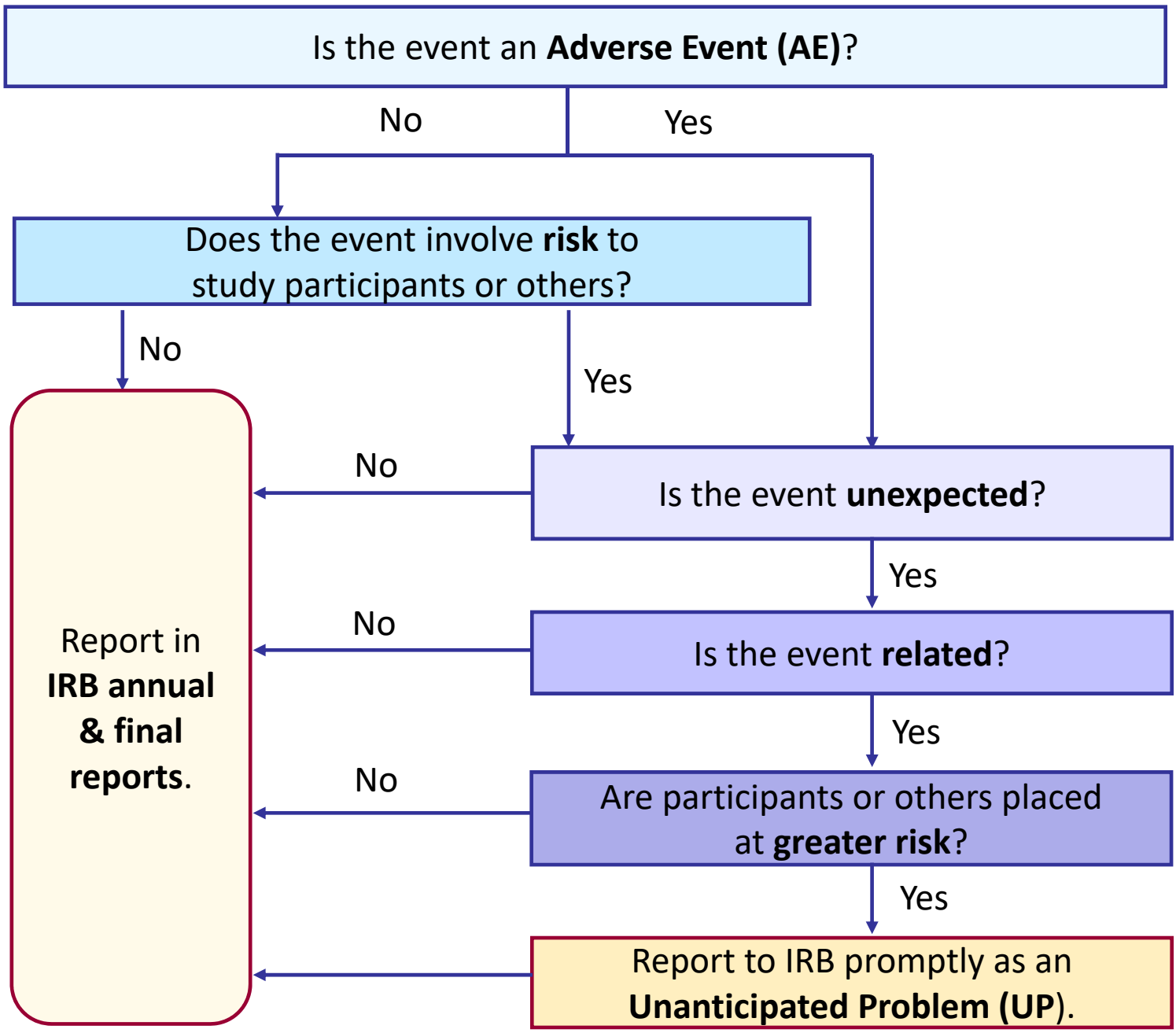
Institutional Review Board (IRB) Reporting

An event involving research conduct and/or a research participant



Please note that participant or other complaints must also be reported promptly to the IRB.

An unanticipated problem (UP) can be an AE in a trial participant or an event that is not considered an AE affecting a trial participant or others. Here are a few examples:

Ex1: UP that is an AE
A participant in a trial testing a new hip replacement device experiences hip swelling more severe than described in documents.
- ✓ Unexpected (severity not described in protocol or accompanying documents)
- ✓ Related to participation in research
- ✓ Placed participants at greater risk of physical harm

Ex2: UP affecting participants that is not an AE
An investigator conducting research collects individually identifiable sensitive information about illicit drug use by surveying college students. The data are stored on a laptop computer without encryption, and the laptop is stolen from the investigator's car.
- ✓ Unexpected (theft not anticipated)
- ✓ Related to participation in the research
- ✓ Placed the participants at a greater risk of psychological/social harm

Ex3: UP affecting others that is not an AE
A research team conducting interviews draws gunfire at field site, with a bullet hitting a spouse of a participant and a research coordinator.
- ✓ Unexpected (gunfire was not anticipated)
- ✓ Related to research conduct
- ✓ Placed participants and others (participants' family members and research personnel) at a greater risk of physical and psychological harm

USC School of Pharmacy
International Center for Regulatory Science
SC CTSI

Institutional Review Board (IRB) Reporting Definitions

Document created by Amelia Spinrad | Spinrad@usc.edu

Adverse Event (AE): Any untoward medical occurrence associated with the use of a medical product in humans, whether or not considered medical product.
21 CFR 312.32 & 21 CFR 803.3

Others: Persons who are not participants in the trial, but are affected by the trial. Examples include the participants' sexual partners participants, participants' family members, research personnel, and anyone else as applicable.
HHS Unanticipated Problems Involving Risks & Adverse Events Guidance (2007) & UCSD IRB: https://irb.ucsd.edu/Decision_tree_UPRs.pdf

Unexpected: Any research event occurring in one or more participants or others involved in a research protocol, the nature, severity, or frequency of which is not consistent with either: the known or foreseeable risk of research events associated with the procedures involved in the research that are described in

a) the protocol–related documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document, and
b) other relevant sources of information, such as product labeling and package inserts; or the expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.
HHS Unanticipated Problems Involving Risks & Adverse Events Guidance (2007)

Related: Any research event related or possibly related (there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research) to participation or role in the research.
HHS Unanticipated Problems Involving Risks & Adverse Events Guidance (2007). https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html

Greater Risk: Any risk where research places participants or others are at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.
HHS Unanticipated Problems Involving Risks & Adverse Events Guidance (2007)

Unanticipated Problem (UP): Any incident, experience, or outcome that meets all of the following criteria: unexpected, related, and greater risk. UPs from externals sites must also be reported to by internal site investigator to internal site IRB promptly.

Promptly: Term not defined by CFR. Refer to your specific IRB requirements. For example USC IRB requires reporting of UP reporting within 10 calendar days.
HHS Unanticipated Problems Involving Risks & Adverse Events Guidance (2007) & 45 CFR 46.103(b)(5)