An adverse event occurred on a different study and my sponsor is asking me to report it for my study. What do I do?

Occasionally, a sponsor will request that an external adverse event be reported for a study on which the event did not occur. For example, an adverse event of side effects from a certain drug may be reported on several studies involving that drug, even if the adverse event occurred in a subject enrolled on only one specific study. In this case, the non-study adverse event should be reported to the IRB in the same manner as other events; the investigator should determine whether the event represents an Unanticipated Problem according to the IRB definition. If the event meets the reporting requirements, it should be reported to the IRB using the "Unanticipated Problem Report" form in AURA.

If the event does not meet reporting requirements, it may be included in the summary of events reported at the time of continuing review for this study.

If the adverse event does not meet IRB reporting requirements and it is submitted to the IRB office as an unanticipated problem, it may be returned to you. Please see the Policies and Procedures page for the University of Chicago BSD/UCMC IRBs unanticipated problem reporting policy.

If an adverse event does not meet the IRB reporting criteria, does it need to be reported to the IRB? What if my sponsor tells me the adverse event must be reported?

If the PI determines that an adverse event (AE), whether internal or external, does not meet the IRB Unanticipated Problem (UP) reporting criteria, it should not be submitted to the IRB for review as an unanticipated problem. Please note that the BSD/UCMC IRB reporting criteria may differ from sponsor or other reporting criteria. Any adverse event submitted as a UP that does not meet the IRB reporting criteria will be returned.

All AEs that do not meet UP reporting criteria can be summarized at the time of continuing review. Any sponsor that insists that an AE that does not meet our reporting criteria be submitted should be notified of the IRB's Unanticipated Problem reporting policy.

My sponsor wants me to submit a list of adverse events (AEs) more frequently than at the time of continuing review. Should I submit these per the sponsor request?

If the adverse event lists contain AEs that **do** meet the U of C Unanticipated Problem reporting criteria, these AEs should be submitted to the IRB on an individual basis as unanticipated problems. All other AEs that **do not** meet the IRB reporting criteria should be summarized at the time of continuing review. Any list of AEs not meeting unanticipated problem reporting criteria

that are submitted to the IRB at a time other than during the continuing review process will be returned to the PI, as per the above.

As these AEs do not represent a change to the approved study, they should not be submitted with an amendment. An amendment is only needed if AEs require a change in the protocol (such as a consent form change) and thus an amendment would only be expected to report an AE if the AE meet the criteria for a UP report.

What safety events do I report at time of continuing review?

For studies involving an experimental drug, device, or other intervention, it is probable that events will have occurred on study that are **expected** safety events and/or events that do **not** suggest that the research places subjects or others at a risk of unknown harm or addition/increased frequency of harms. These are events that do not meet the criteria for reporting as an Unanticipated Problem. However, it is the expectation of the IRB that these events will be reported to the IRB; reporting of these events should be done at the time of continuing review.

With a continuing review submission, researchers are expected to report all safety events that have occurred in the prior year, regardless of whether they met the criteria for reporting as an unanticipated problem and regardless of whether a sponsor deemed the event "serious." A summary of events should be provided on the AURA continuing review form. Detailed lists of these events can be uploaded to the continuing review form in addition to providing the summary. Researchers are expected to report both internal events that occurred with UChicago subjects and, for multisite studies, external events.

View 1.4, question 1 of the continuing review form asks the researcher to report any deviations that have occurred. Question 2 asks the researcher to report other events, as follows:

> "Safety and Other Reporting: Please summarize other problems, adverse events or safety concerns that occurred in the past year at all sites (including UChicago). Please separate those that have occurred under the University of Chicago protocol versus those events occurring at other sites."

The "not meeting reporting requirements" in this sentence refers to not meeting "Unanticipated Problem" reporting requirements. Please provide a summary of all problems and safety concerns/events that have occurred at all sites since the previous continuing review, or, if this is the first continuing review submission, since the original approval of the protocol.

If applicable, a detailed list of events can be uploaded in view 1.7 of the continuing review form in addition to providing the summary.

What are a PI's responsibilities in the event a subject discloses an intent to harm self or others?

Clinical guidance suggests that should any participant indicate either verbally or in writing an intent to harm oneself or others, it is imperative for the investigator to get the person to the ER for an assessment of risk. This can be done either voluntarily by the participant, with the investigator accompanying the participant to the ER, or better, the researchers contact Security and indicate that they need an escort to the ER for a person indicating risk. The researchers can also page the Psychiatrist on call who will guide them in this process.