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**


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

7. REFERENCES
   NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules

8. REVISION HISTORY
   8.1 Version 9.20.2019 approved 10/1/2019

9. STANDARD OPERATION PROCEDURES APPROVAL

Approved by: [Signature]

Date Approved: 10-1-19

TU IBC Chair


version 9.20.2019