1.0 Reason for Policy

This policy describes the types of incidents that researchers must report to the Institutional Biosafety Committee (IBC) and the types of incidents that the IBC administrative office must report to the NIH-OBA. It describes the process the IBC and the IBC office staff will follow to review and address research-related incidents involving potentially hazardous biological agents, including incidents from research subject to the NIH Guidelines.

2.0 Scope of Policy

This policy applies to the IBC, IBC staff, and the University of Minnesota research community.

3.0 Policy Statement

Researcher Reporting

Principal Investigators must promptly report any research-related accidents or incidents involving potentially hazardous biological agents to the IBC office and/or University Health and Safety (UHS). The report must be either the IBC Incident Report Form (fillable PDF document) or the Incident Report via eProtocol. IBC senior staff and UHS biosafety staff will confirm that both groups have submitted IBC incident report. Submission of the IBC Incident Report Form (emailing the fillable PDF document
or via eProtocol) confirms the Principal Investigator’s assurance that all of the information included on
the form is accurate to the extent of his/her knowledge. Incident reports must be submitted to the IBC
office or the Biosafety Officer within ten working days of knowledge of the event. If the incident occurs
in a BL2 or BL3 laboratory and involves recombinant or synthetic nucleic acids, agents used for gene
transfer, or infectious agents created with recombinant gene transfer techniques, it must be reported to
the IBC office and UHS immediately. If the incident involves a serious adverse event resulting from
human gene transfer in clinical research the report must reported to the IBC office and UHS
immediately.

The IBC senior staff, the IBC, and UHS consult and work closely together throughout the course of the
incident report to ensure that the correct process is followed depending on the type or severity of the
incident. Biosafety and/or occupational health experts from UHS will review the incident report and
dee if a full investigation is necessary. All subsequent follow-up will be recorded and reported to the
IBC Office.

NIH-OBA Guidance reporting requirements will be followed throughout the course of the incident
report. The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
(NIH Guidelines - Nov 2013) states that "...any significant problems, violations of the NIH Guidelines,
or any significant research-related accidents and illnesses" must be reported to NIH OBA within 30
days. Certain types of accidents must be reported on a more expedited basis. Spills or accidents in BL2
laboratories resulting in an overt exposure must be immediately reported to NIH OBA. Spills or
accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential
exposure must be immediately reported to NIH OBA. Failure to adhere to the containment and biosafety
practices articulated in the NIH Guidelines must also be reported to OBA.

The following must be reported to the IBC office:

- Events that are unexpected, involve new or increased risks, and are related to the research
- Personal injury, accident, or spill resulting in an overt or potential exposure
- Environmental release

Incident Report:

- The Principal Investigator (PI) makes and files an incident report which:
  - Outlines the details of the event, location of the incident, and number of people involved
  - Type of hazardous biological agent involved
  - Describes any personal injury information (i.e. cut, needle stick, splash to eyes or mouth,
    etc.)
  - Environmental release information
  - Treatment and/or clean-up procedures
  - Provides an assessment using professional judgment of the likely impact of the event on
    the lab staff and the environment
  - Identifies the steps to be taken by the PI to mitigate a reoccurrence of the incident
Administrative Review and Action:

- The IBC senior staff, in consultation with the Biosafety Officer and/or the IBC Chair and/or the IBC Vice-Chair will determine whether an incident involving recombinant or synthetic nucleic acid research qualifies for immediate reporting to the NIH-OBA or within 30 days to the NIH-OBA. If the incident requires immediate reporting, the Executive Director of HRPP will be notified and provided with the incident details and other NIH-OBA requested documentation for review and approval by the Institutional Official.

- For all incident reports, the IBC senior staff and the Biosafety Officer will consult and review the report to determine whether an IBC review is required. If a fully convened IBC review is required, all committee members will receive the incident report, accompanying documents, the original application, and other relevant documents as appropriate before the next scheduled IBC meeting.

- The IBC will make determinations concerning:
  
  o Whether the an incident NOT involving accidents or spills resulting in an overt or potential exposure (related to recombinant DNA research) must be reported to the NIH-OBA
  o Whether the study should continue, or be suspended
  o Recommendation to the Institutional Official that the event be reported (see IBC Policy 407 Reporting Requirements)

- If the study is continued, the IBC or IBC Chair will assist the Biosafety Officer with follow-up recommendations and make further decisions regarding:
  
  o Whether changes are required in the plan or protocol to assure continued safety
  o Whether the time frame for continuing review reports should be modified
  o Whether additional information is required from the researcher or through a monitoring or audit mechanism (e.g. additional lab inspections or follow-up)

- All actions are recorded in the IBC Meeting Minutes.

Notification to Researcher and Limited Appeal:

The outcome of the IBC’s review is reported to the investigator in the usual manner. If the IBC recommends suspension or termination of application approval for a study based on the incident, the researcher may have an opportunity to submit an appeal.

4.0 Required approvals for this document

<table>
<thead>
<tr>
<th>Title</th>
<th>Name</th>
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<tbody>
<tr>
<td>Executive Director, HRPP</td>
<td>Debra Dykhuis</td>
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5.0 Revision History

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<tr>
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<tr>
<td>05/13/15</td>
<td>Update for NIH OBA time requirements</td>
<td>06/22/15</td>
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<td>Update staff and minor text</td>
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<tr>
<td>03/16/12</td>
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<td>03/05/10</td>
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To obtain a copy of a historical policy, e-mail at ibc@umn.edu or call 612-626-5654