Monday Morning Practice Pearls #27

If consenting is an ongoing process, what does re-consenting mean?

The Investigator is required to inform subject of new findings (e.g., toxicities) and to ensure that the subject is willing to participate on the clinical trial. This process is then documented in CRIS including willingness of subject to continue the trial.

However, when the term re-consenting is used, it means having the research participant re-sign the consent document (i.e., the current IRB approved version).

The IRB or sponsor may ask for subjects to be re-consented as a result of a protocol amendment.

In addition to the IRB or sponsor, state laws may also dictate re-consenting. This is not applicable for the state of Maryland though.

What does this mean for you?

1. Re-consent a patient only if the IRB requires it.
2. DO NOT re-register the patient with the CRO.

One last thing….Remember that for children who were initially assented and their LAR was consented, you will need to consent the child when they turn 18 years of age.