

**Template for Reporting Incidents Related to Research Subject to the
NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids
to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA)**

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 OBA 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 OBA. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH OBA.

This template is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*. This template is also available on the NIH OBA Web pages as a Word document (http://oba.od.nih.gov/oba/ibc/FAQs/Incident_Reporting_Template.doc) in which the fields will expand according to the amount of text entered. Use of this template is not required and other formats for submitting reports may be acceptable.

**A separate template for reporting Human Gene Transfer Adverse Events is available at:
http://oba.od.nih.gov/oba/rac/Adverse_Event_Template.pdf**

Please note that submitting this completed template to NIH OBA does NOT fulfill the reporting requirements of other agencies. You should verify with the other parties to whom you must report whether the use of this template is acceptable.

Completed reports may be sent via U.S. mail, courier service, e-mail, or facsimile to:

**Attention: Incident Reports
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892-7985
(For all non-USPS deliveries use Zip Code 20817)
Telephone 301-496-9838
Fax 301-496-9839
E-mail: oba@od.nih.gov**

NIH OBA Incident Reporting Template

For reporting Human Gene Transfer Adverse Events a separate template is available at:
http://oba.od.nih.gov/oba/rac/Adverse_Event_Template.pdf

Does this incident involve research subject to the <i>NIH Guidelines</i> ?	<input type="checkbox"/> YES <input type="checkbox"/> NO If no, this incident does not have to be reported to OBA
Institution name:	
Date of report:	
Reporter name and position:	
Reporter telephone:	
Reporter email:	
Date of incident:	
Name of principal investigator:	
Is this an NIH funded project?	<input type="checkbox"/> YES <input type="checkbox"/> NO
If yes, please provide:	NIH grant or contract number:
	NIH funding institute or center:
	NIH program officer contact information (name, email etc):
What was the <u>nature</u> of 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 - please describe:

Did the Institutional Biosafety Committee (IBC) approve this research	<input type="checkbox"/> YES <input type="checkbox"/> NO If yes, on what date?
If yes, please provide:	Approval date:
	Approved biosafety level(s) for the research:
	Additional approval requirements:
What section(s) of the <i>NIH Guidelines</i> is the research subject to?	
Has a report of this incident been made to other federal or local agencies? If so please indicate by checking the appropriate box.	<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: (name)_____ <input type="checkbox"/> State/Local Public Health <input type="checkbox"/> Federal/State/Local Law Enforcement <input type="checkbox"/> Other – please describe:
Description of recombinant or synthetic agent or material involved (please indicate strain, attenuation etc. as relevant.)	

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 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 initial report please indicate when results will be available).
- Equipment failures.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

DESCRIPTION OF INCIDENT: (continued)

Has the IBC reviewed this incident?	<input type="checkbox"/> YES <input type="checkbox"/> NO If yes, please provide a copy the minutes of the IBC meeting in which the incident was reviewed.
Has a root cause for this incident been identified?	<input type="checkbox"/> YES <input type="checkbox"/> NO If yes please describe:
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)	

- **Please provide copies of any documents referenced in this report.**
- **Additional information may be requested by OBA after review of this report depending on the nature of the incident.**