Monday Morning Practice Pearls #19

What is the Safety Monitoring Committee (SMC) and what are my responsibilities as a research nurse?

Per NIH policy and CCR SOP # PS-9, the SMC provides oversight and monitoring of the conduct of certain types of protocols to ensure the safety of participants and the validity and integrity of the data. This is independent from any sponsor monitoring.

Types of protocols that will require SMC review

1. All NCI CCR multi-institutional treatment protocols where NCI CCR is the coordinating site and there is no designated Data and Safety Monitoring Board (DSMB) or equivalent.
   Note: The SMC will not monitor a multi-site CTEP-sponsored protocol if this is the only SMC qualifying criteria for the protocol.
2. All protocols using gene transfer or gene therapy methodology.
3. All protocols that the CCR believes require special attention due to high public interest or public perception of risk or potential conflict of interest (e.g., studies where the PI or an AI holds a patent on any agent being used in the protocol).
4. All protocols that are deemed by the IRB, Clinical Director, or Branch Chief to pose potentially very high risk to patients.

Note: Your protocol should specify if a SMC will be used.

SMC Factoids

- SMC meets quarterly
- Protocols will be reviewed initially as soon as possible after their annual NCI-IRB continuing review date. Subsequently, each protocol will be reviewed as close to annually as the quarterly meeting schedule permits or more frequently as may be required by the SMC.
- Studies will be monitored across the sites for unusual, significant toxicities that are related to the investigational agents being used.
- For protocols where the PI or AI hold a patent, review will also focus on the potential perception of a conflict of interest regarding issues such as the continuing study relevance vs. PI benefit.
- Use the SMC report template.

Role of the Research Nurse

Your role in the SMC process will vary from team-to-team. In general, you should:

- Meet with your Protocol Specialist to determine who will do what for report preparation thru post-approval (see flow diagram on page 2).
- Review all data in the report for completeness and discrepancies, including:
  - Accrual table to date by year per treatment arm
  - AE table of all grade 3 or greater expected or unexpected AE that are related to research
- For multi-institutional trials: frequency of monitoring and completeness of data submission by participating sites

Notification

- PI receives email notification from Susan McMullen of the due date for submission of the SMC report.
- Usually, notification is sent out ***2 months*** prior to the review date.
- If there is no protocol related treatment and no protocol related toxicity within the review period, then, the PI or proxy (e.g., Research Nurse) should let Susan McMullen know.

Report Preparation

- Follow SMC report template. Please note the **data cut-off date** and the **due dates** referenced in the email notification email.
- For the AE portion of the template, prepare per document attached to notification email.

Approval

- Approval from the SMC will be sent to the PI and research contact (e.g., Research Nurse).
- Approval outcome letter should be uploaded into iRIS.
- A copy should be saved in the regulatory files.

Post-Approval

- In iRIS, go under the DSMB/SMC Outcome letter submission tab.
- Open a new form and complete the appropriate information.
- Make note of the **date of the review** and whether any outcome action is required.
- Upload the outcome letter in iRIS. Submit and apply signoff in iRIS.

M2P2 website