IBC: Reporting Requirements

Policy number: 407

Date: 05/15/15

Policy Owner: Executive Director, HRPP

References:
NIH Guidelines Section IV-B-2-b-(7)
NIH Guideline Sections -Appendix G-II-B-2-K and G-II-C-2-a
NIH Template for Reporting Incidents Related to Research Subject to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids to the NIH-OBA

Cross references:
101 Role of Institutional Official
405 Non-Compliance with Policies & Procedures
407A Reporting Requirements of SAE in HGT research
408 Suspension and Termination
409 Incident Reporting

Definitions:
None

1.0 Reason for Policy

This policy describes the regulatory requirements for reporting significant problems with or violations of the NIH Guidelines, any significant research-related accidents or illnesses risk, serious and continuing non-compliance with Institutional Biosafety Committee (IBC) policies and procedures, and suspension or termination of IBC approval of research.

2.0 Scope of Policy

This policy applies to the University Human Research Protection Program (HRPP) staff, the IBC, and the Institutional Official (IO).

3.0 Policy Statement

The IBC, IBC senior staff, University of Minnesota (UMN) investigators or other UMN staff persons may contact the National Institutes of Health Office of Biotechnology Activities (NIH-OBA) staff for consultation if there is any uncertainty if the nature or severity of a reported
incident (to the UMN IBC office or University Health Services (UHS)) warrants reporting to NIH-OBA.

**Administrative Procedure**

The IBC senior staff will notify the IBC Chair, the IBC Vice-Chair, the HRPP Executive Director, and the UHS Biosafety Officer of the following incidents:

- Any significant problems, violations of the NIH Guidelines, or any significant accidents or illnesses involving potentially hazardous biological materials (including but not limited to: recombinant or synthetic nucleic acid molecules, human or animal fluids/cells/products, infectious agents (human, animal, or plant), agents intended for genetic transfer, and biological toxins).

- Any serious or continuing non-compliance with IBC policy or the requirements or determinations of the IBC. If the IBC determines an investigation is necessary, the IO is notified.

- Any suspension or termination of IBC approval.

In all instances where reporting to the NIH-OBA is required, the HRPP Executive Director will notify the following University persons:

- The Principal Investigator
- The IO
- Appropriate academic or departmental leadership

The Institutional Official will notify one or more of the following as required by the *NIH Guidelines* and UMN Regents Policy:

- The head or appropriate designee of the funding department or agency, as applicable
- The appropriate designee of the sponsoring company or organization, as applicable
- Partner institutions, as applicable
- The NIH-OBA.

For serious or continuing non-compliance issues, the Executive Director and IBC Chair will draft a letter that outlines the nature of the event, the findings of the IBC, the reasons for its conclusions, actions taken by the IBC, the basis for reporting the matter, and plans for continued investigation or corrective action. The letter will identify the principal investigator or location, the title and IBC identifier(s) of the application(s) affected by the incident report, and suspension/termination. This letter is signed and transmitted by the IO.

For other NIH-OBA reportable incidents, IBC senior staff will complete the “NIH Template for Reporting Incidents Related to Research Subject to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids to the NIH-OBA” and forward all required documentation to the HRPP Executive Director and IBC Chair. The Executive Director with assistance from the IBC senior staff or the IBC Chair will draft a letter that outlines the nature of the incident and the actions taken by the IBC or that will be taken by the IBC. This letter and all other material is reviewed and signed by the IO. Transmission of the completed incident report is performed by the IO or by other staff of the Office for the Vice President for Research.
For incident reports that require the timeframe of “immediate” reporting to NIH-OBA, the “NIH Template for Reporting Incidents Related to Research Subject to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids to the NIH-OBA” will be completed with as much information as possible or in lieu of the template, a letter from the IO will include as much information as possible about the incident. After the UHS investigation is completed and the IBC has reviewed the information from the incident, a follow-up report using the “NIH Template for Reporting Incidents Related to Research Subject to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids to the NIH-OBA” will be completed and sent to NIH-OBA.

The NIH Guidelines Reporting Requirements

NIH-OBA 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. Appendix G of the NIH Guidelines specifies 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.

Specific Excerpts from the NIH Guidelines:

SECTION IV. ROLES AND RESPONSIBILITIES
Section IV-B. Responsibilities of the Institution
Section IV-B-1. General Information
Each institution conducting or sponsoring recombinant or synthetic nucleic acid molecule research which is covered by the NIH Guidelines is responsible for ensuring that the research is conducted in full conformity with the provisions of the NIH Guidelines. In order to fulfill this responsibility, the institution shall:

Section IV-B-1-j. Report any significant problems, violations of the NIH Guidelines, or any significant research-related accidents and illnesses to NIH/OBA within thirty days, unless the institution determines that a report has already been filed by the Principal Investigator or Institutional Biosafety Committee. Reports shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax).

Section IV-B-2. Institutional Biosafety Committee (IBC)
Section IV-B-2-b. Functions
Section IV-B-2-b-(7). Reporting any significant problems with or violations of the NIH Guidelines and any significant research-related accidents or illnesses to the appropriate institutional official and NIH/OBA within 30 days, unless the Institutional Biosafety Committee determines that a report has already been filed by the Principal Investigator. Reports to
NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax).

Section IV-B-7. Principal Investigator (PI)
Section IV-B-7-a-(3). Report any significant problems, violations of the NIH Guidelines, or any significant research-related accidents and illnesses to the Biological Safety Officer (where applicable), Greenhouse/Animal Facility Director (where applicable), Institutional Biosafety Committee, NIH/OBA, and other appropriate authorities (if applicable) within 30 days. Reports to NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax);

APPENDIX G. PHYSICAL CONTAINMENT
Appendix G-II. Physical Containment Levels
Appendix G-II-B. Biosafety Level 2 (BL2)
Appendix G-II-B-2. Special Practices (BL2)
Appendix G-II-B-2-k. Spells and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules are immediately reported to the Institutional Biosafety Committee and NIH/OBA. Reports to NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax). Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.

Appendix G-II-C. Biosafety Level 3 (BL3)
Appendix G-II-C-2. Special Practices (BL3)
Appendix G-II-C-2-q. Spells and accidents which result in overt or potential exposures to organisms containing recombinant or synthetic nucleic acid molecules are immediately reported to the Biological Safety Officer, Institutional Biosafety Committee, and NIH/OBA. Reports to NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax). Appropriate medical evaluation, surveillance, and treatment are provided and written records are maintained.

APPENDIX K. PHYSICAL CONTAINMENT FOR LARGE SCALE USES OF ORGANISMS CONTAINING RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES
Appendix K-IV. Biosafety Level 2 (BL2) - Large Scale
Appendix K-IV-A. Spells and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules are immediately reported to the Biological Safety Officer, Institutional Biosafety Committee, NIH/OBA, and other appropriate authorities (if applicable). Reports to NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax). Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.

Appendix K-V. Biosafety Level 3 (BL3) - Large Scale
Appendix K-V-A. Spells and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules are immediately reported to the Biological Safety Officer, Institutional Biosafety Committee, NIH/OBA, and other appropriate authorities (if applicable). Reports to NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax). Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.

APPENDIX P. PHYSICAL AND BIOLOGICAL CONTAINMENT FOR RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULE RESEARCH INVOLVING PLANTS
Appendix P-II. Physical Containment Levels
Appendix P-II-B. Biosafety Level 2 - Plants (BL2-P)
Appendix P-II-B-1-b-(3). The Principal Investigator shall report any greenhouse accident involving the inadvertent release or spill of microorganisms to the Greenhouse Director, Institutional Biosafety Committee, NIH/OBA and other appropriate authorities immediately (if applicable). Reports to the NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax). Documentation of any such accident shall be prepared and maintained.

Appendix P-II-C. Biosafety Level 3 - Plants (BL3-P)
Appendix P-II-C-1. Standard Practices (BL3-P)
Appendix P-II-C-1-b-(3). The Principal Investigator shall report any greenhouse accident involving the inadvertent release or spill of microorganisms to the Biological Safety Officer, Greenhouse Director, Institutional Biosafety Committee, NIH/OBA, and other appropriate authorities immediately (if applicable). Reports to the NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax). Documentation of any such accident shall be prepared and maintained.

APPENDIX Q. PHYSICAL AND BIOLOGICAL CONTAINMENT FOR RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULE RESEARCH INVOLVING ANIMALS
Appendix Q-II-B. Biosafety Level 2 - Animals (BL2-N)
Appendix Q-II-B-1-c.e. Records (BL2-N)
Appendix Q-II-B-1-c.e-(1). Any incident involving spills and accidents that result in environmental release or exposures of animals or laboratory workers to organisms containing recombinant or synthetic nucleic acid molecules shall be reported immediately to the Animal Facility Director, Institutional Biosafety Committee, NIH/OBA, and other appropriate authorities (if applicable). Reports to the NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax). Medical evaluation, surveillance, and treatment shall be provided as appropriate and written records maintained. If necessary, the area shall be appropriately decontaminated.

Appendix Q-II-C. Biosafety Level 3 - Animals (BL3-N)
Appendix Q-II-C-1-c.e. Records (BL3-N)
Appendix Q-II-C-1-c.e-(2). Any incident involving spills and accidents that result in environmental release or exposure of animals or laboratory workers to organisms containing recombinant or synthetic nucleic acid molecules shall be reported immediately to the Biological Safety Office, Animal Facility Director, Institutional Biosafety Committee, NIH/OBA, and other appropriate authorities (if applicable). Reports to the NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax). Medical evaluation, surveillance, and treatment shall be provided as appropriate and written records maintained. If necessary, the area shall be appropriately decontaminated.

NIH Guideline Reporting Requirements for Serious Adverse Events (SAE) in Human Gene Transfer (HGT) Research

The NIH Guidelines, Appendix M-1-C-4 requires Principal Investigators must submit a written report on: (1) any serious adverse event that is both unexpected and associated with the use of the gene transfer product (i.e., there is reasonable possibility that the event may have been caused by the use of the product; investigators should not await definitive proof of association before reporting such events); and (2) any finding from tests in laboratory animals that suggests a significant risk for human research participants including reports of mutagenicity, teratogenicity, or carcinogenicity. The report must be clearly labeled as a “Safety Report” and must be
submitted to the NIH Office of Biotechnology Activities (NIH OBA) and to the local Institutional Biosafety Committee within the timeframes set forth in Appendix M-I-C-4-b. Principal Investigators should adhere to any other serious adverse event reporting requirements in accordance with federal regulations, state laws, and local institutional policies and procedures, as applicable. Principal Investigators may delegate to another party, such as a corporate sponsor, the reporting functions set forth in Appendix M, with written notification to the NIH OBA of the delegation and of the name(s), address, telephone and fax numbers of the contact(s). The Principal Investigator is responsible for ensuring that the reporting requirements are fulfilled and will be held accountable for any reporting lapses. The three alternative mechanisms for reporting serious adverse events to the NIH OBA are: by e-mail to oba@od.nih.gov; by fax to 301-496-9839; or by mail to the Office of Biotechnology Activities, National Institutes of Health, MSC 7985, 6705 Rockledge Drive, Suite 750, Bethesda, Maryland 20892-7985.

Any serious adverse event that is fatal or life-threatening, that is unexpected, and associated with the use of the gene transfer product must be reported to the NIH OBA as soon as possible, but not later than 7 calendar days after the sponsor’s initial receipt of the information (i.e., at the same time the event must be reported to the FDA). Serious adverse events that are unexpected and associated with the use of the gene transfer product, but are not fatal or life-threatening, must be reported to the NIH OBA as soon as possible, but not later than 15 calendar days after the sponsor’s initial receipt of the information (i.e., at the same time the event must be reported to the FDA).

The IBC and Institutional Review Board will collaborate on the reporting requirements in research that includes human subjects.

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4.0 Required approvals for this document

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

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To obtain a copy of a historical policy, e-mail IBC at ibc@umn.edu or call 612-626-5654

Page 6 of 6