Rev 07/19/16 kbk

Unanticipated Problems Involving Risks to Subjects or Others

Instructions & Report Form

Note: Form to submit to IRB Chair appears at end of document

Federal regulations [45CFR46.103(b)(5) and 21CFR56.108(b)(1)] require the IRB to ensure that investigators promptly report "any unanticipated problems involving risk to subjects or others" (UPIRTSO). The IRB defines UPIRTSO as any problem or event which in the opinion of the local investigator was unanticipated, serious and at least possibly related to the research procedures. These should be reported to the IRB within 10 working days using the attached form signed by the principal investigator.

The following events meet the IRB's definition of UPIRTSO and should be reported within the 10 day time frame:

- Any serious event (including on-site and off-site adverse events, injuries, side effects, deaths or other problems) which in the opinion of the local investigator was unanticipated, involved risk to subjects or others, and was possibly related to the research procedures;
- Any serious accidental or unintentional change to the IRB-approved protocol that involves risk or has the potential to recur;
- Any deviation from the protocol taken without prior IRB review to eliminate apparent immediate hazard to a research subject;
- Any publication in the literature, safety monitoring report (including Data and Safety Monitoring Reports), interim result or other finding that indicates an unexpected change to the risk/benefit ratio of the research;
- Any breach in confidentiality that may involve risk to the subject or others;
- Any complaint of a subject that indicates an unanticipated risk or that cannot be resolved by the research staff; or
- Any other serious and possibly related event which in the opinion of the investigator constitutes an unanticipated risk.

Anticipated (expected) problems are those that are already described as potential risks in the consent form, listed in the Investigator's Brochure or part of an underlying disease. These do NOT meet the IRB's definition of UPIRTSO and should be reported in summary form only at the time of IRB continuing review, regardless of whether serious or related. For example, if death is an expected outcome, this event should be reported only at the time of continuing review.

Serious problems/events are those which in the opinion of the local investigator involve risk to subjects or others. Examples include death, hospitalization, disability as well as breach of confidentiality. ***Non-serious*** problems/events do NOT meet the IRB's definition of UPIRTSO and should be reported in summary form only at the time of IRB continuing review.

Problems/events that are unanticipated and serious should be reported to the IRB within 10 days *only* if in the opinion of the local investigator they are possibly, probably or definitely ***related*** to the research procedures. Those serious, unanticipated problems/events that the local investigator deems unlikely or ***not related*** do NOT meet the IRB's definition of UPIRTSO and should be reported in summary form only at the time of IRB continuing review.

All problems/events that do NOT meet the IRB's definition of UPIRTSO should be reported to the IRB in summary form (using a table or spreadsheet) at the time of annual continuing review. Accompanying documentation (sponsor report forms, etc.) should NOT be included with this summary. If received, such accompanying documentation will be returned to the investigator.

Unanticipated Problems and Events
Study Title:
PI:
IRB#:
Date Submitted to IRB:

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Reporting Form for Unanticipated Problems Involving Risks to Subjects or Others

IRB Number:	
Current Principal Investigator:	
Study Title:	

Provide the following information for <u>each</u> unanticipated problem/event that is serious and possibly related to the research procedures. Attach any summary or report from sponsor or DSMB with corresponding reference number.

Reference #:	
Date of Event:	
Date of Report:	

On-site ☐ **Off-site** ☐ **Initial report** ☐ **Follow up report** ☐

Describe problems/event:

Possibly related ☐ **Probably related** ☐ **Definitely related** ☐

Does this problem/event alter risk to past, present or future subjects?
Yes ☐ **No** ☐ **Don't Know (Insufficient Information)** ☐

Based on your, the local investigator's judgment, should this problem/event be added to the consent form as a potential risk?
Yes ☐ **Provide revised consent form with changes highlighted.**
No ☐ **Explain why not:**

Based on your, the local investigator's, analysis of this problem/event,
should currently enrolled subjects be notified? **Yes** ☐ **No** ☐
should subjects who have completed the study be notified? Yes ☐ **No** ☐
Explain:

_____ _____
Principal Investigator's Signature Date

Unanticipated Problems and Events
Study Title:
PI:
IRB#:
Date Submitted to IRB: