ADVERSE EVENTS/UNANTICIPATED PROBLEMS ASSESSMENT

Not all adverse events constitute unanticipated problems that need to be reported to the University of Utah 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.

1. Adverse Event (AE) occurs
2. Local PI evaluates the event, in conjunction with the sponsor (if applicable)
3. 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 not listed in the consent form?
   - YES
   - NO
4. STOP. AEs that are expected 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.
5. 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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