COMMON EXAMPLES REQUIRING EVENT REPORTING:

- Adverse events that are serious, unexpected, and related
- Breaches of confidentiality involving risks
- Data safety monitoring board or sponsor safety reports altering risk/benefit
- Unexpected change in risk level
- Protocol deviations, violations, or unintentional changes involving risks
- Participant complaints
- Use of incorrect version of consent form/script
- Lack of consent or HIPAA authorization
- Individuals engaged in research prior to IRB approval
- Enacting amendments without prior IRB approval
- Use of unapproved documents
- Audit findings
- Other problem or finding that could influence the safe conduct of the research

UNANTICIPATED PROBLEMS INVOLVING RISKS TO SUBJECTS OR OTHERS (UPIRSO):
Unexpected events (given the nature of the research procedures and subject population) that are related or possibly related to participation in the research and suggest subjects, research staff, or others are placed at greater risk by the research than previously expected. Unanticipated problems involving risks to subjects or others may be medical or non-medical in nature.

KEY DEFINITIONS:

- **Serious adverse event (SAE):** An adverse event that is fatal or life threatening, permanently disabling, requires or prolongs hospitalization, or results in significant disability, congenital anomaly, or birth defect.

- **Unexpected adverse event:** An adverse event that has not been previously observed or is not consistent in nature, severity, or frequency with existing risk information, such as in the investigator’s brochure, research protocol, consent form, or other available information (e.g., IND application for an investigational drug).

- **Unanticipated adverse device effect:** Any serious adverse effect on health or safety, or any life-threatening problem or death caused by (or associated with) a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application; any other unanticipated, serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

- **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.
NONCOMPLIANCE:
Failure (intentional or unintentional) to comply with applicable federal regulations, state or local laws, the requirements or determinations of the IRB, or university policy regarding research involving human subjects. Noncompliance can result from action or omission. Noncompliance may be non-serious (minor) or serious, and may also be continuing (see below).

KEY DEFINITIONS:
- **Non-serious or minor noncompliance:**
  - Does not increase risk to research participants,
  - Compromise participants' rights or welfare, OR
  - Affect the integrity of the research/data or the human research protection program.

- **Serious noncompliance:**
  - Increases risk to research participants,
  - Compromises participants' rights or welfare, OR
  - Affects the integrity of the research/data or the human research protection program.

- **Continuing noncompliance** (serious or non-serious)
  - Previously reported, OR
  - Pattern of ongoing activities that indicate a lack of understanding of human subjects protection requirements that may affect research participants or the validity of the research and suggest the potential for future noncompliance without intervention.

EXAMPLES:
- **Minor Noncompliance:**
  - Lapses in continuing IRB approval
  - Failure to obtain exempt determination before exempt research involving human subjects is conducted
  - Over enrollment of participants
  - Minor changes in or deviations from an approved protocol, or administrative errors.

- **Serious Noncompliance:**
  - Conducting or continuing non-exempt human subjects research without IRB approval
  - Lack of legally effective informed consent from research participants
  - Failure to report or review serious adverse events, unanticipated problems, or substantive changes in research
  - Inappropriate oversight of the research to ensure the safety of human subjects and the integrity of the research/data.

- **Continuing Noncompliance:**
  - Repeated failures to provide or review progress reports resulting in lapses of IRB approval
  - Inadequate oversight of ongoing research
  - Failure to respond to or resolve previous allegations or findings of noncompliance.