National Institutes of Health

Draft NIH Incident Reporting Template

Comments on this document can be made through the NIH comment portal found at: https://osp.od.nih.gov/comment-form-draft-nih-biosafety-policy-for-research-involving-biohazards.

Comments will be accepted until **October 19, 2026**.

Background

The NIH Biosafety Policy for Research Involving Biohazards (the Policy) requires reporting to NIH of certain incidents that pose a significant risk to human health. Incidents that must be reported include personnel exposures (including, but not limited to aerosol/inhalation/respiratory, percutaneous/sharps/needlestick, animal bite/scratch, mucous membrane/ocular, broken skin, oral/ingestion), inactivation/decontamination failure, equipment/mechanical failure, PPE failure, loss of containment, loss of biohazardous materials/animals, spills, and administrative failures. For additional information see Section III-B of the Policy.

Purpose

As stated in Section III-B of the Policy, institutions are required to use this template for incident reporting when an incident meets the criteria specified in the Policy. NIH is committed to ensuring all institutions comply with the Policy, including its transparency aims.

Instructions for Completing this Template

All fields must be fully completed in every final report. If an element does not apply, indicate not applicable. If all information is not available for initial reports, complete as much of Parts 1 and 2 as possible. Do **not** include attachments. NIH reviews incident reports and additional information may be requested after review depending on the nature of the incident and appropriateness of the response. NIH may indicate additional measures to be taken as appropriate to promote safety and compliance with the Policy. The report should be written, as much as possible, in lay language to promote maximal public transparency. Completed reports must be sent to NIH.

National Institutes of Health

Redaction and Posting of Incident Reports

- All reports for incidents occurring during the conduct of research subject to the Policy and NIH's final response (when the report is required to be submitted to NIH) must be posted on a public-facing webpage on the website of the institution conducting the research. If an IBC is externally administered, the report must be posted on the website of the institution where the incident occurred.
- Incident reports should not include any personally identifiable identification of individuals involved in the incident (aside from the Principal Investigator's name). Reports may be redacted to protect proprietary or private information. This information could include trade secret information and other confidential commercial information, and specific information whose disclosure would directly compromise institutional or national security. Institutions should articulate criteria for redaction in IBC operating procedures to promote consistency and proper redaction practices.
- Most institutions should be able to adequately document their biosafety reviews of incidents without the need to include private and or proprietary information in their reports. If it is necessary to include such information in material submitted to NIH, please clearly mark it as such in the report.
- Information that is widely available from other public sources such as institutional webpages, publications describing an investigator's research, or public grants databases (e.g., names of IBC members and PIs, biological agents used in research, including Select Agents, grant numbers) is not considered private or proprietary and may **not** be redacted from reports.

Part 1. Institutional Information	
Institution name:	
Unique institutional identifier for report (e.g., 2026-001):	
Date report submitted to NIH:	
Date incident occurred:	
Indicate initial submission or final report:	☐ INITIAL ☐ FINAL ☐ OTHER (please describe)
Name of principal investigator responsible for the research:	
Did this incident occur while conducting NIH-funded research?	☐ YES ☐ NO
NIH grant or contract number (if applicable):	

NIH funding institute or center (if applicable):	
NIH program officer name and email address (if applicable):	
Was this research reviewed and approved by the IBC? If yes, list approval date:	☐ YES ☐ NO Date of Approval:
Has the IBC reviewed this incident? If yes, list date of review corresponding to the IBC meeting minutes.	☐ YES ☐ NO Date of Review:
Part 2. Incident Information	
What was the approved biosafety level of the research?	☐ BSL-1/ABSL-1 ☐ BSL-2/ABSL-2 ☐ BSL-2/ABSL-2 enhanced (describe specific enhancement(s) in incident narrative) ☐ BSL-3/ABSL-3 ☐ BSL-3/ABSL-3 enhanced (describe specific enhancement(s) in incident narrative) ☐ BSL-4/ABSL-4 ☐ Not approved by the IBC
What was the nature of the incident?	☐ Failure to obtain or maintain IBC approval ☐ Failure to follow approved containment conditions or approval requirements ☐ Personnel exposure: ☐ Aerosol/inhalation/respiratory ☐ Percutaneous/sharps/needlestick ☐ Animal bite/scratch – List species: ☐ Mucous membrane/ocular ☐ Broken skin ☐ Oral/ingestion ☐ Other – Provide brief description: ☐ Inactivation/decontamination failure ☐ Equipment/mechanical failure ☐ PPE Failure

	☐ Loss of containment ☐ Loss of biohazardous materials/animals ☐ Spill ☐ Other – Provide brief description:
What was the nature of biohazardous material involved in incident? Provide full agent name, description of strain or construct (attenuated, etc.).	
Has a report of this incident been made to other agencies? If so, indicate:	☐ CDC ☐ State or local Public Health ☐ USDA ☐ Funding agency/sponsor ☐ FDA ☐ Law enforcement (provide agency) ☐ EPA ☐ Other (please describe): ☐ OSHA

Part 3. Incident Narrative

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:

- The general location of the incident/violation (e.g. BSL/ABSL, vivarium, non-laboratory space) **Note – do not identify specific laboratories by building name or room number**
- Who was involved in the incident/violation, including others present at the incident location? **Note – do not identify individuals by name. Provide only position titles (e.g., researcher, graduate student, animal care worker)**
- The specific actions taken immediately following the incident, and by whom, to limit any health or environmental consequences of the event
- Relevant biosafety-related 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
- Equipment failures or facility issues
- The personal protective equipment (PPE) in use at the time of the incident and any PPE failure
- Any specific occupational health requirements for laboratory personnel involved in the research
- Any injury or illness associated with the incident and medical surveillance required or treatment provided (e.g., post-exposure prophylaxis)

DESCRIPTION OF INCIDENT:

Part 4. Root Cause Analysis and Corrective Actions
Describe the root cause of this incident. A description of corrective actions must be included that details measures taken by the institution to mitigate any identified problems (e.g., training, modifying protocols, use of additional safety equipment). For measures identified but not yet taken, include a timeline for their implementation.
DESCRIPTION OF ROOT CAUSE AND CORRECTIVE ACTIONS: