Office of Human Research Ethics Training Tips
New Safety Information Reporting Requirements

New Safety Information: Information previously unknown to the IRB that suggests new or increased risk to participants or others. New Safety Information is reportable in IRBIS **within 7 calendar days** of the investigator becoming aware of the information.

TABLE 1, New Safety Information

Reporting Requirements When UNC is the Reviewing IRB
Internal adverse events that are (1) unexpected, (2) related or possibly related to participation in the research, and (3) serious or suggest that there are new or increased risk(s) to subjects
External adverse events that are (1) unexpected, (2) related or possibly related to participation in the research, (3) serious or suggest that there are new or increased risk(s) to subjects, and (4) warrant a change to the protocol or consent or subject notification (See 3.3 for additional information)
Interim analysis, data and safety monitoring report, findings from other studies, findings from animal or in-vitro testing, or other finding(s) that indicate (1) there are new or increased risks to subjects or others, or (2) subjects are less likely to receive any direct benefits from the research
Unanticipated adverse device effect
Protocol deviation that harmed subject(s) or others or placed subject(s) or others at increased risk of harm. **All other protocol deviations are summarized at continuing review**
Protocol deviation that is made to eliminate an immediate hazard to a subject without IRB approval
Intentional or unintentional failure to follow applicable federal human subject protection regulations, the requirements or determinations of the IRB, the IRB-approved study protocol, or University policies when that failure adversely affects the rights or welfare of participants, such as: • Conducting human subjects research without an IRB-approved protocol or exemption • Starting research prior to meeting the conditions required by the IRB and receiving an IRB notification of approval, or conducting research during a lapse in approval • Failure to obtain informed consent • Deviating from the informed consent or recruitment process approved by the IRB • Failure to provide a participant with new information about study risks or procedures that may affect the participant's willingness to continue/participate in the study (i.e., by not reconsenting participants or by using an old version of a consent document to consent a new participant) • Initiating changes to the protocol without IRB approval, including using unapproved materials (e.g., fact or information sheets, recruitment materials, questionnaires, focus group guides, scripts, or other materials provided to participants) • Failure to complete IRB- or institutionally-required human subjects protection training prior to engaging in human subjects research • Enrollment of participants beyond what has been approved by the IRB in a study that is greater than minimal risk
Breach or potential breach of subject confidentiality or privacy.
Complaint by or on behalf of a research subject that (1) indicates that the rights, welfare, or safety of the subject have been adversely affected, or (2) cannot be resolved by the investigator. Subject complaints about payment should be resolved by the study team. See SOP 1403 for additional information.
Allegation of noncompliance
Audit, inspection, or inquiry by a federal agency
Written report from a federal agency (e.g., FDA Form 483)
State board action that (1) will affect the ability to conduct or complete the research as approved by the IRB or (2) increases risks to subjects or others (e.g., suspension of professional license)
Incarceration of a subject enrolled in a research study that is not approved to involve prisoners
Institution-, investigator-, or sponsor-initiated hold or early closure as a result of safety concerns
Reporting Requirements When UNC is Ceding IRB Review to Another IRB
Unanticipated Problem Involving Risk to Subjects or Others (UPIRSO) or Serious Noncompliance or Continuing Noncompliance determinations by an external IRB to which UNC cedes IRB review and oversight when the event involved UNC subjects or researchers
Suspension or termination by an external IRB to which UNC cedes IRB review and oversight

Note: This table is subject to revision. Please see OHRE website for current version.