

SOUTHERN ILLINOIS UNIVERSITY CARBONDALE

Institutional Biosafety Committee

| IBC Policy # | 300 |
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| Policy Title | Memoranda 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 the documents of application for IBC permission to conduct research activities with r/sNAs, pathogenic microorganisms, or other regulated activities with biological hazards. The documents are called Memoranda of Understanding and Agreement (MUAs).

Policy Definitions

<u>BMBL</u> 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.

<u>MUA</u> 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.

<u>NIH Guidelines</u> 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.

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

<u>Regulated Activities</u> include any research, teaching, and/or contracted service activity with r/sNAs or biological hazards conducted by SIUC faculty, staff, volunteers, and students.

Policy Statement

All Principal Investigators (PIs) at SIUC who work with r/sNAs, pathogenic microorganisms, or other regulated activities with biological hazards as defined and listed in the BMBL must request permission from the IBC by completing and submitting an MUA. Work may not begin until the MUA has been reviewed and approved by the IBC.

General Procedures

Two different forms of MUA are used: one is used for PIs working with r/sNAs, and the other is used by PIs working with pathogenic microorganisms. The forms are available on the Office of Research Compliance (ORC) website.

The PI is responsible for making an initial determination of the required levels of physical and biological containment in accordance with the NIH Guidelines and institutional policies; the PI must request assistance from the IBC Chair or the IBO if needed. MUAs will be submitted to ORC, who will send them to the Chair and the IBO for pre-review. Following pre-review and initial questions/clarifications, the MUA will be distributed to the entire Committee for review and vote at a regularly scheduled meeting.

The IBC will review the submission and approve activities that are determined to be in congruence with the NIH Guidelines. This review includes assessment of the containment levels required by the NIH Guidelines for the proposed research; assessment of the facilities, procedures, practices, and training and expertise of personnel involved in recombinant or synthetic nucleic acid molecule research or work with pathogens; for recombinant or synthetic nucleic acid molecule research involving human research, participants assessment includes biosafety issues (e.g., administration, shedding).

The MUA, once approved by the Committee, will be valid for three years, subject to annual review by the Chair and the IBO. After three years, the MUA must be resubmitted and reviewed by the entire Committee.

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

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