

IBC Policy Number: 1	Version Number: 1.1
Effective Date: March 16, 2017	
Title:	Reporting Requirements for Incidents Involving Recombinant and Synthetic Nucleic Acid Molecules

Purpose

The purpose of this policy is to set forth the incident reporting requirements for research involving recombinant or synthetic nucleic acid molecules as required by the National Institutes of Health ([NIH](#)) [Office of Biotechnology Activities \(OBA\)](#).

Regulatory Background

The [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules](#) (*NIH Guidelines*) require institutions to report certain incidents involving recombinant or synthetic (r/s) nucleic acid molecules to the NIH OBA. Incidents that must be reported to NIH OBA within 30 days include exposures, the escape or improper disposition of a transgenic animal, spills of high-risk materials occurring outside of a biosafety cabinet, failure to adhere to the containment and biosafety practices articulated in the *NIH Guidelines* and use of material without approval from the Institutional Biosafety Committee. Certain types of events, such as exposures to material that requires BSL 2 containment or higher, must be reported immediately to NIH OBA.

Scope

This policy applies to all faculty, staff and students who conduct research with r/s nucleic acid molecules that fall within the scope of the *NIH Guidelines*; and to the Biosafety Officer, Institutional Biosafety Committee (IBC), and IBC Administrator who investigate, review, mitigate, and report such incidents.

Responsibilities

Biosafety Officer (BSO) is responsible for reporting any incident involving r/s nucleic acid molecules to the IBC. The BSO is also responsible for investigating the incident to identify root cause, training needs; for developing corrective action measures; for reviewing the draft report with the IBC Chair, the Director of Research Integrity and Assurance (RIA) or designee; and for submitting the final incident report to the NIH OBA.

Institutional Biosafety Committee (IBC) is responsible for reviewing and discussing incidents at each committee meeting and ensuring compliance with all applicable regulations for incident reporting.

IBC Administrator is responsible for assisting the BSO with gathering information for the report and for ensuring that a copy of the final report is forwarded to the Institutional Official, IBC and RIA Director. The administrator will also provide requested documentation to OBA and maintain report copies in a secure file maintained within the RIA office.

Principal Investigator (PI) is responsible for full compliance with the *NIH Guidelines* in the conduct of r/s nucleic acid molecule research, for ensuring that the reporting requirements are fulfilled and will be held accountable for any reporting lapses.

Researchers (including principal investigators), Students and staff (if the event involved an exposure) are required to perform the recommended first aid and seek treatment as outlined in “Emergency Response Guidelines for Laboratory Workers”, posted in every laboratory and the [EHS website](#). This process includes reporting the incident to a supervisor and/or Principal Investigator, identifying and securing equipment that may have been involved in the incident and participating in the incident investigation.

Supervisors and Principal Investigators are responsible for ensuring that students and staff are aware of appropriate procedures for responding to and reporting exposures and spills; verifying that the appropriate first aid and treatment has been provided if the incident involved an exposure; participating in the investigation conducted by the Biosafety Officer; and reporting the following events involving r/s nucleic acid molecules to the BSO on the day that the incident occurred:

- Exposure
- Breach of containment that results in release to the environment
- Failure to obtain approval from the IBC prior to initiation of research

Definitions/Terms

Recombinant or Synthetic (r/s) nucleic acid molecules are defined as:

- Molecules:
 - that are constructed by joining nucleic acid molecules and
 - 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.

Exposures are defined as any of the following:

- Needlesticks or other percutaneous injuries from a contaminated sharp item
- Splashes to mucous membranes (eyes, nose, mouth)
- Bites/scratches from animals that have been exposed to any r/s nucleic acid molecules whether or not the exposure leads to illness

Overt Exposures are defined as:

- Exposures that have been assessed to be significant by the BSO and the treating clinician, and involve materials that require BSL 2 or higher containment practices.

Significant spill, loss of containment or release are defined as:

- Release of untreated r/s nucleic acid molecules that require biosafety level 2 containment into the sanitary sewer system or municipal trash
- Theft or loss of r/s nucleic acid molecules that require biosafety level 2 containment
- Escape of a transgenic animal

Policy

Any significant problems, violations of the *NIH Guidelines* (Section IV-B-2-b-(7)), or any significant research-related accidents, exposures, spills, loss of containment, release, and illnesses, hereinafter referred to collectively as “incidents,” must be reported to the NIH OBA as outlined below:

- Principal Investigators and supervisors must notify the BSO of exposures, loss of containment, release and spills involving r/s nucleic acid molecules. Notifications should be

made the day that the event occurred.

- If the incident involves r/s nucleic acid molecules that fall within the scope of the *NIH Guidelines*, the BSO will notify the IBC Chair and the IBC Administrator.
- For events that result in significant exposure to r/s nucleic acid molecules that require BSL 2 containment, the BSO will send an incident summary, via email, to the NIH OBA within 24 hours. The BSO will also forward a copy of the email notification to the IBC Chair and RIA Director or designee.
- Using the template provided by the NIH OBA, the BSO will prepare an incident report for review by the IBC Chair and RIA Director or designee. The final incident report will be sent to the NIH within 30 days of the incident. Institutional Official will receive a copy of the final report.
- The BSO will present a summary of all incidents to the IBC at a convened meeting.

Detailed procedures on response to spills and exposures can also be found on the [EHS Website](#) and in the “Emergency Response Guidelines” posted in all Princeton University laboratories.

Research with r/s nucleic acid molecules as described in [Sections III-A, B, C and D](#) of the *NIH Guidelines* must be approved by the IBC prior to initiation. If the use of r/s nucleic acid molecules occurs without approval from the IBC the following steps will be taken:

- Failure to obtain IBC approval prior to initiation of this type of research must be reported to the BSO within 24 hours.
- The BSO will prepare a report for review by the IBC Chair, RIA Director or designee, IBC administrator and the Institutional Official. The report will be sent to NIH OBA within 30 days.

To report an incident please contact the Biosafety Officer @ Phone: 609-258-5294 (After hours, the BSO can be contacted through the Department of Public Safety @ 609-258-1000).

References

- [NIH Guidelines for Research Involving Recombinant DNA Molecules \(NIH Guidelines\)](#)
- [NIH Incident Reporting Site](#)
- [NIH Incident Reporting FAQs](#)

Version History

Version Number	Revision Date	Revisions
1.0	October 12, 2012	Initiation
1.1	March 13, 2017	Placed document in new RIA Template to include Regulatory Background, Scope, Definitions and Terms, and Policy. Removed information on treatment of exposures, incidents and spills. Added new references