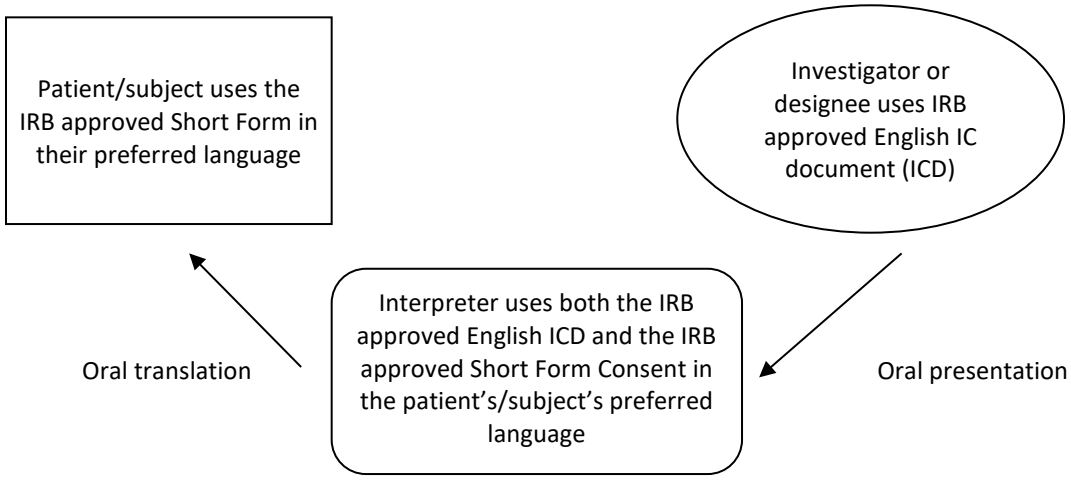
Monday Morning Practice Pearls #25

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 language. What do you do?

Part 2: Consent Discussion and Documentation

Once you have confirmed there is an approved short form in the patient's language and you have secured an interpreter and witness, if applicable (see M2P2 #24), the Investigator or designee can proceed with the consent discussion. The diagram below depicts the process that is used. There must be a witness to the oral presentation present at the location of the investigator/designee. Per NIH HRPP Policy 301, the witness must be fluent in the language of the subject and in English.

Make sure to complete the information on short form including the Institute, PI, Protocol Number and Protocol Title and on page 2, who to contact with questions about the research and questions about rights of the research subject. **Also insert protocol number on the footer information of the short form.**



After the discussion has been completed and all questions answered to the patient's satisfaction, the following signatures are required:

- The short form document is signed by the patient/subject. In the case of subjects who are unable to sign their name (e.g., illiterate, blind or disabled), "making their mark" is acceptable.

IMPORTANT: A non-English speaking patient must not sign ANY research consent document they cannot read.

- The witness to the oral presentation must sign both the short form and a copy of the written summary (i.e., IRB approved English version). When using the CC Language Interpreter Program (LIP), the interpreter will sign as the witness. If using the Cyraphone, a separate witness must sign the consents. The witness must be fluent in the language of the subject and in English. If a bilingual witness is not available, see Note on witness requirements in M2P2 #24.
- The Investigator or individual authorized to obtain consent must sign the written summary (i.e., English approved long version).

- If the IRB approved long form consent document (i.e., English version) has embedded questions, then the investigator would respond on behalf of the patient. The interpreter would ask the subject the embedded question(s) and convey their response to the investigator obtaining consent. Neither the interpreter nor the patient should record the response on any document. The investigator will indicate the response on the English IRB consent document by initialing the patient's response using their (i.e., the investigator) initials. If initials are not required (i.e., there is a yes/no response only), the investigator would answer per the patient's preference. If the patient does not want to provide a response, it is left blank. The explanation of all of this needs to be clearly documented in CRIS.
- The Administrative Sections of both the long form (i.e., 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. DO NOT make extraneous notes/marks in this section. For further guidance, see the OHSRP Consent FAQs.

What to do with the signed and dated consent documents?

1. Provide copies of ALL signed documents to the patient/subject.
2. ALL original signed consent documents (including short form consents and the written summary/English IRB approved consent) are transmitted to the Clinical Center Health Information Management Depart (HIMD) for scanning in the patient's permanent medical record. If using the iMed consent process, the signed consents are automatically uploaded into CRIS when the document is completed (all initials and signatures obtained) and saved.

Documentation

Document the consent process in CRIS using the Documentation of Research Consent progress note and select ALL appropriate types of consent used (e.g., Use of iMed platform, Use of interpreter, Short form consent). The name of the interpreter must be included in the note. This must be done by the individual who conducted the discussion or another staff member present during the discussion. If an investigator is bilingual and conducts the consent process, that must be recorded in the note by selecting "Use of Interpreter."

Notification of PSO and IRB

- PSO must be notified within 1 (business) day after the use of a short-form consent/process via the CCR Short Form Use Notification & Consent/Reconsent Translation Request Portal. See *Frequently Asked Questions Related to Enrolling Non-English Speaking Participants in the CCR* posted under SOP PM-2 on the CCR SOP website.
- The IRB must be notified via Reportable New Information (RNI) form within 7 calendar days. See *OHSRP Guidelines for Enrolling Non-English Speaking Subject* posted under SOP PM-2 on the CCR SOP website.

ONE LAST STEP!

When the translated long form is available, you must provide a copy to the patient; however, this is not considered re-consent and the patient should not sign the translated form. This should be given to the patient within 30 days of the short form consent process. Document in CRIS that the translated long form has been given to the patient by use of an addendum to the Documentation of Research Consent note from the short form process.

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

Related M2P2s: #24 and #26