

INSTITUTIONAL BIOSAFETY COMMITTEE

Charter and Procedures

Mission Statement

The University is committed to maintaining a safe and healthy environment for its students, faculty, staff, and visitors. Research and teaching activities involving biological materials must be conducted in a manner that protects laboratory personnel, the public, and the environment while ensuring compliance with applicable federal, state, and institutional regulations.

The Institutional Biosafety Committee (IBC) provides oversight for research and institutional activities involving biological hazards and recombinant or synthetic nucleic acid molecules conducted at or sponsored by the university. The IBC ensures that such activities are conducted safely and in accordance with *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, the *CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)* guidance, and other applicable federal, state, and institutional regulations.

The IBC serves as a forum where biosafety issues, risks, and compliance matters related to biological research can be reviewed collaboratively. The committee works closely with Environmental Health and Safety (EHS), the Office of Research and Economic Development (ORED), and other institutional oversight committees to ensure safe research practice and regulatory compliance.

Reporting

The Committee reports to the Vice President for Research and Economic Development (“VP for Research”) or their designee.

Goals and Objectives

In support of Environmental Health and Safety (EHS), the designated Biological Safety Officer (BSO), and the University’s research compliance programs, the Committee will:

- Assist with the implementation of a comprehensive biosafety program at the University.
- Develop and maintain policies, procedures, and guidance documents governing the safe possession, use, storage, and disposal of biohazardous materials and recombinant or synthetic nucleic acid molecules in teaching, research, and service activities.
- Review and approve research involving recombinant or synthetic nucleic acid molecules prior to initiation of the research as required by *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*.
- Evaluate risks associated with proposed activities and determine appropriate biological containment levels, facilities, procedures, and personnel qualifications.
- Ensure that only qualified and appropriately trained individuals are authorized to work with biohazardous materials or to supervise such work.
- Receive and review reports from the Biological Safety Officer regarding biosafety incidents, spills, exposures, or other unusual occurrences involving biological agents or recombinant materials.

- Review and provide input on non-emergency compliance violations and enforcement actions related to biosafety.
- Recommend disciplinary action to the appropriate University officials against personnel who violate biosafety regulations, institutional policies, or conditions of approved protocols.
- Report significant problems, violations of *NIH Guidelines*, or research-related accidents or illnesses involving recombinant or synthetic nucleic acid molecules to the VP for Research and the NIH Office of Science Policy as required.
- File an annual report with the NIH OSP as per Section IV-B-2-a-(3) of the NIH Guidelines.
- Review the IBC Charter every three years.
- Maintain a list of the members and their appropriate training and experience.

Membership Composition and Representation

Members are appointed by the President of the University in accordance with the approved procedures for standing committee appointments. All appointments are for an initial three-year term and may be reappointed for successive terms at the discretion of the President of the University.

In accordance with NIH Guidelines, the Committee must include no fewer than five members who collectively possess expertise in biosafety, biological research, and risk assessment.

The membership shall include representation from the following areas:

- The BSO (Biological Safety Officer)
- A representative from the administration who is neither a faculty member nor the BSO, e.g., Assistant VP for Research, Director of Research Integrity and Compliance, etc.
- A representative from Environmental Health & Safety (cannot be the BSO) with expertise in safe handling of biohazardous materials
- Faculty or technical representatives from the various schools, colleges, and offices where biological research is conducted, to include:
 - A member with expertise in animal containment principles if research involving animals is conducted.
 - A member with expertise in plant containment principles if research involving plants or plant pathogens is conducted.
 - A member with expertise in human pathogens, infectious disease, or biosafety practices if research involving human pathogens or human-derived materials is conducted.
- Additional faculty, staff, or technical personnel with experience in biosafety or biological research as appropriate.
- At least two members who are not affiliated with the University (apart from their membership on the Committee) and who represent the interests of the surrounding community with respect to health and protection of the environment.

Non-voting ad hoc consultants with specialized expertise may be invited to assist the Committee in evaluating protocols when necessary.

Subcommittees

Subcommittees may be established as necessary to perform specific duties or address specialized biosafety concerns. Subcommittees shall be comprised of Committee members as appointed by the Chair.

Qualified individuals who are not members of the Committee may be appointed to subcommittees at the discretion of the Chair.

Chair

The Chair is appointed by the VP for Research or their designee following recommendation by the Committee members and the BSO. The Chair shall:

- Be a voting position.
- Possess expertise in biological research or biosafety practices and demonstrate leadership ability.
- Preside at all meetings or designate another member to serve in his/her absence.
- Work closely with EHS, the BSO and the Office of Research and Economic Development to ensure effective implementation of the institutional biosafety program and compliance with all federal, state, and local regulations.
- Schedule regular meetings of the Committee.
- Prepare and distribute an agenda to Committee members at least three working days prior to regular meetings and one day prior to special meetings.
- Approve the draft minutes of the meetings for distribution to the members of the Committee for review and approval.
- Call special meetings and appoint ad hoc sub-committees when necessary.
- Prepare, in collaboration with the Executive Officer, the annual report to the Administrative Council.
- Represent the Committee in Administrative Council meetings when requested.

The BSO shall not be appointed as the Chair of the Committee.

Biological Safety Officer (BSO)

The Biological Safety Officer (BSO) is responsible for supporting the institutional biosafety program and assisting the Committee in the implementation of biosafety policies. The BSO shall:

- Be a voting position.
- Assist in the development, implementation, and maintenance of the University's biosafety program.
- Provide guidance and technical expertise regarding biosafety regulations, risk assessments, and containment procedures.
- Communicate relevant regulatory updates to the Committee and the University community.
- Be responsible for keeping the Committee apprised of all major actions taken to implement and ensure compliance with biological safety rules and regulations.

The BSO shall not serve as the Committee Chair.

Executive Officer

The Executive Officer shall be an administrator in the Office of Research and Economic Development and shall be appointed by the President of the University. The Executive Officer shall:

- Attend all meetings of the Committee without voting privileges.
- Serve as the Institutional/University Officer for the Committee.
- Serve as a consultant to the Committee and aid in the conduct of Committee business.
- Provide administrative support services to the Chair in the conduct and coordination of Committee activities.

Meetings

The Committee shall meet as necessary to conduct its business, but at least quarterly.

Fifty percent plus one of the Committee membership will constitute a quorum and must include the BSO, Committee Chair, and at least one non-affiliated community member. Actions of the Committee shall be taken by the vote of a majority of members present in any meeting at which a quorum is present. Members may participate by remote means when necessary or desirable. In the event that the meeting quorum is not met, the meeting will either be rescheduled, or limited business will take place.

Members are expected to review all information provided prior to the meeting and attend all scheduled Committee meetings. If a member must be absent from a meeting, every effort should be made to designate a proxy. Once a proxy has been designated by the member who plans to be absent from a meeting, notice should be given to the Chair and the name of the proxy provided.

Members with a conflict of interest related to a protocol under review must disclose the conflict and recuse themselves from voting on that protocol.

The proxy for an absent member must be approved by the Chair since special expertise is required for Committee membership. Once approved by the Chair, the proxy will count towards a quorum. However, voting by proxy is prohibited.

Absence from fifty percent (50%) of regular meetings without due cause will result in a request by the Committee to the President of the University, via the Executive Officer, for replacement of that member.

Agendas, Minutes and Reports

The Chair, with assistance from the BSO, shall be responsible for establishing the agenda for meetings. Committee members may also make requests for agenda items. The agenda and relevant materials will be sent to Committee members at least five business days in advance of the meeting.

Minutes of the meetings shall be drafted by ORED staff and approved by Committee members at the following meeting. Approved minutes of Committee meetings shall be posted on the University Standing Committee website.

The Committee will provide periodic reports to the VP for Research as requested.

Amendment of Procedures

These procedures can be amended at any regular meeting of the Committee by a majority vote of the members present, provided that the amendment has been submitted in writing to the members at least one

week prior to the meeting where the voting will take place. Amendments to these procedures are subject to final approval by the Administrative Council.