
Charter of the Princeton University Institutional Biosafety Committee

I. Purpose

The purpose of this Charter is three-fold:

- To delineate the scope, responsibilities, and membership of Princeton University's Institutional Biosafety Committee (IBC)
- To describe the processes utilized in the review and approval of IBC registrations, including modifications (i.e., an amendment in eRIA) to approved IBC registrations.
- To establish that the IBC works in consultation and collaboration with Environmental Health and Safety (EHS), the Institutional Animal Care and Use Committee (IACUC), the Institutional Review Board (IRB) Laboratory Animal Resources (LAR) and the Non-Human Primate Research Program (NRP), to develop and implement IBCs policies, guidelines, and processes to ensure adherence to the requirements set forth by the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC), among other regulatory statutes and guidelines.

II. Scope of the IBCs Oversight

The IBC, which reports to the University's Institutional Official (IO), ensures the safe and compliant conduct of research activities at Princeton University that involve:

- Recombinant and synthetic nucleic acid molecules (r/sNA), as defined in the NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules (NIH Guidelines).
- Biological Dual Use Research of Concern (DURC)
- Biological toxins
- Microorganisms, including viruses, bacteria, fungi, parasitic agents, and prions that could be harmful to humans, plants, or animals
- Infected research animals
- Genetically engineered models (GEMs)
- Human and non-human primate blood and tissues, and other animal tissues that may present zoonotic and/or other infectious disease concern(s)
- Field research with animals and/or animal specimens known to be reservoirs of zoonotic disease.

III. Responsibilities of the IBC:

- Develop, implement, and periodically review policies, procedures, and guidelines related to the activities listed in Section II, Scope of the IBC, to ensure adherence with, at minimum, the requirements set forth by the NIH and the CDC.
- Review proposed research involving the activities listed in Section II, Scope of the IBC, that are conducted at or sponsored by the University, and approve those projects that comply with NIH Guidelines, other applicable regulations, and University policies.
- Perform thorough risk assessments to determine the appropriate containment level for each specific use or application of the activities listed in Section II, Scope of the IBC.

- Assist Principal Investigators (PIs) and others at the University in meeting their responsibilities for full compliance with NIH Guidelines, other applicable regulations, and University policies (e.g., assessing risks, establishing lab-specific policies and procedures, training personnel, and maintaining facilities and equipment), as detailed in [The Princeton University Biosafety Manual](#)
- Provide guidance and support to the Biological Safety Officer (BSO) and the EHS in carrying out the requirements of the University's Biosafety Program, including aspects of the Occupational Health and Safety program (OHSP) (e.g., the medical surveillance program).
- Investigate, and report as needed, any significant problems, violations of NIH Guidelines, or any significant research-related accidents and illnesses and issues to NIH Office of Science Policy (OSP), as detailed in Policy "[Reporting Requirements for Incidents Involving Recombinant and Synthetic Nucleic Acid Molecules](#)".
- Engage with the IO, currently the Dean for Research, to communicate any concerns (e.g., non-compliance, exposures) or need(s) for resources.

IV. Membership

Per the NIH Guidelines, the IBC must comprise no fewer than five members so selected that they collectively have experience and expertise to address the specific research activities conducted at Princeton University and to identify any potential risk to public health or the environment. The Director and/or Associate Director of the Office of Research Integrity and Assurance (RIA), with assistance from the BSO and the IBC Chair, recruits and nominates IBC members. IBC faculty members are formally appointed by the IO for a minimum of a three-year term.

A. The following voting members collectively and properly constitute the IBC:

1. The following *ex-officio* voting members are, at minimum:

- i. The BSO
- ii. The Attending Veterinarian (and/or their alternate or delegate(s)) with expertise in animal containment practices
- iii. A physician from University Health Services with expertise in Infectious Diseases and/or Occupational Health Medicine.

2. The following voting members:

- i. A minimum of three faculty members, one of which is designated as the IBC Chair, with the collective expertise to address the specific research activities conducted at Princeton University, and include r/sNA technology, general issues of laboratory biosafety, the use of infectious materials will serve on the IBC.
- ii. At least two members not affiliated with the University represent the interest of the surrounding community with respect to health and protection of the environment.

B. A representative from RIA serves as the IBC secretary and administrator. The RIA Post-Approval Monitor (PAM) may also attend to facilitate congruence between

IACUC and IBC applications. Additional units may also elect to have a representative attend IBC meetings; e.g., EHS, Department Public Safety, and RIA. Other PU representatives (e.g., Office of General Counsel, Risk Management) may be invited as necessary.

V. Meetings

- A. The IBC will meet as frequently as necessary to meet the needs of the program.
- B. All IBC meeting dates, times and locations are posted, publicly, on the RIA website.
- C. A quorum shall consist of greater than one-half of the voting members and is required at the IBC meetings to conduct all official business.
- D. PIs are encouraged to attend IBC meetings to discuss newly proposed research.

VI. Procedures Related to the IBCs Responsibilities

A. Review of research involving the activities listed in Section II, Scope of the IBC:

1. Types of review:

- i. All proposed research, including modifications (i.e., an amendment in eRIA) to approved IBC registrations, involving the activities listed in Section II, Scope of the IBC, shall be submitted to the IBC, by the PI, using the eRIA IBC Registration form.
- ii. Approved IBC Registrations will be reviewed and approved, at minimum, every 3 years.
- iii. Activities that require review and approval by the IBC at a fully convened meeting prior to initiation of the research include:
 - 1. Research involving r/sNA research that is not exempt from the NIH Guidelines.
 - 2. Research requiring biosafety level 3 containment and involving select agents and toxins.
 - 3. Any research that is brought to the committee for review.
- iv. For research exempted from the NIH Guidelines and requiring biosafety level 1 or 2 are reviewed and approved by the BSO and IBC Chair. These IBC Registrations and amendments that do not require full committee review (FCR), will be placed on the IBC meeting agenda for informational purposes.
- v. Minor changes to an approved IBC Registration can be made and approved by a RIA representative these minor changes include corrections for grammatical errors, typographical errors, addition or removal of personnel (provided that all required training has been completed), and changes in locations (provided that the location is already approved for use of the specific hazard(s)).

2. Outcomes of review:

- i. Decisions (outcomes) of the review of IBC Registrations, including

modifications to approved IBC registrations, that are reviewed during a convened meeting of at least a quorum of the IBC include:

1. Approved - the IBC approves a Registration, as presented, with no requests for clarification or revisions. Note: if any requisite action(s) are not yet completed (e.g., training, lab inspection, installation of a sink, pathology report), "Conditionally Approved" is required.
 2. Approval Withheld - the IBC disapproves the IBC Registration, and the PI is not permitted to conduct the activities (e.g., it involves BSL3 work for which the facilities do not exist).
 3. Tabled - the IBC reviews an IBC Registration and determines that it cannot make a determination at this meeting and must defer the review to a subsequent meeting (e.g., insufficient information has been provided, required changes are so substantive that the Committee determines it must see the Registration again to make a determination).
 4. Modifications Required- the IBC reviews an IBC and determines that, with minor modifications, the registration can be approved. The IBC also determines whether the revised application must be reviewed via second FCR, by a specific IBC member(s), by the BSO, and/or by the IBC Chair.
 5. Conditionally Approved - The IBC has reviewed and approved the IBC Registration; however, approval cannot be granted until other, requisite action(s) are completed (e.g., training, lab inspection, installation of a sink, pathology report). The BSO and IBC Chair may determine whether the requisite action(s) have been satisfactorily completed (i.e., FCR is not required), unless (a) the BSO or IBC Chair request FCR and (b) the information provided changes the risk assessment.
 6. In all cases, any IBC member may request that a Registration be reviewed via FCR at any point during the review process.
- ii. Decisions (outcomes) of the review of IBC Registrations, including modifications to approved IBC registrations, that are reviewed by the BSO and IBC Chair only include:
1. Approved (as described above)
 2. Modifications Required (as described above)
 3. Conditionally Approved (as described above)
 4. Call for FCR - either the BSO or IBC Chair request that a Registration be reviewed via FCR at any point during the review process.

3. Notification(s) to PIs

- i. The outcome of the review of IBC Registrations, including modifications to approved IBC registrations, are communicated to

the PI by RIAs representative who serves as the IBC secretary and administrator, through the eRIA system.

- ii. The BSO and/or IBC Chair may also communicate directly with the PI (or designee).

4. Conflict of Interest

- i. No member of the IBC may participate (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.
- ii. If the IBC Chair's research is under review, the IBC Administrator will assign the BSO to facilitate review and approval of the project.

B. Responsibilities of RIA, the IBC Chair, and the BSO/EHS

For the purposes of this charter, the below responsibilities are only those specific to the support of the IBC's responsibilities.

In all cases, IBC Registration approval is required prior to initiation of activities, and this oversight is a shared responsibility among RIA, the IBC, EHS, and the PI.

1. RIA is responsible for:

- i. Maintaining eRIA (e.g., modifications to the IBC Registration form, data, metrics) and all IBC-related communications (e.g., website, eRIA notifications, emails, brochures).
- ii. Maintaining IBC meeting agendas and minutes.
- iii. Creating appointment letters for IBC voting members.
- iv. Filing reports with external agencies (e.g., annual report and non-compliance reports to OSP).
- v. Ensuring congruency between IBC registrations and IACUC protocols and IBC registrations and IRB protocols.

2. The IBC Chair is responsible for:

- i. Chairing the IBC meetings.
- ii. Assigning reviewers/presenters for the IBC registrations that go to IBC for review.
- iii. Pre-review the minutes from the previous meeting.
- iv. Approving the agenda for the upcoming meeting.

3. The BSO/EHS is responsible for:

- i. Ensuring all personnel involved in the activities listed in Section II, Scope of the IBC, are appropriately trained (e.g., lab safety, biosafety, bloodborne pathogens) prior to IBC approval.
- ii. In collaboration with RIA and LAR, ensure training (initial and continuing) of all IBC members.

- iii. Ensuring review and approval of the use of radioactive materials and other physical hazards (e.g., lasers) prior to IBC approval.
- iv. Communicating the containment level(s) of each hazard to all involved parties (e.g., PIs, LAR), providing the required signage.
- v. In collaboration with RIA and LAR, ensuring compliance with the policies, guidelines, and SOPs set forth by EHS, IBC, IACUC, and LAR in regard to the safe handling and housing of hazards and animals administered hazardous agents, the use of Personal Protective Equipment (PPE) and other safety equipment (e.g., eye wash, biosafety cabinets, scavenging), and proper labeling and waste disposal of hazardous agents.
- vi. Pre-reviewing the minutes from the previous meeting.
- vii. Approving the agenda for the upcoming meeting.
- viii. Reviewing and approving any IBC Registrations that do not go to full IBC when the Chair is conflicted when appointed by the IO to do so.

Approved by a unanimous vote by the IBC on January 25, 2024.