

**INCIDENT REPORTING –
NATIONAL INSTITUTE OF HEALTH (NIH) GUIDANCE**

(For assistance, please contact EHS at (402) 472-4925, or visit our web site at <http://ehs.unl.edu/>)

All recombinant DNA (rDNA) projects at the University of Nebraska-Lincoln (UNL) must adhere to the requirements of the *NIH Guidelines for Research Involving Recombinant DNA 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.

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 recombinant DNA and those projects that are subject to the NIH Guidelines.

- **Overt exposure:** requires immediate reporting if occurring while working under BSL-2 or higher containment.
- **Potential exposure:** requires immediate reporting if occurring while working under BSL-3 or higher containment.
- **Spills, leaks, releases outside of primary containment:** report in accordance with instructions for overt or potential exposure, as applicable.
- **Spills, leaks, releases confined to primary containment:** generally not reportable if containment was not breached and proper cleaning/decontamination procedures were followed.
- **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 in the Appendix of this SOP.

NIH Incident Report

Does this incident involve research	<input type="checkbox"/> Yes
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subject to the NIH Guidelines?	<input type="checkbox"/> No (If no, this incident does not have to be reported to NIH/OBA)
Institution name	
Date of report	
Reporter name and title	
Reporter telephone	
Reporter email	
Date of incident	
Name of Principal Investigator	
Is this an NIH funded project?	<input type="checkbox"/> No <input type="checkbox"/> Yes (If yes, complete the following) NIH Grant or contract number: _____ NIH funding institute or center: _____ NIH program officer contact information: _____
What was the <u>nature</u> of the incident?	<input type="checkbox"/> Personnel exposure <input type="checkbox"/> Spill <input type="checkbox"/> Loss of containment <input type="checkbox"/> Loss of transgenic animal <input type="checkbox"/> Failure to obtain IBC approval <input type="checkbox"/> Failure to follow approved containment conditions <input type="checkbox"/> Other (describe): _____
Did the IBC approve this research?	<input type="checkbox"/> No <input type="checkbox"/> Yes (If yes, complete the following): Approval date: _____ Approved biosafety level for this research: _____ Additional approval requirements: _____
What section(s) of the NIH Guidelines is the research subject to?	
Has a report of this incident been made to other federal or local agencies?	<input type="checkbox"/> No <input type="checkbox"/> Yes (If yes, complete the following): <ul style="list-style-type: none"> <input type="checkbox"/> CDC <input type="checkbox"/> USDA <input type="checkbox"/> FDA <input type="checkbox"/> EPA <input type="checkbox"/> OSHA <input type="checkbox"/> Research Funding Agency/Sponsor (specify): _____ <input type="checkbox"/> State/Local Public Health (specify): _____ <input type="checkbox"/> Federal/State/Local Law Enforcement (specify): _____ <input type="checkbox"/> Other (specify): _____
Description of Incident. Provide a narrative of the incident including a	

<p>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):</p> <ul style="list-style-type: none"> <input type="checkbox"/> The recombinant agent or material involved <input type="checkbox"/> The incident/violation location (e.g., laboratory biosafety level, vivarium, non-laboratory space, etc.) <input type="checkbox"/> Who was involved in the incident/violation, including others present at the incident location- do not identify individuals by name; provide only position titles. <input type="checkbox"/> Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event. <input type="checkbox"/> The training received by the individual(s) involved and the date(s) the training was conducted. <input type="checkbox"/> 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. <input type="checkbox"/> Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation. <input type="checkbox"/> The personal protective equipment in use at the time of the incident/violation. <input type="checkbox"/> The occupational health requirements for laboratory personnel involved in the research. <input type="checkbox"/> Any medical advice/ treatment/surveillance provided or recommended after the incident. <input type="checkbox"/> Any injury or illness associated with the incident. <input type="checkbox"/> Medical surveillance results (if not available at the time of the initial report, indicate when results will be available) <input type="checkbox"/> Equipment failures. 	
<p>Has the IBC reviewed this incident?</p>	<p><input type="checkbox"/> No <input type="checkbox"/> Yes (If yes, provide a copy of the minutes of the meeting in which the incident was reviewed)</p>
<p>Has a root cause for this incident been identified?</p>	<p><input type="checkbox"/> No <input type="checkbox"/> Yes (If yes, describe): _____</p>

<p>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):</p>	
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