Monday Morning Practice Pearls #10

How do I submit a MAJOR protocol deviation to the IRB and what do I include in the submission?

Definitions

Per NIH Policy 801 *Reporting Research Events*, a protocol deviation (PD) is defined as "any change, divergence, or departure from the IRB approved research protocol."

1. Major Deviation – Deviation 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.
2. Minor Deviation – A Deviation that does not have the potential to negatively impact the rights, safety, or welfare of subjects or others, or the scientific integrity or validity of the study.

It is the PI's responsibility to make the determination if the deviation meets the definition of a major deviation.

All deviations that meet the definition of Major must be reported within 7 calendar days of an investigator becoming aware of an actual or suspected deviation. Although protocol deviations are also non-compliance, these should only be reported once as deviations.

How to Report

To report a major PD, use the *Reportable New Event (RNI)* form in PROTECT (see M2P2 #8). The most important part of the form is the section entitled "*Briefly describe the new event*". The IRB and/or the Clinical Director (CD) receiving the report typically do not know anything about the patient nor will they have the protocol readily available to them when reviewing the major PD.

What to Include When Reporting

In the RNI, include:

- Description of the major deviation:
  - Describe event in chronological order.
  - Include relevant information to allow the IRB to assess any risk to participants and/or effect on scientific integrity of the study.
  - Avoid using acronyms
  - Submit any/all supporting documentation that is relevant to the event
- Assessment of the impact on the scientific integrity or validity of the study.
  Ask yourself:
  - Did the deviation have the potential to negatively impact the scientific integrity of the data collected for the study? If so, describe.

  Note: Do not restate the question. If the deviation does not negatively impact the scientific integrity or validity of the study, specify how or why.

- Assessment of the impact on the research participant's rights, safety or welfare, including any potential negative impact.
  Ask yourself:
  - Did the deviation harm or pose a potential risk of harm to the research participant? If so, describe.

  Note: Do not restate the question. If the deviation does not have the potential to negatively impact the research participant's rights, safety or welfare, specify how or why.

IMPORTANT: If the deviation does not have the potential to negatively impact the scientific integrity or validity of the study or the research participant's rights, safety or welfare, it is a minor deviation per Policy 801; therefore, reportable to the IRB in summary form at time of continuing review.

- When describing what steps have you already taken and what step(s) you plan to take as a result of the problem, you have done or plan to do something; do not leave this blank or say that you don't need to do anything. Even for a patient who misses an appointment due to weather, consider building wiggle room into the protocol (see M2P2 #4).

Related M2P2s:

- #8: When do I submit a Reportable Event Form (REF) to the IRB and what happens after the submission?
- #50: What are the new expediated IRB reporting requirements for "events" that happen during research?
- #51: What research "events" need to be reported at the time of continuing review?