Monday Morning Practice Pearls #17

What information needs to be reported to the IRB at the time of continuing review (CR)?

Per Office for Human Research Protections OHRP Continuing Review Guidance (2010), "One of the most important considerations for the IRB at the time of continuing review is whether there is any new information provided by the investigator, or otherwise available to the IRB, that would alter the IRB's previous conclusion that (1) the risks to subjects are minimized, and (2) the risks to subjects are reasonable in relation to anticipated benefits, if any, to the subjects and the importance of the knowledge that may reasonably be expected to result . . . The IRB's continuing review procedures should ensure that the IRB will consider relevant information received since the date of the last IRB review . . ."

At time of CR, the PROTECT application will ask specific information about the progress of the study since initial review or prior CR.

In order for the PSO Manager to accurately answer the CR questions in PROTECT, you will receive an email asking for the following information:

a) Study enrollment
b) Research milestones related to enrollment, follow-up and analysis
c) Research events
    i. If any subject has experienced unexpected harm. Remember to include any AEs that were also unanticipated problem.
    ii. If anticipated adverse events have taken place with greater frequency or severity than expected.
    iii. Subject withdrawal. Withdrawal means the participant requests to be removed or declines further treatment/follow up which include lost to follow up participants. This is does not include screen failures, disease progression or deaths.
    iv. If there any other relevant information to report regarding this study, especially information about risks (e.g., unanticipated problem).
    v. Complaints about the study
    vi. Publications relevant to risk or benefit
    vii. Interim findings
    viii. Data safety monitoring reports (report will need to be provided to the PSO)
    ix. Regulatory actions that could affect safety and risk assessment (e.g., FDA clinical hold)
    x. List of modifications
    xi. Confirmation that IRB expediated reportable events have occurred appropriately
    xii. Instances of protocol non-compliance (e.g., deviation)
    xiii. Use of short form consent including number and language(s)
    xiv. If in the opinion of the PI, there is a change in the risks and potential benefits

NOTE: If any of the above did occur, you will need to explain. For example, if AEs have occurred at a greater frequency than expected, specify what the AE is and how the frequency changed, summary of the interim analysis, or high-level summary of deviations.

d) Cumulative Inclusion Enrollment Report (CIER)
e) Redacted Consent Form(s)

If assistance is needed, please contact the Office of Education and Compliance, ccroec@mail.nih.gov.

Related M2P2s:

- #50: What are the expedited IRB reporting requirements for "events" that happen during research?