

Reportable Categories

Category #1

Must fit all 4:

- On Protocol
- Serious Adverse Event
- Unanticipated
- Related or Possibly related

Category #2

Must fit all 4:

- On Protocol
- Anticipated
- Related or Possibly related
- Occurring at a higher frequency or severity

Category #3

Must fit all 3:

- Unanticipated
- Related or Possibly related
- May alter the risks and therefore warrants changes to the protocol, DSMP, or consent process

Category #4

Must fit all 3:

- Unanticipated
- “Other” events
- May place subjects or others at a greater risk of harm or discomfort