

Events That Investigators Have to Report to Schulman

SECTION 1.0: Purpose

Schulman requires investigators to report the following to the IRB within ten (10) business days of discovery, except as otherwise noted.

SECTION 2.0: Events to Report

1. Unanticipated Problems Involving Risks to Human Subjects or Others (“Unanticipated Problems”) that:

- a. Are unanticipated;**
- b. Are related to or possibly related to participation in research; and**
- c. Suggest that human subjects or others are at increased risk of harm.**

NOTE: Unanticipated Problems must be reported to the IRB within 24 hours of discovery if the Unanticipated Problem involves a death.

2. Information that indicates a change to the risks or potential benefits of the protocol. Such changes include but are not limited to:

- a. An interim analysis or safety monitoring report indicates that the frequency or magnitude of harm or benefit may be different than initially presented to the Board; and**
- b. Awareness of a paper published from another study that shows that the risks or potential benefits of the protocol may be different than initially presented to the Board.**

3. A breach of confidentiality involving a study subject.

4. Change in FDA labeling or withdrawal from marketing of a drug, device, or biologic which is part of the protocol.

5. Changes to the protocol made without prior Board review to eliminate an apparent immediate hazard to a research subject.

6. Incarceration of a subject involved in a protocol not approved to enroll prisoners.

7. Pregnancy of a subject enrolled in a protocol that excludes pregnant subjects.

8. Event, other than an adverse event, that requires prompt reporting to the sponsor.

9. Sponsor/CRO/IRB imposed suspension or termination of the protocol.

10. Medical license suspensions, restrictions or revocations for investigators and sub-investigators.

11. Any licensure and/or credentialing issue involving a member of the study staff.

12. Form FDA 483, FDA Warning Letters, FDA audit reports, Notice of Initiation of Disqualification Proceedings and Opportunity to Explain (NIDPOE) Letters, Disqualified/Totally Restricted List for Clinical Investigators, Debarment List, Restricted List for Clinical Investigators, and Health Canada Notification of Deficiencies Letters.

13. OHRP Determination Letters.

14. Office of Research Integrity Administrative Actions.

15. Complaint of a subject when the complaint indicates unexpected risks or cannot be resolved by the study team.

16. Protocol violation meaning any variation, intentional or unintentional, from an approved study protocol, or deviation from relevant federal regulations or Board requirements, that may affect the subject’s rights, safety, or well being and/or the completeness, accuracy and reliability of the study data.

17. Unanticipated adverse device effect (UADEs): Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application [including a supplementary plan or application], or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

NOTE: UADEs must be reported to the IRB within 24 hours of discovery if the UADE involves a death.

18. Death or change of Principal Investigator (PI)/Qualified Investigator (QI).

19. Change in address of the research site.

20. Change in contact information of the research site.

21. Any conflict of interest, including but not limited to a financial conflict, or the appearance of a conflict of interest with the PI/QI, sub-investigators, or study staff.

22. Any other problem that the PI/QI believes needs to be reported promptly to the IRB.

23. Any study results uncovered by the sponsor/CRO within two years of study closure that could directly affect subject safety.