Monday Morning Practice Pearls #26

You learn that your patient doesn't speak English *BUT* you have an IRB-approved protocol consent in the patient's native language (i.e., the full English version translated). How does the consenting process differ when not using the short-form consenting process?

M2P2 #24 addressed the "unexpected" enrollment of a non-English speaking subject. There are some protocols for which you know you will be enrolling non-English speaking patients during the protocol development period – for example: screening or tissue acquisition protocol or a protocol that is studying a disease or condition that is likely to attract someone who does not speak English. This type of enrollment is referred to as an "expected" enrollment (see NIH HRPP Policy 301 on informed consent).

This means that when the PI expects non-English speaking patients to be screened or enrolled, translation and IRB approval of the long form consent document is required. In order to assure that the translation is accurate, the IRB may choose to have a back translation or review of the document by an IRB member or other person who is fluent in that language. When non-English speaking subjects enroll, they are given a copy of the translated consent document.

So, what are the differences between the short-form consenting process and the consenting process when using the translated long form consent for a non-English speaking patient?

Short Form Process	Long Form Process
Need IRB approval before consenting **(**see M2P2 #24)	N/A - Already have IRB approval
Interpreter needed unless the person obtaining consent is fluent in the prospective patient's language (see M2P2 #24)	Same
Discussion between person obtaining consent and the patient via an interpreter if applicable (see M2P2 #25)	Same
Signatures required on English long form: Person obtaining consent and the witness to the oral presentation who may be the interpreter (see M2P2 #25)	Signatures required on translated long form: Person obtaining consent, and the patient. A note in CRIS will identify the interpreter. *Note:* • *The English long form is not used.* • *Since there is an English version and often a back translated English version, the person obtaining consent may sign on the translated long form.*
Signatures required on the short form: Witness to the oral presentation which is often the interpreter and the patient (see M2P2 #25).	N/A
The Administrative Sections of both the long form (English) and short form consent documents must be completed by the person obtaining consent or other appropriate NIH staff member that was present during the oral presentation	The Administrative Section of the translated long form consent document must be completed by the person obtaining consent or other appropriate NIH staff member that was present during the oral presentation. Only select the second option since a witness is not required.

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