

1. What kinds of incidents involving research subject to the *NIH Guidelines* must be reported to the NIH OSP?

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid 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 NIH 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. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH. Relevant incidents would include spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules in the laboratory, rather than serious adverse events that may occur in the conduct of human gene transfer research.

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2. How serious must a problem be to warrant reporting to NIH OSP?

Any spill or accident involving recombinant or synthetic nucleic acid molecule research of the nature described above or that otherwise leads to personal injury or illness or to a breach of containment must be reported to NIH OSP. These kinds of events might include skin punctures with needles containing recombinant or synthetic nucleic acid molecules, the escape or improper disposition of a transgenic animal, or spills of high-risk recombinant or synthetic materials occurring outside of a biosafety cabinet. Failure to adhere to the containment and biosafety practices articulated in the *NIH Guidelines* must also be reported to NIH OSP.

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. NIH OSP should be consulted if the Institutional Biosafety Committee (IBC), investigator, or other institutional staff are uncertain whether the nature or severity of the incident warrants reporting; NIH OSP can assist in making this determination.

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3. Who is responsible for reporting incidents involving research subject to the *NIH Guidelines* to NIH OSP?

Under the *NIH Guidelines*, incident reporting is articulated as a responsibility of the Institution, IBC, Biological Safety Officer, and Principal Investigator. 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.

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4. What information should incident reports include?

Incident reports should include sufficient information to allow for an understanding of the nature and consequences of the incident, as well as its cause. A detailed report should also include the measures that the institution took in response to mitigate the problem and to preclude its reoccurrence. An [incident reporting template](#) is available to facilitate reporting of incidents under the *NIH Guidelines*. The template may be found on the NIH OSP website. Use of the template is not required and other report formats may be acceptable.

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5. What does NIH OSP do with this information?

NIH OSP staff review incident reports to assess whether the institutional response was sufficient. Depending on the adequacy of the institutional response, NIH OSP may ask the institution to take additional measures as appropriate to promote safety and compliance with the *NIH Guidelines*.

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6. Where should incident reports be sent?

Reports of incidents can be emailed to NIHGuidelines@od.nih.gov.

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7. Where can I get more information about the *NIH Guidelines*?

Questions about the *NIH Guidelines* may be directed to NIH OSP staff at NIHGuidelines@od.nih.gov. Staff may also be reached at (301) 496-9838.

The incident reporting template is available at: [Incident Reporting Template - 2019](#)

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