## Events to Report to Schulman

### Purpose:
Schulman requires investigators, sponsors, CROs and institutions to report the following (as applicable) to the Board within ten (10) business days of discovery, except as otherwise noted.

**NOTE:** This is not a complete list of items that must be reported to Schulman. Rather these are events that must be reported within a specified timeframe after occurrence or discovery.

### Events to Report

1. **Unanticipated Problems Involving Risks to Human Subjects or Others** ("Unanticipated Problems"). Please consult the [Subject Safety Event Reporting Decision Chart](#) to determine if an event meets reporting criteria.

   **NOTE:** Report to the IRB within 24 hours of discovery if the Unanticipated Problem involves a death.

2. **Unanticipated adverse device effect** (UADEs): Please consult the [Subject Safety Event Reporting Decision Chart](#) to determine if an event meets reporting criteria.

   **NOTE:** Report to the IRB within 24 hours of discovery if the UADE involves a death.

3. **Breach of confidentiality** involving a study subject.

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

5. **Incarceration of a subject** while enrolled in a study.

6. **Pregnancy** of a subject enrolled in a study that excludes pregnant subjects.

7. **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.

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

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

10. 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 Inspection Exit Notice or Notification of Deficiencies Letters.**

11. **Investigator-specific enrollment restrictions, holds, or terminations** that are self-imposed or by the sponsor/CRO and not for administrative purposes or business related.

12. **Change of Principal Investigator (PI)/Qualified Investigator (QI) or Sub-Investigator (Sub-I)** due to unforeseen circumstances.

13. **Change in contact information** of the research site.

14. 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-I, or study staff.

15. 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.

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

17. **Changes to the protocol, investigators, or site location** made without prior Board review to eliminate an apparent immediate hazard to a research subject.

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

19. **OHRP Determination Letters.**

20. **Office of Research Integrity Administrative Actions.**

21. Any **other problem or event** that the PI/QI believes needs to be reported promptly to the IRB and/or sponsor.

22. Any **study results** uncovered by the sponsor/CRO within two (2) years of study closure that could directly affect subject safety.