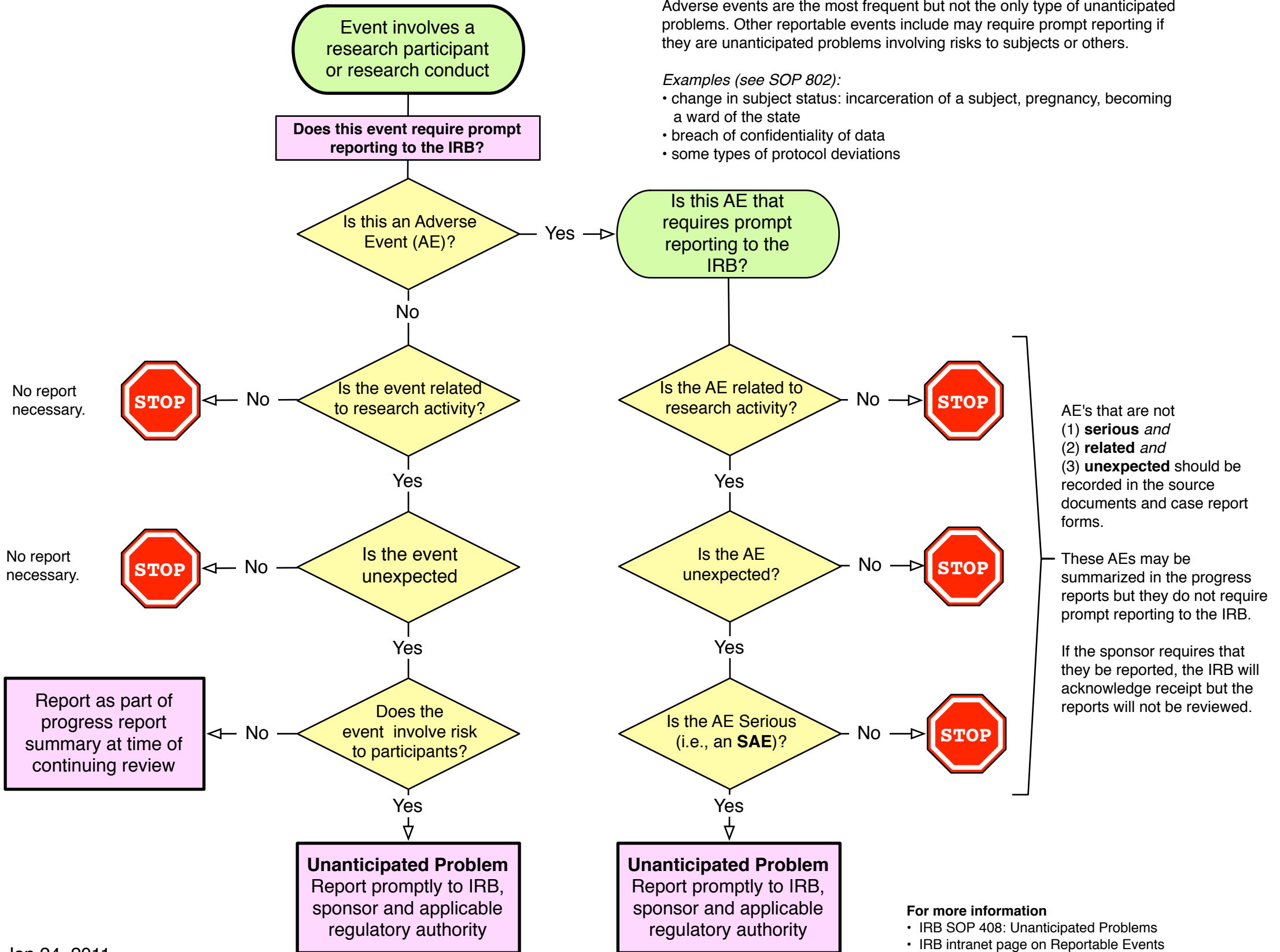


Decision Tree: Unanticipated Problems Involving Risks to Research Participants or Others

Adverse events are the most frequent but not the only type of unanticipated problems. Other reportable events include may require prompt reporting if they are unanticipated problems involving risks to subjects or others.

Examples (see SOP 802):

- change in subject status: incarceration of a subject, pregnancy, becoming a ward of the state
- breach of confidentiality of data
- some types of protocol deviations



For more information

- IRB SOP 408: Unanticipated Problems
 - IRB intranet page on Reportable Events
- <https://intranet.research.chop.edu/display/cmtirb/Reportable+Events>