


Unanticipated Problem Committee Member Review

Beginning, December 8, 2007 Unanticipated Problem reporting has been expanded.

A new page has been added to the Reviewer Checklist form. These review items are based on the study team’s response to questions on the Adverse Event/ORIO form. This page replaces the existing potential Unanticipated Problem checklist questions and will only appear if the AE/ORIO submission contains a potential Unanticipated Problem.

Comments are required for each question on this page.


Edit: Submission Review - REV00024289

Save | Exit | Hide/Show Errors | Print... | Jump To: Unanticipated Problem
Continue >>

Single Member Review for Adv00001942 - IRB Primary Reviewer
 HUM00013085 - AE Test

Print Version of Submission
 Change Log for Submission
 All Issues

Unanticipated Problem Questions

This submission contains one or more potential unanticipated problems. Such events or information must be assessed by the IRB to determine if they constitute "an unanticipated problem involving risks to subjects or others" (45 CFR 46 §46.103 (b)(5)). If the answer to one or more of the first three checklist questions is "No" the event/information is not an "unanticipated problem" and will be routed per standard IRB procedures.

- 1 * Does the event or information suggest that the research places subjects or others at a greater risk of harm than was previously known or recognized?

Yes No [Clear](#)

* Comment Required:
- 2 * Is the event or information related to (caused by) the research?

Yes No [Clear](#)

* Comment Required:
- 3 * Is the event or information unexpected in terms of the nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents and (b) the characteristics of the subject population being studied?

Yes No [Clear](#)

* Comment Required:

Check here to send an email to IRB staff that an IRB chair should be notified immediately about this problem. (NOTE: this email will not be sent until you submit your review). If needed, use the comment boxes above to indicate why a chair should be notified.