



Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*

Instructions for Completing this Template

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH within 30 days.

Certain types of incidents must be reported on a more expedited basis. Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Report any incident involving recombinant or synthetic nucleic acids to the Biosafety Officer (BSO) as soon as possible for further investigation. The BSO will coordinate the submission of all reports to the NIH.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*. Please complete all fields as fully as possible.

Completed reports should be sent to Mark Robbins, IBC Administrator and BSO, via email at mrobbins@mailbox.sc.edu

<p>Does this incident involve research subject to the <i>NIH Guidelines</i>?</p>	<p style="text-align: center;"><input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p style="text-align: center;">If no, this incident does not require reporting to OSP</p>
<p>Date of Report:</p>	
<p>Reporter name and position:</p>	
<p>Telephone number:</p>	
<p>Email address:</p>	
<p>Date of incident:</p>	
<p>Name of Principal Investigator:</p>	
<p>Is this an NIH-funded project?</p>	<p style="text-align: center;"><input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>If yes, please provide the following information (if known)</p> <p><i>NIH grant of contract number:</i></p> <p><i>NIH funding institute or center:</i></p> <p><i>NIH program officer (name, email address):</i></p>

<p>What was the nature of the incident?</p>	<p> <input type="checkbox"/> Failure to follow approved containment conditions <input type="checkbox"/> Failure to obtain IBC approval <input type="checkbox"/> Incomplete inactivation <input type="checkbox"/> Loss of containment <input type="checkbox"/> Loss of a transgenic animal <input type="checkbox"/> Personnel exposure <input type="checkbox"/> Spill <input type="checkbox"/> Other (please describe): </p>
<p>Did the Institutional Biosafety Committee (IBC) approve this research?</p>	<p style="text-align: right;"> <input type="checkbox"/> YES <input type="checkbox"/> NO </p> <p>If yes, date of approval:</p>
<p>What was the approved biosafety level of the research?</p>	<p> <input type="checkbox"/> BL1 <input type="checkbox"/> BL2 <input type="checkbox"/> BL2+ <input type="checkbox"/> BL3 <input type="checkbox"/> BL3+ <input type="checkbox"/> BL4 </p>
<p>What section(s) of the <i>NIH Guidelines</i> is the research subject to?</p>	
<p>Has a report of this incident been made to other agencies? If so, please indicate</p>	<p> <input type="checkbox"/> CDC <input type="checkbox"/> Funding agency/sponsor <input type="checkbox"/> USDA <input type="checkbox"/> State or local Public Health <input type="checkbox"/> FDA <input type="checkbox"/> Law enforcement <input type="checkbox"/> EPA <input type="checkbox"/> Other (please describe): <input type="checkbox"/> OSHA </p>
<p>Nature of recombinant or synthetic material involved in incident (strain, attenuation, etc.)</p>	

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?	<input type="checkbox"/> YES <input type="checkbox"/> 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):