

University of Kentucky

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

This cover form should only be used if the Sponsor requires reporting incidents not required to be reported by the UK IRB Policy on Unanticipated Problem and Safety Reporting.

Protocol IRB #: _____

PI Name: _____

Study Title: _____

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: _____

Submit to:

IRBSubmission@uky.edu

For IRB Completion ONLY

IRB Chair/Vice Chair _____

Date: _____