

The University of Tulsa Institutional Biosafety Committee –Standard Operation Procedures (SOPs)

SOP Title: **Incident Reporting**

SOP Number: **IBC-SOP-005**

Revision Number: 1

Effective Date: 9/20/2019

1. **PURPOSE**

- 1.1 This procedure refers to the IBC only.
- 1.2 The purpose of this document 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 IBC: Institutional Biosafety Committee
- 2.2 RCC: Research Compliance Coordinator
- 2.3 IO: Institutional Official
- 2.4 NIH OBA: National Institutes of Health Office of Biotechnology Activities
- 2.5 PI: Principal Investigator
- 2.6 NIH Guidelines: *NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules*
- 2.7 Laboratory-acquired infections (LAI): 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 BMBL: Biosafety in Microbiological and Biomedical Laboratories
- 2.10 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.
- 2.11 OVERT Exposure: A definitive contact with a Biosafety Level Two (BSL-2) or Biosafety Level Three (BSL-3) recombinant biological agent. According to the NIH rDNA guidelines, this contact would be reportable to NIH Office of Biotechnology Activities (NIH OBA)
*Currently, The University of Tulsa does not conduct research activities that meet the criteria for high containment laboratories (BSL-3, BSL-4) that would result in these types of spills.

3. **RESPONSIBILITIES AND AUTHORITIES**

Research Compliance Coordinator (RCC):

- 3.1 Responsible for monitoring compliance with the NIH Guidelines.

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

IBC Chair:

- 3.3 Submits a report of an incident to the proper agency if not done by the PI, RCC, or IO.

Institutional Official (IO):

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

Principal Investigator (PI):

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

4. NEEDED

- 4.1 Incident Reporting Form https://osp.od.nih.gov/wp-content/uploads/Incident-Reporting-Template_42319.docx

5. PROCEDURE

- 5.1 The University of Tulsa IBC will use the ‘Template for Reporting Incidents Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* to the National Institutes of Health Office of Science Policy (OSP)’. See the link in item 4 and item 6 of this SOP.
- 5.2 The University of Tulsa IBC will use the template referenced above for all incident reporting, including non-funded research.
 - 5.2.1 PIs will submit the incident report to the TU IBC Office.
 - 5.2.2 The TU IBC Office will make the determination on what federal, state, local, private agency (ies) and university offices will receive the incident report.
- 5.3 Within 30 days of the determination that an incident or violation of the *NIH Guidelines* has occurred, a report will be written to include:
 - 5.3.1 The date(s) of the incident;
 - 5.3.2 A description of the incident;
 - The section(s) of the NIH Guidelines violated, if applicable;
 - The sections of the Biosafety in Microbiological and Biomedical Laboratories (BMBL) violated, if applicable
 - 5.3.3 The personnel involved in the incident;
 - 5.3.4 A description of the investigation of the incident, if any;
 - 5.3.5 A description of the measures implemented by the Institution to rectify the situation.

- 5.4 The report will be sent to the appropriate agency (ies) and copies sent to the RCC, IBC Chair, PI and IO.
- 5.5 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.
- Currently, The University of Tulsa does not conduct research activities that meet the criteria for high containment laboratories (BSL-3, BSL-4) that would result in these types of spills.

6. ASSOCIATED FORMS

- 6.1 Incident Reporting form https://osp.od.nih.gov/wp-content/uploads/Incident-Reporting-Template_42319.docx


7. REFERENCES

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
Section IV-B-2-b-(7) https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf

8. REVISION HISTORY

- 8.1. Version 9.20.2019 approved 10/1/2019

9. STANDARD OPERATION PROCEDURES APPROVAL

Approved by:  Date Approved: 10-1-19
TU IBC Chair

https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf