Iowa State University - Institutional Biosafety Committee

ADVERSE BIOSAFETY EVENT REPORT FORM

Use this form to report to the Institutional Biosafety Committee (IBC) any serious adverse event, any noncompliance with NIH Guidelines, or any significant research-related accident or illness leading to—or potentially leading to—harm, or an incident/violation that is dangerous to humans, animals, and/or the environment.

##### A. Identification

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| Principal Investigator (PI):       | Phone:       | Fax:       |
| Title:       |
| IBC Log Number:       | Laboratory Location:       |
| Type of use: [ ]  Infectious Agent/Biological Toxin  [ ]  Recombinant or Synthetic Nucleic Acid Molecules  [ ]  Transgenic Animals [ ]  Experimental Biological Products |
| Approved Biosafety Level:        |

**B. Description of Incident/Violation**

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| --- | --- |
| 1. Date of incident/violation: |       |
|  |  |
| 3. Is this an NIH-funded project? | [ ]  YES [ ]  NO |
| 4. If *Yes*, please provide: | NIH grant or contract number:       |
| NIH funding institute or center:       |
| NIH program officer contact information (name, email, etc.):       |
| 5. If *No*, is the project funded? | [ ]  YES [ ]  NO |
| 6. If *Yes*, please list the funding agencyor foundation: |       |
| 7. If federally funded, please provide the title of the grant application and the grant funding number: |       |
| 8. What was the **nature** of the incident/violation? | [ ]  Personnel exposure [ ]  Spill [ ]  Loss of containment[ ]  Loss of transgenic animal [ ]  Failure to obtain IBC approval[ ]  Failure to follow approved containment condition[ ]  Incomplete inactivation[ ]  Infectious agent(s), toxin, recombinant or synthetic nucleic acid molecules involved, including vector type (e.g., adenovirus), vector subtype (e.g., type 5), and relevant genomic alterations made (e.g., additions, deletions, inactivation without deletion)      [ ]  Other (please describe):       |
| 9. Did the Institutional Biosafety Committee (IBC) approve this research? | [ ]  YES [ ]  NO |
| 10. If *Yes*, please provide: | Approval date:       |
| Additional approval requirements:       |
| 11. Is this study covered by NIH Guidelines? | [ ]  YES [ ]  NO |

|  |  |
| --- | --- |
| 12. If this research is subject to NIH guidelines, what section(s) of the *NIH Guidelines* is the research subject to? |       |
| 13. Description of recombinant or synthetic agent or material involved (Please indicate strain, attenuation etc., as relevant.): |       |
| 14. Has a report of this incident/violation 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):       |
| 15. Please provide a narrative of the incident/violation including a timeline of events. The incident/violation should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident/violation. **Include the following information as applicable:**1. The exact incident/violation location (e.g., laboratory biosafety level, vivarium, non-laboratory space).
2. Who was involved in the incident/violation, including others present at the incident/violation 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)**.
3. Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event.
4. Medical attention sought and obtained as necessary.
5. The training received by the individual(s) involved and the date(s) the training was conducted.
6. 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. Please provide copies of your relevant SOPs.
7. Any deviation from the IBC-approved containment level or other IBC approval conditions at the time of the incident/violation.
8. The personal protective equipment in use at the time of the incident/violation.
9. The occupational health requirements for laboratory personnel involved in the research.
10. Any medical advice/treatment/surveillance provided or recommended after the incident/violation.
11. Any injury or illness associated with the incident/violation.
12. Medical surveillance results (If not available at the time of initial report, please indicate when results will be available.).
13. Equipment failures.
14. Corrective actions implemented or planned to prevent future accidents or adverse events.

Description of Incident/violation:       |

1. **Certification**

 I certify that the above information accurately describes the incident/violation. I agree to cooperate with any investigations of this incident/violation and provide information to the IBC, CDC, NIH, and other federal, state, or local agencies having jurisdiction.

 Signature Date

**Submission Instructions:** Email this form to the **IBC Administrator** at bphc@iastate.edu. If you have any questions about completion of the form, please contact the **IBC Administrator** at 515-294-9581.

1. **For ORE Office Use**

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| Has the IBC reviewed this incident/violation?  | [ ]  YES [ ]  NOIf *Yes*, please provide a copy of the minutes of the IBC meeting in which the incident/violation was reviewed. |
| Name of individual reporting this incident/violation: |       |
| Has a root cause for this incident/violation been identified?  | [ ]  YES [ ]  NOIf *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)      |