Monday Morning Practice Pearls #17

What adverse events (AEs) need to be reported to the IRB at the time of continuing review (CR) and what format needs to be used?

Per NIH Policy 205 *Requirements for IRB Submissions*, "Required materials for Continuing Review (CR) of non-exempt human subjects research: . . . A high-level summary (not a line-item listing) of the following events that have occurred since the time of the last IRB IR or CR review, see Policy 3014-801 Reporting Research Events, e.g.: . . .Adverse Events and Serious Adverse Events that do not meet the definition of an Unanticipated problem (UP) . . ."

Per NIH Policy 801 *Reporting Research Events*, "Investigators must provide the following information to the IRB in summary format at the time of continuing review, or when otherwise specifically requested by the IRB or the OHSRP office of Compliance and Training. Investigators should provide a high-level summary of these events that have occurred since the time of the last IRB review and not a line item listing . . Adverse Events and Serious Adverse Events that do not meet the definition of an UP."

At time of CR, please prove a high-level summary of SAEs/AEs and include a determination of the effect of the SAEs/AEs on the risk profile of the protocol. Please specify that the PI has reviewed the SAEs/AEs. An example:

> Serious Adverse Events: There were a total of 2 SAEs filed during this reporting period: 1 Respiratory, Thoracic and Mediastinal disorders - related to study drug and 1 Cardiac disorder-unrelated to study drug. Adverse Events: There were a total of 124 AEs captured during the reporting period. All adverse events were reviewed by the PI and are within the known risk profile for this study. The risk profile remains the same.

Related M2P2s:

- #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?