FAQs on Incident Reporting

1. What kinds of incidents involving recombinant DNA 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 OSP 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 OSP. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH OSP

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

Any spill or accident involving recombinant DNA 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 OSP. These kinds of events might include skin punctures with needles containing recombinant DNA, the escape or improper disposition of a transgenic animal, or spills of high-risk recombinant 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 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. 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; OSP can assist in making this determination.

3. Who is responsible for reporting incidents involving recombinant DNA 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 from OSP to facilitate reporting of incidents under the NIH Guidelines. The template may be found at: http://osp.od.nih.gov/wp-content/uploads/2016/08/Incident Reporting Template – 2016_1.docx Use of the template is not required and other report formats may be acceptable.

5. What other information needs to be provided?

Depending on the severity of the incident, OSP staff may request the IBC meeting minutes documenting approval conditions for the research, minutes of IBC meetings where the incident was reviewed, policies in place at the time the incident occurred, or any revised policies prepared in response to the incident. Training records for the personnel involved in the incident may also be requested.

6. What does OSP do with this information?

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

7. Do adverse events experienced by participants in human gene transfer trials fall under this incident reporting requirement?

No, adverse events in human gene transfer trials are subject to a separate set of reporting requirements. These are found in Appendices M-1-C-3 and M-1-C-4 of the NIH Guidelines. Serious adverse events that are unexpected and possibly associated with the gene transfer product should be reported to OSP within 15 calendar days of sponsor notification, unless

they are fatal or life threatening, in which case they should be reported within 7 calendar days. Other serious adverse events should be reported to OSP as part of the Principal Investigator's annual report to OSP.

8. To report an incident involving an exposure, loss of containment, a violation of the NIH Guidelines or other compliance issue to OSP contact:

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