

Institutional Biosafety Committee (IBC) Charter

E. O. Lawrence Berkeley National Laboratory

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Policy and Purpose

Lawrence Berkeley National Laboratory (LBNL) requires maintenance of a qualified Institutional Biosafety Committee (IBC) to perform key biosafety functions as required by and in accordance with this charter and the National Institutes of Health (NIH), Centers of Disease Control and Prevention (CDC), Department of Energy (DOE), and LBNL standards.

The IBC is responsible for oversight, administration, and review of Berkeley Lab policies and projects involving research with biological materials that may pose safety, health, or environmental risks. The IBC reports to the Laboratory Director to provide institutional assurance that research is conducted safely. To this end, the IBC assists and advises researchers and line managers in meeting their responsibilities to ensure that the biological aspects of the research are conducted in a *safe* manner using established biosafety standards, principles and functions of [Integrated Safety Management \(ISM\)](#), and work authorization (e.g., PUB-3000, [Chapter 6](#)). *Safe* research includes worker safety, public health, agricultural and environmental protection, ethics, and compliance with applicable biosafety standards and LBNL policies. A graded process is used to define, document, review, and approve biological work and controls as detailed in PUB-3000, [Chapter 26](#). This process involves IBC approval and line management authorization of biological work.

Functions

Functions of the IBC include:

- Administer a program to review, approve, and monitor all LBNL research projects involving biological materials that may pose differing levels of safety, health, or environmental risk to plants, animals, or humans. The goal of this program is to assure work is conducted in a *safe* manner.

In this program, the IBC performs Initial and periodic review and approval of required project biosafety documentation that demonstrates the work will be conducted in a *safe* manner. Researchers and line managers are responsible for identifying and submitting project documentation to the IBC prior to performing biological work and periodically thereafter. The IBC's review includes:

- Assessment of the containment levels, facilities, procedures, practices, training, and expertise of personnel involved in the proposed research and in comparison to biosafety standards;
- Concurrence or approval of research projects that have adequate controls and conform to the biosafety standards; and
- Notifying the Principal Investigator of the results of the IBC's review or approval.

- Serve as a forum to review, make recommendations to appropriate stakeholders, and raise awareness related to biosafety concerns, institutional needs, emerging biosafety issues, and new biosafety requirements.
- Review and approve LBNL biosafety policies, and make recommendations to the Laboratory Director on strategic biosafety matters.
- Review and adopt LBNL emergency plans covering accidental spills and personnel contamination resulting from research and development activities with potentially hazardous biological materials. Site safeguards and security plans for biological etiologic agents (i.e., human pathogens) will also be reviewed.
- Coordinate LBNL response to inquiry from the public or external entities related to the IBC.
- Review violations or incidents and determine level of significance and required reporting. Investigate and report any significant problems with or violations of the NIH Guidelines and any significant research-related accidents or illnesses involving recombinant genomic materials to line management, the Biosafety Officer, the Laboratory Director, and the NIH Office of Biotechnology Activities (OBA) within 30 days, unless the IBC determines that the Principal Investigator or lead researcher has already filed a report.
- Submit an annual report to the Laboratory Director that includes a roster of IBC members, member roles, and a report of significant IBC and Biosafety Program activities.
- Submit an annual report to NIH OBA that includes a roster of IBC members, member roles, and biographical sketches of each member.
- Maintain reviews, minutes, and reports in an orderly and retrievable fashion.

IBC Membership

The Laboratory Director formally appoints all IBC members, and IBC membership is for a minimum three-year period of service. IBC member nominations are managed in the following manner:

- The IBC Chair and Deputy Chair nominations are recommended by the EH&S Division Director to the Berkeley Lab Director, who appoints the Chair and Deputy Chair for a three-year period.
- Other IBC members are nominated by their respective Division Directors to the IBC Chair or Deputy Chair. During the first IBC meeting following such nomination, the IBC will decide by simple majority vote on recommendation of the candidate to IBC membership. The IBC Chair then requests a final decision from the Laboratory Director on appointment of the nominee to serve on the IBC.

As required by NIH, the IBC must have at least five members that are selected to collectively have the experience, expertise, and capability needed to assess the breadth and safety of recombinant and other LBNL research with biological materials, agents, and organisms as needed to identify any potential risks to workers, public health, or the environment. Based on the types of research activities at LBNL, the IBC will normally have the following minimum representation:

- A technical representative from each LBNL Division that conducts research with potentially hazardous biological materials
- The EH&S Biological Safety Officer and Program Manager
- An expert in animal containment principles
- An expert in plant containment principles (if recombinant plant research is conducted)
- An expert in human research protocols
- A health professional from EH&S Health Services
- At least two members not affiliated with Berkeley Lab, who represent the interest of the surrounding community with respect to health and protection of the environment.

IBC member duties include:

- In the absence of the IBC Chair, the Deputy Chair will perform Chair duties.
- All IBC members are voting members. Decisions such as approval of research projects or policies are approved when a majority of IBC members vote for approval. No member of the IBC may be involved (except to provide information requested by the IBC) in the review or approval of a project in which he/she has been or expects to be engaged or has a direct financial interest.
- If an institutional member does not attend three meetings throughout the calendar year or participate in reviews of research projects, the IBC Chair may consult the member's Division Director to ask that a replacement be nominated.
- The IBC Chair is responsible for ensuring that the IBC members are appropriately trained.

The IBC may use consulting experts or establish working groups to execute its responsibilities or acquire needed expertise for select tasks. Consultants or working group members may include, for example, persons knowledgeable in institutional commitments and policies, applicable law, standards of professional conduct and practice, community attitudes, the environment, or any scientific area where the IBC members do not have expertise. Consultants or working group members are not IBC voting members unless nominated and appointed as described previously.

IBC Meetings

The IBC will conduct meetings approximately quarterly and as needed for the conduct of business. A proposed agenda will be developed and distributed before the meeting. Meetings will proceed with no less than five voting members present. Meeting minutes will be taken to accurately reflect the topics of discussion. Meeting minutes will be reviewed, approved by the members, and maintained on file. Meetings will be opened to the public, and minutes will be provided to the public, when requested by the public and in accordance with the scope and requirements of the NIH Guidelines.

IBC and Biosafety Standards

The following standards have specific requirements for IBCs and biological work:

- [Guidelines for Research Involving Recombinant DNA Molecules](#) (NIH Guidelines), Federal Register (current version)
- [Biosafety in Microbiological and Biomedical Laboratories](#), 5th Edition, CDC and NIH.
- [Worker Safety and Health Program](#), DOE 10 CFR 851
- [Biosafety Program and Manual](#), LBNL
- [Health and Safety Manual](#) (PUB-3000) and Biosafety [Chapter 26](#), LBNL

Additional biosafety standards related to LBNL biological work are summarized below:

- Bloodborne Pathogens Standard, Occupational Safety and Health Administration (OSHA) [29 CFR 1910.1030](#)
- Select Agents and Toxins, Health and Human Services (HHS) [42 CFR 73](#), and U.S. Department of Agriculture (USDA) [7 CFR 331](#) & [9 CFR 121](#)
- Plant Pathogens and Pests, USDA [7 CFR 330](#)
- Animal Pathogens, USDA 9 CFR Parts 92, 94, 95 96, [122](#) and 130
- Importation of Human Pathogens , U.S. Public Health Service (USPHS) [42 CFR 71](#)
- Medical Waste Management, California Administrative Code (CAC) Sections 117600 - 118360

IBC Charter Approval

IBC members will review proposed amendments to this charter and make recommendations regarding adoption of amendments. The IBC Chair will submit IBC recommendations regarding charter amendments to the Laboratory Director. The Laboratory Director will approve amendments to the IBC Charter.



Laboratory Director, Steven Chu

3/5/08

Date