



Reporting Local Information

The IRB is concerned for the safety and welfare of participants in research for sites where they serve as the IRB of record (e.g., local sites). Investigators are required to report local problems, concerns, serious risks, and failure to follow the protocol to the IRB for all non-exempt research. These reports must be submitted within **ten (10) business days** of discovery, except as otherwise noted. All reportable items must be submitted on an amendment form. If the UA serves as the IRB of record for another research site, the site must follow all requirements in this guidance.

Items that are non-local (e.g., reports from other sites that the sponsor sends to all sites participating in the study) should be reported on an 'Amendment to Approved Human Research.' These items typically also include changes to the IRB protocol or informed consent.

Events to Report

<p>1. Unanticipated Problems (UP) involving Risks to subjects or others:</p> <ul style="list-style-type: none">a. Are unanticipated;b. Are related or possibly related to participation in the research; andc. Suggest that human subjects or others are at increased risk of harm. <p>NOTE: UPs that involve a death must be <i>reported to the IRB within 24</i> hours of discovery.</p>
<p>2. Information that indicates a new or increased risk (change in the frequency or magnitude of risks or benefits):</p> <ul style="list-style-type: none">a. An interim analysis or monitoring reportb. Published paper or presentation
<p>3. Withdrawal, restriction, or modification of drug/device/biological approval from the FDA or Sponsor</p>
<p>4. A breach of confidentiality involving a subject (e.g., unapproved use or disclosure of PHI)</p>
<p>5. Changes to the protocol made without prior IRB review to eliminate an apparent immediate hazard to subjects.</p> <p>NOTE: Changes made to eliminate risk must be <i>reported to the IRB within 5 business days</i> of discovery.</p>
<p>6. Complaint of a subject that indicated unexpected risks or that cannot be resolved by the study team</p>
<p>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)</p>
<p>8. Medical license suspension, restrictions or revocations, or any licensure or credentialing issues involving PI, co-PI, sub-I, or research staff</p>
<p>9. Incarceration of a subject enrolled in a protocol not approved to enroll prisoners</p>
<p>10. Protocol violations due to investigator or research staff</p>



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| <p>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 [<i>including a supplementary plan or application</i>], or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.]</p> |
| <p>12. Any other problem that the PI believes needs to be reported promptly to the IRB</p> |
| <p>13. Any conflict of Interest previously undisclosed or managed</p> |