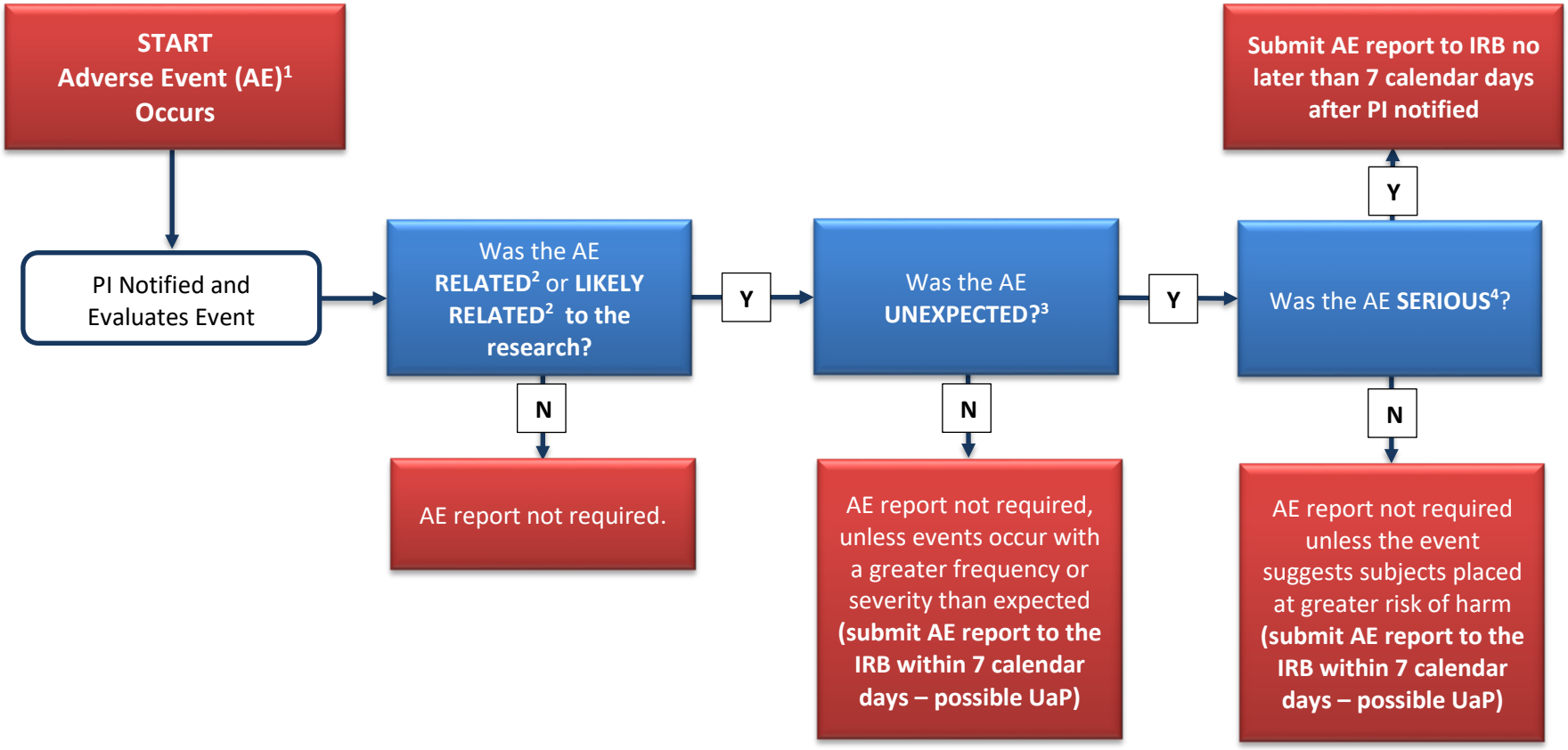
Adverse Event Reporting: Flowchart and Guidance

Revised: February 7, 2020



DEFINITIONS (terms found on page 1 and 2)

1. **ADVERSE EVENT (AE):** an event in that results in harm to research subject during the time of their participation in research. AEs typically represent actual physical harm to subjects, but may also represent psychological, emotional or social harm.
2. **RELATED/LIKELY RELATED:** the event was caused/likely caused by the subject's participation in the research itself.
3. **UNEXPECTED:** the event has not been addressed in one or more of the following – Protocol, IRB application, or Informed Consent Document
4. **SERIOUS:** the event resulted in death, or involved severe social/psychological/emotional trauma, or a life altering/threatening or other serious outcome (see reverse for examples within each category).
5. **NON-SERIOUS:** the event does not meet the definition of a serious adverse event, but resulted in the subject experiencing psychological/emotional distress or social harms such as stigmatization.
6. **UNANTICIPATED PROBLEM (UaP)**: An incident, experience, or outcome that warrants consideration of substantive changes in the research protocol or informed consent process/documents or other corrective actions in order to protect the safety, welfare, or rights of subjects or others.
7. **REPORTING DATE**: 7 days after the event occurs or after the study team becomes aware of the event.

Characterization of Adverse Events (AEs) and Reporting Requirements	
SERIOUS[4] and Related	**Report ASAP, but no later than 7 calendar days of the event, or study team becomes aware of the event**
	Severe Social, Psychological, or Emotional Trauma: Loss of job, insurance, benefits; criminal prosecution, stigmatization of community/group, destruction of familial/social relations.
	Life Altering or Other Serious Event: An event that jeopardizes the subject's physical, mental, emotional, social well-being, or livelihood. This could include, subject or family mental health crisis resulting in hospitalization or prolonged treatment; severe asthma attack; assault, battery, or other threats of physical violence; any incident requiring security measures; in-patient hospitalization or prolonged hospitalization; a persistent or significant disability, incapacity; or other serious adverse events requiring further monitoring.
	Death: For projects involving a health-related intervention, an adverse event report should be submitted if related to the research.
SERIOUS OR NON-SERIOUS UNANTICIPATED PROBLEM (UaP)[6]	**Unanticipated Problem (UaP) Involving Risks to Subjects or Others:** An event that suggests the research places subjects or others at a greater risk of harm than was previously known or recognized and/or is significant to the rights and welfare of human subjects in the study. An event, occurrence, or information that is not expected by the research participants or investigators in terms of its nature, severity, or frequency given the: • Procedures as described in the study documents • Characteristics or qualities typically found in the eligible study participants • Possibility that the event or information has been caused by, or is linked in a significant way to, the research • Potential for greater risk of, or actual harm to, the subjects or others than was previously known or recognized. Depending on the nature of the incident, the study team reports the event as an Adverse Event or ORIO following the time lines for serious or non-serious events. Generally: If the event involved risk of physical/mental harm and harm occurred, **submit an Adverse Event report**. If the event involved risk of harm but no actual harm occurred, or the event involved a data breach, **submit an ORIO**. ***The IRB determines whether the event is a UaP.*** Per federal and institutional policies, the IRB reports UaPs to the U-M Vice President for Research and to the research sponsor, and for federally sponsored research, to the Office of Human Research Protections (OHRP).
NON-SERIOUS[5] and Related	**Report to IRB at any time ten or more such incidents have occurred**
	Social or Psychological Trauma or Upset: Mild to moderate or temporary emotional distress or upset, significant embarrassment, stigmatization of individual or community/ group, disruption of familial/social relationships
	Emergency and/or Urgent Treatment: Emergency Room, physician or other provider visit required to treat non-life threatening physical injury and/or emotional trauma or distress.