University of Nebraska Lincoln

Safe Operating Procedure

(Revised 12/15)

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 at the end of this SOP as a reference and instruction of what information NIH requests for incident reports. Please be

prepared to provide the information in rows **7-10** and **14** (red shaded) when you contact the Biosafety Officer.

NIH Incident Report

1	Does this incident involve research subject to the NIH Guidelines?	❑ Yes ❑ No (If no, this incident does not have to be reported to NIH/OBA)
2	Institution name	
3	Date of report	
4	Reporter name and title	
5	Reporter telephone	
6	Reporter email	
7	Date of incident	
8	Name of Principal Investigator	
9	Is this an NIH funded project?	❑ No ❑ Yes (If yes, complete the following) NIH Grant or contract number:_____ NIH funding institute or center:_____ NIH program officer contact information:_____
10	What was the **nature** of the incident?	❑ Personnel exposure ❑ Spill ❑ Loss of containment ❑ Loss of transgenic animal ❑ Failure to obtain IBC approval ❑ Failure to follow approved containment conditions ❑ Other (describe):
11	Did the IBC approve this research?	❑ No ❑ Yes (If yes, complete the following): Approval date:_____ Approved biosafety level for this research:_____ Additional approval requirements:
12	What section(s) of the NIH Guidelines is the research subject to?	
13	Has a report of this incident been made to other federal or local agencies?	❑ No ❑ Yes (If yes, complete the following): ❑ CDC ❑ USDA ❑ FDA ❑ EPA ❑ OSHA ❑ Research Funding Agency/Sponsor (specify):_____ ❑ State/Local Public Health (specify):_____ ❑ Federal/State/Local Law Enforcement (specify):_____ ❑ Other (specify):_____

14	Description of Incident. 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. (attach additional pages and/or supporting documents, if necessary and as applicable): ❑ Description of the r/sNA agent or material involved (including strain, attenuation, etc., as relevant) ❑ The incident/violation location (e.g., laboratory biosafety level, vivarium, non-laboratory space, etc.) ❑ Who was involved in the incident/violation, including others present at the incident location- do not identify individuals by name; provide only gender and position titles. ❑ 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 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 advice/ treatment/surveillance provided or recommended after the incident. ❑ Any injury or illness associated with the incident. ❑ Medical surveillance results (if not available at the time of the initial report, indicate when results will be available) ❑ Equipment failures.	
15	Has the IBC reviewed this incident?	❑ No ❑ Yes (If yes, provide a copy of the minutes of the meeting in which the incident was reviewed)

16	Has a root cause for this incident been identified?	❑ No ❑ Yes (If yes, describe):
17	Describe measures taken by the institution to mitigate any problems identified. For measures identified but not yet taken, include a timeline for their implementation (attach additional pages and/or supporting documents, if necessary and as applicable):	