Investigator Guidance Series

ADVERSE EVENTS/UNANTICIPATED PROBLEMS ASSESSMENT

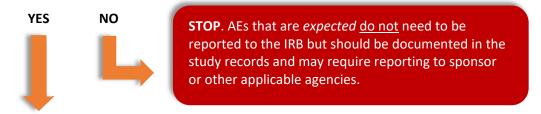
Not all adverse events constitute unanticipated problems that need to be reported to the <u>University</u> of <u>Utah</u> IRB. How do you determine whether or not to submit a report of an adverse event to the IRB? Use the flowchart below to decide whether the event meets IRB reporting requirements.



Was the AE unexpected?

Do any of the following apply?:

- Was the event unexpected from either the participant perspective or study team perspective?
- Was the even unforeseen in terms of nature, severity, frequency, etc.?
- Was the risk <u>not</u> listed in the consent form?



Was the AE definitely or probably **related** to the research?

- "Related" means attributable to procedures of the research. In other words, if the participant was not in the study, could this event have occurred as a result of other factors?
- If an event is deemed only "possibly" related to the research, it does not typically qualify as an unanticipated problem.
- If there is not enough information to attribute relatedness to the research, the
 event likely does not meet the University of Utah IRB's reporting threshold. If
 future information about the event is discovered, a report form may be
 necessary at that time.

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.

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YES

NO



STOP. AEs that are *not related* do not need to be reported to the IRB but should be documented in the study records and may require reporting to sponsor or other applicable agencies.

Are participants placed at a **greater risk of harm** than previously known as a result of the AE?

- This may include physical, psychological, economic, or social harm, etc.
- Please consider whether or not the consent form is being updated with a new risk. If so, it is likely participants are placed at a greater risk of harm as a result of the event.

YES

NO





STOP. AEs that do not pose a *greater risk of harm* than previously known <u>do not</u> need to be reported to the IRB but should be documented in the study records and may require reporting to sponsor or other applicable agencies.

This adverse event may represent a possible unanticipated problem and should be reported to the IRB via a <u>report form</u>.

Please Note: Investigators are required to submit possible unanticipated problems to the IRB as soon as possible after the study team learns of the event. The <u>University of Utah</u> IRB's policy for timeline of reporting is within 10 working days (5 working days for VA).

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