Lawrence Berkeley National Laboratory Institutional Review Board for Human Research Participants Protection Charter

1. Purpose

The Lawrence Berkeley National Laboratory Institutional Review Board (IRB) for Human Research Participants Protection is established to review research performed at LBNL that involves the participation of human subjects. The IRB shall ensure that subjects are treated ethically, and that the risks and benefits of 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 LBNL IRB review, and shall not be performed unless approved by the IRB.

2. Objectives

The Committee shall support the following specific tasks:

- Establishment and maintenance of a Federal-wide Assurance of Compliance.
- Review of research proposals to ensure the protection of human subjects.
- Certification to funding agencies, the Sponsored Projects Office and/or the Department of Energy that research has been reviewed and approved by the IRB.
- Education of LBNL 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 fair treatment of human subjects.
- Reporting of unanticipated problems and/or adverse events to the LBNL Institutional Official and Laboratory Director.
- Additional projects assigned by the Laboratory Director or Institutional Official.

3. Membership

The IRB shall consist of at least five members of 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 LBNL, 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.

The IRB 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 IRB shall be able to ascertain the acceptability of proposed research in terms of regulations, applicable law, and standards of

professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If the IRB regularly reviews research that involves a vulnerable category of participants, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these participants.

The IRB 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 IRB. These individuals may not vote with the IRB.

Members of the IRB shall be nominated by the IRB and appointed by the Institutional Official for a three year term. There shall be no limit to the number of terms a member may serve. At any time, a member can be added, removed, or replaced by the Institutional Official. In the event of the death, resignation, or removal of a member, the Committee shall promptly nominate a new member for consideration by the Institutional Official.

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.

A majority of the membership and at least one member whose primary concerns are in a non-scientific area must be present to convene a meeting and conduct business. Parliamentary processes of the committee shall be governed by the most recent edition of Sturgis' Rules of Order, as necessary.

4. Meetings & Reports

The Chair of the IRB, 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 IRB Chair or their designee to be exempt. The members of the Committee must meet at least once per quarter. Meetings shall be held in person whenever possible. 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 IRB may be subject to further review and approval by the Laboratory Director or his designees. However, these officials may not approve an activity involving human subjects research that is not sanctioned by the IRB.

6. References

- 45 CFR Part 46 (10CFR745), including subparts B, C, and D
- Berkeley Laboratory Health and Safety Manual, (Pub 3000) Chapter 22, Research with Animals and Human Subjects
- LBNL Regulations and Procedures Manual, Section 10.09, Human Subjects Conflict of Interest
- DOE Policy 443.1A, Protection of Human Subjects.
- DOE Order 443.1, Protection of Human Subjects

Approved:

Steven Chu, LBNL Laboratory Director

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