

## Unanticipated Problems FAQs (Updated 11/13/2007)

Q1.

How do I determine if an event is reportable under the new policy?

A2.

Start by opening a "New Unanticipated Problem" just like you used to open a new Adverse Event. The first page has been revised to include a decision tree. Use the decision tree to "categorize" the event using the four possible reporting categories. If your event does not fit into any of the categories, it's not reportable. In this case, click the EXIT word within the fifth category box. This will exit the submission without saving. If it does fit into one of the categories, check the appropriate category and click continue to proceed with the submission. For reporting multiple events within the same submission, indicate all the categories that apply before proceeding with the submission.

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Q2.

What do I tell a sponsor (industry or otherwise) who insists that we report an event that we (the PI) believes is not reportable under the new OHSU policy? The IRB has created a one page "Information Letter on OHSU UP Reporting Policy" that you may download from the IRB website.

A2.

Use this to present to sponsors. If they insist that an event is reportable, even after reviewing our policy and the federal regulations supporting it, they must submit a written statement with the basis of their UP Determination, specifically listing the OHSU UP category in which it applies (1 thru 4). As always, the IRB reserves the right to request additional information upon review of your submission.

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Q3.

What if I start to create a UP submission and I determine it is not reportable, what can I do?

A3.

If you determine that the event does not fit within the four (4) categories on the first page of the UP Questionnaire, you can choose the fifth category and click the EXIT button. This will allow you to exit the submission without saving. If you have gone past this point and have started to complete the report, you can request the PI to "withdraw" the action. This should be an "Available Action" for the PI only. If you are still unable to "withdraw" the submission, contact the Managing Analyst for assistance.

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Q4.

The old AE reporting policy stated that all events must be reported if the events occur within 30 days post procedure or the discontinuation of study drug(s). Does this 30 day window still apply under the new unanticipated problems policy? In other words, if a subject is still being followed but not on study drug or it has been 30 days past their procedure, does the unexpected event still need to be reported?

A4.

The 30 day window no longer applies. If an event meets the definition of unanticipated problem, then it should be reported regardless of time since intervention.

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Q5.

Are VA patients considered OHSU subjects on an OHSU protocol?

A5.

It depends. If there is a separate protocol at the VA, which was reviewed by the VA IRB, then they are VA subjects. If they are VA patients who are recruited into an OHSU study, then they are OHSU subjects.

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Q6.

What if a study has multiple monitoring entities, for instance a DSMB and a medical monitor, which do we submit as the monitoring entity?

A6.

The most comprehensive monitoring entity. In the given example, that would be the DSMB.

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Q7.

If the monitoring plan is incorporated into the protocol, but a few elements are missing or clarifications are needed, does the protocol need to be changed?

A7.

It's always best to change the protocol so that there is one document rather than a patchwork of information. If, however, it's very difficult to change the protocol, then a memo from the sponsor including the missing information will suffice.

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Q8.

I don't understand what I am supposed to report in the Annual Event Summary.

A8.

With respect to Annual Event Summaries, consider what the IRB is trying to accomplish at continuing review. At the time of continuing review, the IRB

should ensure that the criteria for IRB approval under HHS regulations at 45 CFR 46.111 continue to be satisfied.

In particular, the IRB needs to determine whether:

- Any new information has emerged either from the research itself or from other sources that could alter the IRB's previous determinations, particularly with respect to risk to subjects. In most cases, the information regarding any unanticipated problems that have occurred since the previous IRB review will be pertinent to the IRB's determinations at the time of continuing review.
- Provisions under the previously approved protocol for monitoring study data to ensure safety of subjects have been implemented and are working as intended (e.g., the IRB could require that the investigator provide a report from the monitoring entity described in the IRB-approved protocol).

Given that, Investigators must submit an annual event summary of any unanticipated problems (which were hopefully reported) and available information regarding adverse events and any recent literature that may be relevant to the research.

The amount of detail provided in such a summary will vary depending on the type of research being conducted. In many cases, such a summary could be a simple brief statement that there have been no unanticipated problems and that adverse events have occurred at the expected frequency and level of severity as documented in the research protocol, the informed consent document, and any investigator brochure.

Local investigators participating in multicenter clinical trials usually are unable to prepare a meaningful summary of adverse events for their IRBs because study-wide information regarding adverse events is not readily available to them. In such circumstances, when the clinical trial is subject to oversight by a monitoring entity (e.g., the research sponsor, a coordinating or statistical center, or a DSMB/DMC), at the time of continuing review local investigators should submit to their IRBs a current report from the monitoring entity. Such reports should include the following:

- (1) a statement indicating what information (e.g., study-wide adverse events, interim findings, and any recent literature that may be relevant to the research) was reviewed by the monitoring entity;
- (2) the date(s) of the review; and
- (3) the monitoring entity's assessment of the information reviewed.