
# Monday Morning Practice Pearls #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: Determine if Informed Consent (IC) document needs to be translated ASAP & Secure Interpreter and Witness

First, you will need to confirm the risk level (i.e., greater than minimal risk study or a minimal risk) of your protocol as determined by the IRB. This can be found in the NIH IRB Approval (outcome) letter at the "Risk Level". This will let you know if the request for translation needs to occur ASAP or may be delayed.

- If the protocol's risk level is greater than minimal risk (e.g., every drug/device study, observation studies that require a biopsy) you will need to have the consent translated before enrolling the individual.
    - The PI must determine if it is justified to proceed with the short form consenting process because it is in the individual's best interest to enroll prior to the translation. The best interest of the individual means that it is necessary to ensure the rights, welfare, and safety of the individual. See OHSRP Guidance page 3 for examples. If the short form consent process is used, a translated consent should be requested ASAP.
- If the protocol's risk level is minimal risk (e.g., some questionnaire/ blood sample collection studies, natural history studies without CT/MRI scans):
    - A short form consent may be used up to three (3) times in the same language on the study to consent participants beginning on March 1, 2024.
    - After the use of 3 short form consents in a particular language, a translated consent form in that language is required to be used for future participants.

Second, notify the Protocol Support Office (PSO) about any requests for translations.

- Requests for translations are sent to the PSO 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.
- Ideally, the PSO should be notified no sooner than 3 weeks prior to the scheduled appointment and/or planned date of consent (i.e., in-person or telehealth visit at which the informed consent process is planned and the document signed).
- PSO will assess the type of study and determine if/when to submit the request for translation to the NIH library. For greater than minimal risk studies, a request for translation will be made ASAP in an effort to have the translated IC document in time for the visit.
    - Minimal risk studies: PSO will consult with OCD. OCD will review the number of short forms used to date as well as the remaining accrual for the study and will determine if to direct PSO to submit a request for translation.

      NOTE: PSO must be notified if the potential/planned consent involves multiple non-English speaking participants (e.g., enrolling 3 Amharic-speaking family member participants at the same time). Though the IRB is permitting some leeway (e.g., counting a family of "3" who are consented at the same time as a single consent), this information may become crucial to assessing the need to seek translation of an IC document more urgently for a minimal risk study.

## If the PI determines that the short form process is to be used, what happens next?

| Obtaining the Short Form Consent Document(s) |
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| • IRB approved short form consent documents are available in over 45 languages on the NIH IRBO short form website<br>• There are two versions of each short form, which version to use depends on when your protocol was initially approved: before or after the Revision to the Common Rule. If your study was initially approved **prior to or on 01/21/2019,** select from that listing for Pre-Common Rule. If your study was initially approved **after 01/21/2019**, select from the Common Rule versions listing. This will be noted on the top of the short form consent.<br>• For reference purposes, there is an English version of the short form consent on the website. However, the English short form is used for reference only – no one should sign the English short form. |
| **Securing an Interpreter & Witness** |
| Unless the person obtaining consent is fluent in the patient's language, an interpreter will be needed. It is preferable that someone who is independent of the subject (e.g., not a close family member, significant other, partner, etc.) be the interpreter.<br>• To schedule an in-person interpreter, please place an order in CRIS for *Language Interpreter - Social Work* no later than 24 hours prior to the date the service is required. Please contact the CC Language Interpreters Program (LIP) at 301-496-2792 from 7:30 a.m. to 4:30 p.m. Monday through Friday. Note: if the language needed is not a common language (e.g., Mandarin), more than 24 hours may be needed to secure an interpreter. Interpreters secured through CC LIP will also serve as a witness to the short form consent process.<br>• If unable to secure an interpreter via the CC LIP, you will need to use the Cyraphone AND secure a witness to the short form consent process.<br><br>**NOTE on witness requirements:**<br>Per NIH HRPP Policy 301, the witness must be fluent in the language of the subject and in English. If a bilingual witness is not available, the witness should verify with the interpreter that the subject understands the information presented, that all questions have been satisfactorily addressed, and that the subject agrees to participate. This information must be documented in the Documentation of Research Consent progress note. |

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

Related M2P2s:

- #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*.
- #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 (i.e., the full English version translated). How does the consenting process differ when not using the short-form consenting process?*