

Bylaws of the Ohio University Institutional Biosafety Committee

1.0 General

1.1 Name

The name of this committee shall be the Ohio University Institutional Biosafety Committee (IBC).

1.2 Purpose and Authority

The IBC is administered by the Ohio University Vice President for Research (VPR), and supported by the Department of Environmental Health & Safety (EHS). The IBC and its Chair are appointed by the VPR upon recommendation of the University's Biosafety Officer. The Biosafety Officer is an employee of the EHS department. The IBC reports to the VPR on all matters relating to work with biohazardous agents at Ohio University. The committee's scope is defined in the university Policy on Biohazards, 44.107.

The committee is responsible for monitoring and oversight of the use of biohazardous agents to safeguard the health and safety of Ohio University personnel, students, the community, and the environment. The IBC must also insure compliance with applicable federal regulations and guidelines, granting agency guidelines, as well as Ohio University policies and procedures. The specific regulations and guidelines are listed in the university policy; biohazardous agents are defined in the university Biosafety Manual.

The committee formulates policies necessary to establish safe practices for the use of biohazardous agents. It is responsible for establishing policies governing the safe procurement, use, storage, and disposal of biohazardous agents. Committee responsibilities, some of which may be delegated to the University's Biosafety Officer include:

- Reviewing and approving the protocol for each project or each research lab using biohazardous agents.
- Reviewing and approving the University's Biosafety Manual.
- Reviewing the University's Biohazardous Policy, with approval required by the chair.
- Providing input and recommendations on the Biosafety Officer's administration of the Biosafety Manual and biosafety procedures.
- Maintaining official minutes of all meetings of the IBC, with official copies maintained by the Biosafety Officer.

2.0 Membership Provisions

2.1 Composition and Appointment

The voting members of the committee are appointed by the Vice President for Research. The committee has membership as follows:

The Chair of the Committee

The Chair of the Committee shall be a member of Ohio University's faculty or staff who is professionally knowledgeable about one or more aspects of biosafety.

University Members

There shall be a minimum of five Ohio University faculty and staff members, including the chair, who shall be voting members of the IBC. The membership shall include persons knowledgeable in microbiology, infectious disease, recombinant DNA technology, animal experimentation, and plant experimentation. Other areas of expertise desirable for the committee include: medicine, current clinical practice, chemistry, toxicology, occupational health and safety, public health, community attitudes, applicable law, and engineering.

Community Members

There shall be two committee members, not affiliated with the University, who represent the community with respect to health and protection of the environment, herein called "community members". The community members shall be voting members of the IBC.

Ex-Officio Members

The EHS Biosafety Officer and a staff member representing the VPR shall serve as ex-officio members.

2.2 Terms of Office

The terms of service for faculty and staff committee members shall be three years, renewable for three more years. A minimum of two years off the committee is required before additional service in the future is allowed. The term of service for the committee chair shall be one year, renewable for one more year. There is no limit for the terms of service for the community members. All terms begin on July 1 and end on June 30. Each year, at least one university member and no more than two university members shall rotate off the committee.

2.3 Resignation

A member may resign at any time upon written notice to the IBC Chair at least 15 days prior to the effective date. The committee shall recommend to the VPR that a replacement be appointed to complete the term of the member.

2.4 Removal

If a member can no longer serve because of a change in eligibility status or inability to participate fully in the required activities of the committee, the committee shall recommend to the VPR that a replacement be appointed to complete the term of the member.

3.0 Duties of the Officers

3.1 Chair

The Chair shall preside at all meetings of the committee. He/she may assign such additional duties to other members of the committee as deemed necessary for the conduct of the work of the committee and which are not inconsistent or conflicting with the duties otherwise prescribed.

3.2 Biosafety Officer

The Biosafety Officer shall:

- a) Keep or cause to be kept in the EHS office a file of approved minutes of all meetings of the committee, recording therein the date, time and place of holding, the names of committee members present and absent, a record of votes taken, a summary of deliberations and discussions and any other relevant business of the committee; these matters are kept under the direction of the Chair.
- b) Maintain the bylaws, a current membership mailing and e-mail list and minutes of the meetings of the committee.
- c) Perform such other duties as may be prescribed by the bylaws or which may be delegated by the Director of Environmental Health & Safety and on the recommendation by the Chair or by a vote of the committee membership. The BSO has considerable latitude determining how the bylaws will be upheld.
- d) Advise and represent the Director of Environmental Health & Safety as needed in matters related to the Biosafety program.

4.0 Meetings

The committee shall meet at least three times per year to conduct the business of the committee. Official business of the IBC may only be conducted at face-to-face meetings. The Biosafety Officer shall advise the members of the time and place of the meeting, and shall post the information on the EHS Biosafety Webpage. Additional meetings may be

called by the Chair, the Biosafety Officer or the VPR. However, decisions and actions to be taken must be approved by a quorum of the IBC.

4.1 Time and Place of Meetings

The time and place of meeting shall be arranged by the Biosafety Officer.

4.2 Notice of Meeting

Each member of the committee shall be notified in writing or via e-mail of all regularly scheduled meetings at least one week prior to the date of the meeting. Notification of meetings scheduled on short notice shall be via e-mail and/or couriered written notice.

4.3 Rules of Order

All business meetings shall be conducted in accordance with parliamentary procedure unless inconsistent with specific provisions of these bylaws.

4.4 Quorum

The presence of a simple major of the voting members shall constitute a quorum for the transaction of business at any meeting of the committee. No business shall be acted upon by the membership of the committee at any meeting at which a quorum, as herein defined, is not present and the only motion which the Chair shall entertain at such meetings is a motion to adjourn the meeting to a stated time and place.

This shall not preclude the committee from discussing issues of business in the absence of a quorum provided that no action is taken on such items of business.

4.5 Voting

Each voting member shall have one vote, which shall be exercised only by that member and only when in attendance. Motions may be made by any IBC member. Approval of all motions shall be gained with a simple majority.

5.0 Amendment of Bylaws

These bylaws may be amended at a regularly scheduled meeting by the affirmative vote of a majority of the members of the committee. Such amendments will take effect as soon as they are signed by the Vice President for Research.

6.0 Conflict of Interest

A conflict of interest situation exists when the committee is requested to deliberate and recommend action regarding a particular biohazardous agent user who is also a member of the committee.

This member will be allowed to participate in the discussion of the issue but shall not be permitted to make any formal motions or to cast a vote concerning the topic at hand. The member shall be asked to leave the room during any vote affecting the conflict of interest area.

7.0 Open Records

NIH guidelines contain a disclosure provision. The provision requires Ohio University, upon request, to make available to the public all minutes of Institutional Biosafety Committee meetings pertaining to recombinant DNA activities and any documents or reports submitted or received from federal funding agencies which the latter are required to make public (e.g., Memoranda of Understanding and Agreement, reports of guidelines, violations and significant research related incidents, facilities inspection reports, and agency directives to modify projects). In addition, OU is required to forward to NIH any comments by members of the public concerning actions taken by the IBC together with the response of the committee to these comments.

Procedures of Ohio University Institutional Biosafety Committee

1.0 Review and Approval of Biosafety Protocols

1.1 Submission of Protocols

Any full or part-time faculty or research scientist wishing to conduct work involving biohazardous agents shall submit a written biosafety protocol to the IBC. The submission will be in accordance with the procedures in the current university Biosafety Manual and will be on the current IBC Biosafety Review Form. The current version of the form may be found on the EHS Biosafety webpage, along with current submission deadlines.

1.2 Review of Protocols

The IBC review of the submitted protocol will consider:

- i) qualifications of the investigator,
- ii) agents to be employed,
- iii) risks presented by experimental procedures,
- iv) adequacy of containment equipment and facilities,
- v) training level of persons directly associated with the work,
- vi) the need for health surveillance of laboratory personnel,
- vii) regulatory compliance,
- viii) appropriate biosafety level designation, and
- ix) other factors relevant to safe conduct of the study and compliance with regulations and appropriate guidelines.

The IBC does not monitor activities which are appropriately the concern of other established institutional groups, e.g., Radiation Safety Committee, Institutional Research Board, and Institutional Animal Care and Use Committee; however, it will endeavor to interact closely with these groups in a concerted effort to coordinate programs and to minimize health risk to OU personnel, students, and the general public.

It is not the purpose of the IBC to pass judgment on scientific merits, or even to consider "risk" versus "expected benefits" of potentially hazardous research projects. Rather, it is the concern of this Committee to know whether or not the safety precautions proposed for the experimental work are adequate for protection of personnel and the environment.

The make-up of the IBC is expected to include experts in the biosafety topics of submitted protocols. If a protocol involves work outside of the committee's expertise, appropriate experts shall be consulted. This could include other university or community members or it might include regional experts or consultants.

1.2.1 Biosafety Level 1 Protocols

Protocols must be submitted for work at biosafety level one (BSL 1). While Ohio University policy does not require IBC approval for BSL 1 work, some regulatory and granting agencies do require IBC review. BSL 1 protocols will be reviewed only to determine if these protocols are accurately rated as BSL 1, and that they meet appropriate regulatory or granting agency requirements. The IBC may offer recommendations for improved biosafety measures.

1.2.2 Biosafety Level 2 Protocols

Protocols must be submitted and approved by the IBC for work at BSL 2. BSL 2 protocols will be reviewed based on all of the criteria listed in section 1.2.

1.2.3 Biosafety Level 3 and 4

Work at BSL 3 or BSL 4 is not permitted at Ohio University.

1.3 Approval of Protocols

Approval of any protocol will be granted by a simple majority of the favorable voting members.

1.4 Non-Approval of Protocols

For proposals not initially approved, the Biosafety Officer and IBC members will work with the researcher to correct deficiencies and prepare the proposal for approval if appropriate.

For proposals not initially approved, the IBC may vote to table the protocol until the next meeting or vote to send the protocol to Designated Review. Designated Review assigns two committee members to review changes to the protocol prior to the next IBC meeting. By the agreement of both reviewers the protocol may be approved. The reviewers may request that the full IBC reconsider the protocol at the next meeting.

The submitter and the IBC must concur on all matters relating to containment requirements, safe practices, and handling procedures for biohazardous agents. In event of non-concurrence, the recommendations of the Committee shall prevail until such time as they are modified or rescinded by appellate decision of appropriate University officials, starting with the Vice President for Research. Questions relating to recombinant DNA studies will be referred to the NIH Office of Recombinant DNA Activities for final opinion.

1.5 Approved Protocols

Approved protocols will be assigned an approval number by the Biosafety Officer; this number may be required by granting agencies. Notice of approval will be provided to the submitter in writing or email by the Biosafety Officer. Protocols approved at BSL 2 require the signature of the submitter on the final version of the protocol. Approval of all protocols is granted for five years.

1.6 Renewal of Protocols

At the end of the five year approval, the submitter must resubmit their protocol for a renewed approval utilizing the IBC's current submittal process.

1.7 Denied Approval

Any submitter who is denied approval by the IBC may appeal to the Vice President for Research. The appeal request must be in writing and must include the protocol as reviewed by the IBC. The Vice President for Research must consult at least the IBC chair, the Biosafety officer and the submitter before deciding the appeal; others, including the department chair or subject matter experts may also be consulted.

2.0 Amendments to Approved Protocols

Request for amendment of an approved protocol must be submitted in writing to the Biosafety Officer. The request will be reviewed by the Biosafety Officer and forwarded to the IBC Chair or the full committee as appropriate.

When the request is to add new biohazardous agents and all of the following are true:

- a) the new agent does not change the biosafety level of the protocol,
- b) the protocol already contains the same type of agents (ex. infectious bacteria), and
- c) the addition of the new agent does not change any safety practices or procedures outlined on the protocol,

then the IBC Chair may give approval to administratively add the agents to the protocol.

For all other requests, or when the IBC Chair does not give administrative approval, the amendment must be voted on by the full IBC.

1. Approval of these Procedures was given by the IBC on May 29, 2009 by unanimous approval at the regularly scheduled IBC meeting.

Witnessed by: Adriane Mohlenkamp, Biosafety Officer

2. Approval of these Procedures granted by the Vice President for Research.

Rathindra Bose, Ph.D., Vice President for Research and Dean of the Graduate College