

To Whom It May Concern:

This memo has been drafted to address the process of reporting incidents encompassing recombinant DNA exposures as required by the *NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT DNA MOLECULES*. This document consists of multiple provisions describing safety, regulated experiments, and institutional roles and responsibilities. Listed below are excerpts corresponding to the issue of reportable incidents as required by these guidelines. For all questions concerning whether the nature of severity of the incident warrants reporting contact Environmental Health and Safety

Provisions from the Guidelines:

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.

Appendix G-II-B-2-k:

Spills and accidents which result in **overt exposures** to organisms containing recombinant DNA molecules are immediately reported to the Institutional Biosafety Committee and NIH/OBA.

Appendix Q-II-C-1-e-(2).

Any incident involving spills and accidents that result in **environmental release or exposure** of animals or laboratory workers to organisms containing recombinant DNA shall be reported immediately to the Biological Safety Office, Animal Facility Director, Institutional Biosafety Committee, NIH/OBA, and other appropriate authorities (if applicable).

What is Reportable:

Description provided below obtained from the NATIONAL INSTITUTE OF HEALTH FAQ of Interest to IBC, <http://www4.od.nih.gov/oba/IBC/Incidents.htm>.

1. Skin Punctures with needles containing recombinant DNA
2. Escape or improper disposition of a transgenic animal
3. Spills of high risk recombinant material occurring outside of a Biosafety Cabinet
4. Failure of an investigator to adhere to the containment and biosafety practices articulated in the guidelines

What is Exempt:

Description provided below obtained from the NATIONAL INSTITUTE OF HEALTH FAQ of Interest to IBC, <http://www4.od.nih.gov/oba/IBC/Incidents.htm>.

1. Minor spills involving low risk group agents not involving a breach of containment
 - a. Spill must be effectively cleaned and decontaminated
2. Adverse events experienced by participants in human gene transfer trials

Who should Report:

In addition to IBCs, incident reporting is also articulated as a **responsibility of institutions, BSOs, and principal investigators** under Sections IV-B-1-j, IV-B-3-c-(2), and IV-B-7-a-(3), respectively. Institutions have the discretion to determine which party should make these reports, and one report for each incident or set of information is generally sufficient.