DEPARTMENT OF
ENVIRONMENTAL SAFETY,
SUSTAINABILITY & RISK

University of Maryland

Institutional Biosafety Committee Charter and Procedures

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Approved by

Dr. Gregory F. Ball

Vice President for Research

Article I. Introduction

The Vice President for Research (VPR) establishes the University of Maryland (UMD) Institutional Biosafety Committee (IBC) to ensure the safety of all faculty, staff, students, research participants and others involved in biological research at UMD and to protect the general public and the environment from adverse consequences related to biological research. The IBC's work supports UMD in meeting all required standards set by federal, state and local governments, including those found in the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*[1] ("*NIH Guidelines*") which mandate establishment of the IBC.

"Each institution conducting or sponsoring recombinant or synthetic nucleic acid molecule research which is covered by the NIH Guidelines is responsible for ensuring that the research is conducted in full conformity with the provisions of the NIH Guidelines. In order to fulfill this responsibility, the institution shall: ... establish an Institutional Biosafety Committee..." NIH Guidelines, Section IV-B-1.

The UMD ensures appropriate training for the IBC Chair and members, Biosafety Officer and other containment experts (when applicable), Principal Investigators, and laboratory staff regarding laboratory safety and implementation of the *NIH Guidelines*.

The IBC conducts local review and oversight of research involving biological materials. Its scope includes but is not limited to research with clinical specimens, human gene transfer, genetically modified organisms, infectious agents, Select Agents and Toxins, biological agents and toxins, and unfixed human and non-human primate materials.

The IBC also assists UMD in developing specific policies to assure that research conducted with hazardous or potentially hazardous biological agents, be they naturally occurring or synthetically created, is undertaken in appropriate containment settings and consistent with university policies and industry best practices.

Definitions

1. ***Biosafety Manual for University of Maryland***: A guidance document from ESSR describing policies, practices, and procedures for biosafety applicable to PIs and others conducting or reviewing research subject to biosafety provisions. Projects requiring IBC review are subject also to certain parts of the manual and all PIs must comply with applicable provisions.
2. **Biosafety Officer (BSO)**: The individual in the Office of Biosafety who serves as the UMD's subject matter expert in biosafety. The BSO maintains awareness and proficiency in areas of emerging risks and provides strategic direction for the UMD biosafety program.
3. **UMD Office of Biosafety**: A component of the Department of Environmental Safety, Sustainability and Risk (ESSR) that supports compliance with applicable federal, state, local and university requirements for research and which, among other duties, serves as a liaison between the IBC and the PI regarding projects under IBC review.
4. **Principal Investigator (PI)**: The person qualified on the basis of their education, training and experience to lead research and who has overall responsibility for the design, conduct, reporting and scientific integrity of research, including responsibility for full compliance with the *NIH Guidelines* during the conduct of research involving recombinant or synthetic nucleic acid molecules. PIs are responsible for submitting project for review by the IBC before beginning research. PIs are also responsible for ensuring that laboratory staff under their jurisdiction are appropriately trained regarding the same requirements and all other applicable standards.
5. **Non-University User of UMD Facilities**: A non-UMD organization which has obtained a Facility Use License to perform activities at UMD facilities. It is the Non-University User's responsibility to comply with all federal,

state and local regulations, including but not limited to the *NIH Guidelines*. The UMD IBC does not review the work of Non-University Users. A Non-University User of UMD Facilities performing work that is subject to review under the *NIH Guidelines* must obtain independent IBC review for compliance with the *NIH Guidelines*.

Article II. IBC Responsibilities and Processes

The IBC, working with the Office of Biosafety as needed, provides initial and ongoing review for research projects as described below.

A. *Research Involving Recombinant or Synthetic Nucleic Acid Molecules*

The IBC reviews recombinant or synthetic nucleic acid molecule research conducted at or sponsored by UMD for compliance with the current version of the *NIH Guidelines* and approve those research projects that are found to conform to the *NIH Guidelines*. NOTE: The IBC may not authorize initiation of experiments that are not explicitly covered by the *NIH Guidelines* until NIH establishes the containment requirement.

1. *Experiments that require NIH Director/Office of Science Policy ("OSP") approval **and** IBC approval prior to initiation – Sections III-A and III-B of the NIH Guidelines*

   If the IBC determines that the project requires NIH Director/OSP approval and IBC approval before initiation, the BSO submits relevant information on the proposed project to the OSP. Approval of both the IBC and NIH must be obtained prior to initiation of the research.

2. *Experiments involving human gene transfer that require IBC approval prior to initiation– Section III-C of the NIH Guidelines*

   Research cannot be initiated until IBC and all other applicable institutional and regulatory authorization(s) and approvals have been obtained.

3. *Experiments requiring IBC approval before initiation – Section III-D of the NIH Guidelines*

   The Office of Biosafety reviews the project and determine whether it falls within Section III-D of the *NIH Guidelines*. The IBC reviews the project to determine appropriate containment level and precautions.

4. *Experiments requiring IBC notice simultaneous with initiation – Section III-E of the NIH Guidelines*

   After review by the Office of Biosafety, projects which include only work falling within Section III-E of the *NIH Guidelines* may be allowed to initiate prior to IBC approval. For projects falling within Section III-E of the *NIH Guidelines*, the Office of Biosafety informs the PI of the required containment precautions prior to initiation of the experiment. The project will be reviewed at the next IBC meeting.

5. *Experiments that are exempt from the NIH Guidelines – Section III-F of the NIH Guidelines*

   The Office of Biosafety reviews the project to verify if it is exempt from the *NIH Guidelines*. Upon verification, the Office of Biosafety informs the PI of the required containment precautions. Projects that are exempt from the *NIH Guidelines* are not reviewed by the IBC.

B. Research Involving Infectious/Biohazardous Agents/Biological Agents

The IBC reviews research involving infectious/biohazardous agents conducted at or sponsored by UMD. The BSO and IBC consult guidance published in the current edition of the NIH/CDC publication *Biosafety in Microbiological and Biomedical Laboratories*[2] (BMBL) to determine the appropriate containment level and precautions.

1. *Risk Group 2 and Risk Group 3 Infectious Agents to humans, animals, arthropods, and plants*

Biological agents are divided into four Risk Groups, as defined in Appendix B of the *NIH Guidelines* and *BMBL*. Projects involving Risk Group 2 and/or Risk Group 3 agents are reviewed by the IBC. Research with Risk Group 4 agents is not permitted at UMD. Projects involving Risk Group 1 agents are reviewed and approved by the Office of Biosafety; an IBC review is not required.

2. *Biological toxins*

Biological toxins are poisonous substances produced by certain microorganisms, animals, and plants. Although toxins are derived from biological materials, they do not replicate and are therefore not considered infectious. However, they may be extremely toxic in very small quantities and must be managed accordingly. PIs must include biological toxins to their toxin survey submitted for review. IBC reviews all biological toxins except endotoxin, which are reviewed and approved solely by the Office of Biosafety.

3. *Human and Non-Human Primate Source Materials*

Source materials are from humans or non-human primates include cells, tissues, fluids, carcasses and live animals. Human and non-human primate source materials which are known or suspected to contain Risk Group 2 or Risk Group 3 infectious agents are reviewed by the IBC. Projects involving human and non-human primate source materials that are not known or suspected to contain a Risk Group 2 or Risk Group 3 infectious agent are reviewed and approved by the Office of Biosafety; an IBC review is not required.

4. *Biological Select Agents and Toxins*

Biological Select Agents and Toxins (BSAT) are materials designated by the United States Government (USG) pursuant to 7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73 that have the potential to pose a severe threat to public, animal or plant health or to animal or plant products. The IBC, in coordination with the BSO and UMD Responsible Official (RO), reviews and approves all registrations of BSAT.

NOTE: Work with BSAT requires prior approval of the UMD RO and registration with the Federal Select Agent Program, unless using an agent in a quantity specifically exempted under *Permissible Toxin Amounts*[3.]

C. Dual Use Research of Concern

The IBC serves as UMD's Institutional Review Entity (IRE), which is charged with addressing UMD's responsibilities pursuant to the *United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential* (*DURC Policy*) as well as any requests by the appropriate USG funding agency. The IRE and the UMD Contact for Dual Use Research (ICDUR) serve on the institution's behalf to ensure compliance with the *DURC Policy*. The IBC and BSO identify projects which have the potential to involve Dual Use Research of Concern. The IRE reviews all such research in accordance with the *DURC Policy*.

D. Off-Campus Research Sponsored by UMD

Research projects conducted at off-campus locations but sponsored by UMD are reviewed by the IBC if they are subject to IBC review, as outlined in Article II of this document.

E. Periodic Review of Research

IBC reviews projects prior to initiation and periodically thereafter to ensure continued compliance with the *NIH Guidelines* and IBC requirements. Periodic reviews reflect the most updated versions, as applicable, of the *NIH Guidelines*, *BMBL* and other relevant regulatory and guidance information. All active (*i.e.* not archived) projects within a laboratory are subject to periodic review. The IBC reserves the right to review any activity at any time, as needed to fulfill its mission.

F. Occupational Health Planning Guidance

In cooperation with the Occupational Health Unit of the University Health Center, The IBC provides occupational health recommendations for health precautions, medical surveillance and exposure response for research in the scope of this document.

G. Reporting and Communication

1. IBC Review Decisions and Actions

The IBC decisions and actions related to the status of the PI's projects are notified via email to the respective PIs. IBC Chair and BSO are also be included in these email notifications.

2. *Incident Reporting*

The BSO reports research related violations, incidents, accidents, and/or illnesses to OSP, in accordance with the *NIH Guidelines*.

3. Comments from the Public

Upon request, UMD makes available to the public all IBC meeting minutes and any documents submitted to or received from funding agencies, insofar as required by Section IV-B-2-a-(7) of the *NIH Guidelines*. The UMD Office of General Counsel (OGC) answers the request and sends the final documents on behalf of UMD. If public comments are made on IBC actions, the BSO forwards both the public comments and the IBC's response to the NIH OSP, insofar as required by the *NIH Guidelines*.

4. Working with IACUC and IRB

The IBC collaborates with other committees at UMD, including but not limited to the Institutional Animal Care and Use Committee (IACUC) and Institutional Review Board (IRB), to address issues of mutual interest and responsibility.

Article III. Membership

A. The IBC Chair is appointed by the VPR. The IBC Chair is responsible for ensuring IBC members are appropriately trained.

B. Members are recommended by the IBC Chair and the BSO to the VPR, who makes the appointment. Each new appointment shall be for a three (3) years term, which may be renewed at the discretion of the VPR.

C. The IBC includes the following type of membership: Voting Members, Non-affiliated Voting Members (Community Members), and Institutional Members (who are non-voting members).

D. In accordance with the *NIH Guidelines*, the IBC is comprised of no fewer than five voting members who have experience and expertise in recombinant and synthetic nucleic acid technologies, microbiology and biosafety. The committee includes, but is not limited to, the following:

1. The BSO.
2. One Voting Member with expertise in plant, plant pathogen, or plant pest containment principles, when related research described in Appendix L of the *NIH Guidelines* require prior approval from the IBC.
3. One Voting Member as representative of the UMD IACUC, or a Voting Member with expertise in animal containment principles when related research described in Appendix M of the *NIH Guidelines* require prior approval from the IBC.

4. One Voting Member as representative of UMD laboratory technical staff.

5. Alternate members serve as backups for voting members within the same areas of expertise. Voting members and alternate members coordinate their attendance at IBC meetings to ensure representation in their areas of expertise. When both a voting member and their alternate are present at an IBC meeting, only the voting member's vote is counted.

6. Two Community Members who are not affiliated with UMD, apart from their membership on the IBC, and who represent the interest of the surrounding community with respect to health and the protection of the environment. The Community Members are Voting Members.

E. Internal or external personnel with additional expertise, as deemed necessary by the BSO and IBC chair, may be designated by IBC Chair for specific project as *ad hoc* consultants, who are not IBC members and do not have voting authority at the IBC meetings.

Article IV. Meetings, Procedures and Minutes

A. IBC meetings are convened monthly in person or virtually. Meetings may be canceled if there is no business to be conducted. When circumstances warrant urgent committee action, *ad hoc* meetings may be called at the joint agreement of the IBC Chair and BSO.

B. The review and discussion of all projects take place at IBC meetings at which a quorum of the members is present. A quorum requires the attendance of at least five voting members. IBC members with potential conflict of interest are excluded from contributing to the quorum for the relevant projects and must recuse themselves from both the review and voting on those projects. See Article V for more information on Conflicts of Interest.

C. The IBC Chair may invite PIs or other individuals affiliated with a project under review to provide information at IBC meeting. Such individual will not be involved in review or approval of a project.

D. All IBC members are granted access to proposed or ongoing project documents and review them prior to the IBC meeting. A primary reviewer and a secondary reviewer are assigned by the Office of Biosafety to review each project. At the IBC meeting, the primary and secondary reviewers present the IBC with an overview of the assigned project and a proposed motion. Primary or secondary reviewers who are not able to attend the IBC meeting shall provide a written summary of their review and proposed motion to the Office of Biosafety in advance of the IBC meeting. All other IBC members can submit their review and recommendations on the motions.

E. The BSO designates an Office of Biosafety staff member to serve as IBC executive secretary, who is responsible for preparation of meeting agenda and minutes.

F. For tracking purposes, the Office of Biosafety assigns a unique project number to each project.

G. IBC members are bound by confidentiality protections and shall not discuss or disclose the details of meetings or projects to individuals or organizations not associated with the IBC.

H. The following actions may be made for each project under review.

1. **Approval** – the project is approved as reviewed with no modifications required.

2. **Modifications Required to Secure Approval (MRSA)** – the project is approved pending resolution of specifically articulated changes or clarifications, which will be reviewed by the Office of Biosafety.

3. **MRSA with additional designated reviewers** – the project is approved pending resolution of specifically articulated changes or clarifications, which will be subsequently reviewed for approval by the BSO, IBC Chair, or any reviewers designated by the IBC at the time of voting.
4. **Deferral** – the project requires significant changes or clarifications which prevent the IBC from conducting a thorough risk assessment and which must be resolved prior to review at a subsequent IBC meeting.
5. **Disapproval** – the work described in the project may not be conducted at UMD, due to the agent(s), facility/engineering control requirements, and/or other concerns from the committee and other stakeholders, as expressed by the committee at the time of voting.

Article V. Conflicts of Interest

No member of the IBC may be involved (except to provide information requested by the IBC) in the review or approval of a project in which he/she has been or expects to be engaged or has a direct financial interest. In the event that a member of the IBC submits a project for review, they must be recused during the review and voting process for the project. An IBC member who is a collaborator or personal relative of a researcher whose project is reviewed by the IBC will not be present during the review and voting process. IBC members with questions about whether they may have a real or perceived conflict of interest should raise them to the IBC Chair and the BSO.

References

1. National Institutes of Health Office of Science Policy. *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*. https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.htm
2. Centers for Disease Control and Prevention, National Institutes of Health. *Biosafety in Microbiological and Biomedical Laboratories*. https://www.cdc.gov/labs/BMBL.html
3. Federal Select Agent Program. *Permissible Toxin Amounts*. https://www.selectagents.gov/sat/permissible.htm