University of Nebraska Lincoln

Safe Operating Procedure

(Revised 11/17)

INCIDENT REPORTING – NATIONAL INSTITUTE OF HEALTH (NIH) GUIDANCE

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.

Principal Investigators (PIs) are responsible to promptly notify the Biosafety Officer of reportable incidents. The Biosafety Officer will 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 below. Although the *UNL Biosafety Guidelines* apply to work with biological agents in general, NIH reporting requirements are restricted to incidents involving r/sNA projects that are subject to the NIH Guidelines.

- **Overt exposure**: requires immediate reporting if occurring while working under BSL-2 or higher containment. Examples include penetration of the skin with a sharp contaminated with r/sNA or escape of a transgenic animal.
- **Potential exposure**: requires immediate reporting if occurring while working under BSL-3 or higher containment or if working at BSL-2 containment with a high-risk r/sNA material.
- **Spills, leaks, releases**: report in accordance with instructions for overt or potential exposure, as applicable. Minor spills of low-risk agents not involving a breach of containment that were properly cleaned and decontaminated generally do not need to be reported.
- **Escape or improper disposition of transgenic organism**: prompt reporting is required, and in no case should exceed 30 days.
- **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).
- **Failure to obtain appropriate approvals at the prescribed interval**: prompt reporting is required, and in no case should exceed 30 days.

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. The NIH reporting template is reproduced below as a reference and

instruction of what information NIH requests for incident reports. 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
Institution Name:	
Date of Report:	
Reporter name and position:	
Telephone number:	
Email address:	
Reporter mailing address:	
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 ☐Funding agency/sponsor ☐USDA ☐State or local Public Health ☐FDA ☐Law enforcement ☐EPA ☐Other (please describe): ☐OSHA
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)

Has the IBC reviewed this incident?	☐YES ☐NO
Please describe the root cause of this incident:	

Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):