THE UNIVERSITY OF ARIZONA Research & Partnerships

Reportable New Information

The Institutional Review Board (IRB) is concerned for the safety and welfare of participants in research for sites where they serve as the IRB of record. 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.

Submit a Reportable New Information (RNI) in eIRB. If changes to study materials are needed as a result of an RNI, a **separate** Modification should be submitted in eIRB. If the University of Arizona IRB serves as the IRB of record for another research site, the site must follow all requirements in this guidance.

Note: RNI submissions require Department/Center/Section Reviewer approval at the time of submission if the reportable event involves substantial risk to participants, a data breach, another significant issue, or as otherwise requested by the IRB.

Non-local items (e.g., reports from other sites that are distributed by the sponsor to all participating sites) should be submitted as an RNI in eIRB.

Events to Report

1. **Unanticipated Problems (UP)** involving risks to subjects or others that are: a. Unanticipated; b. 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). Information may be uncovered from: a. An interim analysis or monitoring report b. Published paper or presentation c. Sponsor report or FDA correspondence d. Investigator finding
3. Withdrawal, restriction, or modification of drug/device approval from the FDA or sponsor
4. A **breach of confidentiality** involving a subject (e.g., unapproved use or disclosure of PHI)
5. Changes made to the protocol without prior IRB review NOTE: Changes made to eliminate immediate risk to subjects 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-I, sub-I, or research staff

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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 (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. **Local Audit Findings Suggest Need for a Corrective and Preventive Action (CAPA) Plan:** If a local audit identifies significant concerns regarding the overall conduct of a study, including significant protocol deviations, deficiencies in good documentation practices, or other findings that may affect subject safety, data integrity, or regulatory compliance, the auditor and/or IRB may require submission of a CAPA plan. When a CAPA plan is required by the auditor, the auditor **must** review and approve the finalized CAPA plan and provide sign-off to the IRB before the IRB will review the RNI and CAPA plan. To ensure timely resolution of audit findings, the finalized CAPA plan should be submitted to the IRB no later than **one month from the date the need for a CAPA plan is identified**. This timeframe includes sufficient time for the auditor to review and approve the CAPA plan and/or associated audit report. If any audit finding indicates that subjects have been exposed to a **new or increased risk**, or otherwise meets the definition of an **unanticipated problem**, an RNI must be submitted to the IRB as soon as possible and within the applicable reporting timeframe described above. The RNI submission should not be delayed pending completion or approval of the CAPA plan.
13. Any other problem that the PI believes needs to be reported promptly to the IRB
14. Any **conflict of interest** previously undisclosed or managed