Monday Morning Practice Pearls #20

Documentation of protocol-specific training and the impact for the Research Nurse

According to the FDA, the investigator (i.e., the PI) should ensure that there is adequate training for **all staff**, including AIs, research nurses, data managers, NPs, PAs, Fellows, CCR lab staff, and CC staff (e.g., pharmacy, nursing, radiology, OR) participating in the conduct of the study, including any new staff hired after the study has begun to meet unanticipated workload or to replace staff who have left.

Many of the Investigators will delegate protocol-specific training to the Research Nurse. So what does this mean for you as a Research Nurse?

1. Ensure that you have received adequate protocol training from the PI. Ask questions - about the protocol, protocol procedures, and what your specific responsibilities for the protocol will be.
2. Ensure that you have been given the responsibility to provide protocol-specific training to others, specifically the nurses in the CC Nursing Department. This means that this activity needs to be assigned to you by the PI and documented on the Delegation of Authority Log.
3. Remember that all involved in clinical care of your research participants have received training appropriate to their role.
4. Remember to include ancillary departments (e.g., inpatient nursing units, OP clinics, Day Hospital, OR, radiology) in any training, as needed. Think about inviting some of the key departments to a team meeting where the PI will be discussing the protocol.
5. Coordinate and provide inservices for the CC nurses. You may need to do more than one session. Think about tape recording the presentation.
6. Document the training: when, to whom, and content. Use the Protocol Review Log for documentation and attach other information used for training that is not in the protocol. There will be multiple protocol review logs for one protocol.
7. Maintain the protocol review logs in the regulatory file.