

<b>Oklahoma State University Institutional Biosafety Committee</b>		
<b>Reporting Laboratory Incidents</b>	Policy #	GA 108
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	Revision #	2
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## 1. POLICY

The Oklahoma State University Institutional Biosafety Committee (IBC) requires all laboratory biosafety incidents be reported immediately to the laboratory principal investigator (PI) or laboratory manager. In addition, large spills of biohazardous material (i.e., >10 mL in volume) that occur outside of primary containment should be immediately reported to the Biosafety Officer (BSO). All laboratory biosafety incidents occurring in a BSL-2, ABSL-2, BSL-2P, ACL-2, BSL-3, ABSL-3, BSL-3P, ACL-3 must be reported to the BSO within 48 hours. Upon notice, the BSO will report promptly to institutional and federal officials as appropriate. A Laboratory Incident Report Form must be completed by the PI or lab manager and submitted to the Office of University Research Compliance within one week. The Employee Injury Report may be submitted in lieu of the Laboratory Incident Report Form if an employee is injured. The purpose of this standard operating procedure is to establish the reporting requirement and identify incidents that a PI or lab manager must report to the IBC.

### Specific Procedures

#### 1.1 Definitions

##### 1.1.1 Biohazardous material

Materials that present a risk or potential risk to the health of humans, animals, or the environment, such as infectious agents, toxins, recombinant/synthetic nucleic acid molecules, or transgenic animals/plants in all forms.

##### 1.1.2 Laboratory biosafety incident: Any incident that:

- Results in the spill or release of, or exposure to, biohazardous material.
- Places any OSU personnel at risk of harm from biohazardous material.

#### 1.2 Incident Reporting

##### 1.2.1 The IBC requires:

- All laboratory biosafety incidents be reported immediately to the laboratory PI or laboratory manager.
- Large spills of biohazardous material (i.e., >10 mL in volume) that occur outside of primary containment be immediately reported to the BSO.
- All laboratory biosafety incidents occurring in a BSL-2, ABSL-2, BSL-2P, ACL-2, BSL-3, ABSL-3, BSL-3P, ACL-3 must be reported to the BSO within 48 hours.

1.2.2 The BSO will report laboratory biosafety incidents promptly to institutional and federal officials as appropriate. A Laboratory Incident Report Form must be completed by the laboratory PI or laboratory manager and submitted to the Office of University Research Compliance within one week. The Employee Injury Report may be submitted in lieu of the Laboratory Incident

Report Form if an employee is injured. PIs should include the following information when reporting laboratory biosafety incidents:

- Appropriate identifying information for the research protocol, such as the title, PIs name, and the IBC protocol number;
- A detailed description of the laboratory biosafety incident;
- An explanation of the basis for determining that the laboratory biosafety event represents an unanticipated incident; and
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the unanticipated incident.

### **1.3 Review of the Incident**

1.3.1 The BSO will initially review all Laboratory Incident Report/Employee Injury Report Forms. If appropriate to the event or problem, the BSO will also review the protocol, and any other relevant documents pertaining to the incident or problem. After initial review, the BSO will make one of the following determinations:

The incident is NOT an incident involving risks to humans, other animals, or plants. If this is the case, the BSO will take no action, document the review, and add the item to the IBC agenda for reporting purposes.

**OR**

The incident is considered an incident involving risks to humans, other animals, or plants. If so:

- The BSO may determine that immediate action is needed to ensure the safety of those affected; the BSO, in consultation with the IBC Chair, Director of University Research Compliance, and Senior Associate Vice President for Research, may request that the PI suspend some or all of the research pending review of the matter at the next convened IBC meeting. Suspensions ordered by the IBC Committee will follow IBC procedures outlined in the Policy on Noncompliance.
- The BSO or designee will present the incident to the IBC Committee at the next convened meeting. IBC members will be provided a copy of the report form and all appropriate documentation, including the current protocol. The IBC will deliberate and vote to determine whether the incident represents a problem involving risks to humans, other animals, or plants; based on whether the incident placed those affected at an increased risk of harm. If the situation is determined to be an incident involving risks to humans, other animals, or plants, the IBC will deliberate and vote to approve one of the following actions, including, but not limited to:
  - No action;
  - Modification of the research protocol;
  - Increased monitoring of the research;
  - Suspension of the research;
  - Termination of the research;
  - Request for more information pending a final decision;
  - Refer to other organizational entities (e.g. legal counsel, institutional official); or
  - Other actions as appropriate.

The determination and vote will be reported in the IBC meeting minutes and the PI will be notified in writing.

## **1.4 Notification**

1.4.1 No action required: If the situation is not an incident posing risks to subjects or others, the PI will receive a letter indicating that the IBC has received the report and that no other action pertaining to the matter will be required.

1.4.2 Full Committee Review: The PI will be notified by the BSO within five working days of the IBC meeting of the committee's decision and action(s).

If the situation is an incident involving risks to subjects or others, the IBC will inform the following individuals internal to the university of the problem and the recommended action(s)

- Director of Research Compliance;
- Department Head(s);
- College Research Dean(s);
- Institutional Official (Division of the Vice President for Research).

The BSO will also report incidents promptly to federal officials as appropriate.

If the research is supported by an external sponsor, they will be notified.

## **2. SCOPE**

This policy applies to all research laboratories and facilities falling within the purview of Oklahoma State University (Stillwater) Institutional Biosafety Committee.

## **3. RESPONSIBILITY**

The PIs and Laboratory/Facility Managers/Directors/Department Heads have a responsibility to adhere to this policy.

The PI is responsible for prompt submission of all reports of any laboratory biosafety incident to the IBC.

The BSO will review all Laboratory Incident Report/Employee Injury Report forms to determine if suspension of the protocol is warranted and present the matter to the IBC at a convened meeting.

IBC members are responsible for determining if the problem represents an incident involving risks to subjects or others.

The BSO is responsible for sending letters to PIs and appropriate individuals and agencies.

## **4. APPLICABLE REGULATIONS, GUIDELINES, & OSU POLICIES**

- Oklahoma State University Biological Research Safety Plan
- Oklahoma State University Biosafety Policy

## **5. ATTACHMENTS**

- [Biological Exposure Reporting Procedure](#)
- [Laboratory Incident Report Form](#)
- [Employee Injury Report Form](#)