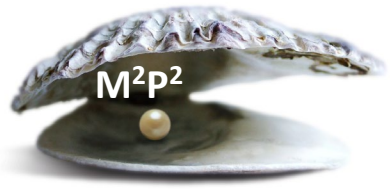

Monday Morning Practice Pearls #2

What is Good Documentation Practice (GDP)?

A basic principle underlying clinical care documentation is *if it wasn't documented, it wasn't done*. This includes procedures performed and discussions between the health care team and the patient/family. In clinical research, it is critical to document everything that occurs as well as everything that does not occur. The quality of the study data is directly affected by the quality of the study documentation.

GDP is a term used to describe standards by which documents are created and maintained. This includes:

- Medical record documentation
- Maintain research records for those items that aren't found in the medical record
- Protocol specific regulatory file

What is the impact for licensed clinical research staff?

All licensed clinical research staff (i.e., MD, DO, NP, PA, RN) need to adhere to their state's Practice Act related to documentation. This typically will include documentation of patient encounters. Consequently, each encounter with a patient participant should be documented in CRIS.

In the CCR, part of the research nurse's role with study coordination includes ensuring that all required documentation is in the medical record. The research nurse does not need to necessarily create all of the documentation but does need to ensure that other members of the research team are held accountable for their role in documentation.

What does ALCOA mean?

The term ALCOA (i.e., attributable, legible, contemporaneous, original and accurate) is synonymous with key attributes for good documentation and quality data applied throughout the drug development process (e.g., manufacturing practices and clinical trials). It is referenced in the FDA guidance entitled *Guidance for Industry Part 11, Electronic Records; Electronic Signatures Scope and Application*.

For more details on clinical research documentation, review the CCR SOP PM-2 *Clinical Research Documentation*.

December 2021