Reporting Unanticipated Problems, Adverse Events, and Protocol Deviations Flowchart

Start Here:
Incident, experience, or outcome

Was it unexpected given known risks to subjects? — No

Yes

Was it related or possibly related to participation? — No

Yes

Does it suggest greater risk of harm to subjects? — No

Yes

Was it a protocol deviation? — No

Yes

Was it a MAJOR Deviation (has effect on subjects or data)? — No

Yes

Was it an Adverse Event or Serious Adverse Event? — No

Yes

No Report Required

Report to IRB at Continuing Review

Submit via Reportable Events Form
- ➢ As soon as possible
- ➢ No later than **10 days** after recognizing the event