Incident Reporting

1. What kinds of incidents involving research subjects must be reported under the NIH Guidelines to the NIH Office of Science Policy (OSP)?

The NIH Guidelines for *Research Involving Recombinant* or *Synthetic Nucleic Acid Molecules* 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.

Spills or accidents in Biosafety Labs Level 2 (BSL-2) laboratories resulting in an exposure must be immediately reported to NIH.

- Relevant incidents include spills and accidents which result in overt exposures to organisms containing recombinant or synthetic nucleic acid molecules (r/sNA) in the laboratory.
- Serious Adverse Events (SAEs) that may occur in the conduct of the human gene research are reported as per the protocol to the Sponsor/CRO.
- Certain types of accidents must be reported on a more expedited basis.

2. What are some examples of incidents that require reporting?

Any spill, breach of containment or accident as shown below, or otherwise leads to personal injury or an illness, must be reported to the NIH OSP.

- Skin punctures with needles containing recombinant or synthetic nucleic acid molecules.
- Spills of synthetic r/sNA materials occurring outside of a biosafety cabinet.
- Failure to adhere to the NIH Guidelines for biosafety practices.
- 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.
- CBS on behalf of the institution will consult with NIH OSP if the IBC, investigator, or other institutional staff are uncertain regarding 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?

Institution | Institutional Biosafety Committee | Biological Safety Officer | Principal Investigator

Notifications: In the event of a spill of study agent or potential exposure of staff to the study agent, the PI must be notified immediately and in turn notify the IBC via your CBS Associate Partner.

The IBC will then determine whether formal notification is required to the NIH Office of Science Policy via the reporting form on the NIH website.

4. What information should incident reports include?

1. Sufficient information to allow for an understanding of the nature and consequences of the incident, as well as its cause.
2. Measures taken to mitigate said problem and preclude its reoccurrence.

An incident reporting template is available to facilitate reporting of incidents under the NIH Guidelines.

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Use of the template is not required and other report formats may be acceptable.

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5. What does the 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 to promote safety and compliance with the NIH Guidelines.

6. Where should incident reports be sent?

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

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

Questions about the NIH Guidelines may be directed to your CBS Associate Partner or NIH OSP staff at:

(301) 496-9838 | NIHGuidelines@od.nih.gov

Questions?

info@clinicalbiosafety.com

1-888-442-2472

clinicalbiosafety.com