Center for Clinical and Translational Science

# ADVERSE EVENT LOG INSTRUCTIONS

## PURPOSE

This tool is used to document, track, and report adverse events.

## HOW TO USE

- Complete the form header by adding the study title and investigator name.
- Upon becoming aware of an adverse event, complete the log entries as follows:
    - Participant Number or ID code, their study start and end dates and a description of the Adverse Event. Note: if the participant has not completed the study, use TBD (To Be Determined) to complete the entry instead of the end date.
    - If the Adverse Event meets the requirements for a Serious Adverse Event mark the "*Indicates SAE" section with an asterisk *. Include the AE start and End dates. Note: if the AE has not resolved mark it as "continuing" or use TBD until the time a stop date becomes available.
    - Assess the intensity of the AE/SAE as either mild, moderate or severe by marking the appropriate category.
    - Assess the causality (or relatedness) of the AE/SAE to the study using the descriptions provided in the causality key.
    - Assess the relationship of the AE/SAE to the study by determining if it is an anticipated (expected) or unanticipated (unexpected) event.
    - Complete the IRB Reporting section by identifying if the AE/SAE was sent for IRB review as "Prompt" or Non-prompt". Be sure to include the serial number of the IRB submission under which it was reported, as it becomes available.
- The study PI should review the form, and sign and date as appropriate.

## GOOD PRACTICE RECOMMENDATIONS

- Use this log to track AE/SAE's for individual participants as well as for the entire study. In order to do so, keep a participant specific copy in the participant's file and a study copy (listing all the AE/SAE's for the study) in the coordinator's binder for reporting at Continuation Review.
- Review and update the log regularly, have the PI sign and date the participant specific copies as they complete the study/at their final study visit
- Be sure to customize the template to make it study specific.