Monday Morning Practice Pearls #50

What are the expedited IRB reporting requirements for "events" that happen during research?

The expedited reporting requirements can be found in Policy 801 *Reporting Research Events*.

Deaths that are possibility, probably or definitely related to the research must be reported within 24 hours of a research team member becoming aware of the death.

The following must be reported to the NIH IRB within seven (7) calendar days of a research team member becoming aware of event:

- Unanticipated Problems (actual or suspected)
- Non-compliance (actual or suspected) not related to a protocol deviation
- Major protocol deviations (actual or suspected)
- Use of the short form consent to enroll a non-English speaking subject
- New information that might affect a participant's willingness to enroll or remain in the study
- Suspension or termination of research activities, including if enrollment to one arm of the study has been put on hold

IMPORTANT: For multi-site studies when NIH IRB is NOT the IRB of record, but the event occurred with a participant enrolled at an NIH site, the above expedited reporting requirements still apply. The event must be reported in PROTECT for OHSRP review.

NOTE: Follow the protocol for appropriate event reporting to the sponsor. Typically for SAEs, this is within 24 hours per the FDA regulations.

How do I report to the IRB?

Expedited reporting of above events is done via PROTECT using the Reportable New Information (RNI) form.

My study has external IRB review – what do I do?

- Follow the reporting requirements of the external IRB.
- If the event happened with a participant enrolled at an NIH site, a RNI still needs to be submitted in PROTECT for OHSRP review.
- If the external IRB makes a determination of serious and/or continuing noncompliance, this must be reported within seven (7) calendar days of notification via PROTECT for OHSRP review.

Definitions:

- Unanticipated Problem:
    - Any incident, experience or outcome that is unexpected, related or possibly related to participation in research and suggests that the research places participants or others at a greater risk of harm than was previously known.
- Non-compliance:
    - Failure of investigator(s) to follow the applicable laws, regulations, or institutional policies governing the protection of human subjects in research, or the requirements or determinations of the IRB, whether intentional or not.
        - Serious non-compliance: non-compliance, whether intentional or not, that results in harm or otherwise materially compromises the rights, welfare and/or safety of the subject and/or materially effects the scientific integrity or validity of the research.
        - Continuing non-compliance: pattern of recurring non-compliance that either has resulted, or, if continued, may result in harm to subjects or otherwise materially compromise the rights, welfare and/or safety of subjects, affect the scientific integrity of the study or validity of the results.
- Major Deviation (subset of non-compliance):
    - Deviations from the IRB approved protocol that have, 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.

Related M2P2:

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