Algorithm for Reporting Unanticipated Problems, Adverse Events, and Deviations

Incident, experience, or outcome

Unexpected given known risks to subjects? → **no**

↓ **yes**

Related or possibly related to participation? → **no**

↓ **yes**

Suggests greater risk of harm to subjects or others? → **no**

↓ **yes**

Deviation? → **no** → **Adverse Event or Serious Adverse Event?** → **no**

↓ **yes**   ↓ **yes**   ↓

MAJOR Deviation (effect on subjects or data)? → **no**   **No report required**

↓ **yes**

Report to IRB at Continuing Review

Attach to Progress Report:

➤ **If have DSMB report**
  • **attach to Section 4**

➤ **Otherwise,**
  • **attach AE/SAE/Minor deviation summary to Section 5**

Submit on Reportable Events and New Information form
➤ **As soon as possible**
➤ **No later than 7 days after recognizing the event**