

Middlebury College Institutional Biosafety Committee Policy

Purpose

Middlebury College's Institutional Biosafety Committee (IBC) is responsible for overseeing research projects conducted at the College that involve recombinant DNA (rDNA), biological agents, and other biohazards.

Function

To ensure that biological research is conducted safely using established biosafety standards and principles, the IBC will oversee administration, education and training, and review of lab safety policies and projects that involve research with hazardous biological and rDNA materials that may pose safety, health, or environmental risks. IBC oversight will consider worker safety, public health, agricultural and environmental protection, ethics, and compliance with applicable biosafety standards and applicable federal, state, and local laws and regulations.

Policy Review

IBC members will review proposed amendments to this policy during regularly scheduled committee meetings and vote on each amendment.

Roles and Responsibilities

Middlebury College

Middlebury College is ultimately responsible for the IBC's effectiveness and may establish procedures to ensure communication and cooperation among all organizations at the College that have biosafety-related responsibilities. Specifically, Middlebury College is responsible to:

- Establish, adopt, and implement policies to ensure that hazardous biological and rDNA research and teaching at the College is conducted safely.
- Establish and support the Institutional Biosafety Committee to oversee compliance at Middlebury College with federal regulations pertaining to research with rDNA and hazardous biological materials.
- Ensure that the IBC meets NIH requirements and functions as detailed in the NIH Guidelines.
- Establish a process to ensure that all research and teaching with rDNA is reviewed by the IBC and that PIs are notified of the results of IBC review.
- Ensure that the IBC Chair and members have appropriate expertise and training to enable them to perform adequate oversight of biological research and teaching at Middlebury College.
- Ensure that all Principal Investigators (PIs), students, and laboratory staff receive the training necessary to ensure laboratory safety and compliance with NIH Guidelines.
- Ensure that major problems, violations, or significant research-related accidents and illnesses are reported to applicable governmental agencies.
- Ensure that all members of the College community who plan to participate in research or teaching with rDNA or biohazardous material successfully complete a biosafety training program endorsed by the IBC.
- Appoint a Biological Safety Officer (BSO) before any member of the College community engages in any biological research at Biosafety Level (BSL) 3 or 4 or at Large Scale (cultures 10 liters or greater in volume).

The senior administrator who oversees the IBC on behalf of the College is the Director of the Natural Sciences.

Institutional Biosafety Committee (IBC)

The IBC is a standing committee of faculty, staff, and community members (see *Composition*) that reports to the Director of the Natural Sciences. This committee is responsible for overseeing all teaching and research-related activities at Middlebury College that involve biohazardous materials, including animal and plant pathogens, biological toxins, radioisotopes, and rDNA molecules. The IBC's primary objective is to safeguard all members of the College community, visitors to the College, the general public, and the environment. To do so, the IBC oversees laboratory and biological safety practices, provides biosafety training, and reviews and approves policies, procedures, and facilities to support safe use of biohazardous materials.

The IBC is constituted specifically to discharge the College's obligations and responsibilities under current government requirements, including those of the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Occupational Health & Safety Administration (OSHA), and any other requirements that overlap with those covered by other College Committees such as the Institutional Review Board (IRB) and the Institutional Animal Care and Use Committee (IACCUC), or by institutional staff responsible for safe handling of radioisotopes and other biohazardous materials.

The IBC works with PIs to ensure that research conducted at the College adheres to NIH Guidelines. It has the authority to suspend or terminate research that is not being conducted in accordance with NIH requirements. It also oversees efforts among individual faculty and departments, Sciences Technical Support Services (STSS), and the Office of Environmental Health & Safety to educate students, faculty, and staff about emergency plans that cover accidental spills and personnel contamination resulting from research with biohazardous materials. The IBC works with PIs to report to the appropriate institutional official and to NIH's Office of Biotechnology Activities (OBA), within 30 days, any significant problems or violations of the NIH Guidelines and any significant research-related accidents or illnesses.

The IBC maintains a website on which the dates, times, and locations of its meetings are published and publicly available in advance of meeting dates. Following committee meetings, meeting minutes in approved NIH format are posted to this website. If public comments are made on IBC actions, the IBC will forward both the comments and the IBC response to NIH OBA.

Composition

The composition of the IBC is dictated by federal regulations (the *NIH Guidelines for Research Involving Recombinant DNA Molecules*). The committee must consist of at least five members, selected so that collectively the IBC has experience and expertise in laboratory biosafety, use of infectious materials, and rDNA technology. The committee must be capable of assessing the safety of rDNA research and able to identify potential risks to public health or the environment. To ensure that all committee members have the requisite basic knowledge, all members of the IBC will complete training in NIH compliance requirements.

Members required by NIH

- A Chairperson.
- At least two members who (other than their membership on the IBC) are not affiliated with the College and who represent the interest of the surrounding community with respect to health and protection of the environment.
- At least one member who represents the laboratory technical staff.

- Members with expertise in rDNA technology, biological safety, and knowledge of physical containment principles for plants, animals, and materials that pose biohazards.

Members required under certain conditions

If the College conducts rDNA research at BSL3, BSL4, or with cultures >10 L volume, an institutional Biosafety Officer must serve on the IBC.

If the College conducts experiments subject to Appendix P, *Physical and Biological Containment for Recombinant DNA Research Involving Plants*: at least one person with expertise in plant, plant pathogen, or plant pest containment principles must serve on the IBC.

If the College conducts experiments subject to Appendix Q, *Physical and Biological Containment for Recombinant DNA Research Involving Animals*, at least one person with expertise in animal containment principles must also serve on the IBC.

The IBC also recruits, as needed, ad hoc members who know and can advise on institutional commitments and policies, applicable law, standards of professional conduct and practice, community attitudes, and the environment.

The IBC Contact Person

The NIH requires the College to name a contact person who will serve as the primary contact with NIH OBA for Middlebury's IBC. This person is the Research Compliance Manager and has the following responsibilities:

- Monitor national, state and local regulatory trends and communicate changes to the IBC and other responsible institutional representatives.
- Organize annual meetings of the IBC, plus others as required by College business.
- Provide administrative support for IBC activities, including preparing meeting agenda, minutes, and notes.
- Archive IBC records, including:
 - minutes of Committee meetings
 - other documents related to Committee activities
- Work with the IBC Chair to compile the annual report; file the report with NIH OBA. The report must include:
 - the roster of all IBC members, clearly indicating the Chair and the contact person
 - biographical sketches of all IBC members
- Work with the IBC Chair to compile the IBC's annual report to senior administration
- Maintain the IBC website and publish meeting dates, times, and locations there so that they are available to the public. Upon request, forward meeting minutes to interested members of the public.
- Make the committee roster and biosketches available to the public.
- Provide access to rDNA and biological safety training materials.
- Facilitate information sharing among the IBC, the IRB, the IACUC, and the STSS.

The IBC Chair

The NIH requires the IBC to have a Chair. This person has the following responsibilities:

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- Recruit and appoint IBC members.
- Chair IBC meetings.
- Communicate IBC concerns to PIs as necessary.
- Represent the IBC at College meetings as needed.
- Submit an annual report on IBC activity to senior administration.
- If a member of the College community plans to conduct research at BSL3 or BSL4, or work with large-scale cultures, work with College administration to appoint a BSO and ensure that this person is also a member of the IBC.
- If the College conducts research with rDNA that requires IBC approval (Appendix P, *Physical and Biological Containment for Recombinant DNA Research Involving Plants*), appoint at least one member with expertise in plant, plant pathogen, or plant pest containment principles.
- If the College conducts experiments subject to Appendix Q, *Physical and Biological Containment for Recombinant DNA Research Involving Animals*, appoint at least one IBC member with expertise in animal containment principles.

Principal Investigators

PIs are responsible to:

- Consult the IBC before initiating or modifying any research involving rDNA, infectious agents, biological toxins classified as select agents, or human or non-human primate blood, tissues, or cells.
- Report any violations of the NIH Guidelines, significant research problems, or research-related accidents and illnesses to NIH OBA and other appropriate authorities (if applicable) within 30 days.
- Be adequately trained in good microbiological techniques and NIH requirements.
- Adhere to IBC-approved emergency plans for handling accidental spills and personnel contamination.
- Comply with shipping requirements for infectious agents and rDNA.

Before starting research with rDNA, infectious agents, or human or nonhuman blood, tissues, or cells, the PI will:

- Make an initial determination of the levels of physical and biological containment needed to comply with the NIH Guidelines.
- Select appropriate microbiological practices and laboratory techniques to be used for the research.
- Ensure that all laboratory staff read the protocols that describe the potential biohazards and applicable precautions.
- Instruct and train laboratory staff in safety practices and techniques and in procedures for dealing with accidents.
- Explain the reasons for any precautionary medical practices (e.g., vaccinations or serum collection) to laboratory staff and tell them what provisions have been made.

While conducting research involving rDNA, infectious agents, or human or nonhuman blood, tissues, or cells, the PI will:

- Observe the laboratory staff's safety performance to ensure that they use the proper safety practices and techniques.
- Investigate any lapses in containment procedures and report them to the IBC.
- Correct practices and conditions that may result in the release of rDNA or infectious agents.
- Ensure the integrity of physical (e.g., biological safety cabinets) and biological (e.g., purity and genotypic and phenotypic characteristics) containment.

PIs may attend IBC meetings at which their research is discussed.

DEFINITIONS

Biohazardous Agents

- Infectious/pathogenic agents classified in the following categories: Class 2, 3, and 4 bacterial, fungal, parasitic, viral, rickettsial, or chlamydial agents as defined by the National Institutes of Health (NIH)
- Other agents that have the potential for causing disease in healthy individuals, animals, or plants

Biological Toxins

Metabolites of living organisms and materials rendered toxic by the metabolic activities of microorganisms (living or dead)

Institutional Biosafety Officer

(define)

Recombinant DNA Molecules

Molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or DNA molecules that result from the replication of such molecules

Gene Therapy

Delivery of exogenous genetic material (DNA or RNA) to somatic cells for the purpose of modifying those cells