KU KMCRI
Kansas Masonic
Cancer Research Institute

UNIVERSITY OF KANSAS MEDICAL CENTER
PROTOCOL REVIEW AND MONITORING COMMITTEE
SERIOUS ADVERSE EVENT SUMMARY REQUIRED FOR ANNUAL REVIEW (CONTINUING REVIEW)

Instructions:

Please complete the HSC Continuing Review Form (and any relevant and related documents) and attach to that form a completed Serious Adverse Event Summary for annual review by the Protocol Review and Monitoring Committee (PRMC).

****The Serious Adverse Event Summary only requires information related to patients that are KU subjects or in the instance that the University of Kansas Medical Center is the institution that registers patients on a particular study and assigns the study IDs.** ***(Please refer to the HSC instructions regarding completion of the HSC continuing review form portion of this submission.)***

1. The following items should be summarized on the Serious Adverse Event Summary:
    a) Please complete the header information: PI name, Date form is being completed, HSC# and PRMC#.
    b) Please summarize each serious adverse event that was reported in the last annual review reporting period with the following information:
        - Date that the Serious Adverse Event was reported to the Human Subjects Committee;
        - The Study ID of the patient that the event involved;
        - A brief description of the event based on CTC categories and descriptions;
        - The Grade of the event (Please click on "Grade" header to see appropriate options for completion;
        - The Relationship to study/study drug/intervention (Please click on "Relationship" header to see appropriate options for completion); and
        - Was the consent form modified as a result of the serious adverse event: Yes or No

****Once the entire Continuing Review Submission (including the Serious Adverse Event Summary) is reviewed and approved the Protocol Review and Monitoring Committee will forward your original submission and appropriate copies on to the Human Subjects Committee for the next available deadline. A copy of the PRMC approval letter will be sent to the principal investigator and appropriate study personnel as well as included in each packet forwarded on to the HSC.**