INSTITUTIONAL BIOSAFETY COMMITTEE STANDARD OPERATING PROCEDURE		
SOP Title: Incident Reporting to Federal Agencies		
SOP Number: IBC-PP-016	Revision Number: 2	Section: Biosafety
Author: Patricia Cox		Effective Date: 9/2/09

1. Purpose

   1.1. This procedure refers to the IBC only.

   1.2. The purpose of this procedure is to describe the process for the submission of incident reports to NIH/OBA or CDC or other government entity.

2. Key Word Definitions

   2.1. BSO: Biological Safety Officer

   2.2. IBC: Institutional Biosafety Committee

   2.3. NIH OBA: National Institutes of Health Office of Biotechnology Activities

   2.4. CDC: Centers for Disease Control and Prevention

   2.5. PI: Principal Investigator

   2.6. IO: Institutional Official

   2.7. Laboratory-acquired infections: LAIs are defined as any infection acquired through laboratory-related activities regardless of whether they are symptomatic or asymptomatic.

   2.8. Accident: An unexpected and undesirable event, especially one resulting in damage or injury.

   2.9 Incident: An incident refers to any significant problem with or violation of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* or Biosafety in Microbiological and Biomedical Laboratories (BMBL) and any significant research-related accident or illness (LAI). Violations can include failure to obtain IBC approval or failure to follow IBC approval conditions.

3. Responsibilities and Authorities

   3.1. Biological Safety Officer

      3.1.1.Responsible for monitoring compliance with the *NIH Guidelines*.

      3.1.2.Submits a report of an incident to the proper agency if not done by the PI, IBC Chair, or IO.

3.2. IBC Chair

3.2.1. Submits a report of an incident to the proper agency if not done by the PI, BSO, or IO.

3.3. Institutional Official

3.3.1. Submits a report of an incident to the proper agency if not done by the PI, IBC Chair, or BSO.

3.4. PI

3.4.1. Submits a report of an incident to the proper agency if not done by the BSO, IBC Chair or IO.

4. Items Needed

4.1. Incident Reporting form

5. Procedure

5.1. Within 30 days of the determination that an incident or violation of the *NIH Guidelines* has occurred, a report will be written to include:

5.1.1. the date(s) of the incident;

5.1.2. a description of the incident;

5.1.2.1. the section(s) of the *NIH Guidelines* violated, if applicable;

5.1.2.2. the sections of the Biosafety in Microbiological and Biomedical Laboratories (BMBL) violated, if applicable

5.1.3. the personnel involved in the incident;

5.1.4. a description of the investigation of the incident, if any;

5.1.5. a description of the measures implemented by the Institution to rectify the situation.

5.2. The report will be sent to the appropriate agency(ies) and copies sent to the BSO, Chair, PI and IO.

5.3. Certain incidents must be reported immediately to NIH OBA including;

5.3.1. Spills or accidents in BSL-2 laboratories that result in an OVERT exposure;

5.3.2. Spills or accidents in high containment laboratories (BSL-3, BSL-4) that result in an overt OR potential exposure.

6. Associated SOPs

6.1. IBC-PP-028 Suspension and/or Termination of Research

6.2. IBC-PP-003 IBC Investigation of an Incident

6.3. IBC-PP-010 Incidents in Research

7. Associated Forms

7.1. Incident Reporting form

8. References

8.1. *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* Section IV-B-2-b-(7)

8.2. Biosafety in Microbiological and Biomedical Laboratories

9. Revision History

9.1. Revised 4/2/13 and approved 5/15/2013

9.2. Revised 7/28/15 and 9/16/2015

10. Approvals

Reviewed by: _____ Date Reviewed
Biological Safety Officer

Approved by: _____ Date Approved
IBC Chair