

Charter of the Human Subjects Committee at Berkeley Lab

1. Purpose

The Lawrence Berkeley National Laboratory (Berkeley Lab) Institutional Review Board, called the Human Subjects Committee (HSC), is established to safeguard the rights, privacy, safety, and welfare of research subjects throughout the Berkeley Lab research community. The HSC shall ensure that subjects are treated ethically and that the risks and benefits of the research are balanced, consistent with the principles set out in the Belmont Report: respect for persons, justice, and beneficence. All human subjects research performed at or funded through the Laboratory, or conducted off-site by Laboratory staff, shall be subject to Berkeley Lab HSC review, and shall not be performed unless approved by the HSC.

2. Objectives

The Committee shall support the following specific tasks:

- Establishment and maintenance of a Federalwide Assurance (FWA) with the Office for Human Research Protections (OHRP).
- Review of research proposals to ensure the protection of human subjects.
- Ensuring compliance with all applicable federal and state regulations; including 45 CFR 46, 10 CFR 745, 21 CFR 56, and DOE Order 443.1C (or current version).
- Certification to funding agencies, the Sponsored Projects Office and/or the Department of Energy that research has been reviewed and approved by the HSC.
- Education of Berkeley Lab human subjects researchers as needed.
- Recommendation of changes in Lab policy relevant to human subjects research to the Institutional Official.
- Oversight of approved research to ensure the continued safety and ethical treatment of human subjects.
- Reporting of unanticipated problems, non-compliance, complaints, and/or adverse events to the Berkeley Lab Institutional Official, Laboratory Director, and the DOE HSP Program Manager according to the requirements of the [DOE Order for Protection of Human Research Subjects](#) and the institutional policies for reportable events.
- Additional projects assigned by the Laboratory Director or Institutional Official.

3. Membership

The HSC shall consist of at least 9 voting members reflective of the different disciplines performing human subjects research at the Lab. At least one member shall have primary concerns in nonscientific areas, and at least one shall have primary concerns in scientific areas. At least one member shall be unaffiliated with Berkeley Lab, which includes lack of affiliation of their immediate family members. The Lab shall strive to ensure this committee reflects varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. Alternate members shall also be appointed as needed, with no specific limit on their number. The Chair shall ensure the maintenance of a Committee roster that lists each member by name, records their education, representative capacity, and

relevant experience with sufficient detail to describe their chief anticipated contributions to Committee deliberations and affiliation to Berkeley Lab, if any.

The HSC shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human participants. In addition to possessing the professional competence necessary to review specific research activities, the HSC shall be able to ascertain the acceptability of proposed research in terms of regulations, applicable law, and standards of professional conduct and practice. The HSC shall therefore include persons knowledgeable in these areas.

If the HSC regularly reviews research that involves a category of subjects vulnerable to coercion, such as children, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, or subject populations vulnerable to group harms, then consideration shall be given to the inclusion of one or more members who are knowledgeable about and experienced in working with these participants or groups. In the case of research that involves prisoners as subjects, in accordance with Subpart C of The Common Rule, the following IRB composition requirements will additionally be met:

- a) A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.
- b) At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement.

The HSC may, in its discretion, invite individuals with competence in special areas to assist in the review of issues, which require expertise beyond or in addition to that available on the HSC. These individuals may be invited to assist in a single case or issue, or may be appointed by the IO to serve as standing Consultants to the HSC, however, these individuals may not vote with the HSC.

More details on Membership are addressed in the HSC Membership Policy regarding processes and requirements.

4. Meetings & Reports

The Chairperson shall be responsible for calling meetings, setting agendas, relaying all necessary information relating to specific responsibilities and timelines, conducting meetings, and reporting outcomes.

In order to vote on a new or amended protocol that requires full board review, there must be minimum of five members present, including a scientist, a nonscientist, and an unaffiliated member. When reviewing FDA-regulated studies, convened members should include at least one physician. A simple majority, or quorum, of voting members must be present to convene a meeting and conduct business. Regulations prohibit any member from participating in the

HSC's review of any study in which the member has a conflicting interest, except to provide information requested by the HSC. Parliamentary processes of the committee shall be governed by the most recent edition of Sturgis' Rules of Order, as necessary.

The HARC Office, in consultation with the Chair of the HSC when needed, shall determine whether a project constitutes research involving human subjects and if so, what category of research is applicable. All research will be reviewed by either an expedited review process or full board review. In the case of exempt category research, a member of the HSC will conduct review of the study according to the institutional policy for Exempt Research Review. The members of the Committee must meet at least once per quarter. The Committee shall provide a report of all recent operations to the Institutional Official and Laboratory Director at least once a year.

5. Additional Reviews and Approvals

Activities and proposals that have been approved by the HSC may be subject to further review and approval by the Laboratory Director or their designees. However, these officials may not approve an activity involving human subjects research that is not sanctioned by the HSC.

6. References

- 45 CFR Part 46 (10 CFR 745), including subparts B, C, and D
- 21 CFR Part 56
- The Belmont Report
- DOE Order 443.1C (or current version), Protection of Human Research Subjects
- Berkeley Laboratory Health and Safety Manual, (Pub 3000) Chapter 22, Research with Animals and Human Subjects
- LBNL Requirements and Policies Manual, Human Subjects Research
- LBNL Requirements and Policies Manual, Conflict of Interest in Research – Human Subjects

Carol J. Burns

Carol Burns, Deputy Director and Institutional Official

Approval Date: 08 / 29 / 2024

Title	Updated HSC Charter
File name	LBNL_HSC_Charter_2024_Update_Final.docx
Document ID	5c6d22461127ea48a86f55494f83da043ef2d3d2
Audit trail date format	MM / DD / YYYY
Status	● Signed

Document History



SENT

08 / 29 / 2024

14:50:49 UTC

Sent for signature to Dr. Carol J. Burns (cjburns@lbl.gov)
 from ksmiller@lbl.gov
 IP: 98.114.198.36



VIEWED

08 / 29 / 2024

14:54:41 UTC

Viewed by Dr. Carol J. Burns (cjburns@lbl.gov)
 IP: 67.164.109.132



SIGNED

08 / 29 / 2024

14:55:15 UTC

Signed by Dr. Carol J. Burns (cjburns@lbl.gov)
 IP: 67.164.109.132



COMPLETED

08 / 29 / 2024

14:55:15 UTC

The document has been completed.