Monday Morning Practice Pearls #8

When do I submit a Reportable New Information (RNI) form to the IRB and what happens after the submission?

You need to submit a Reportable New Information (RNI) form in PROTECT for any of the following:

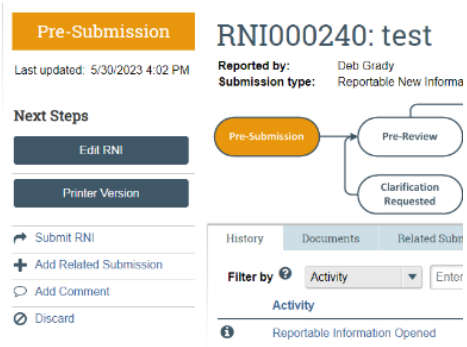
- Non-compliance: Failure of an investigator to follow the applicable laws, regulations, or institutional policies governing the protection of human subjects in research, or the requirements or determinations of the Institutional Review Board (IRB), whether the failure is intentional or not.
- Major protocol deviation: Deviation from the IRB-approved protocol that has, or may have the potential to negatively impact, the rights, welfare or safety of the subject, or to substantially negatively impact the scientific integrity or validity of the study.
- New information that might affect a participant's willingness to enroll or remain in the study. Examples include, but are not limited to:
    - An interim analysis that indicates a new risk or decreased effectiveness of the study intervention such that acceptability of risk is impacted
    - Withdrawal, restriction or modification of marketing approval of a drug, device or biologic used in the research
    - Publication in the literature or new marketing approval of a drug or device shown to be effective for the condition under study
- Complaint: Complaint of a subject that cannot be resolved by the research team.
- Death of a subject that is deemed to be at least possibly due to the research.
- Unanticipated Problem (UP) involving risks to subjects or others
- Short Form Use: Use of the short form consent to enroll a non-English speaking subject.
- Audit: Audit, inspection, or inquiry by a federal agency.
- Confidentiality: Breach of confidentiality
- Unreviewed change: Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject.
- Incarceration: Incarceration of a subject in a study not approved by IRB to involve prisoners.
- Suspension: Premature suspension or termination of the research by the sponsor, investigator, or institution. This includes if enrollment to one arm of the study has been put on hold.

What is the timeframe for reporting to the IRB?

You should report any new information about a study as soon as any research team member becomes aware of it. Per NIH Policy 801 *Reporting Research Events*

- 7 calendar days for: non-compliance, major deviations, new information that might affect a participant's willingness to enroll or remain in the study, UPs, short form use, and suspension. Note: For non-compliance, major deviations and UPs this includes actual or suspected events.
- IMPORTANT: Deaths that are possibly, probably, or definitely related to the research must be reported within **24 hours** of research team member awareness

REMEMBER: Don't forget to hit the submit RNI button in the workspace otherwise, it will not be sent to the IRB.



Related M2P2s:

- #3: What information should be included in the narrative summary when reporting an expediate AE to the IRB or IND/IDE sponsor?
- #10: How do I submit a major protocol deviation to the IRB and what do I include in the submission?
- #50: What are the new expediated IRB reporting requirements for "events" that happen during research?

What happens after the RNI is submitted?

Below is an algorithm to illustrate what happens after you submit an RNI: