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

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

Risk Group	Risk to the Individual and the Community
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 the subject:

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

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