The following events must be promptly reported using xForm 109 in IRBManager:

A. Any event, including on-site and off-site adverse events, injuries, side effects, deaths, or other problems, which in the opinion of the local PI, was unexpected suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized, and was related to or possibly related to the research.

B. Accidental or unintentional change to the IRB approved protocol that involves the potential for increased risk

C. Any deviation from the protocol taken without IRB approval to eliminate apparent immediate hazard to a research participant

D. Any publication in the literature, safety monitoring report, (including Data and Safety Monitoring Reports), interim result, or other finding that indicates an unexpected change to the risk/benefit ratio of the research.

E. Any breach in confidentiality that may involve risk to the participant or others

F. Any complaint of a participant that indicates an unanticipated risk or that cannot be resolved by the research staff

G. Any local death, whether anticipated or not*

H. Incarceration of a participant

I. Any other possibly related event which in the opinion of the investigator constitutes an unanticipated risk.

J. Addition of a black box warning on any drug used in your research (for VA studies, this also includes VA National Pharmacy Benefits Management (PBM) Bulletins or Communications (sometimes referred to as PBM Safety Alerts) relevant to a VA research study
UPIRTSOs – EVENTS TO BE REPORTED

K. Interruptions of subject enrollment or other research activities due to concerns about the safety, rights, or welfare of human research subjects, research staff, or others.

L. Any work-related injury to personnel involved in human research, or any research-related injury to any other person, requiring more than minor medical intervention (i.e., basic first aid), requires extended surveillance of the affected individual(s), or that leads to serious complication or death.

M. Any Data Monitoring Committee (DMC) report or any sponsor analysis describing a safety problem

N. For VA studies, any local Serious Adverse Event (see definition) that is both unanticipated and related to the research

O. Any unanticipated problem involving substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of human research subjects, research staff, or others

P. For VA studies, any problem reflecting a deficiency that substantially compromises the effectiveness of the institution’s human research protection or human research oversight programs.

Q. For VA studies, any serious problem that is both unanticipated and related to the research.

*For VA studies, the following apply to a local research death that is both unanticipated and related to the research:

VA personnel, including WOC and IPA appointees, must ensure oral notification of the Institutional Review Board (IRB) immediately upon becoming aware of any local research death that is both unanticipated and related to the research. The IRB must alert ORO by e-mail or telephone within 2 business days after receiving such notification and provide relevant information as requested. The VA facility Director and the ACOS/R&D must receive concurrent notification.
UPIRTSOs – EVENTS TO BE REPORTED

VA personnel, including WOC and IPA appointees, must ensure written notification of the IRB within 5 business days of becoming aware of the death.