ENVIRONMENTAL HEALTH AND SAFETY
University of Nebraska-Lincoln

Safe Operating Procedure

(Revised 2/20)

INCIDENT REPORTING – NATIONAL INSTITUTES OF HEALTH (NIH) GUIDANCE

Introduction

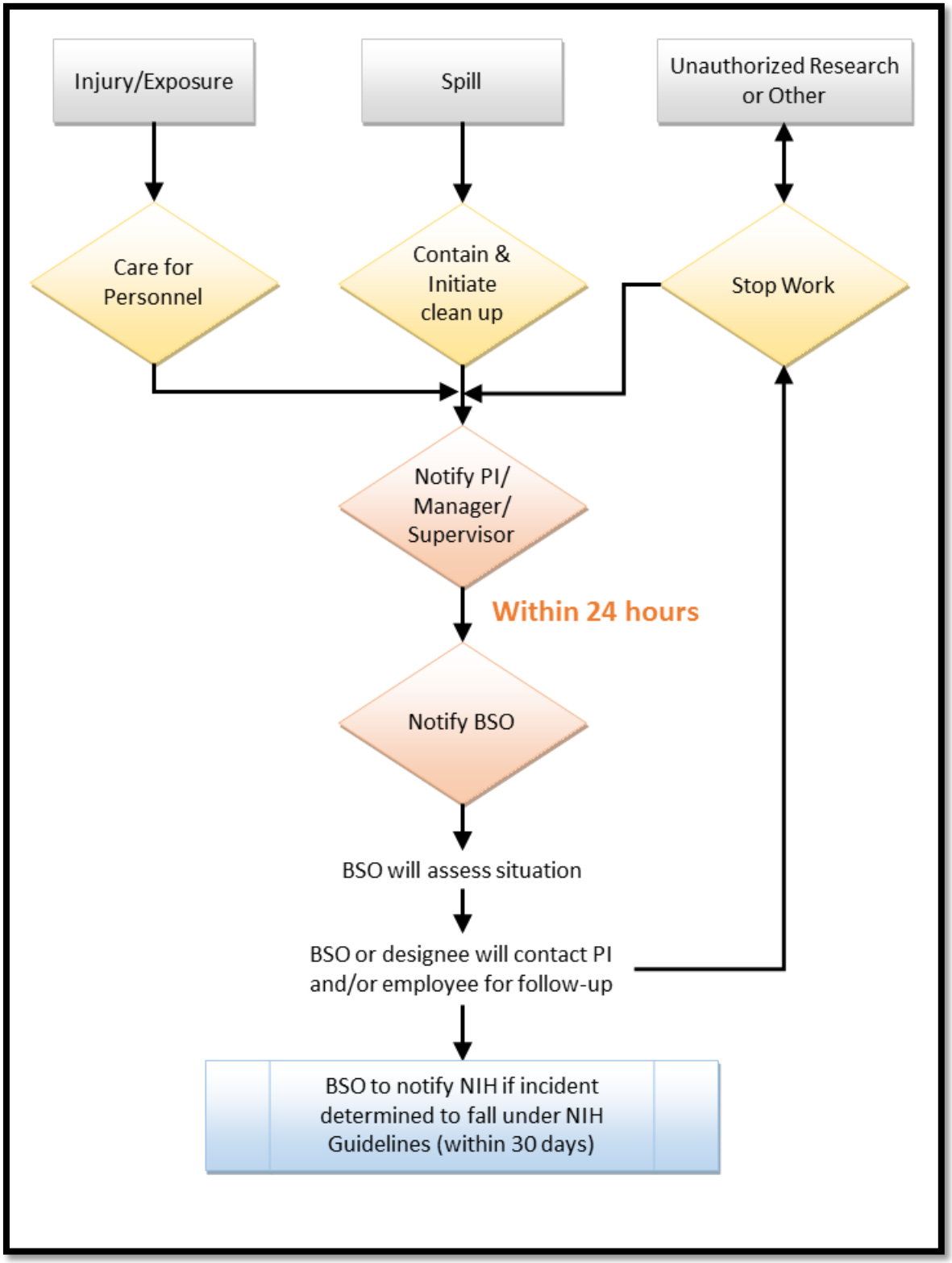
All recombinant or synthetic nucleic acid (r/sNA) projects at the University of Nebraska-Lincoln (UNL) must adhere to the requirements of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*. These guidelines require that certain incidents be reported to the NIH. This SOP describes incidents that are subject to NIH reporting requirements. Reporting of adverse events associated with human gene transfer trials is beyond the scope of this SOP, since this type of work is not conducted at UNL.

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 notify the Biosafety Officer of reportable incidents. The Biosafety Officer will gather the necessary information and ensure that an incident report is filed with the NIH in accordance with the procedures described in the **UNL Biosafety Guidelines**.

Guidance published by the NIH regarding incident reporting is summarized in the flow chart below. Although the **UNL Biosafety Guidelines** apply to work with biological agents in general, **NIH** reporting requirements are limited to laboratory exposures, spills, and other incidents on projects involving r/sNA subject to the *NIH Guidelines*.

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



Spills/Injury/Exposure

Spills or accidents in BSL-2 laboratories resulting in an **overt** exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BSL-3 or BSL-4) laboratories resulting in an **overt or potential** exposure must be immediately reported to NIH. Relevant incidents would include spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules in the laboratory.

Any spill or accident involving recombinant or synthetic nucleic acid molecule research of the nature described above or that otherwise leads to personal injury or illness or to a breach of containment must be reported to NIH OSP. These kinds of events might include skin punctures with needles containing recombinant or synthetic nucleic acid molecules, or spills of high-risk recombinant or synthetic materials occurring outside of a biosafety cabinet or other primary containment device.

Unauthorized research

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

Other

- **Escape, environmental release or improper disposition of r/sNA-containing organism**: prompt reporting is required, 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 and animals.
- **Failure to adhere to containment and biosafety practices prescribed by the *NIH Guidelines***: prompt reporting is required, and in no case should exceed 30 days. Immediate reporting may be required if the incident resulted in an overt or potential exposure (see above).

Reporting

PIs will be expected to 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.

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.**

A 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
- The training received by the individual(s) involved and the date(s) the training was conducted
- The 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
- The personal protective equipment in use at the time of the incident/violation
- The 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:	

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 will be 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 will be expected to comply with any prescribed corrective action.