



Horst Simon
Deputy Director

October 15, 2012

To: LBNL Human Subjects Committee

cc: Gary Karpen, Life Sciences Division Director
Ashok Gadgil, Environmental Energy Technologies Division Director
Howard Hatayama, Office of Institutional Assurance Director
Christine Byrne, Human and Animal Regulatory Committees Office
Dianna Bolt, Human and Animal Regulatory Committees Office

From: Horst D. Simon, Deputy Laboratory Director and Institutional Official

A handwritten signature in black ink, appearing to read "H. Simon".

Re: Revised Institutional Review Board Charter

Attached is a revised Charter for the Laboratory's Institutional Review Board. It was developed with input from the Chair, Vice-Chair and Human Subject Protection Program Manager and reflects changes primarily to paragraph 4 of the section on membership.

To provide some background, the previous charter dated from 2/28/08 and needed to be brought current to reflect the perspectives of current leadership (Director Alivisatos and myself as the Institutional Official). The recent set of reappointment letters also highlighted the need for clarification of the process of appointing members and resulted in a review of the previous charter in that light.

One goal of this revision is to clarify the process of identifying upcoming vacancies, soliciting recommendations for appropriate potential members, and better defining the total committee size in terms of regular and alternate members. The new language is also explicit about formally re-appointing members to additional terms. This provides a check-point for all parties to re-affirm their commitment for another term. The role of an Alternate Member is also included in the charter. Authority to add, remove or replace a member continues to rest with the IO solely. The option of removing members will help to minimize disruptions of the Committee's work due to insufficient member participation.

Also attached are guidelines for implementing this revised Charter.

Thank you for your continued commitment to carrying out the provisions of this Charter and your service in ensuring the protection of human subjects in research conducted by the Laboratory.

Attachments

Lawrence Berkeley National Laboratory

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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 up to seven 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 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. Alternate members shall also be appointed as needed, with no specific limit on their number.

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 be invited to assist in a single case or issue, or may be appointed by the IO to serve as standing Consultants to the IRB, however, these individuals may not vote with the IRB.

Membership planning shall be discussed at an IRB meeting about April of each year, and upcoming vacancies, term expirations, reappointments, and other membership needs shall be assessed. 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 IRB may be nominated by the IRB 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 IRB to confirm that these individuals fall within the needed membership category, and have the requisite knowledge and understanding in order to be an informed participant in discussion of issues that come before the IRB. The IO will make appointments to the IRB from the pool of nominees that have been evaluated by the IRB. The IO has the sole authority to add or replace a member at any time. The IO also has the authority to remove a sitting member for cause at any time. 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. However, each member must be reappointed to serve each additional term. Terms will be staggered to minimize disruption of Committee functions. In the event of the death, resignation, or removal of a member, the Committee shall promptly seek recommendations for and nominate a new member for consideration by the Institutional Official.

Members may be designated as regular members or alternate members. Alternate members may attend any meeting but will only vote in the absence of their designated regular members. They may also be designated to review applications eligible for expedited review processes.

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 regular 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 (10 CFR 745), including subparts B, C, and D
- 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.
- DOE Order 443.1B, Protection of Human Subjects

Guidelines for Implementing the LBNL IRB Charter

3. Membership

Implementation Guidance

- In evaluating nominees for membership, the IRB should consider factors noted under **Membership**.
- It is not expected that nominees will have taken training relative to serving on an IRB when nominated.
- The IRB may request additional information from the recommender or the nominee as necessary.
- The IRB should evaluate its membership at least annually to identify areas where additional expertise may be needed and members whose terms will be expiring.
- The IRB should stagger the terms of its members so that eventually about one third of the members will finish their three-year appointments in any given year..
- Responsibilities of Committee Members
 - Completing initial training as directed by the Chair following appointment;
 - Attending scheduled meetings, with regular members expected to attend at least 50% of all scheduled meetings, and alternates at least 25%;
 - Notifying the HSC administrators promptly when unable to attend a meeting or perform a requested review;
 - Reviewing all materials distributed with the meeting agenda prior to scheduled meetings;
 - Participating as primary or secondary reviewers or conducting expedited reviews when requested by the chair, vice chair, or HSC administrators; and
 - Performing other HSC-related activities when requested by the Chair, Vice Chair, or HSC administrators.
- In replacing or re-appointing a member, consideration should be given to:
 - Attendance at IRB meetings
 - Conduct as an IRB member
 - Unresolved conflict of interest
 - Completion of required training
 - Completion of work assigned or requested
 - Willingness to continue serving on the IRB
 - Management support
- Termination by the IO of a member from the IRB prior to expiration of his or her term requires “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 IRB manager.