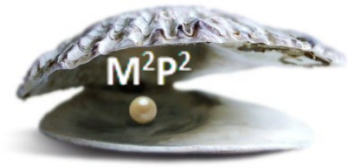

Monday Morning Practice Pearls #27

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

The concept of re-consent is not described or defined in the regulations. However, the Investigator is required to inform patients of new findings (e.g., toxicities) and to ensure that the patient 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 patient to continue the trial.

For recommendations on appropriate re-consenting processes, please refer to the *Guidelines for Reconsenting* posted under SOP PM-2 on the CCR SOP website . How you will provide this new information to the patient needs to be included when submitting an informed consent modification application.

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, or no later than 30 days, 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 AND the child is still participating in the research study, you will need to consent the child when they turn 18 years of age.

For re-consenting of non-English-speaking patients, please see *Frequently Asked Questions Related to Enrolling Non-English Speaking Participants in the CCR* posted under SOP PM-2 on the CCR SOP website.

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