



Title: Reporting of Incidents Involving Recombinant or Synthetic Nucleic Acid Molecules (rsNAM) and Materials	Policy Category:
Issuing Authority:	Responsibility:
Publication Date:	Next Review Date:

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Policy Statement/Background:

In order to comply with federal reporting requirements and to ensure timely and appropriate follow-up, Stony Brook University is required to report incidents involving recombinant and synthetic nucleic acid molecules (rsNAM) to the National Institutes of Health (NIH) and/or other regulatory agencies. This policy outlines the information necessary to determine the nature and extent of the release and appropriate spill management and reporting requirements according to the *NIH Guidelines for Research Involving recombinant and Synthetic Nucleic Acids*. (NIH Guidelines; http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html).

Scope:

All Stony Brook University personnel working with and responding to incidents involving recombinant or synthetic nucleic acid molecules are responsible for adherence to this policy.

Policy:

All Principal Investigators shall immediately report any significant research-related accidents and illnesses involving recombinant or synthetic nucleic acid molecules (rsNAM) as well as violations of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines, 2024) to the Stony Brook University Biological Safety Officer (BSO).

Procedures

Responsibilities

Principal Investigators, Laboratory Supervisors and Laboratory Personnel

Principal Investigators (PI), faculty and other Laboratory Supervisors have the ultimate responsibility for ensuring that all lab personnel are knowledgeable of spill response procedures and that spills are addressed in a prompt manner. Information regarding spill / incident response procedures for biohazardous materials can be found in the Laboratory Emergency Plan.

The PI is responsible for immediately reporting incidents or violations of the *NIH Guidelines* to the Institutional Biological Safety Officer (BSO) in the Department of Environmental Health and Safety (EH&S) (631-632-6410 or ehsafety@stonybrook.edu) if they involve rsNAM materials, occur outside of containment and/or if personnel are exposed.

Biological Safety Officer (BSO)

Report to the Institutional Biosafety Committee (IBC), IBC Chair and Institutional Officials any significant problems, violations of the *NIH Guidelines*, and any significant research-related accidents or illnesses of which he/she may become aware.

Report any significant incident(s) that involves (nonexempt) rsNAM to the NIH within 30 days.

Report any incident(s) occurring in BSL-2 laboratories resulting in a significant overt exposure immediately to NIH.

Report any incident(s) occurring in BSL-3 laboratories resulting in a significant overt **or** potential exposure immediately to NIH.

Provide technical advice to PI's and laboratory personnel regarding laboratory security, safety and emergency plans for spills and personnel contamination related to work performed with rsNAM.

Institutional Biosafety Committee (IBC)

Ensure that all Principal Investigators, Laboratory Supervisors and Laboratory Staff are aware of, understand and follow the procedures outlined in this policy.

Reporting

Notify the Biological Safety Officer (BSO) immediately via email or phone if not already contacted for assistance with spill-clean up.

The BSO will investigate the incident and notify the IBC Chair and EHS Assistant Vice President.

The PI will complete the template for reporting incidents involving rsNAM and submit it to the BSO within 24hrs.

If the IBC Chair and BSO determine that the incident involves (non-exempt) rsNAM the BSO will submit an NIH incident report to the NIH within 30 days.

Incidents occurring in BSL-2 laboratories resulting in an overt exposure will be immediately reported to NIH. Incidents occurring in BSL-3 laboratories resulting in an overt or potential exposure will be immediately reported to NIH.

Definitions:

Recombinant or Synthetic Nucleic Acid Molecules (rsNAM): according to the NIH Guidelines (Section I-B), are defined as: molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids; nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids, or molecules that result from the replication of those described above.

Incident: can refer to but are not limited to the following; splashes to mucous membranes (i.e. eyes, nose, mouth), needle sticks or other percutaneous injuries from contaminated sharp items, bites/scratches from animals that have been exposed to rsNAM, environmental releases or spills of rsNAM outside of containment equipment, theft, loss, improper disposal of transgenic animal or plant materials.

Contact:

Additional information about this policy is available here:

Environmental Health and Safety

Christopher Kuhlow, Biological Safety Officer (BSO), Alternate Responsible Official (ARO)

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<https://ehs.stonybrook.edu/>

Relevant Standards, Codes, Rules, Regulations, Statutes, and Policies:

NIH Guidelines for Research Involving Recombinant Synthetic Nucleic Acid *Molecules* Apr. 2024. https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf

Template for Reporting Incidents Subject to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules to the National Institutes of Health Office of Science Policy (OSP) <https://osp.od.nih.gov/policies/biosafety-and-biosecurity-policy/>

Laboratory Emergency Plan

https://ehs.stonybrook.edu/pdfs/laboratory_emergency_plan.pdf