Table 1. Promptly Reportable Information for studies for which the UNC IRB is the IRB of record and has oversight responsibilities*		
UPIRSO	**Any incident, experience, outcome, or new information that are (1) unexpected, (2) related or at least possible related to participation in the research, and (3) indicates that subjects or others are at a greater risk of harm (including physical, psychological, economic, legal, or social harm)**	**Submit a PRI form in IRBIS within 7 days of the event****
Examples of UPIRSO:		
A single occurrence of a serious, unexpected event that is uncommon and strongly associated with drug exposure (such as angioedema, agranulocytosis, hepatic injury, or Stevens-Johnson syndrome).		
A single occurrence, or more often a small number of occurrences, of a serious, unexpected event that is not commonly associated with drug exposure, but uncommon in the study population (e.g., tendon rupture, progressive multifocal leukoencephalopathy).		
Multiple occurrences of an AE that, based on an aggregate analysis, is determined to be an unanticipated problem. There should be a determination that the series of AEs represents a signal that the AEs were not just isolated occurrences and involve risk to human subjects (e.g., a comparison of rates across treatment groups reveals higher rate in the drug treatment arm versus a control). A summary and analyses supporting the determination should accompany the report.		
An AE that is described or addressed in the investigator's brochure, protocol, or informed consent documents, but occurs at a specificity or severity that is inconsistent with prior observations. For example, if transaminase elevation is listed in the investigator's brochure and hepatic necrosis is observed in study subjects, hepatic necrosis would be considered an unanticipated problem involving risk to human subjects. A discussion of the divergence from the expected specificity or severity should accompany the report.		
A serious AE that is described or addressed in the investigator's brochure, protocol, or informed consent documents, but for which the rate of occurrence in the study represents a clinically significant increase in the expected rate of occurrence (ordinarily, reporting would only be triggered if there were a credible baseline rate for comparison). A discussion of the divergence from the expected rate should accompany the report.		
AEs involving direct harm to subjects enrolled by the local investigator which in the opinion of the investigator or sponsor.		
Unanticipated Adverse Device Effects (UADEs)		
Any other AE or safety finding (e.g., based on animal or epidemiologic data) that indicates subjects or others might be at risk of serious, unanticipated harms that are reasonably related to the research. These would cause the sponsor to modify the investigator's brochure, study protocol, or informed consent documents, or would prompt other action by the IRB to ensure the protection of human subjects. An explanation of the conclusion should accompany the report.		

Reports (including reports from DSMBs/DMCs) that indicate that risks are greater than previously known or that indicate that the research should be modified, suspended, or halted.		
Sponsor or lead investigator/coordinating center-imposed suspension or termination of some or all research activities.		
An unanticipated event related to the research that exposes subjects or others to risk of harm even if not directly, others may include but are not limited to investigators, research assistants, students, and the public.		
An event that involves a potential (1) inappropriate sharing or disclosure of a participant's personal identifiers and/or protected health information, (2) privacy incident (3) security incident, or (4) breach of privacy or confidentiality.		
New information that indicates increased risk, new risk(s), or decrease to potential benefit from what was previously understood, e.g., interim analysis, safety monitoring report, or publication that indicates that the merit of the research, frequency or magnitude of harms or benefits may be different than initially presented to the IRB.		
Serious and Continuing Noncompliance	**Any failure to follow (1) Applicable federal regulations, state or local laws, institutional policies, or other institutional oversight governing human subject protections, or (2) The requirements or determinations of the IRB, including the requirements of the approved investigational plan (i.e., protocol deviations) that is serious or continuing.**	**Submit a PRI form in IRBIS within 7 days of the event****
Examples of Serious and Continuing Noncompliance:		
A protocol deviation that harmed subject(s) or others or placed subject(s) or others at increased risk of harm. All other deviations should be documented by the investigator in a deviation log. This log is subject to review by the IRB or other agency of the UNC-CH HRPP.		
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 or reconsent as required by the IRB.		
Written report from a federal agency (e.g., FDA Form 483) indicative of noncompliance.		
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 (e.g., 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 material, questionnaires, focus group guides, scripts, or other materials provided to participants).		
Failure to complete institutionally required human subjects protection training prior to engaging in human subjects research.		

Failure to complete the IRB application or other forms related to human subject research in a true and accurate manner.		
Enrollment of participants beyond what has been approved by the IRB in a study that is greater than minimal risk.		
Other Promptly Reportable Information	**Any other incident, experience, outcome, or new information that is required to be reported in a timely matter to the OHRE but does not meet the criteria of UPIRSO, Serious or Continuing Noncompliance**	**Submit a PRI form in IRBIS within 7 days of the event or receipt of information****
Examples of Other Promptly Reportable Information:		
IND Safety Reports from sponsors that meet the criteria for reporting to the FDA under 21 CFR 312.32. Such reports must be accompanied by confirmation that the sponsor has submitted the report to the FDA. For more information on IND safety reporting, see FDA's guidance "Safety Reporting Requirements for INDs and BA/BE Studies"		
A complaint or concern expressed by subjects or others about the conduct of the study or a subject's participation.		
Protocol deviation that is made to eliminate an immediate hazard to a subject without IRB approval.		
Allegation of noncompliance		
Audit, inspection, or inquiry by a federal agency		
State board action that (1) will affect the ability to conduct or complete the research as approved by the IRB or (2) increases risk to subjects or others (e.g., suspension of professional license)		
Incarceration of a subject who is actively participating 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.		
Any event, incident or situation that has generated adverse media attention or congressional interest.		

*An event may be evaluated and determined to be more than one type of event (e.g., an event submitted as Serious or Continuing Noncompliance, may also be a UPIRSO)

**If IRBIS is not available to the submitter, they can proceed to notify OHRE Leadership, including the Compliance Manager for alternate methods of submitting.