

Syracuse University Institutional Biosafety Committee



Syracuse University's Vice President of Research has established and given authority to the Institutional Biosafety Committee (IBC) to help ensure all research and teaching activities at Syracuse University involving biological material are conducted in compliance with federal, state and local mandates, and University Policy. The IBC is in place to minimize the risks associated with the possession and use of biohazardous materials (including, human and regulated plant and animal pathogens, infectious material, Select Agents, and human samples). The IBC has the authority to review and approve practices and procedures regarding research and other activities involving biohazardous material, and take appropriate actions to ensure activities are conducted in compliance with applicable regulations and the University's Biological Safety Program.

I. Organization

The IBC shall consist of the following members:

- The University Biosafety Officer
- The Health Services Medical Director
- Faculty and staff representatives from laboratories and departments conducting research involving infectious material and/or recombinant DNA (rDNA)
- Two non-affiliated members
- The Director of the Office Research Integrity and Protection Services (non-voting)
- The Director of Environmental Health and Safety Services (non-voting)
- Ad hoc consultants, as necessary, to review research outside the expertise of current members

II. Responsibilities

The IBC shall:

1. Carry out all the functions required of an Institutional Biosafety Committee as defined in the National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids (NIH Guidelines), including reviewing applications for research involving rDNA to ensure that the research conforms to the NIH Guidelines.
2. Review the biosafety aspects of all research involving infectious material and/or rDNA and ensure approved protocols are consistent with the NIH Guidelines, CDC/USDA guidelines regarding the use of Select Agents, the terms of the University's Biological Safety Program, standard protocols and best management practices.

II. Responsibilities (cont'd)

3. Advise the VP for Research, Provost and other members of the Chancellors Council on all matters related to the use of infectious material and/or rDNA as needed or requested.
4. Provide guidance and support to the Biological Safety Officer and Environmental Health and Safety Services Office in carrying out biosafety related mandates and initiatives.
5. Develop and implement policies, standard operating procedures and best management practices as necessary to ensure that biological use, storage, handling, research, etc. is conducted safely at Syracuse University.
6. Periodically assess compliance relating to the possession and use biohazardous material and review all laboratory biosafety assessments conducted by the Biosafety Officer at least annually to determine that activities are being conducted safely and in accordance with federal guidelines and the conditions of the University's Biological Safety Program (http://supolicies.syr.edu/pub_safe/microbio_safe.htm).
7. Report significant violations of the NIH Guidelines and any significant suspected or alleged violations of protocols, external regulations or University policies or required biosafety practices to the Office of Research, the appropriate institutional official, and when necessary to the NIH Office of Biotechnology Activities.
8. In cooperation with the Office of Research, recommend and require remedial action to correct any violation of NIH Guidelines, external regulation, University policy or required biosafety practices.
9. Review and recommend, in consultation with medical professionals, the need for medical surveillance of individuals working with biohazardous materials as appropriate.
10. Maintain written records of all IBC meetings, actions, decisions and recommendations.

III. Duties:

Each IBC member is responsible and accountable for fulfilling the following:

1. Review all meeting agenda items, including applications, reports, reviews, SOPs, etc., in advance of scheduled meeting and be prepared to participate in discussion and vote as needed.
2. Attend meetings on a routine basis.
3. Attend and participate in trainings, conferences, seminars, etc., as necessary, to enhance knowledge and stay current with regulations, standards of care and trends related to biosafety principles and practices.
4. Participate in application reviews. IBC members with a conflicting interest in a particular application presented to the IBC for review may not participate in any portion of the review of research activities except to provide information requested by the IBC and must recuse themselves from the meeting during the IBC's deliberative discussion.
5. Participate in subcommittees and attend laboratory biosafety assessments and site visits, as needed.
6. Assist with promoting biosafety principles and practices to peers and the University community.
7. All information associated with the IBC is confidential and proprietary ("Confidential Information"). Members shall not disclose Confidential Information to any third party, and shall not make or use copies of any IBC documents or the Confidential Information in whole or part for any purposes other than as needed to serve as a member of the Syracuse University IBC.

The Biosafety Officer will support the IBC in the following manner:

- Conduct biosafety assessments on compliance of lab activities with approved biosafety protocols.

- Review and evaluate written applications and standard operating procedures involving biohazardous material and/or rDNA for compliance with the Biological Safety Program, NIH Guidelines, OSHA Bloodborne Pathogen Standard, biosafety protocols and best management practices.
- Conducted periodic review of the written Biological Safety Program to ensure written text reflects current regulatory guidance and/or requirements.
- Develop and provide general biosafety training and Bloodborne Pathogen training.
- Participate as a voting member of the IBC and attend IBC meetings.
- Coordinate emergency response for biohazard spills and investigate associated laboratory accidents and incidents.
- Maintain an inventory of biohazardous agents that are stored or used at the Syracuse University.

IV. Committee Review Classifications

1) Full Committee Review:

Refers to teaching and research activities that require full IBC review and a “vote to approve” prior to initiation. Activities involving the materials described below require full committee review:

- NIH “Covered” rDNA
- Human pathogens
- Select Agents (including exempt quantities of Select Agent Toxins)
- Regulated animal and plant pathogens (USDA and APHIS)
- Human samples known to be contaminated (e.g. blood from known HIV positive patients).

During the review process, IBC members are provided with the Full Committee Review Form, application, and any supporting materials submitted by the Principal Investigator, at a minimum of one week prior to the IBC meeting. A majority vote of the full IBC is required for approval.

2) Designated Member Review:

Refers to teaching and research activities that do not require a full committee review. Designated member review activities require an IBC designee (e.g. the Biosafety Officer, another IBC member) to review applications, standard operating procedures and/or registrations. Activities involving the items described below require DMR.

- NIH “Exempt” rDNA
- Human samples (i.e. blood, urine, saliva, etc.)
- Biological toxins
- Mammalian cell lines (including human).

During the review process, IBC members are provided with a copy of the Designated Member Review Form, the application, and any supporting materials submitted by the Principal Investigator, at a minimum of one week prior to the IBC meetings. Approval is granted if the IBC Biosafety Officer does not receive any comments or a request by any IBC member for a full committee review at the IBC meeting or by the date of the next IBC meeting. Any IBC member may initiate a full committee review of a protocol qualifying as a designated member review. Any comments or concerns are presented to the IBC and must be addressed prior to approval.

V. Meetings:

1. The IBC meets monthly to review applications/protocols that require full committee review. A meeting may be cancelled in the absence of new agenda items and/or if no IBC member requests a full committee review of a designated member review application.
2. Applications and associated evaluations will be provided to the IBC no less than one week in advance of scheduled meetings. All IBC documents are distributed via email.
3. A quorum shall consist of at least one-half of the IBC's voting membership, which must include the Biosafety Officer or designee. All issues requiring IBC action are decided based on the majority opinion of all voting members of the IBC.
4. IBC meeting times, dates, locations, and minutes are available to the public upon request.