ENVIRONMENTAL HEALTH AND SAFETY
University of Nebraska-Lincoln

Safe Operating Procedure

(Revised 5/25)

NATIONAL INSTITUTES OF HEALTH (NIH) INCIDENT REPORTING FOR RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULE WORK

Introduction

All recombinant or synthetic nucleic acid (r/sNA) projects at the University of Nebraska-Lincoln (UNL) must adhere to the requirements of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*. These guidelines require that any "significant problems, violations of the National Institutes of Health (NIH) Guidelines, or any significant research-related accidents and illnesses, must be reported to NIH OSP" Office of Science Policy. This SOP describes incidents that are subject to NIH reporting requirements.

Incidents Subject to the NIH Guidelines Reporting Process

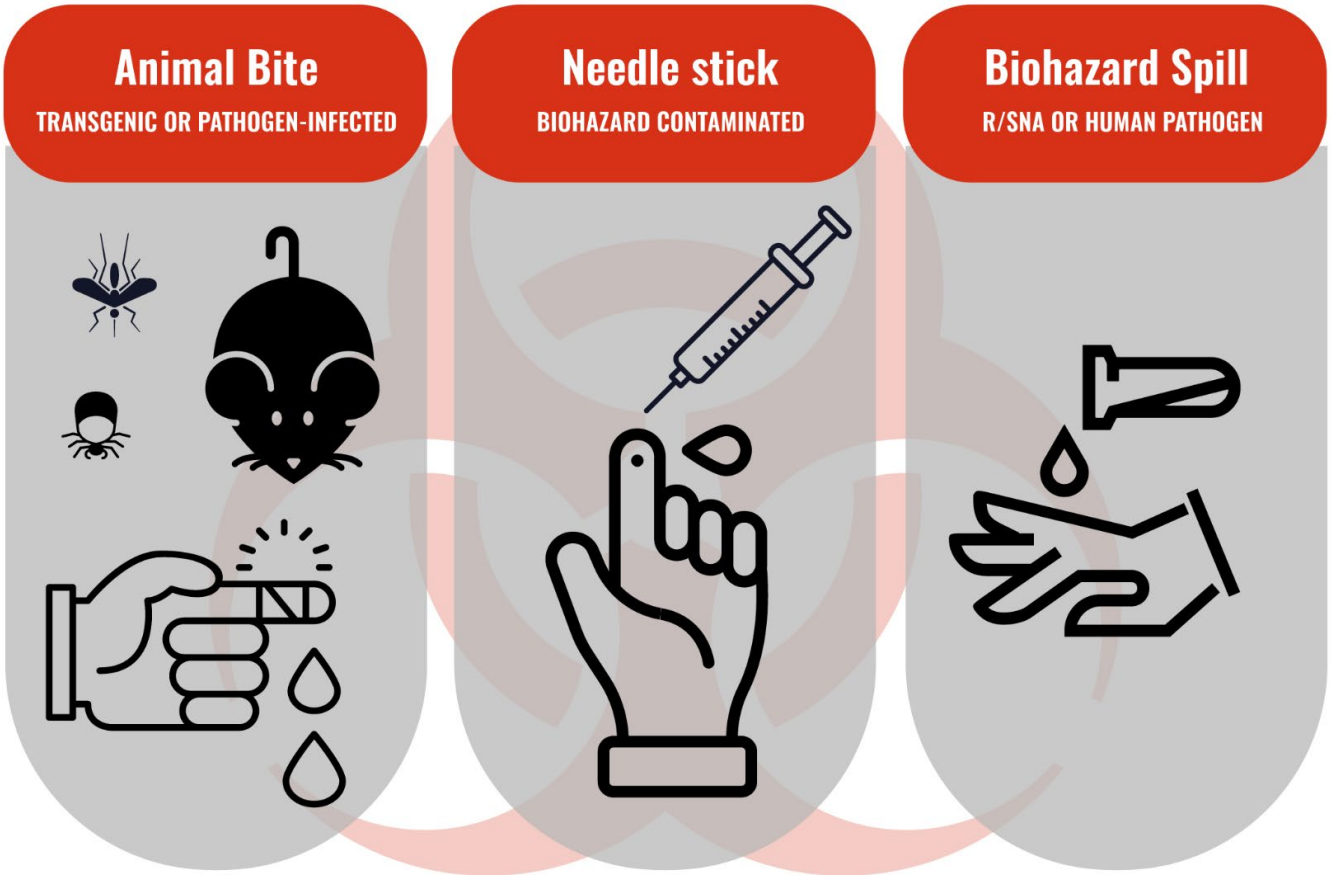
- Failure to obtain or maintain IBC approval and/or NIH approval prior to starting work or failure to request approval to lower containment of research covered by the *NIH Guidelines* is considered a "violation of the NIH Guidelines" and is reportable to NIH within 30 days.

- Escape, environmental release or improper disposition of r/sNA-containing organism requires prompt reporting, and in no case should exceed 30 days. Examples include escape of genetically modified animals, release of pollen from genetically modified plants outside the greenhouse or within the greenhouse to wild-type plants or not ensuring proper destruction/biological inactivation of genetically modified plants, animals, and microorganisms.

- Any spills, accidents, or other incidents that breach containment or exposures to laboratory or other research personnel or animals to viruses, cells or organisms **containing r/sNA** have to be reported to the Institutional Biosafety Committee (IBC), NIH OSP (within 30 days) and if applicable, other appropriate authorities (USDA – United States Department of Agriculture, CDC – Centers for Disease Control and Prevention, state and local public health departments).

Examples of reportable events to NIH might include skin punctures with needles/sharp objects containing recombinant or synthetic nucleic acid molecules, bites or scratches involving genetically modified animals or animals treated with recombinant or synthetic nucleic acids, escape of a transgenic animal, or spills of recombinant or synthetic materials occurring outside of a biosafety cabinet or other primary containment device.

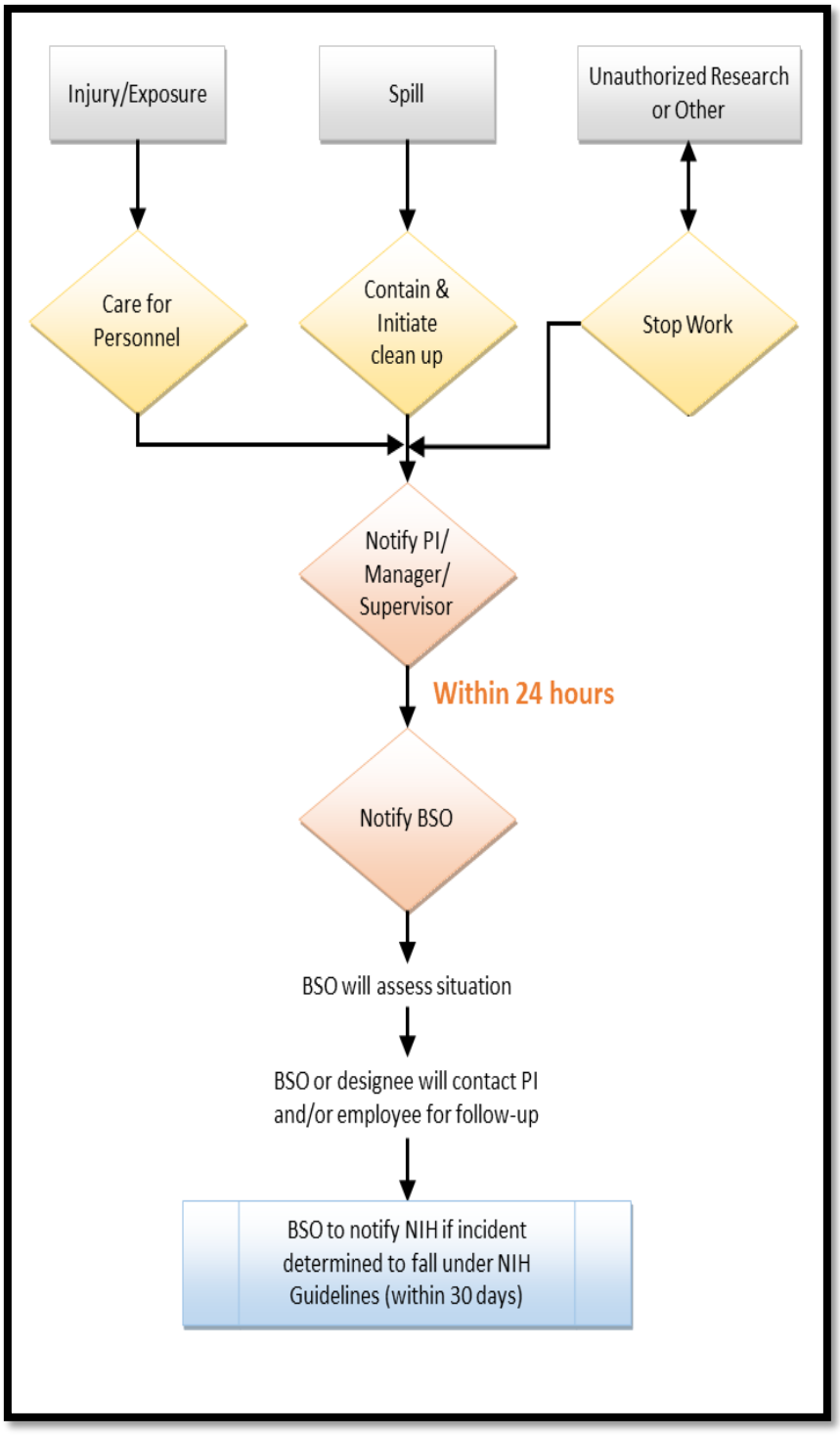
REPORTABLE INCIDENTS



Information concerning noncompliance with the *NIH Guidelines* may be reported by any person. If you have concerns about potential non-compliance with the *NIH Guidelines* at UNL, please contact the Biosafety Officer at ibc@unl.edu or 402.472.4925.

Principal Investigators (PIs) have a responsibility to promptly and in some cases immediately (within 24 hours) notify the Biosafety Officer of reportable incidents. The Biosafety Officer will gather necessary information and ensure that an incident report is filed with the NIH in accordance with the procedures described in the **UNL Biosafety Guidelines**.

Flow chart for reporting injuries, exposures, spills and other incidents involving r/sNA



Steps for Reporting:

- If there is an injury/exposure the first step is to care for personnel.
- If there is a spill, the first step is to contain the spill and initiate clean up.
- If there is unauthorized research of other incident the first step is to stop work.

In all cases the second step is to notify the PI/Manager/Supervisor **and within 24 hours notify the BSO.**

The BSO will assess the situation then the BSO or their designee will contact the PI and/or employee for follow up.

The BSO will notify NIH if the incident is determined to fall under NIH Guidelines (within 30 days)

Reporting

PIs must provide sufficient information to allow for a thorough understanding of the incident. This means a description of who, what, when, where, why, how long, cause and contributing factors, potential consequences, actions taken, mitigating factors, and steps to prevent recurrence. Relevant portions of the NIH reporting template are reproduced below. Please be prepared to provide relevant information when you contact the Biosafety Officer. Refer to form in Appendix A for necessary information to provide.

Follow up and Corrective Actions

Ideally, all issues surrounding an incident will be resolved prior to reporting to NIH or other regulatory authority. However, NIH or other agencies may require additional corrective actions and/or follow up for certain incidents. The BSO is responsible for responding to any corrective action or information requests from the NIH and assuring that they are promptly implemented. PIs and affected lab workers are expected to comply with any prescribed corrective action.

Appendix A

Incident Reporting Form – print and complete

Does this incident involve research subject to the *NIH Guidelines*?	☐ YES ☐ NO If no, this incident does not require reporting to OSP
Date of incident:	
Name of Principal Investigator:	
Is this an NIH-funded project?	☐ YES ☐ NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*
What was the nature of the incident?	☐ Failure to follow approved containment conditions ☐ Failure to obtain IBC approval ☐ Incomplete inactivation ☐ Loss of containment ☐ Loss of a transgenic animal ☐ Personnel exposure ☐ Spill ☐ Other (please describe):
Did the Institutional Biosafety Committee (IBC) approve this research?	☐ YES ☐ NO If yes, date of approval:
What was the approved biosafety level of the research?	☐ BL1 ☐ BL2 ☐ BL2+ ☐ BL3 ☐ BL3+ ☐ BL4
What section(s) of the *NIH Guidelines* is the research subject to?	

Has a report of this incident been made to other agencies? If so, please indicate	☐ CDC ☐ USDA ☐ FDA ☐ EPA ☐ OSHA	☐ Funding agency/sponsor ☐ State or local Public Health ☐ Law enforcement ☐ Other (please describe):
Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)		

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. **Include the following information as applicable.**

Description of:

- The incident/violation location (e.g., laboratory biosafety level, vivarium, non-laboratory space)
- Who was involved in the incident/violation, including others present at the incident location?
- **Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)**
- Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event
- Training received by the individual(s) involved and the date(s) the training was conducted
- Institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation
- Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation
- Personal protective equipment in use at the time of the incident/violation
- Occupational health requirements for laboratory personnel involved in the research
- Any medical surveillance provided or recommended after the incident
- Any injury or illness associated with the incident
- Equipment failures

DESCRIPTION OF INCIDENT: (use additional space as necessary)	
Please describe the root cause of this incident:	