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 preferred language for healthcare language (i.e., the full English version translated). How does the consenting process differ when not using the short-form consenting process?

As of March 1, 2024, the NCI IRB requires, for greater than minimal risk studies, that a fully translated long form be used for patients that do not speak English. See M2P2 #24 for more information and the requirements for minimal risk research. See also NIH HRPP Policy 301 on informed consent and the OHSRP *Guidance for obtaining consent to participate in research from non-English speaking participants*.).

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
Interpreter needed unless the person obtaining consent is fluent in the prospective patient's language (see M2P2 #24)	Same
Witness to the entire process required. This may be the interpreter (see M2P2 #24)	None required unless patient is blind or illiterate (see M2P2 #48).
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 must identify the interpreter. ***Note:*** • *The English long form is not signed.* • *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 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.
After use of short form, notify • PSO within 1 business day • IRB within 7 calendar days	

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

Related M2P2s:

- #24: *You learn that your patient doesn't speak English and you don't have an IRB-approved protocol consent in the patient's preferred language for healthcare. What do you do? Part 1: Seeking IRB Approval & Securing Translator*.
- #25: *You learn that your patient doesn't speak English and you don't have an IRB-approved protocol consent in the patient's preferred language for healthcare. What do you do? Part 2: Consent Discussion and Documentation*
- #48: *A patient that is blind wants to enroll in a study. How do I enroll someone that cannot read the informed consent document? (includes information about patients that cannot sign the document).*