Table of Contents

1. Overview

Purpose

The Drexel University Institutional Biosafety Committee (IBC) is a university-wide committee of subject matter experts and community representatives responsible for ensuring that Drexel University safeguards personnel health and the environment through safe work practices while conducting biological research at or sponsored by the University.

1.1 Authority

Institutions that receive support from the National Institutes of Health (NIH) for recombinant or synthetic nucleic acid research are required to establish and register an IBC with the NIH Office of Science Policy (OSP) in compliance with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (hereafter referred to as the "NIH Guidelines"). Institutions receiving support for recombinant or synthetic nucleic acid research from the NIH are required to have all recombinant or synthetic nucleic acid research reviewed by an IBC irrespective of the funding source. If research is conducted without approval, the NIH has the authority to withdrawal research support from that project, laboratory, or the entire university.

The IBC has been established in compliance with the above requirements.

1.2 Scope

The IBC is responsible for overseeing all recombinant and synthetic nucleic acid research, as specified in the NIH Guidelines, conducted at or sponsored by Drexel University. Additionally, the IBC provides oversight for the use of pathogens, infectious agents, chemical carcinogens, and cytotoxic agents in research at the University.

Studies that involve the introduction of recombinant DNA (plasmids), gene transfer vectors (including viral vectors), genetically engineered micro-organisms, or genetically engineered infectious agents (including live vaccines that are experimental in nature and/or not FDA approved for the specific study population) into human subjects are beyond the scope of the IBC. These studies are reviewed by the Western Institutional Review Board Biosafety Committee under contract to Drexel University.

The IBC as currently constituted does not have the requisite expertise to evaluate recombinant DNA studies involving plants. Therefore, the *de novo* generation of transgenic plants is also beyond the scope of the current IBC. Appropriate expertise will be recruited into the IBC as needed.

1.3 Charge

The Drexel University Institutional Biosafety Committee is responsible for reviewing all University research activities that are conducted by faculty, staff, students, and/or visiting scientists at, or under the auspices of Drexel University, and that involve the use of:

- recombinant or synthetically derived nucleic acid molecules,
- gene drive modified organisms (GDMOs),
- pathogens affecting humans, animals, or plants,
- materials potentially containing human pathogens (e.g., unfixed human specimens, human blood)
- human cell lines that are not well-characterized or require containment at Biosafety Level 2 or higher

- *de novo* generation of transgenic animals (using recombinant DNA technology to add foreign DNA or subtract a portion of the animal's genome).
- The analysis of, or experimentation, with sera, blood products, or other human specimens (secretions, excretions and tissue) in Drexel research laboratories or those labs that are NOT accredited with the College of American Pathologists (CAP) or with the Joint Commission
- Research protocols involving the use of biological toxins, Select Agents, chemical carcinogens/mutagens, and cytotoxic drugs
- Dual Use Research of Concern
- Pathogens with Enhanced Pandemic Potential

The above will be collectively referred to as biohazardous materials in this document.

The purpose of these reviews is to ensure that all activities involving biohazardous materials and the facilities used to conduct such work comply with all applicable external regulations and University policies. The IBC's primary objective, however, is ensuring that such activities meet standards of good biological safety practice emphasizing protection of personnel, the general public, and the environment. To this end, the IBC shall assist principal investigators and other researchers in meeting their responsibilities; impose requirements, and review and approve policies, procedures, programs, and facilities pursuant to the safe use of biohazardous materials.

2. Definitions

Biohazardous Materials: Collective term for recombinant and synthetic nucleic acid molecules, pathogenic organisms, cytotoxic agents, and carcinogens/mutagens.

Carcinogens/mutagens: A physical or chemical agent that is directly involved in causing cancer or that changes the genetic material, usually DNA, of an organism and thus increases the frequency of mutations above the natural background level.

Chair: The chairperson of the Institutional Biosafety Committee

Cytotoxic Agents: Any agent or process that kills cells.

Dangerous gain-of-function (GOF) research: Scientific research on an infectious agent or toxin with the potential to cause disease by enhancing its pathogenicity or increasing its transmissibility.

Dual Use Research of Concern: Life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

Infectious Agents/Pathogen: An agent such as a virus, bacterium, prion, fungus, viroid, or parasite that causes disease in its host. A human pathogen is one in which the host is human.

Institutional Official: A senior official who represents the University to the Office of Science Policy (OSP).

NIH Guidelines: Document titled "NIH Guidelines For Research Involving Recombinant Or Synthetic Nucleic Acid Molecules" released in April 2024 by the Department of Health and Human Services, National Institutes of Health

Pathogen with pandemic potential (PPP) is a "pathogen that is likely capable of wide and uncontrollable spread in a human population and would likely cause moderate to severe disease and/or mortality in humans."

Pathogen with enhanced pandemic potential (PEPP) is "a type of PPP resulting from experiments that enhance a pathogen's transmissibility or virulence, or disrupt the effectiveness of pre-existing immunity, regardless of its progenitor agent, such that it may pose a significant threat to public health, the capacity of health systems to function, or national security. Wild-type pathogens that are circulating in or have been recovered from nature are not PEPPs, but may be considered PPPs because of their pandemic potential."

Principal Investigator: Faculty member at or above the level of Lecturer who has primary responsibility and accountability to direct the proper conduct of a scientific research project or program. If the research is conducted by a team of researchers at a research site, the Principal Investigator is the leader responsible for that team whose name appears as Principal Investigator on the grant application or award.

Recombinant and Synthetic Nucleic Acid Molecules: In the context of the NIH Guidelines, recombinant and synthetic nucleic acids are defined as:

1. molecules that are (a) constructed by joining nucleic acid molecules and (b) that can replicate in a living cell, i.e., recombinant nucleic acids;
2. nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids, or
3. molecules that result from the replication of those described in (1) or (2) above.

Select Agents (Biological Select Agents or Toxins): A bacterium, virus, protozoan, parasite, or fungus that can be used purposefully as a weapon in bioterrorism or biological warfare that has been declared by the U.S. Department of Health and Human Services (HHS) or by the U.S. Department of Agriculture (USDA) to have the "potential to pose a severe threat to public health and safety." The agents are divided into (1) HHS select agents and toxins affecting humans; (2) USDA select agents and toxins affecting agriculture; and (3) Overlap select agents and toxins affecting both.

3. Acronyms

ABSL Animal Biological Safety Level

BMBL Biosafety in Microbiological and Biomedical Laboratories

BSL	Biological Safety Level
BSO	Biological Safety Officer
CDC	Center for Disease Control and Prevention
DURC	Dual Use Research of Concern
EHRS	Drexel University Department of Environmental Health and Radiation Safety
IACUC	Institutional Animal Care and Use Committee
IBC	Institutional Biosafety Committee
IRB	Institutional Review Board
IRE	Institutional Research Entity
NIH	National Institutes of Health
OSP	National Institutes of Health Office of Science Policy
PPP	Pathogen with Pandemic Potential
PEPP	Pathogen with Enhanced Pandemic Potential
RG	Risk Group
USDA	United States Department of Agriculture

4. Institutional Biosafety Committee

4.1 Organization

The IBC's functions are separated into three distinct roles:

1. Oversight committee for recombinant and synthetic nucleic acids as specified in the NIH Guidelines, including gene drive.
2. Oversight committee for pathogenic organisms, chemotherapeutic drugs, carcinogens, and cytotoxic agents, including Select Agents.
3. Functioning as the Institutional Review Entity (IRE) for Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP) in accordance with the United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential.

In fulfilling each of these roles, the IBC will act as three separate committees with each "committee meeting" conducted sequentially when the IBC is convened. Separate meeting agendas will be prepared, separate meeting materials will be distributed, and separate minutes will be recorded.

If the need to assume the role of IRE occurs, new procedures will be published.

4.2 Membership

The NIH Guidelines specify that the IBC will have no fewer than five members. Based on NIH Guidelines and the types of research activities at Drexel, the IBC membership will include:

- Three or more scientists from Drexel, who conduct research with potentially hazardous biological materials, including recombinant or synthetic nucleic acid molecules.
- At least two individuals with no affiliation to the institution beyond membership on the IBC.
- The Biological Safety Officer (BSO), normally the Executive Director of Environmental Health and Radiation Safety (voting ex officio member)
- The attending veterinarian from the University Laboratory Animal Resource who serves as the IBC's expert in animal containment principles (voting ex officio member).
- The Office of Research and Innovation Associate Vice Provost of Research Compliance & Regulatory Affairs (voting ex officio member).
- Other individuals from any component or discipline in the University serving as either voting or nonvoting members.

Non-voting ex officio members include the Institutional Official, the IBC Administrator, and the IACUC Administrator.

When necessary, consultants may be invited to IBC meetings by the Chair, Institutional Official, or Associate Vice Provost of Research Compliance & Regulatory Affairs to provide expert advice. However, invited consultants will not be allowed to vote on any protocol without an official appointment to the IBC from the Institutional Official.

New members to the IBC will be provided with links to the following resources:

1. NIH Guidelines and BMBL,
2. 42 CFR Part 73, 7 CFR Part 311, and 9 CFR Part 121 (on Select Agents),
3. A video titled "Dual Use Research: A Dialogue" and,
4. The IBC Charter and Procedures Manual (this document).

Each new member will receive orientation to the IBC from the Office of Research and Innovation Regulatory Compliance Administration and the IBC Chair. No protocol reviews will be assigned to a new member until 2-3 meetings have been attended. Once the attendance requirement is met, new members will initially be assigned as a secondary reviewer for new or amended protocols. After serving as a secondary reviewer on 4-6 protocols, the new member will begin to receive primary reviewer assignments.

4.3 Appointments and Terms

The committee chair and all committee members (except ex officio members) are appointed by the Institutional Official for three-year terms. Individuals may be reappointed to additional terms. Ex officio members by their very nature are neither appointed nor subject to terms. The Institutional Official may make additional ex officio appointments to the committee, (e.g., the Institutional Official could decide that the Director of Public Safety should be a member).

The Chair and Biological Safety Officer should make appointment recommendations to the Institutional Official (through the of Associate Vice Provost of Research Compliance & Regulatory Affairs) to appropriately constitute the IBC.

Members will be evaluated annually by the Institutional Official with input from the IBC Chair and Director of Regulatory Compliance. Evaluations will be based on satisfactory attendance, meeting at least 75% participation and active participation in the review process. The Institutional Official may remove any member of the IBC based on the results of the annual evaluation or at any time for cause.

4.4 Relationship with Other Committees

All human participant protocols involving gene transfer or gene therapy, as defined in the NIH Guidelines, shall be reviewed by the Western Institutional Review Board Biosafety Committee.

The collection of tissue samples, specimens, human body fluids, or similar materials used in research will require IRB approval as a condition of IBC approval. A Human Specimen Collection IBC Checklist is available to be used in conjunction with Institutional Review Board (IRB) review of studies involving the collection, analysis, and/or experimental manipulation of sera, blood products, or other specimens (e.g., stool, urine, sputum, and other secretions) derived from human subjects. The checklist is used to determine the type of Institutional Biosafety Committee (IBC) consideration/review required for the study

All protocols involving the use of biohazardous materials with animals will be reviewed by the IBC in coordination with the Institutional Animal Care and Use Committee (IACUC).

4.5 Annual IBC Review

All aspects of the IBC organization and functions will be reviewed annually. Review activities will be conducted each September by a subcommittee composed of the IBC chair/co-chairs, the BSO, the attending veterinarian, and the IBC Administrator. Additional members may be added as needed to complete planned subcommittee activities. Functions of the subcommittee will include:

- Annual review of the IBC Charter and Procedures Manual
- Annual review of the IBC website organization and content (including all IBC forms)
- Annual review of membership and member performance
- Preparation of an annual report on IBC activities for presentation to the Associate Vice Provost of Research Compliance & Regulatory Affairs
- Discussion and planning in reference to the October Biosafety and Biosecurity Month in October
- Preparation of the annual update to NIH-reportable IBC information

5. Meetings

5.1 Schedule

The IBC will meet as often as necessary to fulfill its obligations. The meeting schedule and submission deadlines are posted on the website. At the time of this writing, the committee meets on the last Tuesday of each month at 12:30 PM. To accommodate the University closing for winter break, the December meeting normally occurs on the third Tuesday of the month.

At the discretion of the Chair, the committee may use audiovisual means, such as a teleconference or videoconference, to meet and conduct IBC business. Minutes must be recorded, and any member of the public requesting attendance will be provided with access to the audiovisual meeting. IBC business involving biohazardous materials other than recombinant or synthetic nucleic acid may, at the Chair's discretion, be conducted by email. The IBC may not use email to conduct any business that involves recombinant or synthetic nucleic acid and requires a vote of the IBC members at a convened meeting.

5.2 Quorum and Voting

A quorum consists of a majority (more than half) of voting members of the Committee, at least one of which is an unaffiliated member, and one is a faculty member.

Approval of any motion before the committee is approved with a majority affirmative vote of the members present. The Chair has voting privileges on all motions. For reasons other than conflict of interest, abstentions from voting do not alter the quorum or change the number of votes required.

5.3 Agenda and Minutes

An agenda, together with relevant materials, will be sent to committee members at least 5 days in advance of the meeting. Minutes for all meetings will be drafted by the IBC Administrator and reviewed by committee members at the following meeting. Once the committee approves the minutes, the IBC Administrator will redact proprietary and private information from the minutes in accordance with Section 9.3. Approved minutes will then be posted on the Drexel University Biosafety website starting June 2025.

Meeting minutes record the following information: (i) the date and place of the meeting (ii) time at which the meeting was convened; (iii) approval of minutes from the prior meeting; (iv) whether and why the meeting was open or closed; (v) individuals in attendance; (vi) a list each protocol reviewed (including the IBC number, PI name, protocol title, description of materials involved, approved biosafety level, and applicable section of NIH Guidelines); (vii) all major motions; (viii) results of votes on proposed motions; and (ix) the time of meeting adjournment.

6. Submission and Review Processes

6.1 Exemptions

Experiments involving some recombinant or synthetic nucleic acid molecules are exempt from the NIH Guidelines and do not require registration with the Institutional Biosafety Committee. Specific details about exempt experiments can be found in Section F (Exempt Experiments) and Appendix C (Exemptions) of the NIH Guidelines.

The BSO can advise Principal Investigators whether the exemptions apply to their specific experiment.

6.2 Application Forms

Information submitted to the IBC for review and potential approval will be communicated to the IBC on one or more forms:

- The **General Biohazard Form (Form A)** will be used for all research activities involving biohazardous materials. If the research includes the use of pathogenic organisms or human/primate samples but does not involve recombinant or synthetic nucleic acid molecules, cytotoxic agents, chemical carcinogens/mutagens, or animals, then this is the only form required to be submitted.
- If the research involves the use or generation of recombinant or synthetic nucleic acid molecules, investigators will also complete and submit the **Recombinant DNA Registration Addendum (Form B).**
- If the research activity involves the use of chemical carcinogens/mutagens or cytotoxic agents, the investigator will complete and submit the **Hazardous Substance Addendum (Form C).**
- If the research involves the use of biohazardous materials with animals, investigators will complete and submit the **Animal Use Addendum (Form D).**
- If the approved protocol requires changes to procedure, use of new biohazards, changes in animal model, changes in personnel, etc. complete and submit the **Protocol Amendment Form (Form E).**
- If the work only includes low-risk research that involves the collection of human cells, tissues, or fluids, the investigator will complete the **Low-Risk Human Specimens Review Form (Form F).** These forms are reviewed by a sub-committee of the IBC consisting of, at minimum, the IBC Chair and Biosafety Officer. Investigators who are seeking IRB approval for such work will complete the **Human Specimens Collection IBC Checklist** to determine if the work can be covered solely by a Form F or if the work requires full IBC approval.
- If a change in PI is required, complete and submit the **Change in PI Form (Form G).**

All application materials must be submitted electronically to the IBC Administrator (biosafety@drexel.edu) by the deadline listed on the calendar.

6.3 Pre-review

Protocols are assigned to a pre-meeting review team by the IBC Administrator.

The IBC Administrator prepares the review materials, consisting of all related application documents and reviewer assignments. A pre-meeting review team for each application consists of a primary reviewer and two secondary reviewers. Amendments are reviewed by a primary and secondary reviewer. For protocols involving animals, the attending veterinarian is assigned as one of the secondary reviewers. The pre-review package is sent to the committee by the Friday following the submission deadline.

The review process is a team effort. The steps and responsibilities of the pre-meeting review processes are:

1. The primary reviewer collects comments from the secondary reviewer(s) and combines them into a single list of recommendations. The primary reviewer sends the comments to the Principal Investigator via email.
2. The investigator revises the protocol to incorporate the changes suggested by the reviewers. To help facilitate the review process, a point-by-point cover letter will be requested to be submitted with the revised protocol. The assigned reviewers are reminded of the need for expediency and to complete the pre-review in a timely fashion. The revised copy is submitted electronically, along with a cover letter outlining all changes, by the investigator to the IBC Administrator (biosafety@drexel.edu).

6.4 Convened Committee Review

The IBC Administrator prepares the full committee review packet, consisting of all revised application documents, reviewer assignments, meeting agendas, meeting minutes from the previous meeting, and the Zoom meeting link (if the meeting will be held virtually). The full committee review packet is sent to the committee at least 5 days in advance of the convened meeting.

1. The primary reviewer is responsible for presenting the application at the meeting. If the primary reviewer is unable to attend the meeting, then the primary reviewer provides all comments to the secondary reviewer for presentation at the meeting.
2. If the investigator is present at the meeting, the investigator will have the opportunity to describe the proposed project and to answer questions from the committee but must leave the room before the committee's final deliberation and vote on the protocol.
3. Any IBC member named on a protocol under review will be excused from the meeting for the duration of the protocol presentation, discussion, and decision on its approval.

6.5 Expedited Reviews

In certain circumstances, the IBC can elect to expedite a protocol or amendment submission review process. The expedited review procedures will be dependent on the biohazardous materials involved.

6.5.1 Protocols and amendments involving rDNA

The NIH Guidelines do not prescribe how IBCs should be convened, but they do speak to the preparation of meeting minutes (Section IV-B-2-a-(7)) and they encourage institutions to accommodate public attendance at meetings (Section IV-B-2-a-(6)). IBC meetings should be convened in a manner that allows for fulfillment of these two expectations. Because email exchanges cannot fulfill these expectations of the NIH Guidelines, it is not acceptable for IBCs to consider and vote on rDNA protocols by email.

Expedited Meeting Review Process:

1. The protocol will be pre-reviewed as described above (Section 6.3). The PI will resubmit the revised protocol or amendment and point-by-point cover letter to the IBC Administrator (**biosafety@drexel.edu**).
2. The IBC Administrator will work with the committee to select a date and time that works with the committee to achieve quorum either in person or in a synchronous Zoom meeting.
3. The revised protocol will be presented to the committee by email prior to the selected meeting date. During the meeting the primary reviewer will present a summary of the protocol or amendment, associated risks, and the changes that were made in response to the pre-review at the meeting.

4. A motion and vote will be made on the determination of the protocol or amendment.

6.5.2 Protocols and amendments involving biohazardous materials that do not include rDNA

IBC business involving biohazardous materials other than rDNA may, at the Chair's discretion, be conducted by email.

Expedited Email Review Process:

1. The protocol will be pre-reviewed as described above (Section 6.3). The PI will resubmit the revised protocol or amendment and point-by-point cover letter to the IBC Administrator (**biosafety@drexel.edu**).
2. The revised protocol will be presented to the committee by email. The primary reviewer will prepare a summary of the protocol or amendment, associated risks, and the changes that were made in response to the pre-review.
4. The committee will vote on approval via a Microsoft Forms questionnaire to collect the votes for approval or some similar asynchronous approach. The results from the Forms questionnaire will be saved on the IBC SharePoint site.

6.6 Committee Actions

Protocols are presented and discussed individually. After presentation and discussion, the IBC votes on the disposition of the protocol. Possible outcomes include:

- **Approval** – When the IBC has determined that all review criteria, based on the IBC Policies and federally mandated regulations, have been adequately addressed by the Principal Investigator, the IBC may approve the research, thus providing the Principal Investigator permission to perform the research. An electronic copy of the approval notice will be sent to the Principal Investigator within five working days.
- **Defer approval of protocols pending minor changes** – If IBC votes to defer approval pending changes, the Office of Research and Innovation will communicate the necessary changes to the investigator within five working days via email. The investigator will submit the changes to the protocol and form and provide a point-by-point response on a cover letter to the IBC Administrator. The IBC Administrator will forward the response to the Chair for review and approval.
- **Table** – During its review, a protocol may require (i) further clarification in order for the IBC to make a judgment, (ii) the presence of committee members with specific expertise at the IBC meeting, (iii) external consultation, (iv) deferred review due to other circumstances. If consideration of the protocol cannot be completed during an IBC meeting, the IBC can defer or table review. The investigator will receive a letter within five working days describing the status of the protocol and the reason(s) the application was tabled. If the application requires clarification or additional information, the letter will outline the necessary revisions that will facilitate reconsideration by the IBC.
- **Approval Withheld/Tabled** – When the IBC determines that a protocol has not adequately addressed all of the requirements of the IBC Policies and regulations as applicable, the IBC may withhold approval. This action indicates that there are considerable safety issues and the need for substantial revisions. The investigator will receive a letter within five working days describing the reasons for withholding approval of the study and outlining the necessary revisions for

reconsideration by the IBC. The pre-meeting review team or an IBC member assigned by the Chair may confer with the investigator to review committee concerns and issues. A revised copy of the protocol must be submitted within 90 days for review by the committee or the application will be inactivated. The investigator must also submit a point-by-point response in a cover letter. The revised protocol will be reviewed at a meeting convened by the IBC.

6.7 Ad hoc Approval of Revisions

For applications that received deferred approval pending minor changes, the Chair may approve the protocol as having met the conditions, ask the original pre-reviewers to evaluate the acceptability of the revisions, designate one or more members of the IBC to evaluate the acceptability of the revisions, or present the revised protocol to the IBC. The IBC Administrator may accept minor revisions that are administrative in nature, such as completion of training.

6.8 Approval Term

Protocols are approved for three years. A protocol may be terminated or inactivated by the principal investigator at any time during this approval period by notifying the IBC through the protocol close out procedures. A protocol may be administratively inactivated by the IBC for safety concerns.

After three years, a new application must be submitted. If there are no changes to the protocol, the premeeting review may be omitted from the review process described in Section 6.3.

6.9 Amendments

Investigators who need to modify their protocols must submit a Protocol Amendment Form (Form E). Amendments involving changes to procedure, such the use of new biohazards or changes in the animal model, will be reviewed by the full committee at the next meeting. Addition of personnel and other administrative changes may be approved by the IBC Administrator. Changes in location may be approved by the IBC Administrator upon consulting with the Biosafety Officer. All ad hoc approvals will be reported to the IBC at the next meeting.

Investigators who request a change in PI must submit Change in PI Amendment Form (Form G). Signatures from the departing and incoming PI are required. An amendment involving changes to PI will be reviewed by the full committee at the next meeting.

6.10 Protocol Close-out

The Biosafety Close-out Request Form is located on the Biosafety Website. Close-out forms are to be submitted via email to **biosafety@drexel.edu.** Once the protocol has been closed prior to its expiration, it cannot be reactivated. A new protocol must be submitted to the IBC for review and approval before initiating any activities involving biohazardous materials.

All biosafety protocols at Drexel University must be closed when they meet one of the following criteria.

Completion of Study

The study objectives and experimental procedures as outlined in the protocol have been completed, and all biohazardous materials have been appropriately transferred or disposed of through Environmental Health and Radiation Safety (EHRS).

Once the biohazardous materials have been appropriately transferred or disposed of, Principal Investigators are advised to submit the close-out request form within 10 days of the study's completion.

Study Discontinued

Studies are discontinued when there is an inability to initiate or continue the study due to circumstances such as loss of funding or transfer to a different department. Discontinuation of a study will include appropriate disposal or transfer of all biohazardous materials as arranged through EHRS.
Once the biohazardous materials have been appropriately transferred or disposed of, Principal Investigators are advised to submit the close-out request form within 10 days of the cessation of studies.

Departure from Drexel University

The Principal Investigator is departing from Drexel University and there are no plans to continue the research at Drexel University, and all biohazardous materials have been appropriately transferred or disposed of through EHRS.

- **a.** Principal Investigators are advised to reference the **ORI-003 Investigator Guidance - Departing Faculty Checklist.ashx (drexel.edu)** once departure notice has been given.
- **b.** Once the biohazardous materials have been appropriately dispositioned, Principal Investigators are advised to submit the close-out request form within 10 days of the departure date.
- **c.** If a Principal Investigator departs without closing or transferring their protocol(s) to another qualified Drexel PI, the protocol(s) will be administratively closed within 7 days of the PI's departure by the IBC Office.
    - **i.** In adherence with **ORI 002 Procedures for Principal Investigator Eligibility and Responsibilities Final.ashx (drexel.edu)**, it is the PI's Department's responsibility to support any required follow-up or management of the open protocol.

New Protocol Submission at the End of Three Years

When a PI submits a new protocol for their on-going study at the end of the three-year approval period, the expiring protocol will be administratively closed by the IBC Office once the new protocol has been approved by the IBC. No work can be conducted on an expired protocol.

6.11.1 Biohazardous Material Disposition Methods

Prior to the protocol's closure, the Principal Investigator is responsible for ensuring all biohazardous materials are appropriately transferred or disposed of.

Disposal through EHRS

Please refer to the Drexel's **Hazardous Waste Management Plan** or contact EHRS **ehrs@drexel.edu** about the proper disposal of the biohazardous materials.

Biohazardous Materials Transfer to Another Drexel University PI

Contact EHRS **ehrs@drexel.edu** about the proper transfer of biohazardous materials to another Drexel University PI as the process to transfer biohazardous materials can vary.

Biohazardous Materials Exported to Another Institution

If the PI plans to transfer biohazardous materials to another institution, the PI should refer to **EHRS Laboratory Safety Manual** – XII. Biological Safety. Section N. Transporting and Shipping Biological Materials. Contact EHRS as **ehrs@drexel.edu** with questions. If biohazardous materials are exported internationally, the PI must also contact Export Control (**export@drexel.edu**).

7. Conflict of Interest

No member of the IBC may be involved in the review or approval of a project in which the member has been or expects to be engaged or has a financial interest, except to provide information on the project to the IBC.

Should an IBC member declare involvement in any way in a research protocol under review by the IBC, or state a conflict of interest with a research protocol, then the member:

- Is excluded from discussion and voting except to provide information requested by the IBC.
- May be asked to leave the meeting room for discussion and voting.
- Is not counted towards quorum.

8. Appeals

Decisions of the IBC may be appealed. To begin the appeals process, please email biosafety@drexel.edu.

9. Public Participation

9.1 Open Meetings

When possible and consistent with protection of privacy and proprietary interests, meetings of the IBC are open to the public for the portion of the meeting overseeing the use of recombinant and synthetic nucleic acid molecules. Members of the public wishing to attend an IBC meeting need to contact The Office of Research and Innovation Biosafety Office at **biosafety@drexel.edu** for the date, time, and location of the meeting and, if necessary, the Zoom meeting link.

9.2 Availability of Minutes

For all IBC meetings convened after June 1, 2025, minutes from IBC proceedings involving the use of recombinant and synthetic nucleic acid molecules will be posted on the University Biosafety website following approval.

Minutes from IBC meetings that were convened prior to June 1, 2025 and any documents submitted to or received from funding agencies that must be available to the public (e.g., IBC roster and member biographical sketches) will be made available to the public upon request.

Materials to be released or posted on the website will be reviewed by The Office of Research and Innovation's Biosafety Office for redaction prior to release. Any questions pertaining to redactions that fall outside of the redaction checklist will be referred to the Office of General Council and the Associate Vice Provost of Research Compliance and Regulatory Affairs. If the request is from news media, the Office of University Communications will act as the point of contact with the University.

If public comments are made on Institutional Biosafety Committee actions, the institution shall forward both the public comments and the Institutional Biosafety Committee's response to the Office of Science Policy, National Institutes of Health via email at NIHGuidelines@od.nih.gov.

9.3 Redactions

The following information will be redacted before releasing minutes to the public:

- Trade secret information and other confidential commercial information,
- Home telephone numbers and home addresses of IBC members, research personnel, or professional staff,
- Laboratory or animal research facility locations,
- Specific information whose disclosure would directly compromise institutional or national security,
- The names of non-government research sponsors, and
- Hazardous substance addendum reviews

To the extent that they do not pertain to recombinant or synthetic nucleic acid molecule research, the following items will also be redacted before releasing minutes to the public:

- ULAR reports,
- Safety Office reports,
- Other similar reports to the committee,
- Names of individuals not directly associated with the IBC or activities overseen by OSP (e.g., the name of an animal caretaker or EHRS staff member).

10. Reports

10.1 Annual Reports

The IBC, through the Institutional Official, will file an annual report with OSP that includes:

- A roster of all IBC members and their roles on the committee (e.g., chair, BSO)
- Biographical sketches of all IBC members.

The report is generally prepared for the Institutional Official by The Office of Research and Innovation's Biosafety Office

10.2 Reports to the Institutional Official

The IBC, through The Office of Research and Innovation's Biosafety Office, will provide the following reports to the Institutional Official:

- Meeting minutes
- Incident reports detailing any accidents, spills, and potential or actual exposure to biohazardous materials
- Incidents of non-compliance
- Suspensions of protocols by the IBC
- Terminations of protocols by the IBC for cause

10.3 Incident Reports

Principal Investigators are responsible for reporting to the BSO any of the following incidents:

- Spill or accident involving biohazardous materials that lead to personal injury or illness including, for example, skin punctures with needles.
- Spill or accident involving biohazardous materials that leads to a breach of containment, including, for example, the escape or improper disposition of a transgenic animal or spills of high-risk materials occurring outside of a biosafety cabinet.
- Any spill or accident in a BL2 laboratory that results in actual exposure.
- Any spill or accident in a BL3 or BL4 laboratory that results in potential or actual exposure.
- Failure to adhere to the required containment and biosafety practices.
- Violations of the NIH Guidelines, including performing activities with biohazardous materials not specified in a protocol approved by the IBC.

Any incident that is reported to the BSO or is discovered by the BSO during inspections will be reported to the IBC Chair and The Office of Research and Innovation's Biosafety Office. The incident will be discussed at the next scheduled IBC meeting.

Any significant problems, violations of the NIH Guidelines, or any significant research-related accidents and illnesses involving recombinant or synthetic nucleic acid must be reported to NIH OSP within 30 days.

Spills or accidents in BL2 laboratories resulting in an overt exposure to recombinant or synthetic nucleic acid and spills or accidents occurring in BL3 or BL4 laboratories resulting in an overt or potential exposure to recombinant or synthetic nucleic acid must be immediately reported to NIH OSP.

In instances when OSP reporting is required, the Chair will notify the Institutional Official, and the Director of Regulatory Compliance will draft a report for the Institutional Official to submit to OSP.

11. Responsibilities

11.1 Committee Members

All IBC members are responsible for actively supporting IBC activities and responsibilities as described in this document. Specific responsibilities include:

- Providing knowledge and expertise on biosafety issues, particularly in their acknowledged area(s) of expertise.

- Attending and actively participating in IBC meetings. Attendance at less than 75% of meetings convened will be cause for reconsideration of the appointment during the annual evaluation by the Institutional Official.
- Performing comprehensive and timely reviews of applications and amendments as assigned and communicating the results according to the procedures outlined in Section 6.
- Maintaining a working knowledge of the NIH Guidelines and BMBL.

11.2 Committee Chair

The Committee Chair is responsible for providing leadership for the IBC to identify, develop and adopt policies or programs to promote safe biological research and compliance with biosafety requirements. To do so, the Chair needs to understand all functions, policies, and procedures of the IBC and the University's Biosafety Program. Specific responsibilities include:

- Serving as a voting member of the IBC
- Direct the proceedings of convened meetings of the IBC.
- Assist the IBC Administrator in drafting letters from the IBC regarding IBC decisions and actions.
- Signing IBC letters, as needed.
- Determining adequacy of researcher responses to IBC conditions for protocol approval, if necessary, in collaboration with the Biological Safety Officer.
- Reporting to the IBC and the Institutional Official any laboratory accidents, any significant problems or violations, and any significant research-related injuries or illnesses associated with any significant problems or violations, and any significant research-related injuries or illnesses associated with biohazardous materials.
- Ensuring that IBC members are appropriately trained through new member orientation, , and informed of new or revised regulations or institutional policies and procedures.
- Assisting in the development and implementation of new standard operating procedures (SOPs).
- Assisting with periodic reviews of IBC policies and procedures.
- Participating in periodic review of the IBC Charter and update as necessary.
- Representing the IBC to internal and external groups.

11.3 Committee Vice Chair or Co-Chair

The Committee Vice Chair or Co-Chair is responsible for acting as chair when the chair is unavailable. The vice chair is expected to learn the role of chair with the expectation to succeed to the chair at the end of the chair's appointment.

11.4 Institutional Biosafety Officer

The Biological Safety Officer (BSO) is responsible for the daily management of the biosafety program. Specific responsibilities related to the IBC include:

- Conducting periodic inspections to ensure rigorous adherence to laboratory safety standards, and compliance with all applicable biosafety regulations and guidelines.
- Investigating laboratory accidents and report to the IBC Chair and the Associate Vice Provost of Research Compliance & Regulatory Affairs any significant problems or violations, and any significant research-related injuries or illnesses associated with biohazardous materials,

recommending corrective actions and communicating these corrective actions to involved laboratory personnel.
- Developing and implementing emergency plans for handling accidental spills and personnel contamination resulting from work with biohazardous materials.
- Providing technical advice on laboratory security, research safety procedures, administrative and engineering controls, facility design, and compliance requirements.
- Maintaining the general laboratory, biosafety, and recombinant DNA training modules within BioRAFT.
- Assisting with the general oversight of IBC operations to promote compliance.
- Serving as a permanent voting ex officio member of the Institutional Biosafety Committee.

11.5 Institutional Official

The responsibility for the Biosafety Program at the University rests with the Executive Vice Provost for Research & Innovation, who is the Institutional Official (IO). Specifically, this responsibility includes:

- Establishing an Institutional Biosafety Committee that meets the requirements and carries out the functions detailed in the NIH Guidelines.
- Identifying individuals with collective experience and expertise in research involving biological hazards used in Drexel University labs for appointment to the Committee.
- Evaluating the IBC members with input from the IBC Chair and the Associate Vice Provost of Research Compliance & Regulatory Affairs
- Notifying the NIH Office of Science Policy (OSP) of any reportable incidents.
- Conducting an annual assessment of the allocation of resources to the IBC.

11.6 Principal Investigator

The Principal Investigator is responsible for full compliance with the NIH Guidelines in the conduct of recombinant or synthetic nucleic acid molecule research, all applicable federal, commonwealth, and local laws and regulations, and Drexel University requirements for the protection of people and the environment from biohazardous materials. Specifically, this responsibility includes:

- Ensuring that laboratory staff are appropriately trained in both general biosafety practices and protocol specific biosafety procedures.
- Establishing appropriate laboratory techniques and procedures to be used for the research.
- Securing IBC approval prior to initiating or modifying research involving biohazardous materials.
- Supervising the performance of laboratory staff to ensure that the required safety practices and techniques are used.
- Adhering to the procedures and conditions specified in the approved protocol.
- Ensuring the proper working order of physical containment systems (e.g., biological safety cabinets).
- Complying with the Occupational Health program as it applies to the specific research being conducted.
- Reporting any significant problems with procedures or containment practices, violations of the NIH Guidelines, or significant research-related accidents and illnesses to the IBC.

11.7 Office of Research and Innovation Biosafety Office

The Office of Research and Innovation Biosafety Office consists of the IBC Administrator and Associate Vice Provost of Research Compliance & Regulatory Affairs. Individuals in these positions are responsible for providing supervisory oversight of the IBC to ensure that it has established and implemented policies consistent with meeting its charge and for providing administrative support to the IBC. Specific responsibilities include:

- Managing IBC email account and submissions for research.
- Providing administrative support for the IBC by scheduling meetings, arranging meeting space and taking meeting minutes.
- Notifying PIs of the results of IBC review.
- Maintaining accurate and complete IBC records.
- Distributing initial applications to primary and secondary reviewers.
- Distributing meeting materials to IBC members.
- Maintaining the IBC webpages.
- Assigning primary and secondary reviewers.
- Providing the necessary liaison between the research personnel, the IBC, federal and regulatory agencies.
- Serving as the office of record for documentation involving IBC.
- Providing all necessary documentation, forms, regulatory guidelines and regulations, to Principal Investigators.
- Maintaining IBC registration forms and records.
- Training new members of the IBC on the responsibilities and operations of the committee.
- Assisting the Institutional Official in filing annual updates and other reports to the NIH/OSP.
- Communicating with IRB or IACUC when protocols involve human subjects or animals.
- Monitoring Federal and state regulations, draft revised policies and procedures to remain in compliance with those regulations.

12. Resources

The functions of the IBC frequently require reference to information relating to recombinant nucleic acids, Select Agents, and dual use agents. Resources available in each area are linked below:

12.1 NIH Guidelines

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) PDF

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) HTML

12.2 Select Agents

Select Agents
USDA Regulations 7 CFR Part 331 (plants)
USDA Regulations 9 CFR Part 121 (animals)
HHS Regulations 42 CFR Part 73

Select Agents and Toxins List (also available in PDF format)
Responsible Official Guidance Document

13. Revision and Advisory Members

13.1 Revision

Version 002/Effective Date 06/04/2025– Revised document to put into new format and include changes to NIH Guidelines

13.2 Advisory Members

The Office for Research and Innovation appreciates the following individuals who served as Advisory Members:

Advisory Members	
Fred Krebs, PhD Master of Science in Infectious Disease Program Director Fundamental Concepts in Infectious Disease Certificate Program Director Translational Research in Infectious Disease Certificate Program Director Co-Chair, Drexel University Institutional Biosafety Committee (IBC) Associate Professor Department of Microbiology and Immunology Drexel University College of Medicine	Jon Chase, MS Biosafety Officer Assistant Vice President Environmental Health and Radiation Safety Drexel University
Arthur Frank, MD, PhD Professor Emeritus and Clinical Professor Environmental and Occupational Health Drexel University Dornslife School of Public Health	