

University of Kentucky

**IRB Cover Form for Non-Prompt Reporting of Problems/Adverse Events**

This cover form should be used if the Sponsor requires the PI to report incidents not required to be reported by the [UK IRB Policy on Unanticipated Problem and Safety Reporting](#) or if the PI wishes to report an incident which does not meet prompt reporting guidelines.

Protocol IRB #: \_\_\_\_\_

PI Name: \_\_\_\_\_

Study Title: \_\_\_\_\_

If you run out of room in any of the following boxes, please continue providing your information in a separate memo with the IRB # and signed by the PI. Attach all in a single PDF file to the E-IRB Unanticipated Problem Report ("Other Review").

**Describe the event(s) you are reporting** (if available, attach report information provided by sponsor):

These problems/events are included in the \_\_\_\_\_ Investigator's Brochure in the IRB-approved protocol records. *(provide date)*

These problems/events have been reviewed and analyzed by the Data Safety Monitoring Board (DSMB) and included in the \_\_\_\_\_ report on file with the IRB. *(provide date)*

**Required:**

*Check the applicable box:*

This submission contains \_\_\_\_\_ *(provide #)*

Internal problem(s)/adverse event(s)

This submission contains \_\_\_\_\_ *(provide #)*

External problem(s)/adverse event(s)

**Principal Investigator:** \_\_\_\_\_ **Date:** \_\_\_\_\_

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**For IRB Completion ONLY**

IRB Chair/Vice Chair \_\_\_\_\_ Date: \_\_\_\_\_