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To Whom It May Concern:

SUBJECT: UK IRB Policy on Problems/Adverse Events That Require Prompt Reporting to the IRB

Federal regulations require IRBs to establish written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and applicable regulatory agencies, of any unanticipated problems involving risk to human participants or others. Please note that these written procedures may be different than those established by sponsors and/or other institutions. The University of Kentucky Institutional Review Boards' (IRB) policy on prompt reporting of problems involving risks to subjects or others and adverse events is contained within the UK IRB "Unanticipated/Anticipated Problem/Adverse Event Reporting" SOP which can be accessed at: [http://www.research.uky.edu/ori/human/SOPs\\_&\\_Policies.htm#2](http://www.research.uky.edu/ori/human/SOPs_&_Policies.htm#2). This letter only addresses the policy pertaining to problems/adverse events that require prompt reporting to the UK IRBs. The criteria are as follows:

(1) serious or life-threatening, AND (2) unanticipated AND (3) related to the study procedures; OR, (4) an unanticipated/anticipated death related to the research.

All problems/adverse events falling under the first three criteria above must be reported, using the appropriate UK Internal/External Prompt Reporting Form, within the following timeframes:

- If the event involves unanticipated life-threatening experiences, the event must be reported within 7 calendar days of the investigator's receipt of the information.
- All other serious and unanticipated events/problems must be reported within 14 calendar days of the investigator's receipt of the information.
- Follow-up reports on serious or life-threatening and unanticipated and possibly associated events should be reported within 14 calendar days of the investigator's receipt of information.

All unanticipated deaths and anticipated deaths related to the study procedures occurring during a research study must be reported using the appropriate UK Internal/External Prompt Reporting Form according to the following timeframes:

- If the death is related\* to the study procedures it should be reported immediately (Le. within 48 hours) by the investigator upon receipt of the information.
- If the death is not related\* to the study procedures (i.e., due to underlying disease progression), the death must be included in the summary of problems/adverse events submitted to the IRB at the time of continuation review in the designated summary format (per the instructions provided in the Continuation Review report form). Refer to UK's "Policy on IRB Continuation Review Reporting"

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\*If there is insufficient information to determine if the *internal* event is associated, it should be reported according to the applicable timeline for prompt reporting. If there is insufficient information to determine if the *external* event is associated, it does not need to be reported until Continuation Review (CR) time.

If an 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) (e.g., because it may affect the safety and/or welfare of subjects; or it changes the risk level of the study; or the frequency of the same event significantly increases) the PI is responsible for submitting the appropriate UK Internal/External Prompt Reporting Form according to the applicable timeline for prompt reporting.

If the problem/adverse event results in a revision to the informed consent document or the protocol, the principal investigator must also submit a modification request for IRB review and approval. In some cases, newly discovered information and/or unanticipated risks may require the IRB to review the protocol more frequently than once a year.

Thomas Foster, Pharm.D.  
Medical IRB Chairperson

Norman VanTubergen, Ph.D.  
Nonmedical IRB Chairperson

For additional information, please see the "UK Policy on Prompt Reporting for Unanticipated Problems, Serious or Life-Threatening Events, and Anticipated or Unanticipated Related Deaths to the Institutional Review Board (IRB) and Institutional Biosafety Committee (IBC), and the "UK Policy on Non-Prompt Reporting Anticipated Problems/Anticipated and Unanticipated Unrelated Deaths to the IRB". For the reporting forms for events that require prompt reporting to the IRB, please see: [http://www.research.uky.edu/ori/human/IRBReviewTypes.htm#UP\\_AE](http://www.research.uky.edu/ori/human/IRBReviewTypes.htm#UP_AE). For the optional form for submitting events that do not require prompt reporting to the IRB, please see: [http://www.research.uky.edu/ori/human/IRBReviewTypes.htm#UP\\_AE](http://www.research.uky.edu/ori/human/IRBReviewTypes.htm#UP_AE).

Problems/adverse events that are submitted to the IRB on the prompt reporting form that are found not to meet the IRB's prompt reporting requirements will not be reviewed by the IRB and will be returned to the investigator. The investigator will be asked to follow procedures for submission of reports to the IRB according to the Policy on Non-Prompt Reporting.