



## **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.
- 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 and/or adverse events to the Berkeley Lab Institutional Official, Laboratory Director, and the DOE HSP Program Manager.
- Additional projects assigned by the Laboratory Director or Institutional Official.

### **3. Membership**

The HSC shall consist of up to nine regular members, representing different disciplines. 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, prisoners, 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 individuals who are knowledgeable about and experienced in working with these participants or groups.

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.

#### **4. Meetings & Reports**

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

In order to vote on a new or amended protocol that requires full board review, there must be a minimum of five members present, including a scientist, a nonscientist, and an unaffiliated member. When reviewing FDA-regulated studies, convened members must 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 initial or continuing 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 Chair of the HSC, in consultation with the Committee, shall determine whether a project constitutes research involving human subjects. All research will be reviewed by either an expedited review process or full board review unless found by the HSC Chair



or their designee to be exempt. 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, Protection of Human 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, Human Subjects Conflict of Interest.

A handwritten signature in cursive script that reads "Carol Burns".

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**Carol Burns, Deputy Director and Institutional Official**

**Approval Date: October 8, 2021**