

# 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.



Any incident which results in a potential exposure(s) to study agent(s) must be immediately reported to CBS (your Institutional Biosafety Committee) and may then be reportable to the NIH OSP

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



Skin punctures with needles containing **study agent(s)**



Spills of study agent(s) during preparation or administration



Failure to adhere to the IBC approved procedures



Splash, droplet, or aerosols that lead to mucus membrane exposures (eyes, nose, or mouth)



Unexpected illness, signs, or symptoms that occur after handling the study agent(s)

### 3. Who is responsible for reporting incidents?



Study  
Staff



Site  
Regulatory Team



Biological Safety  
Officer



Principal  
Investigator

Notifications to your CBS IBC: [cbsTeam@clinicalbiosafetysafety.com](mailto:cbsTeam@clinicalbiosafetysafety.com)

CBS will assist the Institution and the PI in reviewing the incident, determine if formal notification of NIH OSP is warranted, and will notify your IBC of the incident.

Note that at anytime, the Institution or PI, at their discretion, can directly notify the NIH OSP.

### 4. What information should incident reports include?

It is highly recommended that the Institution and the PI work with CBS to complete the NIH OSP Incident Report.

The Institution and the PI can refer to the instructions provided in the NIH OSP Incident Reporting Template.



[https://osp.od.nih.gov/wp-content/uploads/Incident-Reporting-Template\\_42319.docx](https://osp.od.nih.gov/wp-content/uploads/Incident-Reporting-Template_42319.docx)



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



888-442-2472



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