

Responsibility Reminder

March 2010

REPORTING UNANTICIPATED PROBLEMS

Compass IRB expects the following unanticipated problems to be reported by Investigators/Sponsors/CROs:

- Adverse events which in the opinion of the principal investigator are both unexpected and related.
- An unanticipated event related to the research that exposes participants to potential risk
- An unanticipated event related to the research that exposes individuals other than the research participants (e.g., investigators, research assistants, students, the public, etc.) to potential risk
- Information that indicates a change to the risks or potential benefits of the research. For example:
 - An interim analysis or safety monitoring report indicates that frequency or magnitude of harms or benefits may be different than initially presented to the IRB.
 - A paper is published from another study that shows that the risks or potential benefits of your research may be different than initially presented to the IRB.
- A breach of confidentiality.
- Incarceration of a participant in a protocol not approved to enroll prisoners.
- Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a research participant.
- Complaint of a participant when the complaint indicates unexpected risks or cannot be resolved by the research team.
- Protocol violation (meaning an accidental or unintentional change to the IRB approved protocol) that harmed participants or others or that indicates participants or others may be at increased risk of harm.
- Event that requires prompt reporting to the sponsor.
- Sponsor imposed suspension for risk.
- Any other event that indicates participant or others might be at risk of serious, unanticipated harms that are reasonably related to the research.

The principal investigator is responsible for reporting all unanticipated problems to trial sponsors and Compass IRB; however, he/she may delegate the data collection and communication of such events to appropriate clinical site research personnel. Any recommendations to amend the protocol or consent in light of the information contained in the report should also be documented.

It is required that the investigators use the Unanticipated Problem Report Form as a type of cover/summary sheet when submitting these types of reports to Compass IRB.

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For your reference

In attempt to mirror the FDAs 2009 Industry Guidance regarding Adverse Event Reporting (<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126572.pdf>) and AAHRPP Accreditation Standards, Compass IRB now only requires reports on "unanticipated problems." The Unanticipated Problem Reporting Form can be found on our website under the FORMS link. Please help us match the industry guidance by only submitting your safety reports and/ or individual reports for adverse events that are considered "unanticipated problems." Compass IRB knows that this may be a change from how your site has ran reporting thus far, so we would like to thank you in advance for your patience and cooperation while we make this transition.