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

Decision Tree Requirements Version 1: January 2008