Reporting Local Information

Investigators must report the following information to the IRB within ten (10) business days of discovery, except as otherwise noted. All reportable items must be submitted on a Reportable Local Information Form. Non-local items requiring changes to the protocol should be reported on a Request for Amendment form.

Events to Report

1. **Unanticipated Problems (UP)** involving Risks to subjects or others:
   - a. Are unanticipated;
   - b. Are related or possibly related to participation in the research; and
   - c. Suggest that human subjects or others are at increased risk of harm.
   NOTE: UPs that involve a death must be reported to the IRB within 24 hours of discovery.

2. Information that indicates a **new or increased risk** (change in the frequency or magnitude of risks or benefits):
   - a. An interim analysis or monitoring report
   - b. Published paper or presentation

3. Withdrawal, restriction, or modification of drug/device/biological approval from the FDA or Sponsor.

4. A breach of confidentiality involving a subject (e.g. unapproved use or disclosure of PHI)

5. Changes to the protocol made without prior IRB review to eliminate an apparent immediate hazard to subjects.
   NOTE: Changes made to eliminate risk must be reported to the IRB within 5 business days of discovery.

6. Complaint of a subject that indicated unexpected risks or that cannot be resolved by the study team.

7. Audit, inspection, or inquiry by a Federal Agency (FDA 483, FDA Warning letters, FDA Audit reports, Notice of Disqualification, OHRP Determination letter, Debarment or Restricted list)

8. Medical license suspension, restrictions or revocations, or any licensure or credentialing issues involving PI, co-PI, sub-I, or research staff.

9. Incarceration of a subject enrolled in a protocol not approved to enroll prisoners.

10. Protocol violations due to investigator or research staff

11. Unanticipated adverse device effect (UADEs):
   - Any serious 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 \(\text{including a supplementary plan or application, or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.}\)

12. Any other problem that the PI believes needs to be reported promptly to the IRB.

13. Any conflict of Interest previously undisclosed or managed.