Children's
Healthcare of Atlanta

Institutional Review Board
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Event Type	Timing of IRB Submission	Required Form
Unanticipated Problem Internal or External UPs are events (adverse events or not) that are assessed by the PI as unexpected, related to study participation, **and** involving risk for participants or others.	Report within 10 days of becoming aware of the event	Event Reporting Form (Section B1)
Death Internal or External that is possibly, probably, or definitely related to the study	Report within 10 days of becoming aware of the event	Event Reporting Form (Section B2)
Death Internal that is not related to the study (i.e., death from cancer that is related to disease progression, not the study)	Report at renewal	Include a summary with the submission form
Adverse Audit, Adverse DSMB/DSMC Report, or Enforcement Action Form FDA 483, FDA Warning Letter, Adverse Sponsor audit results, or Suspension of medical license, DSMB report that reports increased risk or requires stopping the study, etc.	Report within 10 days of becoming aware of the event	Event Reporting Form (Section B3)
Participant Complaint Any internal complaint from a subject or others relating to an alleged breach of the subject's rights, safety or welfare or the integrity of the study	Report within 10 days of becoming aware of the event	Event Reporting Form (Section B4)
Protocol Deviation or Violation Any internal substantive unintentional change to the protocol or procedures involving risks or with the potential to recur (i.e., subject refused required blood draw) that adversely affected the rights, welfare or safety of subjects; the integrity of the research data; OR the subject's willingness to continue	Report within 10 days of becoming aware of the event	Event Reporting Form (Section B5)
Other Unanticipated Information Internal or external information that	Report within 10 days of becoming aware of the event	Event Reporting Form

changes the risk benefit ratio or that indicates subjects might be at greater risk of harm (i.e. Breach of Confidentiality; Pregnancy; Incarceration, etc.)		
Non-Compliance Any action (or inaction) of the study team at Children's associated with the conduct or oversight of the study that fails to comply with federal or state regulations or institutional policies. Examples of non-compliance include, but are not limited to, failure to obtain IRB approval, study expiration, using expired documents, non-study staff consenting subjects, failure to obtain informed consent, assent, etc.	Report within 10 days of becoming aware of the event	Non-Compliance Reporting Form

Events not reported within required time frame will be reviewed for potential non-compliance.

Definitions:

Internal events (those occurring in research at Children's or at a site under the Children's IRB jurisdiction)

External events (those occurring in research at a site over which another IRB has jurisdiction)

Related: Associated or having a timely relationship with; a reasonable possibility exists that an outcome may have been caused or influenced by the event in question (e.g., administration of a study drug), although an alternative cause/influence may also be present. Related events may be definitely, probably, or possibly related.

Unrelated: Unassociated or without a timely relationship; evidence exists that an outcome is definitely related to a cause other than the event in question.