Reporting of Incidents Involving Recombinant or Synthetic Nucleic Acids to the NIH Office of Biotechnology Activities (OBA)

What kinds of incidents involving recombinant or synthetic nucleic acid must be reported to the NIH OBA?

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIHGuidelines*, or any significant research-related accidents and illnesses" must be reported to NIH OBA within 30 days. Certain types of accidents must be reported on a more expedited basis. Spills or accidents in BL2 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.

How serious must a problem be to warrant reporting to OBA?

Any spill or accident involving recombinant or synthetic nucleic acid research of the nature described above or that otherwise leads to personal injury or illness or to a breach of containment must be reported to OBA. These kinds of events might include skin punctures with needles containing recombinant DNA, the escape or improper disposition of a transgenic animal, or spills of high-risk recombinant or synthetic materials occurring outside of a biosafety cabinet. Failure to adhere to the containment and biosafety practices articulated in the *NIH Guidelines* must also be reported to OBA.

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. OBA should be consulted if the Institutional Biosafety Committee (IBC), investigator, or other institutional staff are uncertain whether the nature or severity of the incident warrants reporting; OBA can assist in making this determination.

Who is responsible for reporting incidents involving recombinant or synthetic nucleic acid to NIH OBA?

Under the *NIH Guidelines* incident reporting is articulated as a responsibility of the Institution, IBC, Biological Safety Officer, and Principal Investigator. Institutions have the discretion to determine which party should make these reports, and one report for each incident or set of information is generally sufficient.

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)

Does this incident involve research subject to the *NIH Guidelines*?	□ YES □ 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:	
Reporter mailing address:	
Date of incident:	
Name of principal investigator:	
Is this an NIH funded project?	□ YES □ 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 **nature** of incident?	□ Personnel exposure □ Spill □ Loss of containment □ Loss of transgenic animal □ Failure to obtain IBC approval □ Failure to follow approved containment conditions □ Other - please describe:

Did the Institutional Biosafety Committee (IBC) approve this research	□ YES □ 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 *NIH Guidelines* 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.	□ CDC □ USDA □ FDA □ EPA □ OSHA □ Research Funding Agency/Sponsor: (name)_____ □ State/Local Public Health □ Federal/State/Local Law Enforcement □ 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?	□ YES □ 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?	□ YES □ 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.**