Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)

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.

PIs must complete this form and submit it to the IBC Chair within 5 days of the incident. The IBC will review and finalize the report to NIH OSP.

Note that certain types of incidents must be reported on a more expedited basis and should be immediately reported to NIH OSP, and the UA IBC Chair copied on the report.

Spills or accidents occurring in Biosafety Level (BL) 2 laboratories resulting in an overt exposure must be immediately reported to NIH. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH. Relevant incidents would include spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules in the laboratory, rather than serious adverse events that may occur in the conduct of human gene transfer research.

Completed reports may be sent to the IBC Chair.

For those reports, which must be immediately reported to NIH OSP, the submission is through email to NIHGuidelines@od.nih.gov. Be sure to copy the IBC Chair on the submission.

Does this incident involve research subject to the *NIH Guidelines* (i.e. non-exempt research)?	☐YES ☐NO If no, this incident does not require reporting to NIH OSP (All incidents are required to be reported to the IBC and EOHS)
Institution Name:	**University of Akron**
Date of Report:	
Reporter name and position:	
Telephone number:	
Email address:	
Reporter mailing address:	
Date of incident:	
Name of Principal Investigator:	
Is this an NIH-funded project?	☐YES ☐NO If yes, please provide the following information (if known) *NIH grant of contract number:* *NIH funding institute or center:* *NIH program officer (name, email address):*

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

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?	☐YES ☐NO
Please describe the root cause of this incident:	

Describe measures taken by the institution to mitigate any problems identified (e.g. training, modifying protocols, use of additional safety equipment). For measures identified but not yet taken, please include a timeline for their implementation (use additional space as necessary):

- **Additional information may be requested by NIH OSP after review of this report depending on the nature of the incident.**
- **Submitting this completed template to NIH OSP does <u>NOT</u> 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.**