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 408):
- 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

AE’s that are not (1) serious and (2) related and (3) unexpected should be recorded in the source documents and case report forms.

These AEs may be summarized in the progress reports but they do not require prompt reporting to the IRB.

If the sponsor requires that they be reported, the IRB will acknowledge receipt but the reports will not be reviewed.