Monday Morning Practice Pearls #19

What is the Monitoring Committee/Board and what are my responsibilities as a Clinical Research Coordinator (CRC)?

There are two types of Monitoring Committees/Boards for the CCR:

- Data and Safety Monitoring Board (DSMB): certain CCR-held clinical protocols will have safety oversight by a Sponsor (OSRO) convened DSMB.
- Safety Monitoring Committee (SMC): which advises the Clinical Director, the Institutional Review Board (IRB), and other senior leaders at the NCI CCR as appropriate on the safety and continuing scientific validity of clinical protocols being conducted by NCI CCR investigators.

These committees/board are independent of the research team and operate under a charter that describes the membership, responsibilities, and operations of data review and meeting conduct. The protocol will specify if a monitoring committee/board is required and which type will be used.

As a CRC, you may be asked by your PI, PSO Manager and/or OSRO to obtain data or to review data that will be submitted to the committee. Please ensure that you are reviewing your data in the study database on a routine basis for accuracy and completeness.

For more information on the OSRO DSMB, including meeting calendar, please visit Office of Sponsor and Regulatory Oversight (OSRO) Data and Safety Monitoring Board (DSMB) website.

For more information on the CCR SMC, please visit the PSO website and scroll down to "NCI CCR SMC Charter."

References:

NIH HRPP Policy 503 - Data and Safety Monitoring

NIH Policy for Data and Safety Monitoring (June 1998)