| INSTITUTIONAL BIOSAFETY COMMITTEE<br>STANDARD OPERATING PROCEDURE | | |
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| SOP Title: Incidents and Investigation of Incidents | | |
| SOP Number: IBC-PP-036 | Revision Number: 0 | Section: Biosafety |
| Author: Patricia Cox | | Effective Date: 12/14/16 |

1. Purpose

1.1. This procedure refers to IBC jurisdiction only.

1.2. The purpose of this procedure is to define the IBC's policy on incidents and describe the procedure for investigating incidents.

2. Key Word Definitions

2.1. 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 or noncompliance.

2.2. Noncompliance: Examples include deviation from a previously approved protocol; failure to fully disclose information relevant to the IBC review; conducting research before/without IBC approval; failure to follow IBC policies and procedures.

2.3. Laboratory-acquired infection: An LAI is defined as an infection acquired through laboratory related activities regardless of whether it is symptomatic or asymptomatic.

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

2.5. CDC: Centers for Disease Control and Prevention

2.6. IBC: Institutional Biosafety Committee

2.7. PI: Principal Investigator

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

2.9. BSO: Biological Safety Officer

2.10. ORC: Office of Research Compliance

2.11. USDA: United States Department of Agriculture

2.12. VPR: Vice President for Research

3. Responsibilities and Authorities

3.1. IBC Chair

3.1.1. Initiates and manages an investigation.

3.2. IBC Member

3.2.1. Participates in an investigation;

3.2.2. Evaluates the results of the investigation and determines the appropriate course of action.

3.3. BSO

3.3.1. Submits the report to the appropriate government agency.

3.4. Director, ORC

3.4.1. Reviews the final report.

3.5. VPR

3.5.1. Reviews final report;

3.5.2. Provides institutional support for the investigation of the incident.

3.6. PI

3.6.1.Responsible for reporting any incident to the BSO or Chair.

4. Items Needed

4.1. Incident report submitted by PI;

4.2. IBC application and other related material;

4.3. Supporting material obtained during the investigation such as interview transcripts, photographs, etc.

5. Procedure

5.1. Once an incident has been reported and an investigation is warranted, the BSO and Chair will meet to determine the investigative subcommittee;

5.1.1. The subcommittee may be composed of the Chair and BSO;

5.1.2. The Chair may elect to create a subcommittee of the IBC membership to conduct the investigation depending upon the nature of the incident;

5.1.3. If the incident appears to be criminal in nature, the Chair and/or BSO will notify and assist with the police and appropriate university officials.

5.2. the BSO will notify the ORC Director of the incident;

5.2.1. The Director may or may not initially involve the VPR based on the nature/seriousness of the incident.

5.3. The Chair will notify the IBC of the incident and will ask for volunteers to serve on the investigative subcommittee. The Chair will determine if a conflict of interest exists with any potential subcommittee member.

5.4. The Chair will preside over the subcommittee.

5.5. The BSO will be present for all subcommittee functions.

5.6. The subcommittee will collect information by conducting confidential interviews of individuals associated with the incident. The subcommittee may also visit the laboratory and other associated facilities.

5.7. The Chair will prepare a report of the subcommittee's findings and submit it to the IBC.

5.8. The Chair will call for a meeting (which may be the regularly scheduled meeting) to discuss the report.

5.9. The IBC will recommend a course of action including steps to prevent or mitigate the chance of reoccurrence and recommend any sanctions if needed.

5.10. The Chair will prepare a final report to include the results of the investigation and any recommended actions.

5.11. The PI and department head will be informed of the results and given two weeks to respond.

5.12. The report will be submitted to the BSO for recordkeeping and transmission to the appropriate federal agency if required as per SOP IBC-PP-016.

5.13. The report will be reviewed by the ORC Director and the VPR.

5.14. When noncompliance is found, the IBC and Mississippi State University will act promptly;

5.14.1. To halt the research, if deemed necessary, as per SOP IBC-PP-028;

5.14.2. Assure remedial action regarding any breach of regulatory or institutional requirements;

5.14.3. Address the question of the investigator's fitness to conduct research with biohazardous material.

5.15. When an LAI or accident is identified, the IBC and Mississippi State University will act promptly;

5.15.1. Ensure that any infected/injured personnel receive medical treatment and counseling;

5.15.2. To halt the research, if deemed necessary, as per SOP IBC-PP-028;

5.15.3. To review laboratory procedures, training and facilities to eliminate or mitigate a reoccurrence.

5.16. Any significant problems or violations of the *NIH Guidelines* or BMBL including any significant research related accidents and illnesses are to be reported to the NIH OBA, CDC, and/or USDA within 30 days if it has not already been done so by the PI or institution. Certain incidents must be reported immediately to NIH OBA including; spills or accidents in BSL-2 laboratories that result in an OVERT exposure; spills or accidents in high containment laboratories (BSL-3, BSL-4) that result in an overt OR potential exposure.

5.16.1.1. Reports will be sent to the Office of Biotechnology Activities at the address stated in Section IV-B of the *NIH Guidelines* and to the CDC and/or USDA depending upon the agent as per SOP IBC-PP-016.

6. Associated SOPs

   6.1. IBC-PP-016 Reporting to Federal Agencies

   6.2. IBC-PP-028 Suspension and Termination of Previously Approved Research

7. Associated Forms

   7.1. IBC application and any related paperwork

   7.2. Incident report template

   7.3. Incident report from PI if necessary

8. References

   8.1. *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* Section IV-B-1-j

   8.2. Biosafety in Microbiological and Biomedical Laboratories

9. Revision History

   9.1. NOTE: This is a revised SOP combining IBC-PP-003 Investigation of an Incident and IBC-PP-010 Incidents in Research.

10. Approvals

Reviewed by: _____ Date Reviewed: _____
Biological Safety Officer

Approved by: _____ Date Approved: _____
IBC Chair