Does the event involve noncompliance with the protocol, IRB requirements, or regulations?

Could the noncompliance issue affect the subject's safety or well being?

Does this event involve noncompliance with the IRB requirements?

Is the event a serious, unanticipated problem involving risk to subjects or others?

Did it impact UI subjects or others associated with the UI study or the conduct of the study at UI?

Did you receive new information (positive or negative)?

Could this information impact the willingness of subjects to participate or continue participating in the study?

UNIVERSITY OF IOWA IRB REPORTABLE EVENT DECISION TREE

SUBMIT A NONCOMPLIANCE REPORTABLE EVENT FORM (REF)

SUBMIT AN UNANTICIPATED PROBLEM REPORTABLE EVENT FORM (REF)

SUBMIT A NEW INFORMATION REPORTABLE EVENT FORM (REF)

STOP

NO

YES

YES

NO
Was this a Serious Adverse Drug Event?

YES → Did this Serious Adverse Event occur in a UI/VAHCS subject?

YES → Was this an unanticipated serious adverse device effect in a non-UI/VAHCS subject?

NO → STOP

NO → STOP

SUBMIT A SERIOUS ADVERSE DRUG REPORTABLE EVENT FORM (REF)

Was this a Serious Adverse Device Effect?

YES → Did this Serious Adverse Effect occur in a UI/VAHCS subject?

YES → Was this a Serious Adverse Event possibly related to participation in the research study?

NO → STOP

NO → STOP

SUBMIT A SERIOUS ADVERSE DEVICE REPORTABLE EVENT FORM (REF)

UNIVERSITY OF IOWA IRB REPORTABLE EVENT DECISION TREE