

## EXTERNAL ADVERSE EVENT REPORTING

An External Adverse Event is an event that occurs in a non-USC participant that has been reported to the USC Investigators. In multi-site trials, investigators receive from the sponsor safety reports including IND Safety Reports and MedWatch Reports. Such reports are considered External Adverse Event Reports. The USC IRB will accept submission of these External Adverse Events only when they meet specific criteria.

USC Investigators are to report to the USC IRB External Adverse Events as follows (see flowchart below):

If the External Adverse Event occurred in the same study as is being conducted at USC, the event should be reported if it is serious AND unexpected AND related to the drug/device/intervention. Such reports undergo expedited review if there is no change in the protocol and/or informed consent form and full board review if the event results in changes in the protocol or consent, or the study requires a hold/suspension.

If the External Adverse Event occurred in a study not conducted at USC the event should be reported if it is serious AND unexpected AND related to the drug/device AND requires a change in the protocol and/or informed consent form, or the study requires a hold/suspension. Such reports are reviewed by the full board.

If the informed consent document is required to be revised, the IRB may require that all current and previous subjects be re-consented. The IRB chair, at his/her discretion, may refer any other adverse event to the full board for review.

Other external adverse events should be reported in summary format at the time of continuing review. The only exception is if after review by the Sponsor or DSMB, the event prompts a change in the risk-potential benefit profile. This change in the risk-potential benefit profile should be reflected in an amendment to the USC IRB approved research proposal which should include the Sponsor or DSMB's assessment of this change and the USC PI's assessment of the change.

The External Adverse Event should be reported using iStar for all iStar studies and for legacy studies that have been converted to iStar. For legacy studies that have not yet been converted the report should be submitted using the External Adverse Event paper forms. Events should not be grouped, only one event per form or iStar submission. Pertinent supporting documents should be attached.

**Flowchart for Considering External Adverse Event Reporting**

