

**University of Wisconsin-La Crosse
Institutional Biosafety Committee (IBC)
Operating Guidelines and Organizational Policies
(Approved by IBC 11/18/2024)**

I. Purpose of the Board

- A. The University of Wisconsin-La Crosse (UWL) Institutional Biosafety Committee (IBC) is charged with responsibility for oversight of research and instructional activities using biological materials that entail a potential risk to humans, animals, plants, or the environment. These activities include, but are not necessarily limited to, studies involving recombinant or synthetic nucleic acid molecules; infectious agents or pathogens; biological toxins; human or non-human animal-derived tissues, fluids, and cells; toxic chemicals used to elicit a biological response; or other substances that may be toxic to living organisms. The IBC is authorized to approve, require modifications to secure approval, or disapprove these proposed research activities. The IBC is authorized to fully investigate potential violations or compliance issues and take action to suspend, rectify, and/or mitigate such issues. The IBC is further authorized to suspend or revoke authorization for previously approved research that is not being conducted in accordance with the approved protocol, the IBC's requirements, federal or state laws or regulations, or institutional policies applicable to biological research. The IBC may also suspend or revoke authorization for previously approved research when the research or its conduct creates an unexpected serious potential threat to safety, health, or the environment. In addition, the IBC is authorized to draft and implement policy and to set other requirements related to the use of biological materials in research or teaching, and to conduct assessments and serve as the institutional review entity for potential Dual Use Research of Concern (DURC) and research involving Select Agents or Toxins.

II. Statutory Authority of the Committee

- A. The Institutional Biosafety Committee (IBC) is mandated by the US Department of Health & Human Services, National Institutes of Health (NIH), NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (59 FR 34472 and subsequent amendments), effective 4 July 1994, for research involving recombinant or synthetic nucleic acid molecules; and cells, organisms, and viruses containing such molecules conducted at institutions receiving support for such research from NIH. The NIH Guidelines are applicable to all such research conducted at the institution regardless of funding source. Additional requirements for biohazardous materials requiring oversight by the IBC are set forth by the US Department of Health & Human Services, Centers for Disease Control & Prevention (CDC), Biosafety in Microbiological and Biomedical Laboratories (effective 1984 and subsequent amendments).
- B. The Chancellor, as chief executive officer of the University, is responsible for ensuring that the UWL IBC operates in accordance with all applicable laws. The Chancellor has designated the Associate Vice Chancellor for Academic Affairs/Research Integrity Officer (RIO) to monitor the operation of the IBC and to appoint its membership.

III. Review Policies and Procedures

- A. The IBC shall establish policies and procedures for the review of research and instructional activities involving biological materials that entail a potential risk to humans, animals, plants, or the environment and shall disseminate these broadly and regularly to all appropriate faculty, staff, and students at the University. The IBC shall issue (and update as needed) a substantive booklet, the *Biosafety Manual*, which includes required review policies and procedures. This document and other resources are available in electronic format through the UWL Office of Research & Sponsored Programs (ORSP) IBC webpage.

IV. Membership of the Board

- A. Federal law requires that each IBC shall have at least five (5) members who possess sufficient expertise, experience, and breadth of knowledge to provide complete and adequate review of research activities commonly conducted at the institution. The IBC membership must have professional competence necessary to review specific research activities, as well as knowledge of institutional regulations and commitments, applicable laws, and standards of professional conduct and practice.
- B. The law further requires that each IBC shall include the following types of individuals in its membership:
 - 1. At least two members of the IBC must not be otherwise affiliated with the institution apart from their membership on the IBC and must represent the interests of the surrounding community with respect to health and protection of the environment. These members are referred to as community representatives.
 - 2. At least one member must have expertise in plant, plant pathogen, or plant pest containment principles if research is conducted at the institution subject to the NIH Guidelines Appendix L, *Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Plants*.
 - 3. At least one member must have expertise in animal containment principles if research is conducted at the institution subject to the NIH Guidelines Appendix M, *Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Animals*.
 - 4. In the event a research protocol involves gene drive modified organisms (GDMOs), the institution must ensure the IBC has adequate expertise (e.g., specific species containment, ecological or environmental risk assessment), using ad hoc consultants if necessary. Such expertise should enable the IBC to fulfill its obligation to assess the impact on ecosystems.
 - 5. In the event a research protocol involves the use of recombinant or synthetic nucleic acid molecules with human participants, at least one member must have adequate experience and training in human gene transfer. This requirement may be met by either a full member or ad hoc consultant.
 - 6. It is strongly recommended that the IBC include at least one representative member from the institution's laboratory staff.

- C. The law also instructs the following:
1. One IBC member must be designated to serve as the institutional contact for the National Institutes of Health (NIH) Office of Science Policy (OSP). UWL has designated the Associate Vice Chancellor for Academic Affairs/Research Integrity Officer (RIO) for this role.
 2. At least one member must be designated as the Biological Safety Officer (BSO) if research is conducted at the institution with recombinant or synthetic nucleic acid molecules at Biosafety Level 3 (BSL3) or higher or in large-scale (greater than 10 liters), or if the institution conducts any research involving gene drive modified organisms (GDMOs).
 3. The institution must file an annual report with NIH OSP including the following:
 - a. A roster of all IBC members indicating the Chair; contact person; Biological Safety Officer (BSO) if applicable; plant, animal, or human gene transfer experts (if applicable); and community representatives
 - b. Biographical sketches for all members
- D. The UWL IBC will consist of not fewer than five (5) full voting members who are appointed by the Associate Vice Chancellor for Academic Affairs/Research Integrity Officer (RIO) with the concurrence of the Provost under the authority of the Chancellor.

V. Term of Appointment

- A. Each voting member of the IBC will serve for a three-year term. Appointments to the IBC shall be staggered in rotation, such that no more than one-third of the IBC would be reappointed or replaced in a given year.
- B. The Associate Vice Chancellor for Academic Affairs/Research Integrity Officer (RIO) may reappoint any member for additional term(s).

VI. Permanent and *Ex Officio* Members and *Ad Hoc* Consultants

- A. The Committee shall elect a Chair from among its faculty and academic staff membership who will convene meetings and serve as a voting member of the full committee. The Chair shall be elected at the last meeting of the IBC in the Spring Semester or immediately thereafter. The elected Chair shall begin their term on September 1st of the same year and shall serve a one-year term. This individual may be re-elected for a period commensurate with their term of appointment (see above, Section V).
- B. The Associate Vice Chancellor for Academic Affairs/Research Integrity Officer (RIO) shall serve as a permanent, non-voting, *ex officio* member and consultant to the IBC and shall be referred to as the “IBC Administrator.”
- C. The Associate Vice Chancellor for Academic Affairs/Research Integrity Officer (RIO) shall appoint an IBC Coordinator for a period of 3 years, with an option to seek reappointment. Ordinarily, the IBC Coordinator shall be a member of UWL faculty or

academic staff. The Coordinator reports directly to the RIO and shall serve as an *ex officio*, voting member of the IBC. The Coordinator shall provide primary review of all IBC protocols, renewals, and revisions; determine whether review by the full IBC is required; and may approve protocols that do not require review by the full IBC. The Coordinator may work with the IBC Chair or other committee members in making decisions about a protocol, renewal, or revision. In the event alternate or additional expertise is needed to evaluate protocols that do not require full IBC review, the Coordinator may designate or collaborate with another IBC member with relevant expertise to conduct the primary review and provide approval.

- D. The Research & Compliance Specialist from the Office of Research & Sponsored Programs (ORSP) shall serve as a permanent, non-voting, *ex officio* member, and consultant to the IBC.
- E. The IBC has the authority, at its discretion, to invite individuals with specialized expertise to participate in its sessions as non-voting, ad hoc consultants. The IBC also has the authority to appoint subcommittees and ad hoc committees of subject matter experts to address specific issues.

VII. Meetings

- A. The IBC Chair is responsible for convening the IBC according to an established routine schedule that permits researchers to have their projects reviewed in a timely manner. The full membership of the IBC shall meet at least one (1) time during the calendar year.
- B. A majority of the full appointed voting membership shall constitute a quorum for the purpose of holding an official meeting. A majority of those voting members present at an official meeting shall be sufficient to issue official verdicts, actions, and judgments.
- C. All meetings shall be conducted in accordance with the State of Wisconsin's Open Meetings Law and any other appropriate state and/or federal regulations governing the operation of this public IBC.
- D. Meeting minutes will be taken at every IBC meeting in accordance with federal requirements.
- E. Meeting minutes can be requested by the public in writing according to UWL's public records notice. In accordance with federal guidelines, certain information may be redacted from IBC minutes prior to public sharing to protect matters of a private and/or proprietary nature.
- F. In accordance with federal guidelines, if public comments are made on the IBC's actions, UWL will forward the public comments and the IBC's response to the NIH Office of Science Policy (OSP) by email. Public comments can be submitted in writing to the Office of Research & Sponsored Programs (ORSP). ORSP will forward public comments to the IBC and facilitate submission of the IBC's written response to the submitter(s) and the NIH OSP.

VIII. Review of Exempt Protocols

- A. All activities involving biological materials that entail a potential risk to humans, animals, plants, or the environment must have a corresponding biosafety protocol registered with the IBC. Activities that are not subject to the NIH Guidelines or that are exempt from the NIH Guidelines under Section III-F may have the protocol reviewed only by the IBC Coordinator and/or designee, rather than the full IBC, to verify the activity is in fact exempt and, if applicable, the section of the NIH Guidelines under which the activity is categorized has been correctly determined.

IX. Conflict of Interest Procedures

- A. Any member of the IBC who has an actual or apparent conflict of interest in the initial or continuing review of a research project may not participate in the IBC's deliberations or voting (except to provide general or specialized information that may be requested by the IBC).
- B. It is the responsibility of the individual IBC member to identify a conflict of interest and remove themselves voluntarily by informing the IBC Chair. The specific nature of the conflict of interest need not be revealed.
- C. If someone believes that there is an actual or apparent conflict of interest in the participation of an IBC member in a particular case, and that person has not removed themselves from the proceedings, a challenge may be raised either by a member(s) of the IBC or by the researcher(s) whose project is under review. A conflict-of-interest challenge must be raised prior to the IBC's action on the project and takes immediate precedence as a point of order during an official meeting.
- D. The IBC minutes must clearly show that any member with a conflict of interest was excused from the deliberations due to the conflict of interest.

X. Institutional Review

- A. Affirmative decision of the IBC may be subject to further review by University officials. The Associate Vice Chancellor for Academic Affairs/Research Integrity Officer (RIO), Provost/Vice Chancellor for Academic Affairs, and/or Chancellor may, at their discretion, conduct additional, independent inquiry into a decision of the IBC and may, if their findings so warrant, disapprove a research project previously authorized by the IBC. Such action is anticipated only in extraordinary circumstances, such as when a decision by the IBC conflicts with federal regulations or institutional policies. Written explanation of the rationale for the decision will be documented by the RIO, Provost, and/or Chancellor, and will be provided to the IBC and researcher and kept on file in IBC records.
- B. In no case may the Associate Vice Chancellor for Academic Affairs/Research Integrity Officer (RIO), Provost/Vice Chancellor for Academic Affairs, and/or Chancellor approve a research project that the IBC has previously disapproved.

Operating Guidelines and Organizational Policies of the University of Wisconsin-La Crosse Institutional Biosafety Committee adopted September 12, 2023, and revised November 18, 2024.



Sandra Grunwald
Associate Vice Chancellor for Academic Affairs &
Research Integrity Officer (RIO)

11/17/2024

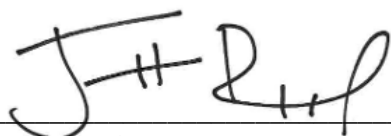
Date



Betsy Morgan
Provost & Vice Chancellor for Academic Affairs

11/18/2024

Date



James Beeby
Chancellor

11/18/2024

Date