

Northern Illinois University

Institutional Biosafety Committee

Policy



Northern Illinois University Institutional Biosafety Committee

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Purpose

Northern Illinois University Institutional Biosafety Committee (IBC) policy promotes safety in research studies, promotes safe handling of biological agents, reduces risk of infection, provides for safe disposal of infectious laboratory wastes, and maintains compliance with applicable institutional policies and regulatory requirements.

The IBC is responsible for monitoring and oversight of the use of biohazardous agents to safeguard the health and safety of NIU personnel, students, the community, and the environment. The IBC must also ensure compliance with applicable federal regulations and guidelines, granting agency guidelines, as well as NIU policies and procedures.

The IBC is committed to incorporating health and safety practices governing all NIU personnel working with biohazardous materials in research and/or teaching activities at NIU. The NIU Biosafety Program is established to reduce the risk of potential occupational exposure and unintended environmental release of infectious agents, biological toxins, Select Agents/Toxins and recombinant deoxyribonucleic acids (rDNA) in a research and/or teaching environment.

Scope

IBC review and approval is required prior to using the following types of biohazardous agents:

- Recombinant or synthetic nucleic acid molecules, as defined by the NIH Guidelines, section 8.2 (<http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines>). Protocols seeking exemption under section 1.7 require review and approval by the IBC Chair ([http://osp.od.nih.gov/sites/default/files/Experiments that are Exempt from the NIH Guidelines.pdf](http://osp.od.nih.gov/sites/default/files/Experiments%20that%20are%20Exempt%20from%20the%20NIH%20Guidelines.pdf)).
- Any microorganism (including but not limited to bacteria, viruses, fungi, rickettsia, protozoa, or parasites) or infectious substance, or naturally occurring, bioengineered or synthesized component of any such microorganism or infectious substance that is capable of causing death, disease or other biological malfunction in a human, an animal, or a plant.
- Select Biological Agents and Toxins, High Consequence Livestock Pathogens, and Restricted Plant Pathogens 42 CFR 73, CFR121 and 7 CFR 331, <https://www.selectagents.gov/>
- Any biological toxin: a toxic material or product of plants, animals, or microorganism (including but not limited to bacteria, viruses, fungi, rickettsia, or protozoa), or infectious substance, or recombinant or synthesized molecule (whatever the origin and method of production)
- Any human blood or body fluid (<http://www.osha.gov/SLTC/bloodborne pathogens/index.html>)
- Cell lines derived from human or non-human primate tissues.
- The definition also includes projects involving known biohazards that do not appear to fall into one of the above criteria (e.g. prions or cell lines known to be infected with viruses). If in doubt as to whether a material constitutes a potential biohazard, the NIU Biological Safety Officer should be consulted.

NIU policy requires that all research and/or teaching involving infectious agents, biological toxins, Select Agents/Toxin, and rDNA be conducted in a safe manner. Biosafety containment practices protect the faculty, staff, students, volunteers, and visitors from exposure to infectious agents, biological toxins, Select Agents/Toxins, and rDNA and prevent the release of biohazards into the environment. Although federal regulations allow exemptions for some types of rDNA and other agents, the principal investigator (PI) must submit an application for all projects using rDNA and biohazardous materials, agents and toxins so that the IBC is aware of the activities and can verify that they are exempt.

To ensure the safe handling of infectious agents, biological toxins, Select Agents, toxins, and

rDNA, NIU investigators must comply with all of the following guidelines and regulations that are relevant:

- U.S. Department of Health and Human Services NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
- Centers for Disease Control and Prevention (Biosafety in Microbiological and Biomedical Laboratories)
- U.S. Department of Labor Occupational Safety and Health Administration (Blood-borne Pathogens Standard, 29 CFR 1910.1030)
- NIU Office of Research Compliance, Integrity and Safety (<http://niu.edu/divresearch/compliance/>)
- NIU Institutional Biosafety Committee Policies
- Other applicable federal, state and local regulations.

Roles and Responsibilities of the Institution

- Establish and implement policies that provide for the safe conduct of recombinant DNA research and ensure compliance with the NIH Guidelines for the safe handling of biological materials and other potentially hazardous agents (e.g. carcinogens)
- Establish the Institutional Biosafety Committee, (IBC)
- Ensure that the IBC has adequate expertise to review the research conducted at the institution
- Provide appropriate training for the IBC Chair and members, Biological Safety Officer, PIs, and laboratory staff
- Report any significant problems, violations of the NIH guidelines, or any significant research-related accidents and illnesses to the NIH/OBA within 30 days
- File an annual report with the NIH Office of Biotechnology Activities that includes a roster of IBC members clearly indicating the Chair, contact person, Biological Safety Officer, plant expert, and animal expert. Biographical sketches of any new members will be included.
- Establish procedures that the IBC shall follow in its initial and continuing review and approval of applications, proposals and activities
- Make available, upon request, all IBC meeting minutes and any documents submitted to or received from funding agencies that those agencies are required to make available to the public
- Make IBC meetings open to the public whenever possible and consistent with protection of privacy and proprietary interests.

Responsibilities of additional stakeholders

Principal Investigator

- Faculty, staff, retired faculty or staff and students who are under the oversight of a faculty or staff advisor member who is also listed on the protocol may submit an application to the IBC. This individual must be the point of contact. Exceptions can be made with the approval of the review board, please contact Office of Research Compliance, Integrity and Safety (ORCIS) for additional information.

- Determine the known or potential biohazards associated with the proposed research by way of a documented Risk Assessment. For recombinant DNA, the PI shall not initiate or modify those experiments requiring approval of the IBC until that proposed research or modification has received approval from the IBC and has met all other requirements of the appropriate governing local, state and/or federal agencies.
- Submit an IBC application form as requested or otherwise required by applicable guidelines, regulations, or standards.
- Provide personnel under his/her supervision with knowledge of biohazards to which they may be exposed and safety procedures to be followed. In order to achieve this, the PI must:
 - Be knowledgeable of good laboratory safety practice and demonstrate a positive safety attitude.
 - Provide laboratory staff with copies of procedures describing potential biohazards and appropriate precautions. The procedures and other information addressing biosafety- related issues should be produced in the form of a standard operating procedure (SOP).
 - Provide laboratory staff with documented formal and informal instruction and training in the practices and techniques required to ensure safety and in the procedures for dealing with accidental spills, personnel contamination, and other laboratory accidents.
 - Ensure that all participants complete the CITI training “Basic Introduction to Biosafety”
 - For more information on the CITI training see <http://niu.edu/divresearch/compliance/bio/training/index.shtml>
 - Maintain an up-to-date Laboratory Safety Plan.
 - Report any significant problems, violations of the NIH Guidelines, or any significant research-related accidents and illnesses to the Biological Safety Officer, IBC, and other appropriate authorities within 30 days.

Department Chair

- Ensure that, prior to initiation of work, each investigator using biohazardous agents files a protocol with IBC and that approval has been granted prior to the initiation of the research.
- Ensure that students have had instruction in safety procedures in teaching laboratories or field situations where biohazardous agents are used.
- Determine that appropriate facilities and safety equipment are available for proposed research or instruction involving biohazardous agents.

Employee/ Student Lab Workers

- All employees and student lab workers are required to follow the procedures listed in this policy, to follow alternate procedures that have been approved by the IBC for their specific laboratory or specific project, and to follow any additional safety procedures that have been adopted by the relevant PI
- Complete the CITI “Basic Introduction to Biosafety” training before work with

- biological agents.
- Employees and student lab workers are directed to seek guidance from their PI, Department Chair, the Biological Safety Officer or the IBC if they are unclear about any biosafety procedures.

Biological Safety Officer

- Assist in the preparation and periodic updating of a biosafety manual
- Consult with investigators on matters related to laboratory safety, appropriate handling and containment of biohazardous agents, decontamination, and disposal of infectious wastes.
- Help investigators develop appropriate emergency measures for dealing with accidental spills and personnel contamination.
- Annually inspect and periodic visits of laboratories in which biohazardous agents are employed to ensure compliance with prescribed safety guidelines and rectification of any deficiencies.
- Investigate incidents involving biohazardous agents to determine causes and appropriate corrections. Upon completing the investigation, the Biological Safety Officer will prepare a written report of findings for review and action, if any, by the IBC
- Monitor intra-campus transport
- Provide information for off-campus shipment of biohazardous materials
- Review plans for new facilities and modifications of existing structures where etiologic agents or rDNA materials will be used.
- Develop, arrange, or conduct training programs for laboratory personnel using biohazardous agents
- Serve as liaison between NIU and outside regulatory agencies concerned with the use of biohazardous agents
- The Biological Safety Officer, with concurrence by the Vice President for Research and Innovation Partnerships or chairperson of the IBC (or in his/her absence, by at least three other technically qualified members of the Committee), may temporarily stop any work with biohazardous agents that create a recognized hazard to personnel, the public or environment, or involved experiments prohibited by the institution. The convened IBC will then review the problem and forward written recommendations to the Vice President for Research and Innovation Partnerships for final action.

IBC Committee Policy

Membership and requirements

The IBC must be comprised of no fewer than five members, so selected that they collectively have experience and expertise in rDNA technology and the capability to assess the safety of rDNA research and to identify any potential risk to public health or the environment related to biosafety and physical containment. Membership will include:

1. At least two members not affiliated with the institution (apart from their membership on the IBC) and representing the interests of the surrounding community with respect to health and protection of the environment
2. At least one member having expertise in plant, plant pathogen or plant pest

- containment principles
3. At least one member having expertise in animal containment principles
 4. The NIU Biological Safety Officer
 5. Three faculty members with expertise in recombinant DNA and/or biological safety
 6. At least one member with expertise in the health sciences, (for example Nursing, Medical Lab Sciences, Kinesiology and Physical Education)

No member of the IBC may be involved in the review or approval (except to provide information requested by the IBC) of a project in which he/she has been or expects to be engaged or has a direct financial interest.

Quorum

A quorum of the committee will be a simple majority of its membership.

Length of service

Individual members of the IBC will have a term length of three years. After that time, membership renewals will be at the discretion of the Vice President for Research and Innovation Partnerships (or designee).

Meeting Schedule

Meetings will be scheduled six times a year, generally in January, March, May, July, September and November of each year. Submission deadlines for these meetings will be posted on the IBC website.

Additional meetings may be scheduled as required. The finalized meeting dates and copies of meeting agendas may be obtained by calling the Office of Research Compliance, Integrity and Safety.

Review Procedures

i. Reviewed by IBC Chair

BSL-1 or exempt rDNA activity: The Chair will sign a letter notifying the PI of the determination of his review. A copy of the approval/notification letter and the application will be maintained in the Office of Research Compliance, Integrity and Safety for documentation purposes. As long as the activity does not significantly change, no additional action is required by the IBC or the PI.

ii. Reviewed in Full Committee

Non-exempt rDNA activity, or BSL – 2 and higher biocontainment (except blood draws by finger-stick): The application will be reviewed at the next available IBC meeting. Annual continuation and a new application after three years are required.

iii. Designated Review of Protocols

Annual Continuations with minor revisions and blood draws by finger-stick: at least one member of the IBC, designated by the IBC chair and qualified to conduct the review, will be assigned to review the protocol and be given the authority to approve, require modifications in (to secure approval), or request full committee review of those protocols. All IBC members will receive a copy of these protocols and may provide the designated reviewer with comments and/or suggestions for the designated reviewer's consideration only. Any IBC member may call for a review of the protocol by the convened IBC.

Note: Blood draws using venipuncture require Full Committee review. Under exceptional circumstances, as determined by the IBC chair, designated review may be used for protocols if not prohibited by federal regulations.

iv. Select Agents

In addition to IBC approval, research involving Select Agents, a subset of pathogenic organisms or toxins, requires submission of an application to the CDC <http://www.cdc.gov/od/sap> and submitting to Federal Bureau of Investigation (FBI) background check before any research has begun. Please contact the Office of Research Compliance, Integrity and Safety for further assistance if you plan to use select agents.

Amendments

For minor changes to a protocol, such as a change in personnel (not including the PI), the PI needs to simply notify the IBC. All other changes, (such as a change in previously described procedures, PI, quantity of material, organism or cell lines used), must be submitted to the IBC committee for review before the requested change is implemented.

Training

Basic biosafety training is available online at no cost to participants. CITI Program (<https://about.citiprogram.org/en/homepage/>) provides the biosafety training via the module “Basic Introduction to Biosafety”. Participants must register and select Northern Illinois as their Organization Affiliation to gain access. An informational questionnaire is provided to assist those who may have multiple modules to complete due to the type of research.

The CITI certification for biosafety is in effect for three years. After three years the individual needs to repeat the “Basic Introduction to Biosafety” module.

Institutional Biosafety Committee Authority

The IBC can approve or disapprove protocols. The IBC is the link between the university and regulatory agencies, and has an overlapping role with other NIU committees, including the Institutional Review Board (which reviews human subjects research), and the Institutional Animal Care and Use Committee (which reviews research, teaching and testing protocols that involve animals). In issues of noncompliance, the IBC makes recommendations to the Vice

President for Research and Innovation Partnerships to stop further research in non-compliant laboratories or for other corrective actions.

Protocol Termination and Issues of Noncompliance

Research involving any of the biohazardous materials listed in this document must be registered with the IBC. This will establish a level of biosafety containment for one's laboratory, help ensure that one's research is conducted in compliance with applicable biosafety regulations and protect other investigators at NIU and the University from penalties.

Regardless of the source of one's funding, non-compliance with NIU biosafety policy may lead to suspension, limitation, or termination of all NIH funding to NIU. Specifically, non-compliance with the *NIH Guidelines* can result in:

1. suspension, limitation, or termination of financial assistance for the noncompliant NIH-funded research project and of NIH funds for other recombinant DNA research at NIU, or
2. a requirement of prior NIH approval of any or all recombinant DNA projects at NIU.

Protocol Termination

i. Completed or inactive projects

The PI will notify the IBC when a research protocol involving rDNA and biohazardous materials, agents, and toxins is completed or no longer active. The IBC shall contact the PI if there are any questions or concerns regarding Termination of Approval.

ii. Failure to submit renewal or resubmission

If the PI fails to provide a renewal or resubmission form to the IBC before the protocol expires, a letter will be sent to the PI and copied to the Department Chair. All research activities pertaining to the research described in the expired protocol must cease. If the PI does not provide a renewal or resubmission by the next IBC meeting, this issue is added to the agenda and the IBC determines whether to terminate the IBC protocol. Termination of the IBC protocol may require termination of any related IACUC or IRB protocols and notification of the Vice President for Research and Innovation Partnerships. The Vice President for Research and Innovation Partnerships may in turn notify NIU Sponsored Programs Administration and other relevant agencies (National Institutes of Health Office of Laboratory Animal Welfare, granting agencies) for further action.

iii. Delinquent PI responses to IBC Review Correspondence

Failure to respond to submission review correspondence (administrative, preliminary, or full-committee) within 30 days will result in a Final Notice Letter from the Research Compliance Coordinator. If the PI fails to respond to the Final Notice Letter in 30 days, this will result in withdrawal of the original submission. The PI must contact the Research Compliance

Coordinator if unable to respond to correspondence on a timely basis.

iv. Non-compliance with NIU Biosafety Policy

A PI who is found by the IBC to be in violation of Federal, State, or NIU guidelines and policy governing the use of biohazardous agents, potentially hazardous human materials, or recombinant DNA molecules may have his/her IBC approval suspended by the IBC, pending further investigation and final action by the IBC. In the event that the IBC's final action includes revocation of IBC approval of the protocol, the IBC is authorized to notify the Vice President for Research and Innovation Partnerships, who is in turn authorized to notify the Sponsored Programs Administration and other relevant agencies (National Institutes of Health Office of Laboratory Animal Welfare and Office of Biotechnology Activities granting agencies). Termination of the IBC protocol may lead to termination of related IACUC or IRB protocols.

Procedure for Reporting Allegations of Non-compliance

Allegations, may be reported by concerned individual to any of the following:

- Employee Relations
- IBC Chair
- Any IBC member
- NIU Biological Safety Officer
- Director of Office of Research Compliance, Integrity and Safety
- Vice President for Research and Innovation Partnerships

The IBC chair is responsible for the receipt and disposition of all complaints. All allegations will remain confidential to the extent possible. When the complainant wishes to be openly identified, the IBC Chair will acknowledge receipt of the allegations to the complainant in writing. The NIU Whistleblower Policy should be consulted for specific information on individual protection.

The IBC Chair will appoint a subcommittee to determine if the complaint has sufficient substance to warrant a full investigation. All persons involved in the investigation will be informed of the purpose of the investigation and the manner in which it will be conducted.

The subcommittee, in its investigation, will examine all pertinent documents and procedures, will interview involved personnel, and will report its findings to the entire IBC. The IBC will then vote either in a convened meeting or electronically for the following options:

- accept the recommendations of the investigating subcommittee
- offer further suggestions or comments
- request a convened meeting to discuss the concern and/or the report. A single member's request for a convened meeting to consider a concern will result in a convened meeting.

Based upon the report of the investigation, the IBC will determine required actions, if any. IBC determinations may include, but are not limited to:

- investigation did not reveal an issue of non-compliance
- investigation revealed non-compliance

- related aspects of the program require further review
- other related institutional programs may require review.

For any noncompliance with IBC policy, the IBC must prescribe corrective actions along with appropriate deadlines and reporting requirements. The IBC must determine whether the noncompliance meets the criteria for actionable. as determined by the IBC”.

Examples of corrective actions include:

- terminate approval of the respective research protocol
- suspend approval of the respective research protocol pending completion and acceptance by the IBC of an independent audit of the study and/or the submission, by the PI, of a written plan for the correction and/or prevention of the problem
- institute an IBC-mandated corrective action plan and independent audit of the study
- other actions as the IBC deems appropriate, including recommendations to the Vice President for Research and Innovation Partnerships for the confiscation and destruction of rDNA and/or biohazardous materials.

The IBC Chair will communicate, in writing, the results of the IBC evaluation of a reported concern to the person responsible for the situation of concern, the PI, the Vice President for Research and Innovation Partnerships, the Director of Research Compliance, Integrity and Safety, and the complainant (if the complainant wishes to be notified of the outcome). The communication will include a summary of the concern, the findings of the investigation, determinations of the IBC, and the recommended corrective actions/sanctions. The letter will also inform the person(s) responsible for the situation reported of his/her option to appeal the decision, within ten days of receipt of this letter, by writing the IBC Chair detailing the basis of the appeal and requesting a meeting with the IBC.

The IBC is obligated to report within thirty days, through the Vice President for Research and Innovation Partnerships, any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses to NIH’s Office of Biotechnology Activities unless the institution determines that a report has already been filed by the PI or Biological Safety Officer.

Please visit the Office of Research Compliance, Integrity and Safety website (<http://niu.edu/divresearch/compliance/>) for forms and additional information pertaining to biosafety, animal research, and human subjects’ research.

Date	Reviewed by	Changes
2/19/2019	IBC	Update training requirements
11/6/2020	IBC	Minor revision
6/27/2022	Biosafety Officer	Minor revision