UNIVERSITY OF KENTUCKY INVESTIGATOR QUICK GUIDE TO IRB REPORTING REQUIREMENTS

The following serves as an abbreviated guide of common events that may occur during the conduct of a human research study which the Principal Investigator (PI) reports to the IRB. Applicable policies or procedures are referenced for details and timelines. This list is not all inclusive and does not include items that the investigator prospectively submits for review by the IRB during the conduct of a human study such as protocol modifications or continuing and final review submissions.

➔ ANYTHING NEW THAT YOU DIDN'T ANTICIPATE THAT INCREASES RISK.

New information may be generated from a number of sources including the Food and Drug Administration (FDA), published literature, results on clinicaltrials.gov, or from a commercial sponsor requesting a change in the consent form.

➔ UNANTICIPATED PROBLEMS AND ADVERSE EVENTS (UP/AE)

Unanticipated problem - any unforeseen or unexpected incident or experience (including an unanticipated adverse event) which is not described in the general investigational plan, current application or with the investigator brochure, or in the consent document.

Adverse event – an undesirable effect detected in participants in a study. The effect may be the result of:

- the interventions and interactions used in the research;
- an underlying disease, disorder, or condition of the subject; and/or
- other circumstances unrelated to the research or any underlying disease, disorder, or condition of the subject.

Record events that DO NOT meet the prompt reporting criteria and report to the IRB with the Continuation Review.

For details including prompt and non-prompt reporting timelines, download the “UK Policies on Prompt and Non-Prompt Reporting for Unanticipated/Anticipated Problems/Events” and Reporting Forms at http://www.research.uky.edu/ori/human/IRBReviewTypes.htm#UP_AE

For a listing of what events the Food and Drug Administration (FDA) considers to be Serious Adverse Events (SAE) for FDA regulated research, see the FDA MedWatch website at http://www.fda.gov/Safety/MedWatch/HowToReport/ucm053087.htm.

➔ DATA AND SAFETY MONITORING COMMUNICATIONS

If a Data Safety Monitoring Board (DSMB) or external monitoring entity is associated with the study, the PI must solicit and provide the IRB with communications or documentation including DSMB summary reports, meeting minutes, determinations, conclusions, etc.

➔ PROTOCOL VIOLATIONS

Protocol Violations – any exception or deviation involving a single subject that is not approved by the IRB prior to its initiation or implementation. These protocol violations may be major or minor violations. If either a protocol deviation or protocol exception occurs without prior IRB review and approval, the Principal Investigator is responsible for completing a Protocol Violation Reporting Form within 14 days. See http://www.research.uky.edu/ori/IRB-Survival-Handbook.html#ProtocolViolation. Indicate if investigator made a change in the research in order to eliminate apparent immediate hazard to subjects.

➔ FAILURE TO FOLLOW REGULATIONS OR IRB REQUIREMENTS


➔ FDA DETERMINATION CORRESPONDENCE

Any ruling from FDA such as IND/IDE correspondence received after IRB approval, IND/IDE sponsor transfer or a clinical hold.

➔ UNRESOLVED SUBJECT COMPLAINT

See IRB Subject Complaint SOP at http://www.research.uky.edu/ori/SOPs_Policies/C2-0500-Subject_Concerns-Complaints.pdf

➔ AUDIT, INSPECTION, OR INQUIRY BY A FEDERAL OR EXTERNAL AGENCY

See the ORI QIP website for Inspection Preparation Resources http://www.research.uky.edu/ori/QIP/QIP%20Main.htm

➔ BREACH OF CONFIDENTIALITY

See confidentiality resources at http://www.research.uky.edu/ori/IRB-Survival-Handbook.html#Privacy

➔ SUBJECT INCARCERATION

See prisoner resources at http://www.research.uky.edu/ori/IRB-Survival-Handbook.html#Prisoners