Oakland University

Institutional Biosafety Committee Charter

Introduction

Oakland University (OU) is committed to the highest standards of safe and ethical research and complies with all federal, state and local laws and regulations, and University policy. For this purpose and in compliance with Section IV-B-1-b of the National Institute of Health (NIH) *Guidelines for Research Involving Recombinant DNA Molecules,* the University has instituted an Institutional Biosafety Committee (IBC) to provide local review and oversight of research utilizing recombinant DNA and/or biohazardous materials.

The Oakland University Institutional Biosafety Committee is registered with the Office of Biotechnology Activities (OBA) under the auspices of the National Institute of Health (NIH) and the required reports are filed annually.

All research, teaching and testing at Oakland University involving recombinant DNA, genetically modified organisms, infectious agents, select agents and/or cultured cell lines must be approved by the IBC before research begins. Once approved Investigators are responsible for conducting the research as described in the approved application and for submitting all revisions to the application describing any departures from the original before revisions are implemented. All research is subject to inspection or audit.

Authority

The University President has designated the Vice Provost for Research (VPR) as the Institutional Official (IO) with authority over the Institutional Biosafety Committee. The Office of the Vice Provost for Research also provides the IBC with administrative support.

Committee Composition

1. The IBC is comprised of no fewer than five members selected to ensure that their collective experience and expertise includes the following:

    - Recombinant DNA technology
    - Biosafety and physical containment

- Knowledge of: Institutional commitments and policies; applicable laws; standards of professional conduct and practice; community attitudes; and environmental considerations.
- Be capable of assessing the safety of recombinant DNA research and identifying potential risks to public health and safety.

2. At least two members shall not be affiliated with the institution and who represent the interests of the surrounding community. These may be officials of state or local public health or environmental protection agencies, members of other local governmental bodies, or persons active in medical, occupational health, or environmental concerns in the community. At least one of the two community members shall have applicable laboratory experience.
3. The OU Biosafety Officer (BSO) will serve as a permanent voting member of the committee.
4. The Regulatory Compliance Coordinator/Committee Administrator shall serve as an alternate member when needed to meet quorum. Alternates will be given access to all documents for review with the regular committee members.
5. The institution must ensure appropriate training for the IBC Chair and members regarding laboratory safety and implementation of the NIH Guidelines.
6. New members are recommended to the Vice Provost for Research (VPR) by the IBC Chair, Research Compliance Manager, or Regulatory Compliance Coordinator.
7. Committee members are appointed by the VPR for terms of three years, which are renewable.

Committee Responsibility

The Institutional Biosafety Committee is charged with the review of research involving recombinant DNA and/or biohazardous materials at Oakland University

The Committee responsibilities include:

1. Review of all applicable research including a risk assessment. This includes review of:
    a. the containment level
    b. the facilities
    c. training and expertise of Principal Investigator (PI) and personnel
2. Notifying the principal investigator of IBC review and approval.
3. Periodically reviewing recombinant DNA research conducted at the institution to ensure compliance with the *NIH Guidelines*.
4. Setting containment levels and modifying containment levels for ongoing experiments as warranted.
5. Implementing contingency plans for handling accidental spills and personnel contamination resulting from recombinant DNA research.
6. Reporting to Office of Biological Activities and institutional officials within 30 days any:
    - Substantial problems or violations of the NIH Guidelines; and
    - Significant research related accidents or illnesses.
7. Reviewing Institutional procedures and practices.
8. Performing such other functions as may be delegated to the IBC.

9. For human gene transfer experiments, the IBC is responsible for providing oversight in accordance with NIH Guidelines Section IV-B-2(1), Section I-E, Section III-C and appendix M.

Meeting Requirements

1. The Institutional Biosafety Committee shall meet as needed, but at least four times per year. Monthly meetings are scheduled and may be cancelled by the IBC chair if appropriate.
2. The review of all applications shall take place at convened meetings at which a quorum of the members is present. This must include at least one community member. A quorum consists of a majority of the members.
3. A convened meeting shall be conducted in person, or via conference call.
4. Upon review, applications can be approved as written, approved pending modifications, or denied approval.
5. The committee chair may appoint designated reviewers to review and approve applications that require modifications, and minor amendments to the protocol. .
6. Minutes of the meeting are approved by the IBC Chair and the Biosafety Officer before their final approval by the committee.
7. The NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) has been adopted as OU Biosafety Manual.
8. The meeting will be open in part to the public and meeting dates will be posted on the biosafety website. Portions of the committee deliberations may be closed to the public for reasons of privacy or proprietary interest.
9. Members having a financial or personal interest (conflict of interest) in the outcome of the research (e.g. equity interest, salary, stipend, dividends, royalties), must recuse themselves during deliberations and voting except to provide specific information requested by the IBC. Members may never vote on a protocol for which they are principal investigator or responsible faculty member.

Training

All researchers conducting research involving biohazardous materials must be familiar with the *Biosafety in Microbiological and Biomedical Laboratories (BMBL) Manual*, University policy and all relevant federal, state and local laws and regulations. Information on Training is located on the Laboratory Safety and Compliance website. http://www4.oakland.edu/?id=6068&sid=201

References

- Oakland University Laboratory Safety and Compliance http://www4.oakland.edu/?id=6081&sid=201
- NIH Guidelines for Research Involving Recombinant DNA Molecules http://oba.od.nih.gov/rdna/nih_guidelines_oba.html
- Biosafety in Microbiological and Biomedical Laboratories (BMBL) http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm
- Recombinant DNA Advisory Committee (RAC) http://oba.od.nih.gov/rdna_rac/rac_about.html

IBC Related Definitions and Acronyms

Biosafety Level (BSL): A description of the degree of physical containment being employed to confine infectious agents or organisms containing recombinant DNA molecules and to reduce the potential for exposure of laboratory workers, persons outside of the laboratory, and the environment. There are four Biosafety Levels which consist of a combination of laboratory practices and techniques, safety equipment, and laboratory facilities. Each combination is specifically appropriate for the operations performed the documented or suspected routes of transmission of the infectious agents, and the laboratory function or activity. The BSLs described in this charter should be differentiated from Risk Groups, as described in the *NIH Guidelines* and the *World Heath Organization Laboratory Biosafety Manual.* In Appendix G of the *NIH Guidelines*, these are graded from BSL-1 (the least stringent) to BSL-4 (the most stringent). Risk groups (RG) are a method used to classify human etiological agents based on hazard to both the individual and to the community. There are four risk groups (RG1-RG4). These correlate to but are not equivalent to biosafety levels. Determining the risk group of a biological agent can be part of the biosafety risk assessment and helps in assigning the correct biosafety level for containment.

Biological Safety Officer (BSO): An individual appointed by an institution to oversee management of biosafety risks. The NIH Guidelines require that a BSO be appointed when the institution is engaged in large-scale research or production activities, or in research requiring containment at BSL-3 or BSL-4. The duties of the BSO are described in section IV-B-3 of the NIH Guidelines.

Institution: In the context of the NIH Guidelines, an institution is any public or private entity, including federal, state, and local governments.

Institutional Biosafety Committee (IBC): An institutional committee created under the NIH Guidelines to review research involving recombinant DNA. The role of IBCs has evolved over time, and many committees also review other forms of research that entail biohazardous risks as part of their institutionally assigned responsibilities.

National Institutes of Health (NIH): One of the world's foremost medical research institutions and the preeminent federal funder of medical research in the U.S. The NIH, comprised of 27 separate Institutes and Centers, is one of eight health agencies within the Public Health Service, which is an agency within the U.S. Department of Health and Human Services. The goal of NIH research is to acquire knowledge to help prevent, detect, diagnose, and treat disease and disability. The NIH mission is to uncover knowledge that will lead to better health for everyone.

NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines): A document created in 1976 that outlines principles for the safe conduct of research employing recombinant DNA technology. The NIH Guidelines detail practices and procedures for the containment of various forms of recombinant DNA research, for the proper conduct of research involving genetically modified plants and animals, and for the safe conduct of human gene transfer research. As a “living” document, it is periodically revised to keep pace with the changing state of science.

Office of Biotechnology Activities (OBA): The NIH office responsible for developing, implementing, and monitoring NIH policies and procedures for the safe conduct of recombinant DNA activities, including human gene transfer.

Recombinant DNA Advisory Committee (RAC): An NIH advisory committee whose principal role is to provide advice and recommendations to the NIH Director on (1) the conduct and oversight of research involving recombinant DNA, including the content and implementation of the NIH Guidelines, and (2) other NIH activities pertinent to recombinant DNA technology. A major element of this role is to examine the science, safety, and ethics of clinical trials that involve the transfer of recombinant DNA to humans. More details about RAC membership and responsibilities can be found on the RAC page of the OBA Website, as well as in its Charter.

Recombinant DNA molecules: Under the current NIH Guidelines, these are molecules constructed outside of living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or molecules that result from their replication.