Monday Morning Practice Pearls #48

A patient that is blind wants to enroll in a study. How do I enroll someone that cannot read the informed consent document?

- If a potential research participant cannot read the informed consent document due to blindness (with no Braille consent form available) or illiteracy, the verbal long form consent process should be used.
- The IRB must approve use of the verbal long form consent process prior to enrolling the patient.
- The investigator obtaining consent must read the long form consent document to the blind/illiterate patient.
- A witness must be present for the entire oral consent discussion.
- The blind/illiterate patient must sign and date the long form if able – see below if the patient is unable to write.
- The investigator obtaining consent and witness must sign and date the long form.
- The process must be documented in CRIS – include the names of all persons present during the oral consent discussion.

What if my patient cannot sign the informed consent document?

- If the patient can read but because of some disability, cannot sign the informed consent document, the long form informed consent document should be used for English-speaking patients.
    - The patient can "make a mark" such as an "X" on the signature line, leave the date blank if the patient is unable to write the date.
- If the patient is blind or illiterate, use the process above for oral long form consent process and the patient can "make a mark" on the long form.
- If a patient cannot write at all, the IRB must approve a consent process that specifically includes verbal agreement from the patient.
- In all cases, the informed consent process must be documented in CRIS – include the names of all persons present during the consent process.

References:

- NIH HRPP Policy 301 *Informed Consent* on the NIH HRPP Policy and Guidelines website.
- IRBO Informed Consent FAQ #28

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