

## IOWA STATE UNIVERSITY Institutional Biosafety Committee

### Adverse Biosafety Event Reporting Guidelines

#### Background

The Institutional Biosafety Committee (IBC) is mandated by the Office of the Vice President for Research (VPR) to "...assess the safety of recombinant and synthetic nucleic acid molecule projects as well as biological, personnel, and public health risks."

In addition, the Office of Research Ethics (ORE), on behalf of the VPR, must report "... any significant problems with or violations of the *NIH Guidelines*, and any significant research-related incidents or illnesses" to the appropriate institutional official and National Institutes of Health (NIH) Office of Science Policy (OSP) within 30 days (Section IV-B-2-b-(7)). In addition, spills or accidents in BL2 laboratories resulting in an overt exposure must be immediately reported to the appropriate institutional official and NIH. Spills or accidents occurring in high containment (BL3) laboratories resulting in an overt or potential exposure must be immediately reported to an institutional official and NIH.

In order to make these assessments, the IBC must be informed of 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 that is dangerous to humans, animals, and/or the environment. Examples include, but are not limited to, the following:

- Spills or accidents in BL1, BSL1, and ABSL1 laboratories resulting in release to the environment
- Spills or accidents in BL2, BSL2, or ABSL2 laboratories resulting in an overt exposure
- Spills or accidents occurring in BL3, BSL3, or ABSL3 laboratories resulting in an overt or potential exposure
- Accidents that lead to personal injury or illness
- Accidents that lead to a breach of containment (e.g., skin punctures with needles, escape or improper disposition of a transgenic animal, failure to follow animal biosafety containment procedures in an animal care facility)
- Illness or hospitalization of an employee following work with infected animals
- Failure by an employee to adhere to the containment and biosafety practices articulated in the *NIH Guidelines*, CDC-Biosafety–*Biosafety in Microbiological and Biomedical Laboratories*, etc.

#### Policy

Investigators should promptly inform the IBC of all accidents or adverse events using the [Adverse Biosafety Event Report Form](#). Investigators must also follow the reporting requirements for [Accidents and Injuries](#) as outlined on the Environmental Health and Safety website.

If the employee believes they are suffering from an exposure to the pathogen, they must inform their supervisor immediately. The supervisor must immediately notify EH&S, ORE, or Occupational Medicine and promptly complete (i.e., within 24 hours) the First Report of Injury (FROI) form. See [Exposure to Human Pathogen Reporting Procedures](#) for more information.

## What Will Happen

Upon receiving an adverse event report or a First Report of Injury, the Director of the Office of Research Ethics (DORE) will work with the principal investigator (PI), or individual involved in the event, and the University Biosafety Officer (EH&S) to thoroughly understand what happened to activate the reporting process. The DORE, in consultation with any of the following—investigator, Institutional Official (IO), Chair of the IBC, IBC Administrator, University Biosafety Officer (Biosafety Officer), Attending Veterinarian, and Department Chair—will also determine if immediate suspension of the project in question is required while the accident is reviewed by the IBC.

The IBC will receive a copy of the adverse event report. The adverse event report may also be shared with other offices in order to meet mandatory reporting requirements; however, information will be shared only on a need-to-know basis, and reasonable steps will be taken to address privacy needs.

The IBC will review the report to determine: (1) if additional information is needed (e.g., information from others who may have been involved, swabbing of surfaces is needed to determine contamination points, etc.); (2) if the incident was properly handled; and (3) if any corrective actions may need to be implemented for the project or at ISU to help prevent similar accidents in the future.

In cases that involve noncompliance or that require external reporting, a summary of the incident and the committee's actions and/or recommendations will be forwarded to the IO for review and approval. The Institution has the authority to impose additional corrective actions to reestablish compliance for the project and to help avoid similar situations in the future. At the discretion of the IBC or DORE, the IO will also be informed in cases involving serious harm or that are evidence of trends that may require institutional intervention (e.g., multiple instances for a project or lab).

The ORE assists the Institutional Official (IO), Vice President for Research, in determining when a report to the NIH OSP is required; the DORE submits the report on behalf of the IO. Generally, verbal reports are made to the OSP when an adverse event report is received that appears to involve a significant problem or NIH violation, while the IBC review is conducted (i.e., a written or verbal report must be submitted to OSP within 30 days or sooner depending on nature of the incident. A formal report is submitted following IBC and IO review of the event. Names of individuals involved in the event are not reported to OSP.

The Biosafety Officer, as the Responsible Official, notifies the appropriate federal agency if a select agent is involved in the adverse event.

## Resources

Office of Research Ethics  
Environmental Health and Safety  
Office of Science Policy, NIH  
CDC-Biosafety—*Biosafety in Microbiological and Biomedical Laboratories*, 6<sup>th</sup> Edition