

Policy and Procedure for Recombinant DNA/Biohazardous Material Incident Reporting

Originator: Department of Environmental Health and Safety

Vice Presidents: Business Affairs and Research

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SUMMARY:

The University of Louisville is required to report incidents involving recombinant DNA (rDNA) and/or biohazardous research to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) and other outside agencies as appropriate depending on the material involved. This policy outlines the information necessary to determine the nature and extent of the incident, as well as the appropriate reporting requirements and process according to the *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)*.

SCOPE:

This policy applies to any individual, including a principal investigator, researcher, instructor, laboratory or clinical manager who works in a laboratory or clinic utilizing recombinant DNA.

DEFINITIONS:

Incidents include:

- Spills or accidents resulting in overt exposure (skin punctures with needles containing rDNA, exposure of broken skin or mucous membranes) at Biosafety Level 2 (BSL-2),
- Spills or accidents occurring in Biosafety Level 3 (BSL-3) laboratories outside of a biosafety cabinet resulting in an overt or potential exposure,
- Violations of the *NIH Guidelines* containment or biosafety practices, or significant problems leading to a breach of containment (including escape or improper disposal of a transgenic animal),
- Any significant-research-related accidents or illnesses.

Recombinant DNA molecules are defined in the context of the *NIH Guidelines* as:

- Molecules that are constructed outside of living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell,
- Molecules that result from the replication of those described above, or
- Synthetic DNA segments which are likely to yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or a pharmacologically active agent) are considered as equivalent to their natural DNA counterpart.

RESPONSIBILITIES/PROCEDURES:

Principal Investigator, Researcher, Laboratory/Clinical Manager or Other Laboratory Personnel

Reporting Responsibilities

1. The University personnel involved must immediately report the incident to the Principal Investigator and the Institutional Biological Safety Officer in the Department of Environmental Health and Safety (852-6670; biosafe@louisville.edu).
2. Exposed personnel must follow appropriate response plans for exposure prophylaxis that include seeking medical attention as necessary and completing the First Report of Injury Form. Spills must be contained and cleaned up appropriately. The Principal Investigator is ultimately responsible for reporting the incident to the Institutional Biological Safety Officer should the personnel involved be unable to do so in a timely manner.
3. The Institutional Biological Safety Officer will notify the Director of Environmental Health and Safety, the Chair of the Institutional Biosafety Committee the Director of Research Resources and the Office of the Executive Vice President for Research as needed.
4. The Principal Investigator and the Institutional Biological Safety Officer will collectively complete the NIH OBA Template for Reporting Incidents Involving Recombinant DNA at http://oba.od.nih.gov/rdna_ibc/ibc_faq.html. The Incident Report Form will be completed in a timely manner as determined by the nature of the incident and agency reporting timelines.
5. In conjunction with the IBC Chair, the Institutional Biological Safety Officer will submit the final incident report to the respective federal agency on behalf of the university. The final incident report will be reviewed by the IBC and corrective actions recommended and instituted as necessary. Copies of the incident report will be provided to the Director of Environmental Health and Safety, the Director of Research Resources, the Chair of the Department and the Dean for Research of the College involved with follow-up being conducted as necessary.

Reportable Incidents and Timelines

1. The following incidents should be reported immediately to the Principal Investigator, the Institutional Biological Safety Office (852-6670; biosafe@louisville.edu) and the Chair of the Institutional Biosafety Committee:
 - a. Spills or accidents in a Biosafety Level 2 (BSL-2) laboratory resulting in an overt exposure, injury or illness of personnel.
 - b. Spills or accidents in a Biosafety Level 3 (BSL-3) laboratory resulting in an overt potential exposure, injury or illness of personnel.
 - c. Release of a Risk Group 2 or 3 agent/genetic material from a primary containment device (e.g., biological safety cabinet, centrifuge, or primary container into the laboratory)
 - d. Spills or accidents that lead to personal injury or illness or breach of containment (e.g., aerosols released outside of containment, skin punctures with needles containing Risk Group 2 or 3 agents or genetic material from these agents).
 - e. Failure to adhere to the containment and biosafety practices described in the NIH Guidelines.
2. The following timelines will be used for institutional incident reporting to the agency:
 - a. Section IV-B-2-b-(7) of the *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)* states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research related accidents and illnesses" must be reported to the Office of Biotechnology Activities (OBA) within 30 days.
 - b. Appendix G of the *NIH Guidelines* specifies that certain types of accidents/incidents (i.e., 1.a and 1.b) must be reported immediately. A follow-up report will then be submitted as needed.