Charter under **Membership**. It is not expected that nominees will have taken training relative to serving on an HSC when nominated. The HSC may request additional information from the recommender or the nominee as necessary.

The IO will make appointments, as designated by the CEO, from the pool of nominees that have been evaluated. The IO has the sole authority to add or replace a member at any time. In replacing or re-appointing a member, consideration should be given to:

- o Attendance at HSC meetings
- o Conduct as an HSC member
- o Unresolved conflict of interest
- o Completion of required training
- o Completion of work assigned or requested
- o Willingness to continue serving on the HSC
- o Management support

The IO also has the authority to terminate a sitting member from the HSC prior to expiration of his or her term when there is “just cause.” Just cause for removal may include, but is not limited to, excessive unexcused absences, misconduct, unresolved conflict of interest, failure to complete required training, or a consistent pattern of failure to complete work as assigned or requested by the chair, vice chair, or HARC Office staff.

B. Expectations for Committee Members

The following expectations apply to all voting and alternate members, including the Chair.



- Complete initial and continuing education as defined in the Training Policy, preferably within the first 3 months following appointment;
- Attend scheduled meetings, with all members expected to attend at least 2/3 of all scheduled meetings. **Exception** Leaves of absence may be granted when requested in advance, and justified.
- Notify the HSC administrator promptly when unable to attend a meeting or perform a requested review;
- Review all materials distributed with the meeting agenda prior to scheduled meetings;
- Disclose and avoid conflicts of interest that could be perceived to impact the independence of their decision making, such as:
 - Members who have any disclosable financial interests (a) that would reasonably appear to be affected by the research; or (b) in entities whose financial interests would reasonably appear to be affected by the research, must recuse themselves from committee action.
 - Members who believe existing circumstances may directly affect their objectivity may request that they be recused from committee action.
 - Members with research or managerial interests in protocols that come before the committee should recuse themselves to avoid even the appearance of a conflict. This includes situations where:
 - The member is staff on the protocol
 - The member shares joint research interests and relationships with the protocol lead investigator(s) and/or co-protocol lead(s)
 - The member supervises or is supervised by the protocol lead investigator(s) and/or co-protocol lead(s)
- Attend a working session with the HARC Office on review processes prior to being designated as eligible to perform independent expedited review;
- Participate as primary or secondary reviewers or conduct expedited reviews when requested by the Chair, Vice chair, or HARC staff; and
- Perform other HSC-related activities when requested by the Chair, Vice Chair, or HARC staff.

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 Authorities
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 Authorities



45 CFR 46	https://www.ecfr.gov/current/title-45/part-46	The Common Rule regulations - HHS	Regulatory Authorities
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 Authorities
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 Requirements
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 Requirements
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 Requirements
Berkeley Lab's Federalwide Assurance for Protection of Human Subjects	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 Requirements
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 Requirements
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 Document
OHRP Guidance - Reviewing Unanticipated Problems	https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html#AA	Formal regulatory guidance from OHRP	Reference Material
OHRP Guidance - Reporting Incidents	https://www.hhs.gov/ohrp/compliance-and-reporting/guidance-on-reporting-incident/index.html	Formal regulatory guidance from OHRP	Reference Material
FDA Guidance - What is a Serious Adverse Event	https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event	Formal regulatory guidance from FDA	Reference Material
HSC Website	https://commons.lbl.gov/display/harc/Human+Subjects+Committee	Website for the Human Subjects Committee that holds extensive resources.	Reference Material