# UNIVERSITY OF KENTUCKY INVESTIGATOR 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) should report to the IRB.** :

## → UNANTICIPATED PROBLEM INVOLVING RISKS TO SUBJECTS OR OTHERS (UPIRSO)

See the IRB Policy on Unanticipated Problem and Safety Reporting & Prompt/Nonprompt guidance

***This is an event that:***

- ***Is unexpected*** (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied; and
- ***Is related or possibly related*** to participation in the research; and
- ***Suggests that the research places subjects or others at a greater risk of harm*** (including physical, psychological, economic, or social harm) than was previously known or recognized.

**Note:** *According to federal guidance, "UPIRSO's" typically warrant consideration of substantive changes to the protocol or informed consent process or corrective actions in order to protect the safety, welfare, or rights of subjects.*

## → UNANTICIPATED ADVERSE DEVICE EFFECT (UADE)

This is an unanticipated, serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, an investigational device.

## → CHANGE IN PROTOCOL STATUS

Such as suspension, discontinuation, completion of a study, FDA Clinical Hold, etc.

## → ANYTHING NEW THAT YOU DIDN'T ANTICIPATE WHICH 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 a sponsor that may require a change in the consent form.

## → DATA AND SAFETY MONITORING COMMUNICATIONS

If study has a Data Safety Monitoring Board (DSMB) the PI must solicit and provide the IRB with communication or documentation including DSMB summary reports, meeting minutes, determinations, conclusions, etc.

## → ALLEGATIONS OR OVERSIGHT AGENCY COMPLIANCE ACTIONS

Including actions by government oversight agencies (FDA Warning Letter, OHRP Determination Letter); lawsuits; or negative press coverage (TV, radio, publication) regarding Human Research Protections.

## → PROTOCOL VIOLATIONS

See the Protocol Violation Information, Form and SOP
Any exception or deviation involving a single subject that is not approved by the IRB prior to its initiation.

## → FAILURE TO FOLLOW REGULATIONS OR IRB REQUIREMENTS See Noncompliance in the IRB Survival Handbook

## → FDA CORRESPONDENCE

Any ruling from FDA (e.g., IND/IDE correspondence, clinical hold, FDA Form 483 or Warning Letter).

## → INVESTIGATOR MEDICAL LICENSE RESTRICTION OR SUSPENSION

## → UNRESOLVED SUBJECT COMPLAINT See the IRB Subject Complaint SOP

## → AUDIT, INSPECTION, OR FEDERAL AGENCY INQUIRY, NEGATIVE PRESS, OR LAWSUIT

See the ORI QIP website for Inspection Preparation Resources

## → BREACH OF CONFIDENTIALITY See confidentiality resources in the IRB Survival Handbook

## → SUBJECT INCARCERATION See prisoner resources