UK External Prompt Reporting Form					
PI Name:		**IRB Protocol #:**		**IBC #:**	
Title of Study:					

For Reporting *External* Unanticipated Problems Involving Risks to Subjects and Others or Research-Related Deaths to the Institutional Review Board (IRB)

This form should be used for reporting **external** problems/adverse events that meet the criteria for prompt reporting in the required timeframe as outlined in the *UK IRB Policy on Unanticipated Problem and Safety Reporting*. The majority of IND Safety Reports, MedWatch Reports, and CIOMS Reports **may not meet the criteria to** qualify as unanticipated problems involving risks to subjects or others. If the Sponsor requires the PI to submit reports to the IRB that do not meet the prompt reporting criteria, the PI may submit the *Cover Form for Non-Prompt Reporting of Problems/Events*.

***Please do not use this form if the event occurred with research subjects involved in research projects that fall under the purview of the UK IRB ("internal"). For internal reports, use the *UK Internal Prompt Reporting Form*.**

INSTRUCTIONS: Complete all applicable items. If items do not apply to your research, insert "N/A" (Not Applicable). Submit to: **IRBSubmission@uky.edu**

PI Telephone Number: _____

PI E-mail Address:

Project is extramurally funded:	○ Yes ○ No	If yes, list agency(ies)/sponsor(s):

Reporter name: _____

Reporter Telephone number: _____

Reporter E-mail address: _____

Optional (If you need the special reference numbers in the IRB approval letter, complete this box.)	
Site Adverse Event #:	
Sponsor's Identifier:	

Check the applicable boxes for the problem/adverse event:	
1. ☐	The problem/adverse event suggests that the research places subjects at a greater risk of harm than was previously known or recognized (including physical, psychological, economic, or social harm); and
2. ☐	The problem/adverse event was unexpected; and
3. ☐	The problem/adverse event is related or possibly related to participation in the research.
4. ☐	The problem/adverse event involves an unanticipated or anticipated death which is related to the study procedures.
5. ☐	The problem/adverse event does not fall under the IRB's prompt reporting requirements, but in the **PI's** judgment, prompt reporting of the event(s) is in the best interest of the subject (s) because it may affect the safety and/or welfare of subjects and/or change the risk level of the study.

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Problem/Adverse Event is listed in the Consent/Assent Form: ◯ Yes ◯ No ◯ No Consent Form

Consent/Assent should be revised:	◯ Yes If yes, attach revised form with changes highlighted. ◯ No ◯ No Consent Form

Presently enrolled subjects should be informed of problem/adverse event? ◯ Yes ◯ No

If yes, describe your plan for informing subjects _____

Risk/Benefit Ratio has changed in light of problem/adverse event: ◯ Yes ◯ No

Attach the Unanticipated/Serious Adverse Event/Safety Report	
Is the study closed to accrual and no active subjects currently enrolled or being followed or receiving research-related intervention?	
◯ Yes	If yes, PI may attach more than one report to this form. How many External Reports are attached? ____
◯ No	If no – the study is still open to accrual or there are active subjects currently enrolled and being followed or receiving test article – a separate form must be submitted for each event.

For Clinical Studies where the Principal Investigator (PI) is not a physician:

If this report is for a clinical study and the Principal Investigator (PI) is not a physician, a sub-investigator who is licensed to recognize, diagnose, and treat adverse events (e.g., MD or DMD) must review this report, and you, the PI, must confirm that an MD/DMD sub-investigator has reviewed and acknowledges the contents of this report:

Confirmed? ◯ Yes ◯ No

Principal Investigator Signature: _____ Date _____