Institutional Biosafety Committee Guidebook

This guidebook includes all of the information previously found on the UNMC Institutional Biosafety Committee (IBC) website.

After clicking into a topic, navigation within the book or page can be found on the left side of your screen. Above the page lists your current location within the content structure. If needed you will find a search function at the top of the page which may also be used for fast navigation.

If you have any questions, please contact us at 402-559-6463 or by email at ibcora@unmc.edu

    - Dual-Use Research of Concern
    - Experiments Requiring IBC Approval
    - Federal Mandates for the Institution
    - Policies

- Resources
- Submission Deadlines
- Training

About Us

The Institutional Biosafety Committee (IBC) is dedicated to protecting the health and safety of everyone at UNMC who works with biohazardous agents. Some of our major responsibilities include:

- Reviewing and approving recombinant DNA research projects to ensure compliance with NIH guidelines
- Notifying principal investigators of the results of our reviews and approvals
- Drafting campus biosafety policies and procedures, including the creation of emergency plans in the case of accidental spills and personnel contamination
- Reporting any problems, violations, accidents or illnesses to the appropriate offices

For further details about the IBC's roles and responsibilities, refer to Section IV-B-2-b of the NIH Guidelines.

Chairs & Administrators

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What is Biosafety?

Biosafety is a set of principles and practices, either studied or applied, that are intended to address the safe handling and containment of infectious microorganisms and hazardous biological materials.

Safe use of biological and biohazardous materials involves:

- Appropriate facilities and equipment (containment)
- Adequate training and hazard awareness
- Following proper laboratory practices as determined by risk assessment
- Complying with Institutional, federal, state, and local regulations

UNMC Biosafety Program

The UNMC Department of Environmental Health & Safety (EHS) oversees the Biosafety Program, which:

- Seeks to protect workers, students, the community, and the environment from potential exposures to biohazardous materials.
- Provides biosafety guidance for research, clinical, and teaching activities at UNMC.
- Provides guidance and resources for special topics: safe handling practices, waste disposal, decontamination, and more.
- Oversees the development and implementation of compliance trainings.

- Assists Principal Investigators (PIs) with IBC requirements.
- Containment facility design recommendations and review
- Laboratory inspections and in person lab or project specific trainings

Forms

Form Type	Download Instructions
Adverse Event Report	Download PDF
Laboratory Inspection Checklist BL2	Download PDF
Laboratory Inspection Checklist BL3	Download PDF
Laboratory Inspection Checklist ABL2	Download PDF
Laboratory Inspection Checklist ABL3	Download PDF
CDC-Form 2 (Select Agent Transfer)	Visit the CDC Form 2 webpage for Guidance Documents and Forms (Fillable and Print Only)
CDC-Form 3 (Select Agent Loss, Theft, Release)	Visit the CDC Form 3 webpage for Guidance Documents and Forms (Fillable and Print Only)
CDC-Form 4A (Select Agent Clinical Diagnosis)	Visit the CDC Form 4 webpage for Guidance Documents and Forms (Fillable and Print Only)
CM Laboratory Inspection Checklist	Download PDF
Autoclave Core Facilities Biosafety Inspection Checklist	Download PDF
Biological Spill Procedures	Download PDF
Decision Tree for Biological Spill Clean Up	Download PDF
Laboratory Re-commissioning ABSL-3 & BSL-3 Checklist	Download PDF
Biosafety Risk Assessment Summary	Download PDF

Frequently Asked Questions

Click on a question below to view the answer details. For any additional questions not covered below, contact the IBC Administrative office at ibcora@unmc.edu or 402-559-6463.

Do I need to fill out an IBC application?

If your work involves recombinant DNA and/or infectious Risk Groups 2 or 3 agents, you will need an IBC protocol.

An IBC protocol is also required for work involving human gene transfer, toxins of biological origin, and transgenic plants or animals where the genome is altered using recombinant DNA.

For further questions, please contact Dr. Jenna McKenzie.

How do I submit an IBC application?

The IBC no longer utilizes paper forms. Please complete an electronic application on RSS.

How do I submit a change to my protocol?

Please submit a Change Request on RSS.

The Change Request button can be found within your application on the upper right hand corner. Using this button will set your application to edit mode.

How do I complete my annual continuing review?

On RSS, in the IBC protocol, please click on the “Continuing Review” button on the left-hand side of the screen.

Please answer all questions and submit a Change Request (see previous question) if you have indicated that you are making changes to your protocol.

Why am I unable to submit my application and/or continuing review?

To avoid issues, please only use specific browsers (Mozilla Firefox or Google Chrome) to submit applications.

Once all the red arrows are no longer remaining and the PI signs the application, you may save and submit.

Why am I unable to access my application?

If the application is locked, someone else may be in it. All personnel must use the “Close Application” button when logging out of a protocol to make it available for others.

NOTE: *Do not use the “Complete/Close Protocol” button found on your list of protocols, as this will send a request to terminate the protocol.*

I accidentally requested to terminate my protocol. What should I do?

Please email the IBC administrative office (ibcora@unmc.edu) and clarify that you do not wish to have your protocol deleted.

To log out of a protocol, please use the “Close Application” button within the application. Do not use the “Complete/Close Protocol” button found on your list of protocols, as this will send a request to terminate the protocol.

When will my protocol be reviewed?

The IBC meets on the second Thursday of each month. In order for a protocol to be reviewed at a meeting, it must be submitted 10 days prior to the meeting date.

Visit the Submission Deadlines page for a list of upcoming meeting dates and associated protocol deadlines.

How can I complete my assigned IBC training?

Your training will appear on Canvas within 48 hours of assignment. If you do not see it after this time, please contact the IBC administrative office (ibcora@unmc.edu).

Policies & Procedures

The IBC is committed to making the application and review process as easy as possible for you. In the sections within this chapter, you will find definitions, explanations, policies and procedures relating to biosafety guidelines at UNMC.

Beyond the sections within this chapter, additional information on relevant topics can be found at these links:

- Review the biosafety manual
- View the export control website

If you have questions or need more information, please don't hesitate to contact us at 402-559-6463 or by email at ibcora@unmc.edu.

Application Process

Experiments using Biosafety Levels 1-3 (BL-1, BL-2 or BL-3) containment must be reviewed and approved prior to the initiation of experiments. Experiments using BL-4 are not authorized for conduct at UNMC.

The application process is as follows:

For the review of a new protocol not using human gene transfer protocols

1. Create an application electronically through RSS.
2. On the black bar, select "IBC". Under the red IBC APPLICATION heading, select "New Protocol." Once the application is complete, sign and submit the application.
3. Following the review process by the IBC Committee, the principal investigator may be asked to amend the pre-application. (During this review process, all laboratories will be requested to have a laboratory inspection by the Biosafety Officer. View the Laboratory Inspection Checklist forms that are available to you.
4. The PI will submit the amended application with the signature page to the IBC Chair for a final review.
5. Once the protocol successfully complies to the requirements of the NIH Guidelines, a letter approving the protocol authorizing initiation of the experiments will be sent to the PI.

For the review of a new protocol using human gene transfer protocols

The IRB and IBC review may occur simultaneously. Review per the process above as well as the following points:

1. Include a copy of the documents submitted to the NIH/OBA in fulfillment of the submission requirement for human gene transfer experiments as outlined in the NIH Guidelines, and a copy of the letter from the NIH/OBA to the PI about the results of the Recombinant DNA Advisory Committee's initial review.
2. Provide a copy of the letter from the NIH/OBA to the PI stating that the review process has been satisfactorily completed must also be sent with this application if it was not included with the original submission documents.

3. It is requested that the PI submit a copy of the IRB approval letter to the IBC chair to complete the application.

Continuing review of approved IBC protocols

IBC protocols are approved for 1 year intervals after which time a re-review is required. Prior to the expiration date, the principal investigator and designated contact will be notified that the IBC protocol is up for re-review and instructed to do the following:

1. Complete a continuing review in RSS and submit.
2. Projects that are active with a change in protocol will require the submission of a Request for Change in Protocol in RSS for review with the continuing review form.
3. Individuals listed as investigators or laboratory support on projects must have active IBC training.
4. A laboratory inspection will be scheduled by the biosafety officer during this review process.
5. Following review by the IBC, if it is determined that the protocol meets re-approval (including that training is current) and the laboratory passes inspection, the proposal will be approved for another year.

Request for Change of approved IBC protocols

IBC protocols that require any change in personnel, labs, procedures, biohazardous agents, etc. must be reviewed and approved by the IBC prior to initiating any changes:

1. Complete a Request for Change in RSS and submit.
2. Review may be performed, administratively, by the IBC Chair or by the full committee.
3. Following review, approval notice will be sent informing the PI of approval.

Adverse event reporting

Any event (i.e. laboratory incident) that involves containment of personnel and/or the environment with a biohazardous agent must complete a report form. Please refer to IBC Policy #24 for complete details.

Definition of Biohazardous Agent

The purpose of the definition is to identify individuals who must take the Biosafety Training. Biohazardous materials are defined as materials of biological origin that have the capacity to produce deleterious effects on humans or animals. They include:

1. recombinant DNA molecules that are transferred into human research participants (human gene transfer),
2. recombinant DNA that is introduced into animals (transgenic animals),
3. synthetic DNA segments which are likely to yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or pharmacologically active agent),
4. microorganisms where there is a deliberate transfer of a drug resistant trait or of recombinant DNA containing genes for the biosynthesis of products potentially toxic for vertebrates,
5. microorganisms classified as risk group 2 (RG-2) or risk group 3 (RG-3) agents whether infectious or defective (NOTE: RG-4 agents are not allowed on the UNMC/UNO campuses),
6. microorganisms where more than two-thirds of the DNA from RG-2 or RG-3 agents is cloned into other nonpathogenic agents,
7. biological products derived from RG-2 or RG-3 microorganisms,
8. clinical/medical waste e.g., diagnostic specimens, that are used in research and known or reasonably expected to contain pathogens classified as RG-2, RG-3, or RG-4 agents, and
9. culture of more than 10 liters of a biological agent.

Basis for the Classification of Biohazardous Agents by Risk Group

Risk Group	Risk to the Individual and the Community

RG-1	Agent that is not associated with disease in healthy adult humans
RG-2	Agent that is associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available
RG-3	Agent that is associated with serious or lethal human disease for which preventative or therapeutic interventions may be available (high individual risk but low community risk)
RG-4	Agent that is likely to cause serious or lethal human disease for which preventative or therapeutic interventions are not usually available (high individual risk and high community risk)

Dual-Use Research of Concern

According to the National Institutes of Health, dual use research of concern (DURC) is "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."

The following documents can provide further clarification on this subject:

- NIH Office of Science Policy Dual Use Research of Concern
- UNMC IBC Policy #42: Dual Research of Concern Oversight

IMPORTANT NOTICE

On May 6, 2024, the US Government released a new *Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential* (USG DURC-PEPP Policy). This policy which supersedes previous DURC policies, goes into effect on May 6, 2025. Guidance for implementing this policy can be found in the USG Implementation Guidance (USG DURC-PEPP Guidance).

Updates to UNMC Policy and procedures are in progress. More information will be posted as it becomes available.

Experiments Requiring IBC Approval

Experiments that require IBC approval include those that involve:

- the deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally,
- the deliberate transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into human research participants (human gene transfer),
- the deliberate formation of recombinant DNA containing genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight,
- using risk group 2 or risk group 3 agents as host-vector systems,
- the cloning of DNA from risk group 2 or risk group 3 agents into non-pathogenic prokaryotes or lower eukaryotic host-vector systems,
- the use of infectious or defective risk group 2 or risk group 3 agents,
- whole animals in which the animal's genome has been altered by stable introduction of recombinant DNA or DNA derived into the germ-line (transgenic animal),
- viable recombinant DNA-modified microorganism tested on whole animals,
- genetically engineered plants by recombinant DNA methods,
- more than 10 liters of culture, and
- the formation of recombinant DNA molecules containing no more than two-thirds of the genome of an eukaryotic virus.

Working with Select Agents

A sub-category of risk group agents referred to as Select Agents as defined in "The Antiterrorism and Effective Death Penalty Act of 1996, Public Law #104-132, Regulation 42CFR 72.6" are referred to as specific toxins and pathogens as regulated by the Department of Health and Human Services and/or the USDA.

These agents require special procedures for transfer and possession. Contact the UNMC Biosafety Officer for further information concerning these biohazardous agents.

Federal Mandates for the Institution

Per NIH Guidelines

"As a condition for NIH funding ... institutions shall ensure that research conducted at or sponsored by the institution, irrespective of the source of funding, shall comply with the *NIH Guidelines*."
(*Section 1-D of the NIH Guidelines*)

"(The institution must) establish and implement policies that provide for the safe conduct of ... research and to ensure compliance with the *NIH Guidelines*."
(*Section IV-B-1 of the NIH Guidelines*)

Per Select Agent Rule (42 CFR Part 73)

"An entity may not possess or use ... receive from ..., or transfer within the United States, a select agent or toxin unless such activities are conducted ... in accordance with the provision of this law."
(*Part 73.3 - HHS select agents and toxins*)

"(it is the responsibility of the Institution to) provide information and training at the time of an individuals initial assignment to a work area where select agents or toxins are present ... (and) provide refresher training annually."
(*Part 73.13 - Restricted experiments*)

Policies

Below are UNMC policies relating to biosafety (click policy number to view in PDF format):

- IBC-01: Autoclave Operation and Safety
- IBC-02: Biological Safety Cabinet Certification
- IBC-03: Biological Safety Cabinet Operation
- IBC-04: Biological Spill Clean-Up
- IBC-05: Biohazardous Waste Disposal
- IBC-06: Biosafety Training Program
- IBC-07: Centrifuge Safe Operation
- IBC-08: IBC Application & Review Process: New Protocols (General)
- IBC-09: IBC Application & Review Process: New Protocols Utilizing Select Agents
- IBC-10: IBC Application & Review Process: New Protocols Involving Human Gene Transfer
- IBC-11: IBC Laboratory Inspection Process
- IBC-12: IBC Review Process for Previously Approved Protocols
- IBC-13: Immunization Policy for Research Using Vaccinia Virus
- IBC-14: Paraformaldehyde Room and Biological Safety Cabinet Decontamination
- IBC-17: Laboratory Decommissioning
- IBC-19: Laboratory Commissioning, BL-2
- IBC-20: Laboratory Commissioning, BL-3
- IBC-24: Reporting Adverse Event
- IBC-29: Personnel Access for BL-3 Containment
- IBC-30: Category A High Consequence Pathogens
- IBC-32: Federal Permits for Shipment of Human Pathogens
- IBC-33: Off-site Laboratories
- IBC-34: Biosafety Risk Factor Assessment Process to Determine Appropriate Containment
- IBC-35: Registration Process for the Use of Exempt Recombinant DNA
- IBC-36: Visiting Scientist and Student for Access
- IBC-37: Serum Banking
- IBC-38: Personal Protective Equipment

- IBC-39: Pest Management
- IBC-40: Removal of Materials from the ABSL-3 or BSL-3 Laboratory
- IBC-41: Safe Handling and Disposal of Sharps
- IBC-42: Dual Use Research of Concern (DURC) Oversight
- IBC-43: Use of Human and Nonhuman Primate Tissues, Cells, and Cell Lines
- IBC-44: Allegations of Noncompliance

Resources

Guidelines

- CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) (6th edition; June 2020)
  - Selection, Installation and Use of Biological Safety Cabinets, Appendix A (see page 395 of BMBL)
- Health Canada Laboratory Biosafety Guidelines
- NIH Guidelines for Research Involving Recombinant DNA Molecules (April 2024)
- WHO Laboratory Biosafety Manual(4th edition; December 2020)

Websites

- American Biological Safety Association
- CDC Import Permits Program
- CDC Select Agent Program
- Health Canada Pathogen Safety Data Sheets (PSDSs) (previously MSDS for infectious substances)
- OSHA Bloodborne Pathogen Standard (per 29CFR 1910.1030)
- Risk Group Classification for Infectious Substances
- UNMC Laboratory Safety Manual
- UNMC Shipment of Hazardous Materials or Dangerous Goods Policy
- UNMC Radiation Safety Manual

Submission Deadlines

The IBC meets on the second Thursday of each month. In order for a protocol to be reviewed at a meeting, it must be submitted 10 days prior to the meeting date by 12 PM CT.

IBC Full Board Submission Deadline*	Date of IBC Meeting
December 30, 2024	January 9, 2025
February 3, 2025	February 13, 2025
March 3, 2025	March 13, 2025
March 31, 2025	April 10, 2025
April 28, 2025	May 8, 2025
June 2, 2025	June 12, 2025
June 30, 2025	July 10, 2025
August 4, 2025	August 14, 2025
September 1, 2025	September 11, 2025
September 29, 2025	October 9, 2025
November 3, 2025	November 13, 2025
December 1, 2025	December 11, 2025

**Protocols must be submitted before 12 PM CT on the submission deadline to be reviewed at the next IBC meeting.*

Training

Biosafety Training Program

General biosafety training is required by all individuals conducting research on the UNMC/UNO campuses that involve biohazardous materials. All training modules can be accessed through Canvas.

The NIH Guidelines state it is the responsibility of the institution "to ensure appropriate training for ... principal investigators and laboratory staff regarding safety and implementation of the NIH Guidelines" (Section IV-B-1-h).

Documentation of successful completion of training is required in order to receive an IBC approval, whether involved with a new application or for a re-application. After the initial training, General Biosafety is valid for 3 years. BSL-3 and Select Agent is valid for 1 year.

> Your training will appear on Canvas within 48 hours of assignment. If you do not see it after this time, please contact the IBC administrative office at ibcora@unmc.edu or 402-559-6463.