



SOUTHERN ILLINOIS UNIVERSITY CARBONDALE

Institutional Biosafety Committee

IBC Policy #	310
Policy Title	Activities Requiring a Memorandum of Understanding and Agreement
Date Approved	
Date Reviewed	
Scope	This policy applies to research under the oversight of the Southern Illinois University Institutional Biosafety Committee.

Policy Purpose

This policy describes which research activities require the submission of a Memorandum of Understanding and Agreement (MUA) prior to beginning the work with certain molecules, toxins, or pathogenic microorganisms.

Policy Definitions

BMBL refers to the current edition of the *Biosafety in Microbiological and Biomedical Laboratories*, published by the CDC. The BMBL provides recommended guidance and best practices for the safe handling of biological hazards in laboratory settings.

MUA refers to a Memorandum of Understanding and Agreement, which is a document submitted to the IBC for review and approval of work with r/sNAs or pathogenic microorganisms.

NIH Guidelines means the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*; the set of regulations detailing safety practices and containment procedures for research involving recombinant or synthetic nucleic acid molecules, including the creation and use of organisms and viruses containing recombinant or synthetic nucleic acid molecules.

Principal Investigator refers to the tenured/tenure track faculty member, research faculty member, project/program director, associate director, or senior scientist with a 50% or greater appointment who will be the primary supervisor of work with r/sNAs.

r/sNA refers to recombinant or synthetic nucleic acid molecules. These molecules are subject to the federal *NIH Guidelines* cited above.

Policy Statement

All Investigators at SIUC who plan to work with r/sNAs, human gene transfer, heritable genetic modification of plants or animals, gene drives, biologically derived toxins, or agents infectious for humans, plants, or animals, or those items otherwise regulated under NIH Guidelines must first submit a Memorandum of Understanding and Agreement to the IBC and receive approval prior to beginning activities.

The IBC will review the MUA for concordance with federal, state, and institutional guidelines (including the NIH Guide and USDA-APHIS policies and regulations) and for concordance with the

CDC BMBL for appropriate laboratory techniques and equipment for biological safety and containment.

General Procedures

The NIH Guidelines in Section III detail the activities which require approval prior to initiation. Some activities also include requirements for approval from the NIH Director, or approval from the NIH Office of Science Policy (NIH OSP), in addition to approval from the SIUC IBC. Such activities will be reviewed by the SIUC IBC at the same time they are reviewed by the NIH.

The highest level of approval, from the NIH Director and the IBC, includes deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally.

The next highest level of approval, from the NIH OSP and the IBC, includes experiments involving the cloning of toxic molecules with an LD₅₀ of less than 100 nanograms per kilogram of body weight.

Experiments that require only SIUC IBC approval include, but are not limited to, the following:

- experiments involving human gene transfer
- experiments involving using Risk Group 2, 3, or 4 or restricted agents as host-vector systems
- experiments in which DNA from Risk Group 2, 3, or 4 or restricted agents are cloned into nonpathogenic prokaryotic or lower eukaryotic host-vector systems
- experiments involving the use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of a helper system in tissue culture
- creation of transgenic animals
- creation of transgenic plants using r/sNAs
- experiments involving more than 10 liters of culture
- experiments involving influenza viruses
- experiments involving gene drive modified organisms

Although the NIH does not require IBC permission for work with materials listed in Risk Group 1, the SIUC IBC requires submission of an MUA for those materials to the IBC for review. This gives the committee information regarding all use of r/sNAs and pathogenic microorganisms on campus.

References

Centers for Disease Control & National Institutes of Health. (2020). Biosafety in microbiological and biomedical laboratories (6th ed). https://www.cdc.gov/labs/pdf/SF_19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf

National Institutes of Health. (2024). *NIH guidelines for research involving recombinant or synthetic nucleic acid molecules*. https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf