IRBear Reportable Events Module

What should be submitted to the IRB as a reportable event?

**UNANTICIPATED PROBLEMS** -- Report events that are unexpected in type, severity, and or frequency; related or possibly related to the research; and may place research participants or others at GREATER RISK OF HARM than previously known. These include:

- Data breach/HIPAA violation (loss, theft, or other unauthorized disclosure of private information such as Private Health Information or confidential data) – Report data breaches and HIPAA violations within one (1) business day of learning of the event. Report all other unanticipated problems within seven (7) business days.
- Internal unexpected serious adverse events
- Loss or theft of research equipment, incentives, or other study materials
- Internal laboratory or medication error that may involve risk to a subject(s) or others
- Administered wrong dose of a study medication without evidence of harm
- Incarceration of a research subject participating in a protocol that is not approved to enroll prisoners
- Research subject becomes pregnant (or fathers a child) contrary to the instructions given by the PI and in the consent/parental permission form or assent
- Child subject is transferred from his or her parents/guardians to foster care (child becomes a ward of the state)
- Complaint by a subject or family member
- Enforcement action such as an unfavorable audit report, disqualification or suspension of an investigator by the FDA, or FDA Form 483 or Warning Letter

**PROTOCOL DEVIATIONS** -- Report events that depart from the IRB-approved study protocol within seven (7) business days. These include:

- Enrollment of ineligible subject(s)
- Enrollment of more subjects than approved by the IRB
- Additional study procedure(s) conducted without IRB approval (e.g., additional blood draw)
- Study procedure(s) omitted
- Subject visit outside window
- Improper storage of study drug(s) or device(s)

**COMPLIANCE REPORTS** -- Report failures to follow federal, state, or local regulations governing human research, institutional policies and procedures, or IRB requirements or determinations within seven (7) business days. These include:

- IRB approval expired
- Research activities (including subject follow-up and data analysis) continued after IRB approval expired
- Research activities were conducted without prior IRB approval
- Subjects were not recruited according to the IRB-approved plan
- Use of unapproved recruitment methods or materials
- Informed consent/parental permission and/or assent was not obtained or was obtained improperly
- Invalid consent/parental permission and/or assent form was used (e.g., expired, no IRB stamp)
- Changes were made to informed consent/parental permission and/or assent documents without IRB approval
- Coercion or undue influence of study subjects to obtain their agreement to participate
- Private Health Information (PHI) was collected and recorded without IRB approval
- Scope/intent of the study was changed without IRB approval
- Study staff conducted research activities without appropriate qualifications/training
- Study staff did not receive adequate supervision
- Subjects placed at risk due to no or inadequate monitoring of the data
- Missing or no source documentation

**OTHER REPORTABLE EVENTS** – These include:

- External Serious Adverse Events/IND Safety Reports
- Study Suspension or Termination
- Data Monitoring Reports (with no change to protocol or consent forms)
- Revised Investigator Brochure, Package Insert, or Device Manual (with no change to protocol or consent forms)
- Action Letters
- Other events the study sponsor requires you to report to the IRB