Institutional Biosafety Committee (IBC)
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IBC Policy-Federal Reporting Requirements

Background

It is the responsibility of the Vice President for Research Development and Administration, the OHSU Research Integrity Office (ORIO), and the OHSU Institutional Biosafety Committee (IBC) to comply with all federal reporting requirements with respect to the conduct of research involving recombinant and synthetic nucleic acid molecules. These reporting requirements apply to all non-exempt recombinant DNA research that is conducted at OHSU or conducted using funds awarded to OHSU.

Scope

This policy and procedure establishes guidelines to ensure prompt reporting according to Federal regulations, institutional policy, and OHSU IBC policy. The IBC review processes for the incidents described here are covered under the Protocol Deviations policy or the Research-Related Accidents policy, as applicable.

I. Policy

A. The OHSU IBC will promptly report to appropriate OHSU officials and federal regulatory agencies the following IBC determinations:

1. Significant research-related accidents and illnesses;

2. Significant problems or violations of the NIH Guidelines

B. The following elements must be included in the report, which shall be kept concise and limited to only those details that directly support the actions taken:

1. The nature of the event or events;

2. IBC findings;

3. Actions taken, including any IBC actions taken related to this matter;

4. Clear indication that the issue is resolved or specific plans for continued investigation or action; and

5. Any supplementary information or materials having relevance to the decision or incident.

C. The OHSU IBC will send a letter notifying the principal investigator of the above determinations and will also send a copy to the principal investigator's departmental chair and to the Biosafety Officer.

D. The report will be sent to the IRB or IACUC chair, as appropriate.

E. To comply with the requirement to report promptly, reporting will occur as soon as practicable. The Associate Director of ORIO and/or the IBC Chair shall devise a reporting plan that is appropriate for the reported activity. It may include preliminary reports and follow-up.

II. Guidance/Procedure

A. Reporting details

1. Unless reporting timelines are dictated by another policy or regulation, the Associate Director will create a reporting timeline which must comply with the NIH Office of Biotechnology Activities (OBA) requirements.

a. Spills or accidents in Biosafety Level 2 (BSL-2) laboratories resulting in a documented exposure must be immediately reported to NIH OBA. Spills or accidents occurring in

BSL-3 laboratories resulting in a documented or potential exposure must be immediately reported to OBA.

b. Other reports will be submitted within 30 days.

2. The Associate Director will draft a communication to the regulatory agencies in coordination with legal counsel and the Chief Integrity Officer. A copy will be sent to the Vice President for Research Development and Administration, the Department Chair, and the Principal Investigator.
3. When appropriate, an initial, preliminary report will be sent to OBA with an indication that a final report will follow by the earlier of:
   a. a specific date; or
   b. when an investigation has been completed or a corrective action plan has been implemented.
4. In the event of a very serious problem, a telephone report to NIH OBA may be made to alert the agency to the issue and circumstances. Subsequent written reports will reference the date and time of the initial telephone call.
5. In the case of an urgent written or telephone report, such report will include the nature of the issue, OHSU's investigation process, and the plans for a final report.

B. Recording Reporting

1. A copy of the final signed report will be kept in the appropriate IBC file.
2. Any responses from NIH OBA shall also be filed.
3. Any delay in reporting will be noted in the record with an explanation for the delay.

III. Definitions and Guidance

The NIH has provided guidance on serious or significant problems and types of spills or accidents that warrant reporting to the NIH OBA as reflected below. OBA should be consulted if the IBC, investigator, or other institutional staff are uncertain whether the nature or severity of the incident warrants reporting.

A. Significant Research Related Accidents: Any spill or accident involving recombinant DNA research described in II.A.1.a above or that otherwise leads to personal injury or illness or to a breach of containment must be reported to OBA. These kinds of events might include skin punctures with needles containing recombinant DNA, the escape or improper disposition of a transgenic animal, or spills of high-risk recombinant materials occurring outside of a biosafety cabinet. Minor spills of low-risk agents not involving a breach of containment that were properly cleaned and decontaminated generally do not need to be reported.

B. Significant Problems or Violations: Failure to adhere to the containment and biosafety practices articulated by the IBC, or use of a recombinant DNA agent without IBC approval must be reported to OBA.

IV. Authority

NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules, Section IV-B-2-b-(7) http://oba.od.nih.gov/rdna/nih_guidelines_new.htm#_Toc331174015
NIH Incident Reporting FAQs http://oba.od.nih.gov/oba/ibc/FAQs/FAQs_about_Incident_Reporting.pdf

V. Related policies

IBC Protocol Deviation Policy
IBC Spills and Research-Related Accidents Policy