Monday Morning Practice Pearls #13

What are the responsibilities of the research team when CCR is the coordinating center for a multi-site clinical trial?

Listed below are the major responsibilities associated with multi-site research. Other resources include: CCR SOPs related to multi-site research and the CCR protocol template which identities appropriate language to incorporate in a multi-site study.

Protocol Development and Approval

- Design and develop protocol and template informed Consent (IC) document for use at each collaborating institution
- Select appropriately qualified study sites/site principal investigators
- Ensure that each collaborating institution holds an applicable OHRP-approved Federal Wide Assurance (FWA)
- Ensure each protocol is reviewed and approved by the participating site's IRB prior to enrollment of subjects at that site
- Maintain documentation of all participating site's IRB approvals
- Assure all relevant IRB correspondence (continuing review and amendments) and study status changes are communicated to all affiliate sites
- If CTEP-sponsored, obtain CTEP approval for all protocol versions of protocol prior to IRB submission
    - CTEP will send to manufacturer for review

Communication

- Identify all key participant site staff and their roles
    - Reinforce use of delegation of tasks log
    - Determine plan for regular communication with the external sites and how will this be documented
- Provide periodic updates to affiliated investigators on subject enrollment, general study progress, and relevant scientific advances

Clinical Data Management and Document Management

- Collect and maintain critical documents from affiliated investigators, e.g. resume/CV, medical license, certification of completion of training, laboratory certifications and laboratory norms, signed COI disclosure forms
- Develop and test protocol specific specifications for CCR database(s)
- Provide CCR database(s) training
    - Reinforce role of the CCR research nurse (e.g., data QA/logic checks)
- Store and/or manage data and data analysis
- Protect the confidentiality of data
- Transfer data to manufacturer if applicable

Study Coordination

- Ensure that participating sites are using the correct version of the protocol and consent document
- Register subjects in PRES
- Track subject enrollment for entire study including all participating sites
- Ensure informed consent is obtained and documented from each subject in compliance with federal regulations
- Track, report, and maintain documentation of all serious adverse events and unanticipated problems and disseminate the information to participating sites
    - Use templates for reporting to NIH IRP IRB
    - CTEP specific:
        - Ensure that the participating site knows to copy the research nurse on any expedited AE reports to CTEP
        - CTEP will send ISRs to PI who then send to participating sites
- Ensure drug accountability at all sites
    - Know who is supplying the study drug and how to order, shop and store

Monitoring

- Monitor the research study progress and compliance with the IRB approved protocol
    - Determine type of monitoring that is planned (e.g., on-site and remote)
    - Determine frequency of monitoring
    - Determine who will monitor and communicate monitoring visits with participating sites
- Secure compliance at participating sites that are not adhering to the current version of the research protocol and/or GCP
    - Terminate involvement, if necessary, of non-compliant investigators and reporting such