

UNIVERSITY OF
LOUISVILLE
Bylaws of the Institutional Biosafety Committee

1.0 General

1.1 Name

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

1.2 Purpose and Authority

The IBC reports to the University of Louisville Executive Vice President for Research and Innovation (EVPRI) and is administered by the Department of Environmental Health & Safety (DEHS). The IBC and its Chair are appointed by the EVPRI in consultation with or at the request of the IBC chair and/or Biological Safety Officer (BSO). The BSO is an employee of DEHS. The IBC reports to the EVPRI on all matters relating to work with hazardous biological materials at University of Louisville.

The committee is responsible for monitoring and oversight of the use of hazardous biological materials to safeguard the health and safety of University of Louisville personnel, students, the community, and the environment. The IBC must also ensure compliance with applicable federal, state and local regulations and guidelines, granting agency guidelines, as well as University of Louisville policies and procedures.

The committee monitors and 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 office, include:

- Reviewing and approving the protocol for each project or each research laboratory using hazardous biological materials.
- Continuing review of approved registration.
- Reviewing and approving the University's Biosafety Manual.
- Maintaining the University of Louisville Institutional Biosafety Committee Procedures, with approval required by the EVPRI.
- Maintaining official minutes of all meetings of the IBC.

2.0 Membership Provisions

2.1 Committee Composition

The University of Louisville IBC composition must meet requirements of NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines). When possible, the University of Louisville IBC will seek to achieve member composition that represents the diversity in research disciplines (e.g. medicine, dentistry, biochemistry, biology), units (e.g. colleges of Medicine, Arts and Sciences, Public Health) and campus locations (e.g., Health Sciences Center, Belknap, and Shelbyhurst).

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2.2 Composition and Appointment

The voting members of the committee are appointed by the EVPRI. The committee has membership as follows:

The Chair of the Committee

The Chair of the Committee shall be a tenured member of University of Louisville's faculty who is professionally knowledgeable about one or more aspects of biosafety. The chair of the University of Louisville IBC will be appointed by the EVPRI in consultation with the Executive director of the DEHS and the BSO. The chair will designate a faculty member of the IBC as vice-Chair, to address topic discussions and registration reviews when the Chair is absent or has a conflict of interest.

Voting Members

The University of Louisville IBC will be comprised of at least eight members (at least five of which must be faculty) that collectively have experience and expertise in recombinant or synthetic nucleic acid molecule technology and the capability to assess the safety of recombinant or synthetic nucleic acid molecule research and to identify any potential risk to public health or the environment. The University of Louisville IBC must have members with expertise in animal containment, plant containment, human research, BSL-3 research, and/or dual use research. When conducting gene drive research, the IBC must have a member or ad hoc consultant with adequate expertise in gene drive (*e.g.*, specific species containment, ecological or environmental risk assessment). The University of Louisville IBC will also include the university's BSO, at least two local community representatives and at least one laboratory technical staff member.

Non-voting/Advisory Members

The University of Louisville IBC chair, in consultation, with the BSO can appoint *ad hoc* committee members to serve the committee when specialist advice or other input is deemed necessary. The University of Louisville IBC chair in consultation with the BSO has the authority to establish IBC sub-committees as needed. IBC sub-committees will report to the full IBC committee. The administrator or designate of the University of Louisville IACUC and IRB are ex officio and may be included in sub-committees as needed.

2.3 Terms of Office

Members of the committee are appointed by the EVPRI to renewable three-year term. Upon recommendation of the Chair and BSO to the EVPR, membership of the committee will be adjusted to meet the needs/demands of the IBC. The EVPRI will notify members in writing when/if his/her service is no longer needed.

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2.4 Resignation

A member may resign at any time upon written notice to the IBC Chair at least 30 days prior to the effective date. The IBC chair and BSO shall make recommendations to the EVPRI concerning possible replacements to complete the term of the member. The Chair shall have the right to resign from the chair position upon notifying the BSO, EVPRI, and IBC with three months advance notice whenever possible to allow for an orderly transition.

2.5 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 IBC chair and BSO shall recommend to the EVPRI that a replacement be appointed to complete the term of the member.

3.0 Duties of the Officers

3.1 Chair

The Chair shall oversee the operation and duties of the IBC and will preside at all IBC meetings. 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, or designee, shall:

- a) Prepare and retain 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) Retain a copy of the bylaws, a current membership mailing and e-mail list.
- c) Perform such other duties as may be prescribed by the bylaws or which may be delegated by the Executive Director of DEHS and on the recommendation by the Chair or by a vote of the committee membership. The BSO has latitude determining how the bylaws will be upheld.
- d) Advise and represent the Executive Director of DEHS and the EVPRI as needed in matters related to the Biosafety program.

4.1 Meetings

The committee shall meet at least four times per year to conduct the business of the committee. Official business of the IBC may be conducted at face-to-face meetings, via electronic connection (e.g.

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phone or video conference), or via email vote (when deemed appropriate by the Chair and BSO). The BSO shall advise the members of the time and place of the meeting and shall post the information on the DEHS Biosafety Webpage. Additional meetings may be called by the Chair, the BSO, or the EVPRI. However, decisions and actions to be taken must be approved by a quorum of the IBC.

4.2 Time and Place of Meetings

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

4.3 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 written notice.

4.4 Rules of Order

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

4.5 Quorum

The presence of at least 8 voting members or, if committee consist of 14 members or less, the simple majority of the committee, shall constitute a quorum for the transaction of business at any meeting of the committee. No substantive 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.

4.6 Voting

Each voting member shall have one vote, which shall be exercised only by that member and only when in attendance. In some circumstances, agreed upon by the committee members as part of a motion, an electronic vote (e.g. email) may be used. Motions may be made by any voting IBC member. Approval of all motions shall be gained with a simple majority.

5.0 Amendment of Bylaws

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These bylaws may be amended at a regularly scheduled meeting by the affirmative vote of a majority of the members of the committee present. Once the committee approves the amendment, the revised bylaws will be submitted to the EVPRI for approval. Such amendments will take effect as soon as they are signed by the EVPRI.

6.0 Conflict of Interest

IBC members are prohibited from participating in the review of, deliberative discussion on, or vote relative to any research in which they (or their immediate family members) participate in any way, including but not limited to the following: Study planning and design, Conduct of the study, Data analysis, Subject recruitment, Subject consent, and Authorship. IBC members are likewise prohibited from participating in the deliberative discussion or vote relative to any research in which they (or their immediate family members) have or may appear to have a financial or any other perceived conflict. This member may be asked to participate in the discussion of the issue if requested by the IBC but shall not be permitted to make any formal motions or to cast a vote concerning the topic at hand. The member shall leave the meeting during any vote related to the conflict-of-interest area.

7.0 Open Records

Upon request, UofL shall make available to the public all IBC meeting minutes and any documents submitted to or received from funding agencies which the latter are required to make available to the public. If public comments are made on IBC actions, the institution shall forward both the public comments and the IBC's response to the Office of Science Policy, National Institutes of Health. Persons seeking access to records must apply in writing to inspect them. The Office of University Counsel will determine whether or not the records, or portions of them, are subject to inspection, and will respond to the requester.