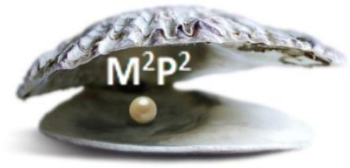

Monday Morning Practice Pearls #27

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

The concept of reconsent is not described or defined in the regulations. However, 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 [45 Part 46.116(c)(5); 21 Part 50.25(b)(5)]. 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). Please note, the verbal notification is not considered a re-consenting.

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 or sponsor requires it. For the IRB, refer to the modification/amendment application and IRB outcome letter to determine if patients need to be reconsented.
2. The timing of re-consent depends on new information contained in the modification/amendment. If a new risk or change in treatment, the expectation is the patient be re-consented ASAP and not wait until the next clinic visit.
3. Enter the re-consent event in PRES. Once in PRES, go to enrollment view, under *Events of Significance* block, select *Re-Consent event* type, date and if applicable, comments.

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.

Please see M2P2 #69 *What is iMedConsent™?* for information about using the iMED consent process.