Drexel University
Institutional Biosafety Committee

Charter and Guidelines

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Definitions

For the purposes of this document, the following definitions apply:

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.

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 OBA.

NIH Guidelines
: NIH Guidelines For Research Involving Recombinant Or Synthetic Nucleic Acid Molecules, November 2013, Department of Health and Human Services, National Institutes of Health

Other Potentially Infected Materials (OPIM)

1. The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, all body fluids in situations where it is difficult or impossible to differentiate between body fluids
2. Any unfixed tissue or organ (other than intact skin) from a human, or non-human primate (living or dead).
3. HIV-containing cell or tissue cultures, organ cultures, and HIV or HBV-containing culture medium or other solutions, and blood, organs or other tissues from experimental animals infected with HIV or HBV.
4. Any pathogenic microorganism
5. Human cell lines

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

1. molecules that are constructed by joining nucleic acid molecules and 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 (i) or (ii) 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.

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
EHS	Drexel University Department of Environmental Health and 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
OBA	National Institutes of Health Office of Biotechnology Activities
OPIM	Other Potentially Infectious Material
r/sNA	recombinant and/or synthetic nucleic acid molecules
RG	Risk Group
USDA	United States Department of Agriculture

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 human health and the environment through safe work practices while conducting biological research at or sponsored by the University.

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 Biotechnology Activities (OBA) in compliance with the *NIH Guidelines for Research Involving Recombinant DNA Molecules* (NIH Guidelines). The NIH requires all institutions receiving research funds to have *all* of its recombinant or synthetic nucleic acid (r/sNA) research reviewed by an IBC regardless of whether that research is directly supported by the NIH. 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.

Scope

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

The introduction of recombinant DNA (plasmids) or 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 IBC.

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 (r/sNA),
- 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).[1]

[1] Examples of recombinant DNA technology include (1) Direct microinjection of a chosen gene construct from another member of the same species or a different species into the pronucleus of a fertilized ovum; (2) Insertion of the desired DNA sequence by

- 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 toxins, select agents[2], chemical carcinogens/mutagens, and cytotoxic drugs
- Dual Use Research of Concern[3]

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.

Committee

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.
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).

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

At the time of this writing, there are no known Select Agent activities or DURC at Drexel University. If the need to assume the role of IRE occurs, a separate charter and guidelines will be developed.

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 Safety (voting *ex officio* member).

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homologous recombination into an in vitro culture of embryonic stems and cells (3) Use of a plasmid or virus to transfer the genetic material into germ cells.

[2] See Appendix A for a list of select agents

[3] See Appendix B for definition

- 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 Director of Regulatory Compliance (voting *ex officio* member).
- Other individuals from any component or discipline in the University serving as either voting or non-voting members.

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

When necessary, consultants may be invited to IBC meetings by the Chair, Institutional Official, or Director of Regulatory Compliance to provide expert advice but 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 copies of the NIH Guidelines, the Center for Disease Control publication "Biosafety in Microbiological and Biomedical Laboratories" (BMBL), 42 CFR Part 73, 7 CFR Part 311 and 9 CFR Part 121(on Select Agents), NIH publication "Dual Use Research of Concern: A Companion Guide," and this document. The new member will receive orientation to the Committee from the Office of Research Regulatory Compliance Administration. No protocol reviews will be assigned until 2 – 3 meetings have been attended. Only then will the member be assigned as a secondary reviewer for new or amended protocols, or reviewer for periodic reports. After serving as a secondary reviewer on 4 – 6 protocols, the member will begin to receive primary reviewer assignments.

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 Director of Regulatory Compliance) 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, active participation in the review process and effective contributions to the committee as a whole. The Institutional Official may remove any member of the IBC based on the results of the annual evaluation or at any time for cause.

Relationship to 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, etc. used in research will require IRB approval as a condition of IBC approval.

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).

Roles and Responsibilities

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 in general and in his or her acknowledged area(s) of expertise in particular.
- Attending and actively participating at IBC meetings. Attendance at less than 75% of convened meetings will be cause for reconsideration of the appointment during the annual evaluation by the Institutional Official.
- Performing comprehensive and timely reviews of applications, amendment and periodic reports as assigned and communicating the results according to the procedures infra.
- Maintaining a working knowledge of the NIH Guidelines.

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 Coordinator 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.
- 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.

Committee Vice Chair

The Committee vice chair is responsible 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.

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 Director of Regulatory Compliance 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 training module.
- Assisting with the general oversight of IBC operations to promote compliance.
- Serving as a permanent voting ex-officio member of the Institutional Biosafety Committee.

Institutional Official

The responsibility for Biosafety Program at the University rests with the Senior Vice Provost for Research, who is the Institutional Official. 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 the collective experience and expertise in research involving all biological hazards used in University labs for appointment to the Committee.
- Evaluating the IBC members with input from the IBC Chair and the Director of Regulatory Compliance
- Notifying the NIH Office of Biotechnology Activities of any reportable incidents.
- Conducting an annual assessment of the allocation of resources to the IBC.

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 is 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.
- Submitting periodic (annual) reports to the IBC on the research being conducted.

Office of Research Regulatory Compliance Administration

The Office of Research Regulatory Compliance Administration consists of the Biosafety Committee Coordinator and Director of Regulatory Compliance. 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 supra 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 for meeting space and taking meeting minutes.
- Notifying PIs of the results of IBC review.
- Reminding PIs when periodic reports are due.
- 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/OBA.
- 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.

Meetings

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 to meet such as a teleconference or videoconference. 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 r/sNA may, at the Chair's discretion, be conducted by e-mail. The IBC may not conduct any business that involves r/sNA and requires a vote of the IBC members by e-mail.

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.

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 Biosafety Committee Coordinator and reviewed by committee members at the following meeting.

Meeting minutes reflect the date and place of the meeting, whether minutes of the prior meeting were approved, individuals in attendance, whether and why the meeting was open or closed, 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), all major motions, and whether motions were approved, and the time of meeting adjournment.

The minutes will follow the form specified in Appendix C.

Submission and Review Processes

Exemptions

The following recombinant DNA molecules are exempt from the NIH Guidelines; therefore, IBC review and registration is not required.

- Those synthetic nucleic acids that:
  1. can neither replicate nor generate nucleic acids that can replicate in any living cell (e.g., oligonucleotides or other synthetic nucleic acids that do not contain an origin of replication or contain elements known to interact with either DNA or RNA polymerase), and
  2. are not designed to integrate into DNA, and
  3. do not produce a toxin that is lethal for vertebrates at an LD_{50} of less than 100 nanograms per kilogram body weight.
- Those that are not in organisms, cells, or viruses and that have not been modified or manipulated (e.g., encapsulated into synthetic or natural vehicles) to render them capable of penetrating cellular membranes.
- Those that consist solely of the exact recombinant or synthetic nucleic acid sequence from a single source that exists contemporaneously in nature.
- Those that consist entirely of nucleic acids from a prokaryotic host, including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well-established physiological means.
- Those that consist entirely of nucleic acids from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).
- Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. A list of such exchangers is available in the NIH Guidelines.
- Those genomic DNA molecules that have acquired a transposable element, provided the transposable element does not contain any recombinant and/or synthetic DNA.
- The purchase or transfer of transgenic rodents for experiments that require BL1 containment.
- The breeding of two different transgenic rodents or the breeding of a transgenic rodent and a non-transgenic rodent with the intent of creating a new strain of transgenic rodent that can be housed at BL1 containment if:

1. Both parental rodents can be housed under BL1 containment; and
2. neither parental transgenic rodent contains the following genetic modifications:
    i. incorporation of more than one-half of the genome of an exogenous eukaryotic virus from a single family of viruses; or
    ii. incorporation of a transgene that is under the control of a gammaretroviral long terminal repeat (LTR); and
3. the transgenic rodent that results from this breeding is not expected to contain more than one-half of an exogenous viral genome from a single family of viruses.

The following may be exempt from the NIH Guidelines depending on the experiment being conducted:

- Recombinant or synthetic nucleic acid molecules containing less than one-half of any eukaryotic viral genome (all viruses from a single family being considered identical, that are propagated and maintained in cells in tissue culture.
- Escherichia coli K-12 host-vector systems.
- Saccharomyces cerevisiae and Saccharomyces uvarum host-vector systems.
- Kluyveromyces lactis host-vector systems.
- Any asporogenic Bacillus subtilis or asporogenic Bacillus licheniformis strain which does not revert to a spore-former with a frequency greater than 10-7 may be used for cloning DNA.
- Recombinant or synthetic nucleic acid molecules derived entirely from extrachromosomal elements of the organisms listed in NIH Guidelines, propagated and maintained in organisms from the same list.

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

Application

Complete the General Biohazard Form (Form A) 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, 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, complete and submit the Hazardous Substance Addendum (Form C).

If the research involves the use of biohazardous materials with animals, complete and submit the Animal Use Addendum (Form D).

All protocols receive full review by the IBC, except low-risk research that involves the collection of human cells, tissues, or fluids. These are reviewed by a sub-committee of the IBC.

All application materials must be submitted electronically to the Biosafety Committee Coordinator (iacuc@drexel.edu) by the deadline listed on the calendar.

Pre-review

Protocols are assigned to a pre-meeting review team by the Director of Regulatory Compliance or designee. The Biosafety Committee Coordinator prepares the review materials, consisting of all related application

documents. The application package is sent to the pre-meeting review team which consists of a primary reviewer, secondary reviewer(s), and, for protocols involving animals, the veterinarian.

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 e-mail.
2. The investigator revises the protocol to incorporate the changes suggested by the reviewers. The revised copy is submitted electronically, along with a cover letter outlining all changes, to the Biosafety Committee Coordinator.

Convened Committee Review

Each committee member receives the revised version of all protocols for review.

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 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.

Committee Actions

Protocols are presented and discussed individually and 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 federal-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 will communicate the necessary changes to the investigator within five working days via e-mail. The investigator will submit the changes to the protocol and form and provide a point-by-point response on a cover letter to the Biosafety Committee Coordinator. The Biosafety Committee Coordinator will forward the response to the Chair for review.
- Table – If the protocol requires clarification in order for the IBC to make judgment, certain committee members with certain expertise is not present, the IBC wishes to seek external consultation, or any of a number of other reasons prevents the IBC from conducting its review, then the IBC may wish to defer or table review. The investigator will receive a letter within five working days describing the status of the study and the reason(s) the application was tabled. If the application requires clarification, the letter will outline the necessary revisions for reconsideration by the IBC.
- Withhold Approval – 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 substantial revisions must be made. 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 convened meeting of the IBC.

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 Biosafety Committee Coordinator may accept minor revisions that are administrative in nature, such as completion of training.

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 in writing or, as part of the periodic review process by completing the appropriate section on the periodic review form. A protocol may be administratively inactivated by the IBC if the principal investigator fails to submit the periodic review form or for safety concerns.

After three years, a new application must be submitted. If there are no changes to the protocol, the pre-meeting review may be omitted from the review process described supra.

Periodic Reports

All activities involving recombinant DNA and other biohazards (except human pathological samples) must be reviewed annually. Each principal investigator of an approved protocol will receive a request to complete a Periodic Report Form in advance of the anniversary date of the initial UBSC approval. This form solicits information regarding whether there have been any changes to the protocol, changes in the personnel, changes in the laboratory locations, etc. The completed form must be returned to the Office of Research no later than two weeks prior to the anniversary dated. Any protocol for which a periodic review form is not received timely may be inactivated.

The UBSC will review the Periodic Report at its monthly meetings. The Committee may vote to:

- Approve the report, effectively allowing the protocol to remain active for another year,
- Defer approval of the report for minor changes, or
- Investigate issues or concerns raised during the review. This could lead to the suspension or termination of the protocol.

The investigator will receive an electronic letter within five working days regarding the committee's decision.

Amendments

Investigators who would like to modify their protocols must submit Form F, the protocol amendment form. Amendment involving changes to procedure, use of new biohazards, changes in animal model, etc., will be reviewed by the full committee at the next meeting. Addition of personnel and other administrative changes may be approved by the Biosafety Committee Coordinator. Change in location may be approved by the Biosafety Committee Coordinator upon consulting with the Biosafety Officer. All ad hoc approvals will be reported to the IBC at the next meeting.

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(s):

- Are 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.
- Are not counted towards quorum.

Appeals

Decisions of the IBC may be appealed to the IBC.

Public Participation

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 need to contact the Biosafety Committee Coordinator to confirm date, time and location of the meeting and so that adequate space can be assured.

Availability of Minutes

All IBC meeting minutes and any documents submitted to or received from funding agencies which the latter are required to make available to the public (e.g., IBC roster and member's biographical sketches) will be made available to the public upon request.

Materials to be released will be reviewed by the Office of General Counsel and the Director of Regulatory Compliance for redaction prior to release. 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 Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax).

Redactions

Trade secret information and other confidential commercial information, home telephone numbers and home addresses of IBC members, specific information whose disclosure would directly compromise institutional or national security, and the names of non-government research sponsors will be redacted before releasing the minutes to the public.

To the extent that they do not pertain to recombinant or synthetic nucleic acid molecule research; ULAR reports, Safety Office reports, and other similar reports to the committee will be redacted from the minutes.

Names of individuals not directly associated with the IBC or activities overseen by OBA (e.g., name of an animal caretaker or EHS staff member) will be redacted.

Reports

Annual Reports

The IBC, through the Institutional Official, will file an annual report with OBA 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 Director of Regulatory Compliance and/or the Biosafety Committee Coordinator.

Reports to the Institutional Official

The IBC through the Director of Regulatory Compliance and the Biosafety Committee Coordinator 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

Incident Reports

Principal Investigators are responsible for reporting to the BSO any of the following incidents:
- Spill or accident involving biohazardous materials that leads 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 an actual exposure.
- Any spill or accident in a BL3 or BL4 laboratory that results in a potential or actual exposure must be reported.
- 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 supra that is reported to the BSO or is discovered by the BSO during inspections will be reported to the IBC Chair and the Director of Regulatory Compliance. 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 r/sNA must be reported to NIH OBA within 30 days.

Spills or accidents in BL2 laboratories resulting in an overt exposure to r/sNA and spills or accidents occurring in BL3 or BL4 laboratories resulting in an overt or potential exposure to r/sNA must be immediately reported to NIH OBA.
In instances when OBA 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 OBA.

Approval of Charter / Signatures

Aleister Saunders, Ph.D.
Interim Sr. Vice Provost for Research
Institutional Official

Date

Fred Krebs, Ph.D.
Associate Professor
Chair, Institutional Biosafety Committee

Date

Appendix A
Select Agent List

Agency	Select Agents
HHS	Abrin
USDA	African horse sickness virus
USDA	African swine fever virus
USDA	Avian influenza virus
OL	Bacillus anthracis
HHS	Botulinum neurotoxins*
HHS	Botulinum neurotoxin producing species of Clostridium*
OL	Burkholderia mallei
OL	Burkholderia pseudomallei
USDA	Classical swine fever virus
HHS	Conotoxins[1]
HHS	Coxiella burnetii
HHS	Crimean-Congo haemorrhagic fever virus
HHS	Diacetoxyscirpenol
HHS	Eastern Equine Encephalitis virus
HHS	Ebola virus*
HHS	Francisella tularensis*
HHS	Lassa fever virus
HHS	Lujo virus
USDA	Foot-and-mouth disease virus*
USDA	Goat pox virus
USDA	Lumpy skin disease virus
HHS	Marburg virus*
HHS	Monkeypox virus
USDA	Mycoplasma capricolum
USDA	Mycoplasma mycoides
USDA	Newcastle disease virus[2, 3]
USDA	Peste des petits ruminants virus
PPQ	Peronosclerospora philippinensis (Peronosclerospora sacchari)
PPQ	Phoma glycinicola (formerly Pyrenochaeta glycines)

Agency	Select Agents
PPQ	Ralstonia solanacearum
PPQ	Rathayibacter toxicus
HHS	Reconstructed 1918 pandemic influenza virus
HHS	Ricin
HHS	Rickettsia prowazekii
USDA	Rinderpest virus*
HHS	SARS-associated coronavirus
HHS	Saxitoxin
PPQ	Sclerophthora rayssiae
USDA	Sheep pox virus
HHS	South American Haemorrhagic Fever viruses: Chapare Guanarito Junin Machupo Sabi
HHS	Staphylococcal enterotoxins (subtypes A-E)
USDA	Swine vesicular disease virus
PPQ	Synchytrium endobioticum
HHS	T-2 toxin
HHS	Tetrodotoxin
HHS	Tick-borne encephalitis (flavi) viruses: Far Eastern subtype Siberian subtype
HHS	Kyasanur Forest disease virus
HHS	Omsk haemorrhagic fever virus
HHS	Variola major virus (Smallpox virus)*
HHS	Variola minor virus (Alastrim)*
PPQ	Xanthomonas oryzae
HHS	Yersinia pestis*

HHS – Health and Human Services Select Agents and Toxins
USDA – Dept. of Agriculture Select Agents and Toxins
PPQ – Dept. of Agriculture Plant Protection and Quarantine Select Agents and Toxins
OL – Overlap Select Agents and Toxins (both HHS and USDA)

* Tier 1 agents

1. Short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$)
2. Some exclusions apply
3. Failure to detect a cleavage site consistent with virulent strains does not confirm the absence of a virulent virus.

Appendix B
DURC List

Dual Use Agents

- Avian influenza virus
- Bacillus anthracis
- Botulinum neurotoxin
- Toxin-producing strains of Clostridium botulinum
- Burkholderia mallei
- Burkholderia pseudomallei
- Ebola virus
- Foot-and-mouth disease virus
- Marburg virus
- Reconstructed 1918 Influenza virus
- Rinderpest virus
- Variola major virus
- Variola minor virus
- Yersinia pestis

Dual Use Research of Concern (DURC) is defined as 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.

Any activities involving unattenuated forms of one or more of the listed agents which aims to produce, or is reasonably anticipated to produce one or more of the listed experimental effects is considered Dual Use Research of Concern.

Experimental Effects

1. Enhances the harmful consequences of the agent or toxin
2. Disrupts immunity or the effectiveness of an immunization against without clinical and/or agricultural justification
3. Confers to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions or facilitates their ability to evade detection
4. Increases the stability, transmissibility, or the ability to disseminate the agent or toxin
5. Alters the host range or tropism of the agent or toxin
6. Enhances the susceptibility of a host population to the agent or toxin
7. Generates or reconstitutes an eradicated or extinct agent or toxin listed

Appendix C
Minutes Template

DREXEL UNIVERSITY

Minutes Of The Institutional Biosafety Committee

Date: _____ Meeting called to order at: _____

Location: _____

Present:

Voting Members

☐ Fred Krebs, PhD, Chair ☐ Arthur Frank, MD, PhD, Chair ☐ Simon Cocklin, PhD
☐ Marie-Luise Faber ☐ Rick Huneke, DVM or ☐ Andrea McCurry (alt.)
☐ Ellie Barbarash, MS, CPEA ☐ Kent Lambert, MS, CHP ☐ Jon Chase, MS
☐ Tom Case, MS, CIH ☐ James Burns, PhD ☐ Michael Akins, PhD
☐ Theresa Connors

out of voting members present. Quorum achieved ☐ Yes ☐ No

Non-voting members

☐ Christina Canamucio (IBC Coordinator) ☐ Rebecca Spangenberg (IACUC Administrator)
☐ Aleister Saunders PhD (Institutional Official)

Consultants, Visitors, Members of the Public

_____

I. Reports

A. Office of Research

_____

B. Chair

_____

C. ULAR

_____

D. Environmental Health and Safety

_____

II. Reminder for Conflict of Interest

The chair reminded the committee of the NIH Guidelines, Section IV-B-2-a-(4) which states: "No member of an Institutional Biosafety Committee may be involved (except to provide information requested by the Institutional Biosafety Committee) 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."

III. Minutes of Previous Meeting

Minutes of the meeting on _____ were: ☐ approved as written. ☐ approved as corrected (see below). ☐ tabled for corrections (see below).	__ Yes __ No __ Abstain

IV. Review of Action Items

A. Approved conditions met, Expedited (Human Subject Specimen Registration)

PI Name: _____ Protocol Number: _____

Sponsor: _____ Reviewer(s): _____

Project Title: _____

Actions / Remarks: _____

PI Name: _____ Protocol Number: _____

Sponsor: _____ Reviewer(s): _____

Project Title: _____

Actions / Remarks: _____

B. Periodic Reports

PI Name: _____ Protocol Number: _____

Project Title: _____

Any incidents, accidents, breech of containment? ☐ Yes ☐ No

Any personal injuries or illnesses involving biohazardous materials? ☐ Yes ☐ No

Does containment level need to be changed? ☐ Yes ☐ No

Training of staff up-to-date? ☐ Yes ☐ No

Any problems or issues not otherwise specified above? ☐ Yes ☐ No

☐ Approved ☐ Approval deferred pending minor changes* ☐ Tabled* ☐ Approval Withheld*	__ Yes __ No __ Abstain
*Issues needing resolution:	

PI Name: _____ Protocol Number: _____

Project Title: _____

Any incidents, accidents, breech of containment? ☐ Yes ☐ No

Any personal injuries or illnesses involving biohazardous materials? ☐ Yes ☐ No

Does containment level need to be changed? ☐ Yes ☐ No

Training of staff up-to-date? ☐ Yes ☐ No

Any problems or issues not otherwise specified above? ☐ Yes ☐ No

☐ Approved ☐ Approval deferred pending minor changes* ☐ Tabled* ☐ Approval Withheld*	__ Yes __ No __ Abstain
*Protocol issues needing resolution:	

C. New Protocols

PI Name: _____ Protocol Number: _____

Sponsor: _____ Reviewers: _____

Project Title: _____

Applicable section of NIH Guidelines _____ ☐ N/A

Biohazardous material(s): _____

Animal species involved: _____ ☐ N/A

Biosafety Level: <select> Special Containment Conditions: _____

PI and lab staff completed required training? ☐ Yes ☐ No

During the presentation of the protocol, the IBC reviewed and considered the following:

☐ Characteristics (e.g., virulence, pathogenicity, toxicity) of the agent
☐ Types of manipulations planned
☐ Adequacy of containment
☐ Need for health surveillance
☐ Proper personal protective equipment
☐ Source(s) of the nucleic sequences (e.g., species)
☐ Nature of the nucleic acid sequences (e.g., structural gene, oncogene)
☐ Host(s) and vector(s) to be used
☐ Whether obtaining the expression of a foreign gene will be attempted and the protein produced

Research characteristics (check all that apply):

☐ Risk Level Low ☐ Risk Level High ☐ Select Agent or Toxin ☐ DURC

☐ Approved ☐ Approval deferred pending minor changes* ☐ Tabled* ☐ Approval Withheld*	__ Yes __ No __ Abstain
*Protocol issues needing resolution:	

PI Name: _____ Protocol Number: _____

Sponsor: _____ Reviewers: _____

Project Title: _____

Applicable section of NIH Guidelines _____ ☐ N/A

Biohazardous material(s): _____

Animal species involved: _____ ☐ N/A

Biosafety Level: <select> Special Containment Conditions: _____

PI and lab staff completed required training? ☐ Yes ☐ No

During the presentation of the protocol, the IBC reviewed and considered the following:

☐ Characteristics (e.g., virulence, pathogenicity, toxicity) of the agent
☐ Types of manipulations planned
☐ Adequacy of containment

☐ Need for health surveillance
☐ Proper personal protective equipment
☐ Source(s) of the nucleic sequences (e.g., species)
☐ Nature of the nucleic acid sequences (e.g., structural gene, oncogene)
☐ Host(s) and vector(s) to be used
☐ Whether obtaining the expression of a foreign gene will be attempted and the protein produced

Research characteristics (check all that apply):

☐ Risk Level Low ☐ Risk Level High ☐ Select Agent or Toxin ☐ DURC

☐ Approved ☐ Approval deferred pending minor changes* ☐ Tabled* ☐ Approval Withheld*	__ Yes __ No __ Abstain
*Protocol issues needing resolution:	

D. Amendment Requests

PI Name: _____ Protocol Number: _____

Sponsor: _____ Reviewers: _____

Project Title: _____

Applicable section of NIH Guidelines _____ ☐ N/A

Biohazardous material(s): _____

Animal species involved: _____ ☐ N/A

Biosafety Level: <select> Special Containment Conditions: _____

PI and lab staff completed required training? ☐ Yes ☐ No

During the presentation of the amendment request, the IBC reviewed and considered how the proposed change might affect the following:

☐ Characteristics (e.g., virulence, pathogenicity, toxicity) of the agent
☐ Types of manipulations planned
☐ Adequacy of containment
☐ Need for health surveillance
☐ Proper personal protective equipment
☐ Source(s) of the nucleic sequences (e.g., species)
☐ Nature of the nucleic acid sequences (e.g., structural gene, oncogene)
☐ Host(s) and vector(s) to be used
☐ Whether obtaining the expression of a foreign gene will be attempted and the protein produced

Research characteristics (check all that apply):

☐ Risk Level Low ☐ Risk Level High ☐ Select Agent or Toxin ☐ DURC

☐ Approved ☐ Approval deferred pending minor changes* ☐ Tabled* ☐ Approval Withheld*	__ Yes __ No __ Abstain
*Protocol issues needing resolution:	

V. Other Business

Meeting adjourned: _____

_____
Fred Krebs, PhD
Institutional Biosafety Committee Chair

Appendix D
References and Resources

National Institutes of Health – Office of Biotechnology Activities:

- Principal Investigator Responsibilities under the NIH Guidelines (PDF download)
- Frequently Asked Questions (FAQs)
- IBC Frequently Asked Questions (FAQs)
- Incident Reporting Template (DOC download)
- Reports of incidents to OBA go to:

Kathryn Harris, Ph.D., RBP
Senior Outreach and Education Specialist
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892
Phone: 301-496-9838
Fax: 301-496-9839
Email: harriskath@od.nih.gov

NIH Guidelines

- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines, April 2016) (PDF download) (HTML)

Dual Use Research of Concern:

- Companion Guide to U.S. government policies for oversight of DURC (PDF download)
- Dual Use Research of Concern: A Dialogue (watch video)

Centers for Disease Control and Prevention (CDC)

- Biosafety in Microbiological and Biomedical Laboratories (BMBL 5th Ed.) (PDF download)

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
- Responsible Official Guidance Document (PDF Download)
- Responsible Official Resource Manual (PDF Download)

Drexel University Laboratory Safety Manual (Section V, Biological Safety, begins page 24) (PDF download)

Pathogen Safety Data Sheets and Risk Assessment (maintained by the Public Health Agency of Canada)

Laboratory Biosafety Manual (from the World Health Organization)