Procedure for Handling Biosafety Incidents or Violations.

1. Internal Reporting

Internal reporting must occur as soon as a violation or incident is discovered.

a. **Principal Investigator (PI)/Supervisor**: Any lab personnel (including students) who has a biosafety concern or has witnessed a biosafety violation must immediately inform their PI/supervisor. The PI must address the concerns or investigate and address the violation. In that case of a serious biosafety violation, the PI must recommend the violator for Biosafety retraining and forward a copy of the retraining certificate to the Institutional Biosafety Committee.

b. **Anonymous Reporting**
Anyone who witnesses a biosafety violation on the ASU campus can directly notify the institutional Biosafety Committee (IBC, ibc@alasu.edu) in good faith without fear of retaliation.

c. **Institutional Biosafety Committee (IBC)**: Violations that cannot be addressed buy the PI must be reported to the IBC. The IBC will review the violation and determine the severity of the non-compliance.

d. **Institutional Official**: In case of serious harm or recuring trends, the Director of the office of research and sponsored programs (ORSP) will be notified by the IBC.

2. Investigation and Resolution Process

When a violation is reported to the IBC, the following steps will be taken:

a. **Initial investigation:** The IBC Chair will conduct a preliminary review to assess the severity and nature of the non-compliance.

b. **Committee Review**: The full IBC will investigate the event, which may include interviewing personnel and inspecting the laboratory/facility.

c. **Determination**: The IBC will determine if the violation was "serious" or "continuing" and outline the required Corrective Action Plan.

d. **Sanctions**: In case of recuring severe violations, the IBC may suspend or terminate the biosafety approval for the project or advise the University officials to restrict laboratory access until compliance is re-established.

3. External Reporting Requirements

ASU is legally required to report specific types of violations to the NIH Office of Science Policy (OSP).

- **Immediate Reports**: Spills or accidents in BSL-2 labs involving overt exposure must be immediately reported or no later than 72 hours following the accident.
- Immediately call 911 if there is a serious exposure, injury, dangerous fumes, or an uncontrolled spill.
- **30-Day Reports**: Any significant problems, violations of the NIH Guidelines, or research-related accidents/illnesses constitutes a trigger for a mandatory 30-day formal report. These include:

a. Administrative & Regulatory Violations

- ***Lapse in IBC Approval***: Conducting research with biohazard without prior IBC approval.

- ***Unauthorized Changes***: Significant modifications to a research project's risk profile or scope without prior notification and approval from the IBC.
- ***Training Failures***: Failure of the Principal Investigator (PI) to ensure that all laboratory personnel are adequately trained in required biosafety practices and techniques.

b. Containment Breaches

- ***Environmental Release***: Any accidental release of a Risk Group 2 or 3 agent outside of primary containment (e.g., a spill outside of a Biosafety Cabinet).
- ***Equipment Failure***: Malfunctions in critical safety equipment, such as a failed centrifuge or a biosafety cabinet that was not certified annually as required.
- ***Improper Disposal***: Failure to follow prescribed sterilization or disposal procedures for biohazardous waste, including rDNA materials.

c. Animal & Plant Incidents

- ***Transgenic Escapes***: The escape or improper disposition of a transgenic animal (e.g., a mouse) or the unauthorized release of transgenic plants, seeds, or pollen.
- ***Animal Bites/Scratches***: Injuries sustained from research animals that are infected or contain rDNA molecules, which are often classified as overt exposures.

d. Personnel Exposures (Standard & Potential)

- ***Potential Exposure in BSL-2***: A potential exposure in a BSL-2 lab (e.g., a splash to the face that did not result in an infection) must still be documented and reported within 30 days.
- ***Research-Related Illness***: Any illness in lab personnel that can be reasonably linked to the biological agents used in the research.