SOUTHERN ILLINOIS UNIVERSITY CARBONDALE

Institutional Biosafety Committee

IBC Policy #	**320**
Policy Title	**MUA Submission and Review**
Date Approved	**November 20, 2025**
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 procedures for submission and review of a Memorandum of Understanding and Agreement.

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.

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.

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

Regulated Activities 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

Investigators working with r/sNA or regulated biological hazards must submit a Memoranda of Understanding and Agreement (MUA) to the IBC for review and approval prior to initiation. MUAs will undergo the review process appropriate to the project scope, which may include chair review or full committee review. No member may participate in the review of any MUA in which they have a conflicting interest. The IBC may approve the MUA, request revisions as a condition of approval, or disapprove the submission. Approved MUAs are valid for three years. To maintain active status of the project beyond the initial three-year approval, the Principal Investigator (PI) must submit the MUA for de novo renewal.

General Procedures

MUA Submission

The IBC utilizes two types of MUA registration forms. One is specific to work involving r/sNAs and

the other for work with pathogenic microorganisms. For both, the PI must conduct an initial risk assessment and determine the appropriate level of containment. NIH Guidelines and BMBL provide containment guidance. The IBC will independently review necessary containment levels.

MUA for R/sNAs

For applications to conduct work involving r/sNAs, the PI must include sufficient information on the MUA registration application, including the purpose and methods of the experiments, the sources of any nucleic acid molecules, nature of the sequences and any host/vector systems. The MUA submission must also include the required physical and biological containment levels, and if applicable, information on any necessary health surveillance.

The PI must sign and date the registration application before submitting the MUA request to the Office of Research Compliance (ORC). Upon receipt, the ORC shall forward the registration application to the Committee Chair and the Institutional Biosafety Officer (BSO). The registration application will undergo an initial administrative pre-review. The PI will receive written notification outlining any requested changes resulting from the pre-review. Once the PI responds to the initial pre-review, the Committee Chair, in consultation with the Institutional Biosafety Officer, assigns the appropriate review category (see Review and Approval).

MUA for Non-Recombinant DNA Research

The submission and review for MUAs for the use of biological materials other than recombinant or synthetic nucleic acids follows the same process as r/sNA MUAs. The PI must provide sufficient information to enable the IBC to understand the purpose and methods of the experiments, all proposed agents, the required containment facilities, any necessary health surveillance, and all known hazards. If the proposed work involves animals, the PI must schedule a meeting with the Director of the Laboratory Animal Program to discuss appropriate animal housing. The application then undergoes administrative pre-review, and the PI receives a memo detailing any requested changes. Once the PI responds to the initial pre-review, the Committee Chair, in consultation with the BSO, assigns the submission to the appropriate review category (see Review and Approval).

MUA Review and Approval

Review and approval categories are based on the criteria below. **No work may begin until the PI receives formal written approval**.

Review Type	For New MUAs Which Include	For Renewals and Amendments of Existing Approved MUAs
Full Committee Review (FCR)	• Work with r/sNAs falling under sections III-A though D of the NIH Guidelines • Work with recombinant RG2 and RG3 agents • Work with recombinant human-derived materials and r/sNAs • Work with arthropods with r/sNAs or RG2 agents (ACL-2) • Work with Select Agents • Dual Use Research of Concern • Any protocol for which an IBC member requests FCR	• Renewals or Amendments containing experiments which fall under sections III-A through D of the If NIH Guidelines • Increase in risk group • Change in biosafety level • Significant change in procedures • Significant change in species, organisms, etc. • Work with Select Agents or Dual Use Research of Concern • Change in PI • Any IBC member requests FCR

Review Type	For New MUAs Which Include	For Renewals and Amendments of Existing Approved MUAs
Chair Review (In Consultation with the BSO)	• New MUA submissions that only contain experiments which fall under section III-E or section III-F of the NIH Guidelines	• Renewals and Amendments when the MUA only contains experiments which fall under section III-E or section III-F of the NIH Guidelines • Minor change in procedures • Minor change in species, organisms, etc. • Change in location • Renewals that contain only experiments falling under Section III-F of the NIH Guidelines • Amendment with minor changes in exempt procedures • Amendment with minor changes in species, organisms, etc.
Administrative Review	• New MUA submissions are not eligible for administrative review	• Amendment requests for change in key personnel (not to include PI) • Amendment requests updating contact information or funding source(s) • Amendment requests to make minor changes to the MUA title • Amendment requests to correct minor grammatical errors • Protocol termination and closing report(s)

For MUAs requiring full committee review, the committee reviews and votes on the submission at a scheduled meeting with quorum present. If the committee requests additional information or revisions, the ORC notifies the Principal Investigator with a memo outlining the required changes. The PI revises the MUA and returns it to ORC. The Chair, in consultation with the BSO, verifies that the revised MUA meets committee criteria and may issue final approval. At the request of any committee member, the revised MUA will be returned to the full committee or assigned to Designated Member Review for approval. If the IBC does not approve a MUA, the ORC provides the PI with a memo explaining the reasons. The PI may submit a new MUA request.

For MUAs involving only those experiments falling under NIH Guidelines Section III-E and III-F, the Chair, in consultation with the BSO, may review and approve the submission after confirming the MUA fits within the appropriate NIH category, includes appropriate biosafety measures, and complies with institutional policies. The Chair shall report on such approvals at the next scheduled committee meeting. The Chair may also elect to assign review through a Designated Member Review process. At any point, the Chair, BSO, or any other committee member may call for Full Committee Review (FCR). If the Chair or other reviewers are unable to approve the MUA, even after requesting revisions of the PI, they must refer the MUA to a convened IBC meeting with quorum present.

In limited circumstances, the IBC Coordinator, in consultation with the Chair, may review and approve certain amendment requests. Amendments eligible for administrative review and approval include only those items considered minor, such as a change in personnel (not to include the PI) or listed contact information, updating listed funding sources, minor change to the MUA title, minor grammatical corrections, and confirmation of receipt for protocol terminations and closing reports. The Chair shall report such approvals to the committee at their next scheduled meeting.

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