

IOWA STATE UNIVERSITY Institutional Biosafety Committee

Responsibilities of Principal Investigators Conducting Research or Teaching Involving Biohazards

General Responsibilities

As part of the general responsibilities for conducting research involving biohazards, the PI should:

- Determine the appropriate physical and biological containment levels.
- Submit an application via a-tune for and receive Institutional Biosafety Committee (IBC) approval before initiating the research or teaching activity.
- Propose appropriate microbiological practices and laboratory techniques to be used for the research or teaching activity.
- Ensure personnel have completed the required training as outlined by the [Required IBC Training Program](#).
- Be adequately trained in good microbiological techniques.
- Have Standard Operating Procedures (SOPs). Information on health and safety, hazard control measures, waste disposal practices, decontamination, and spill and release for work performed under the protocol must be included. Provide and document training on SOPs. Instruct and train staff in: (i) the practices and techniques required to ensure safety, and (ii) the procedures for dealing with accidents.
- Ensure personnel have completed a Hazard Inventory form for potential enrollment in the Occupational Medicine Program.
- Inform the laboratory staff of the reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collection).
- Supervise laboratory staff to ensure that the required safety practices and techniques are employed.
- Correct work errors and conditions that may result in release of biohazards or recombinant or synthetic nucleic acid molecule materials.
- Ensure the integrity of physical containment (e.g., biological safety cabinets) and biological containment (e.g., host-vector systems that preclude survival of the agent outside the laboratory).
- Adhere to IBC approved emergency plans for handling accidental spills and personnel contamination as outlined in the *Biosafety Manual* (<https://publications.ehs.iastate.edu/bsm/>).
- Obtain IBC approval prior to implementation of any amendments or changes in research or teaching activities conducted in the lab.
- Report any significant problems, violations of the [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules](#) (*NIH Guidelines*), or research-related accidents or illnesses, or new information in your project that has bearing on the applicable *NIH Guidelines* to the IBC and the University Biosafety Officer (Environmental Health & Safety). Following are some examples of reportable incidents:
 - Events involving a personal injury or loss of containment
 - Accidental needle sticks
 - Escape or improper disposal of animals used in research
 - Spills of high-risk recombinant or synthetic nucleic acid molecule materials outside of the biosafety cabinet

- Comply with applicable shipping requirements as outlined in the following list:
 - Export Control Regulations
 - Select Agent
 - USDA Animal Plant and Health Inspection Service permit requirements
 - ISU Hazardous Materials Shipping Guide
- Submit an annual review via a-tune if the project will exceed one year.

Responsibilities when Conducting Research Involving Recombinant or Synthetic Nucleic Acid Molecules

All institutions that receive NIH funding for recombinant or synthetic nucleic acid molecules research must comply with the *NIH Guidelines*. Researchers at institutions that are subject to the *NIH Guidelines* must also comply with the requirements even if their individual projects are not funded by NIH. Before initiating research subject to the *NIH Guidelines*, the PI must

- determine whether the research is subject to Section III-A, III-B, III, C, III-D, or III-E of the *NIH Guidelines*;
- determine the appropriate physical and biological containment levels in accordance with the *NIH Guidelines*;
- seek NIH approval, in addition to IBC approval, to conduct experiments specified in Sections III-A and III-B of the *NIH Guidelines*.

Guide to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*

Compliance with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf) is mandatory for every institution that receives NIH funding for research involving recombinant or synthetic nucleic acid molecules. It is the responsibility of each investigator to make sure that their laboratory is in compliance. Investigators must obtain IBC review and approval or a determination of exemption from the *NIH Guidelines* prior to initiation of research. This outline is intended only to serve as a guide to the *NIH Guidelines* and assist investigators in determining the appropriate section for their research.

Section III-A & B—Experiments that Require IBC and National Institutes of Health (NIH) Approval

1. Deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally if such acquisition could compromise the use of the drug to control disease.
2. Cloning of toxin molecules with LD₅₀ of less than 100 ng/kilogram body weight.

Section III-C—Generally not Applicable to Research at Iowa State University

1. Experiments involving the deliberate transfer of recombinant or synthetic nucleic acid molecules into one or more human research participants.

Section III-D—Experiments that Require IBC Approval

1. Experiments using Risk Group 2, 3, 4 or restricted agents as host-vector systems.
2. Experiments in which DNA from Risk Group 2, 3, 4 or restricted agents is cloned into nonpathogenic prokaryotic or lower eukaryotic host-vector systems.
3. Experiments Involving the Use of Infectious DNA or RNA Viruses or Defective DNA or RNA Viruses in the Presence of Helper Virus in Tissue Culture Systems.
4. Experiments that generate transgenic animals, including insects (with the exception of transgenic rodents requiring BL1 containment).
5. Experiments involving viable recombinant or synthetic nucleic acid molecules-modified microorganisms tested on whole animals.

6. Experiments involving whole plants that require BL3-P or BL4-P containment.
7. Experiments involving more than 10 liters of culture.
8. Experiments involving influenza virus.
9. Experiments Involving Gene Drive Modified Organisms

Section III-E—Experiments Requiring IBC Notification (and approval)

1. Introduction into cultured cells of any recombinant or synthetic nucleic acid molecules containing no more than 2/3 of a eukaryotic viral genome (with the exception of Risk Group 3 or 4 agents).
2. Cloning in non-pathogenic prokaryotes and non-pathogenic lower eukaryotes that are not specifically exempt.
3. Generation by embryo injection of transgenic rodents requiring BL1 containment.
4. Experiments involving whole plants that require BL1-P or BL2-P containment.
5. Experiments not specifically addressed in this document.

Section III-F—Experiments that Are Exempt from the NIH Guidelines (but still require IBC review)

1. Synthetic acids that: 1) cannot replicate or generate nucleic acids in any living cell, 2) are not designed to integrate into DNA; and 3) do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 ng/kg of body weight.
2. Use of rDNA or synthetic nucleic acids that are not in organisms or viruses and that have not been modified or manipulated.
3. Those that consist solely of the exact recombinant or synthetic nucleic acid sequence from a single source that exists contemporaneously in nature.
4. 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.
5. 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)
6. Purchase or transfer of transgenic rodents that may be maintained at BL1 containment.
7. The breeding of two different transgenic rodents or the breeding of a transgenic rodent and non-transgenic rodent with intent of creating a new strain that can be housed at BL1 containment.
8. Cloning of all other DNA in *E. coli* K12, *S. cerevisiae*, *S. uvarum*, *Kluyveromyces*, *B. subtilis* and *B. licheniformis* host-vector systems (with the exception of DNA from Risk Group 3 and 4 pathogens).
9. Introduction into culture cells of any recombinant or synthetic nucleic acid molecules containing less than half of a eukaryotic viral genome (with the exception of Risk Group 3 or 4 pathogens).

This is not an all-inclusive list of experiments that are exempt from the NIH Guidelines. Refer to the NIH Guidelines at https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf to review all experiments exempt under Section III-F.

IBC review is not required for synthetic nucleotides that are PCR primers or PCR products.