1. Did it adversely affect the rights and welfare of the participants, result in harm or posed an increased risk of substantive harm to participants, or result in a detrimental change to a participant’s clinical or emotional condition/status?

2. Did it compromise the integrity or validity of the study or result from the willful or knowing misconduct of the investigator or study staff?

3. Is the protocol deviation/incident of noncompliance one that has occurred at the site on previous occasions (e.g., 3 or more deviations for the same subject or of the same type? 

Report the incident using 700 FR 1

Summarize the incident at the time of continuing review using 100 FR 5R