Health Sciences IRBs Unanticipated Problems Reporting Decision Tree, Effective Date 3/1/2013

Start Here

Was the event caused by or associated with a device being tested in a clinical trial?

Yes

Was the event not previously identified in nature, severity, or frequency in any IRB documents (e.g., consent forms, application materials) OR does the event relate to the rights, safety, or welfare of subjects?

Yes

Is the event immediately life-threatening or severely debilitating to other current subjects or non-participants?

Yes

Report to IRB Chair/Director w/in 1 business day

No

If the event is immediately life-threatening or severely debilitating to other participants, report to IRB Chair/Director w/in 1 business day; otherwise, report w/in 10 business days (5 if VA)

No

Was the event probably caused by or associated with study participation?

No

Is the event unexpectedly?

Yes

Report w/in 14 business days

No

Is the event not previously identified in nature, severity, or frequency in any IRB documents (e.g., consent forms, application materials) OR does the event relate to the rights, safety, or welfare of subjects?

No

Was the event probably caused by or associated with study participation?

Yes

Did the event 1) occur on a VA study AND 2) represent an unanticipated or event or unanticipated problem involving risks to subjects or others that occur?

Yes

See the reportable event example table for other events that require reporting to the IRB at https://kb.wisc.edu/hsirbs/18324. If you are unsure whether to report, contact the IRB Office at 263-2362.

No

Was the event probably caused by or associated with study participation?

Yes

Does the event suggest that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized?*

Yes

No

Will the event, effect, or problem result in a sponsor-initiated (or investigator-initiated in the case on non-industry-sponsored research) change to the IRB application, study protocol, or consent documents or result in the provision of new information to participants or others?

Yes

Does the study have a formal, independent data & safety monitoring board (DSMB) or data monitoring committee (DMC)?

Yes

Did the event occur at a site or involve a participant under UW purview?

Yes

Report at continuing review

No

Do not report to the IRB

No

Do not report to the IRB UNLESS the event occurs in local VA subject

Yes

Report w/in 5 business days

* This includes any of the following scenarios per the FDA:

1) Any adverse experience that, even without detailed analysis, represents a serious unanticipated event that is strongly associated with drug exposure (such as agranulocytosis, hepatic necrosis, Stevens-Johnson Syndrome); OR

2) A series of adverse events that, on analysis, is both unanticipated and a problem for the study (i.e., the series of events represents a signal that the adverse events were not just isolated occurrences and represent an unanticipated problem); OR

3) An adverse event that is described or addressed in the investigator’s brochure, protocol, or informed consent documents that occurs at a specificity or severity that is inconsistent with prior observations OR for which the rate of occurrence in the study represents a clinically significant increase in the expected rate of occurrence; OR

4) A single occurrence (more often a small number of occurrences) of a serious, unexpected event not commonly associated with drug exposure, but uncommon in the study population.