



Unanticipated Problem Report Form and Coversheet



This form should be completed for reporting unanticipated problems involving risks to research subjects or others. For further guidance, refer to the [CGIRB Investigator Guidebook](http://www.cgirb.com) at www.cgirb.com.

Blank & incomplete answers result in delayed reviews!

Protocol #: _____

IRB Tracking #: _____

Principal Investigator: _____

Phone: _____

Fax Number: _____

Name and Title of Person Completing this Form: _____

This report is for Subject(s): (Include Subject Initials/#) _____ N/A

A description of the unanticipated problem (or attach separate form/sheet): _____

Additional forms or information may be attached; however, the assessment of the unanticipated problem being reported must be completed below.

- Adverse event (regardless of whether the event meets the FDA definition of “serious adverse event”), which in the opinion of the principal investigator is both unexpected and related.
- Information that indicates a change to the risks or potential benefits of the research
- A breach of confidentiality
- Change in FDA labeling or withdrawal from marketing of a drug, device, or biologic used in a research study.
- Change to the protocol taken without prior CGIRB review to eliminate an apparent immediate hazard to a research subject.
- Incarceration of a subject in a research study not approved to enroll prisoners.
- Event that requires prompt reporting to the sponsor
- Sponsor-imposed suspension for risk
- Complaint of a subject when the complaint indicates unexpected risks or cannot be resolved by the research team
- Allegations or findings of noncompliance
- Significant protocol deviations
- Unanticipated adverse device effect

If any of the above is checked, **corrective actions must be listed below**, including measures taken to ensure that similar problems do not occur in the future. A separate page may be attached if necessary.

Signature (PI or authorized designee)

Signature Date