Institutional Biosafety Committee (IBC)

By-Laws

I. Charge to the IBC
A. The University of Cincinnati IBC is charged by the Sr. Vice President and Provost for Health Affairs with the responsibility for review and approval of all research protocols at the University of Cincinnati involving the use of recombinant DNA and biohazardous agents. These include:
   1. recombinant DNA,
   2. agents infectious to humans, animals or plants, including transactivating proteins
   3. other genetically altered organisms and agents.
B. The committee will assure that UC remains compliant with the National Institute of Health Guidelines for Research Involving Recombinant DNA (NIH Guidelines), the recommendations of the current edition of the Centers for Disease Control’s Biohazards in Microbiological and Biomedical Laboratories (CDC BMBL) and provide guidance to the University of Cincinnati with regard to biosafety compliance issues.
C. The IBC has the responsibility to develop and approve institutional policies and procedures within its area of expertise to ensure:
   1. safety of personnel and the environment,
   2. compliance with institutional requirements, and
   3. compliance with applicable laws and regulations.

II. Committee Membership
A. The Senior Vice President and Provost for Health Affairs will appoint members to the IBC upon recommendation by the IBC Chairperson and with agreement from the Vice President for Research.
B. The IBC will have a minimum of 5 voting members:
   1. A chairperson, to be appointed by the Senior Vice President and Provost for Health Affairs,
   2. One member to represent research staff,
   3. At least two community members and,
4. The Biological Safety Officer

5. The committee may also include a Chair, Director or designee to represent IACUC, EH&S, Facilities Management and the BSL3 Users Committee.

6. All voting members will be registered with the National Institutes of Health pursuant to the *NIH Guidelines for Research Involving Recombinant DNA Molecules*. Information provided in the registration will include:
   a. Name, Department and Professional Title
   b. Business Contact Information
   c. A Curriculum Vitae or NIH Biosketch.

C. The term of membership is 12 months and all terms are automatically renewed annually in August.

D. Attendance at IBC meetings is mandatory; however, it is understood that personal, business and academic conflicts may arise. Therefore, by accepting an appointment to the committee, Regular Voting Members agree to attend at least 6 meetings in the calendar year from January through December.

E. Regular Voting Members are eligible to be reimbursed up to $1000 annually for professional service related activities including travel, subscriptions, memberships to professional organizations, supplies and equipment.

F. A Regular Voting Member may recommend an Alternate Voting Member to substitute for him/herself at regularly scheduled meetings:
   1. The Alternate Voting Member shall be appointed by the Senior Vice President and Provost for Health Affairs in the same manner as a Regular Voting Member.
   2. The Alternate Voting Member must meet the same criteria for membership as a Regular Voting Member.
   3. The Alternate Voting Member shall represent the same area of expertise as the Regular Voting Member.
   4. Alternate Voting Member may not represent the Regular Voting Member at more than half of the regularly scheduled meetings in a calendar year.
   5. An Alternate Voting Member will be registered with the National Institutes of Health (see section II.B.6).
   6. Due to the special nature of representation, a Community Member may not designate an Alternate Voting Member.
   7. Alternate Voting Members may be eligible for reimbursement up to $1000 annually for professional service related activities in lieu of the Regular Voting Member and at the discretion of the Chair.

G. If for any reason a member is unable to complete the term of membership:
   1. The Regular or Alternate Voting Member shall submit a written resignation to the Chair.
2. The Chair shall request the Sr. VP and Provost for Health Affairs to appoint a new member.

III. Chair and Vice-Chair

A. The Chairperson of the Institutional Biosafety Committee shall be appointed by the Senior Vice President and Provost for Health Affairs. He/she will have the following responsibilities:
   1. Preliminarily review all research proposals for completeness and correctness prior to full committee review,
   2. Review and approve biosafety level 1 research proposals and amendments to approved BSL1 and BSL2 research protocols,
   3. Assign protocols to Committee members for review, and
   4. Preside at meetings.

B. A Vice Chair shall be appointed by the Chair who shall have authority to preside over meetings and act on behalf of the Chair in his or her absence.

IV. Meetings

A. The IBC shall meet monthly. IBC members will be notified of exceptions or changes to this schedule and they will be posted on the website.

B. When necessary, the Chair may call a meeting at times other than the scheduled meeting.

C. The members of the IBC shall be furnished with a copy of the agenda and all protocols to be reviewed for the regular meeting one week in advance of a scheduled meeting.

D. A quorum shall consist of a simple majority. A quorum is required for voting.

E. Minutes of the meetings shall be prepared and furnished to each member of the IBC for review. An archive of the minutes shall be preserved in the biosafety office.

V. Policies and Procedures

A. The UC IBC By-Laws will be reviewed annually by the Chair and Biological Safety Officer.

B. Ratification of the By-laws and amendments requires a 2/3 majority vote by all voting members at a meeting.
VI. Responsibilities

A. Principal Investigator (PI):

1. Individuals who have faculty appointments at the University of Cincinnati are eligible to serve as Principal Investigators (PIs) on research proposals.

2. The PI is responsible for the overall conduct of the study per NIH Guidelines, Section IV-B-7-a, General Responsibilities of the Principle Investigator, including modifications to the original submission.

3. The PI is responsible for ensuring laboratory compliance with regulations and all approved IBC policies.

4. The PI will receive all correspondence from the IBC including any continuing review material.

5. The PI may designate, in writing, a secondary person to receive copies of all correspondence.

B. Institutional Biosafety Committee (IBC)

1. IBC Policies will be made available via the website.

2. IBC will promptly review research proposals.

3. IBC protocol forms, policies, and procedures will be periodically reviewed to ensure that the information meets current regulatory requirements and that the IBC has information needed for a complete review of the research.

4. IBC will promptly notify the PI of any actions concerning a reviewed research proposal.

C. Biological Safety Officer (BSO)

1. The institution shall appoint a Biological Safety Officer.

2. The Biological Safety Officer's duties include, but are not be limited to:
   
   i. Conducting inspections at least annually to ensure laboratory standards are rigorously followed;

   ii. Reporting to the Institutional Biosafety Committee and the institution any significant problems, violations of the NIH Guidelines, and any significant research-related accidents or illnesses of which the Biological Safety Officer becomes aware unless the Biological Safety Officer determines that a report has already been filed by the Principal Investigator;

   iii. Developing emergency plans for handling accidental spills and personnel contamination and investigating laboratory accidents involving recombinant DNA research;

   iv. Providing advice on laboratory security;

   v. Providing technical advice to Principal Investigators and the Institutional Biosafety Committee on research safety procedures.
VII. Protocols

A. Protocol Submission
   1. The principal investigator must electronically submit the application forms to the biosafety office.
   2. All protocol applications must use the current approved submission form. The most up-to-date version of the IBC forms are available on the IBC website.
   3. A protocol may be approved for a maximum of three years.

B. Protocol Review Process
   1. The assignment of a designated reviewer from the IBC will be made by the IBC Chair.
   2. IBC members who are involved in a protocol being reviewed will recuse themselves from the meeting during discussion and voting on that protocol. The member will remain part of the quorum.
   3. All protocols are presented by the designated reviewer of the IBC to the full committee for discussion.
   4. Any supporting documentation of the review process shall be submitted to the Biosafety office to be retained as an official record of action and placed in the PI’s file.
   5. The IBC will attempt to complete all reviews within 8 weeks.
   6. A research proposal must be submitted at least two weeks prior to a meeting to be considered at that meeting.

C. Post-Protocol Review Process
   3. Full approval requires a simple majority vote at a meeting of the Committee at which a quorum is present.
   4. The PI will be notified in writing of the IBC Action, which may include:
      i. Full Approval.
         - Post-approval documentation, as described on the IBC website must be submitted immediately upon receipt of the approval notification.
      ii. Approval with provisions
         - The PI will be promptly notified in writing of all provisions.
      iii. Against Approval
         - The IBC will notify the PI in writing the basis for the decision.

D. PIs Rights
   1. The PI may attend any regularly scheduled IBC meeting to answer questions regarding a submitted proposal.
2. The PI has the right to appeal any IBC action in writing to the Chair.
3. Any subsequent actions will be determined at the discretion of the Chair.

E. Amendments and Annual Progress Reports

1. Written notification must be submitted to the biosafety office using the approved form when there is a change in:
   - Personnel conducting the procedures detailed in the approved protocol
   - Location, phone, etc.
   - Changes in procedures, recombinant DNA molecules or biohazardous Agents
     - The Biosafety Officer will determine if an amendment to an existing protocol or a new protocol submission is required.
     - These changes must be reviewed before activities are initiated.

2. Amendments to approved protocols may be reviewed and approved by the Chair or Vice Chair.

3. An annual progress report is due on the anniversary of the protocol approval.

4. A failure to submit the required annual progress report terminates the approval and the BSO will be informed.

VIII. Adverse Events

A. The IBC Chair and BSO will be responsible for investigating any adverse event(s) involving biohazardous agent(s) or recombinant DNA molecule(s).

B. All adverse event(s) must be reported in writing to the BSO and IBC Chair. Examples include, but are not limited to:
   1. work-related exposures
   2. injuries
   3. illnesses
   4. laboratory accidents
   5. any non-compliance with applicable institutional policy and/or Federal, State, and local regulations
   6. research conducted outside the scope of the approved IBC protocol

B. If the adverse event in question involves animals or human research subjects, the IBC Chair and BSO will coordinate their investigation and response with the Institutional Animal Care and Use Committee (IACUC) and/or the Institutional Review Board (IRB).

C. If the adverse event in question involves chemical or radiation hazards, the IBC Chair and BSO will coordinate their investigation with Environmental Health & Safety and/or Radiation Safety
D. The Biosafety Officer will determine if the exposure, injury, illness or incident of non-compliance requires reporting to regulatory agencies.

E. The Institutional Official will be responsible for reporting to agencies outside of the University.

IX. Ad Hoc and Sub Committees

A. The IBC Chair may appoint Ad Hoc and Sub-Committees to the IBC to address special needs that do not fit within the scope of or time available during regularly scheduled meetings.

   1. Sub-committee membership must include at least one voting member of the IBC.

B. Ad Hoc or Sub-committees will serve to advise and make recommendations to the IBC on designated issues.

   1. Ad Hoc or Sub-committees will not have the authority to act on behalf of the IBC.

   2. Ad Hoc or Sub-committees will not have the authority to approve research protocols.

X. Miscellaneous

The reference for administrative and parliamentary procedure for the UC IBC is Robert’s Rules of Order, Newly Revised, 10th ed.