Tips and Reminders: Adverse Event Reporting

Not all adverse events will constitute unanticipated problems (UP) that require reporting to the University of Utah IRB. To be considered reportable, the event must be *unexpected* **AND** *related* **AND** present a *greater risk of harm* to the participant. See below for more details!

Unexpected

- Was the event unexpected from either participant perspective or the study team perspective?
- Was the event unforeseen in terms of nature, severity, frequency, etc.?
- Was the risk NOT listed in the consent form?

STOP

If the AE was expected, it does not need to be reported to the IRB, but may still need to be reported to the sponsor or other applicable agencies

Related

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

STOP

If the AE was unrelated, it does not need to be reported to the IRB, but may still need to be reported to the sponsor or other applicable agencies

Greater Risk of Harm

- This may include physical, psychological, economic, or social harm, etc.
- Please consider whether the consent form is being updated with a new risk. If so, it is likely participants are placed at a greater risk of harm because of the event.

STOP

If the AE does not pose a greater risk of harm previously known, it does not need to be reported to the IRB, but may still need to be reported to the sponsor or other applicable agencies

If all three criteria above are met, the adverse event may represent a possible unanticipated problem and reported promptly to the IRB using the Report Form application in ERICA.