Frequently Asked Questions Related to Enrolling Non-English Speaking Participants in the CCR

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CCR Short Form Use Notification & Consent/Reconsent Translation Request Portal: link

1. When is a translated consent required per the new NIH IRBO policy?
    a. Greater than minimal risk studies (e.g., every drug/device study, observation studies that require a biopsy):
        i. A translated consent is required in the potential participant's preferred language with each/every consent/participant.
        ii. If there is no translated consent document available in the potential participant's language, the enrollment of the individual should be delayed, UNLESS it is determined by the PI that 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.
    b. Minimal risk studies (e.g., some questionnaire/ blood sample collection studies, natural history studies without CT/MRI scans):
        i. A short form consent may be used up to three (3) times in the same language on the study to consent participants during the lifetime of the study.
        ii. 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.

2. Who will pay for the translation?
    a. The PI/team. While there is one OCD CAN that will be used by PSO to request all translations from the library, the PI will be responsible for reimbursing CCR OCD for the translations. CCR will have a tracking system to help with this process and expects to reach out to PIs approximately quarterly to handle payments.

3. Where do I look to see if my study is greater than minimal risk or minimal risk?
    a. Refer to an NIH IRB Approval (outcome) letter at the "Risk Level".

4. When should PSO be notified that a short form/process was used to consent a non-English speaking participant?
    a. With no exception, PSO must be notified within 1 (business) day after the use of a short-form consent/process for a new participant to any CCR study using the portal.
        i. If a short form consent/process is used to *reconsent* a participant where PSO has already requested the translation, you do not need to notify PSO of this particular short form consent/process use.
        ii. The NIH IRB must be notified within 7 days after the use of a short-form consent to any CCR study via an RNI submission in PROTECT – this includes for all short form consent/process use, including new participants as well as for reconsent.

5. When should the research team let the PSO know about a potential non-English speaking participant and/or that an informed consent document (ICD)needs to be translated?
    a. For 04C0165 and 01C0129 (until it closes): Do not notify PSO in advance, notify PSO within 1 (business) day after the use of a short form consent/process.
    b. For all other studies, notify PSO as follows of the potential/planned consent using the portal:
        i. Notify PSO 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 consent is planned to be signed).
        ii. PSO will assess the type of study and determine if/when to submit the request for translation. For example:
            - Greater than minimal risk studies: PSO will submit the request ASAP in an effort to have the translated ICD 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 ICD more urgently for a minimal risk study.

6. How does the research team notify PSO about a potential non-English speaking participant and/or that an ICD needs to be translated?
    a. Requests should be submitted through the new "Notification of Short-Form Use/Request of Consent Translation" portal located here.

7. Who will request the ICD translation from the library?
    a. CCR PSO Manager/PSO designee. Clinical Research Coordinator (CRCs) and other study team members should not submit requests for translations of ICDs.

8. Do assent documents need to be translated?
    a. The short answer is yes.
    b. The new requirement to translate ICDs does not explicitly address assents, as there has never been an equivalent "short form" process for assent documents. The following is OHSRPs guidance to study teams when enrolling minor participants who do not speak English:
        i. When enrolling a non-English speaking minor participant, the best practice would be to provide that person with an assent translated into their preferred language.
        ii. If no translated assent document is available, and the protocol requires written documentation of assent, the study team should obtain verbal assent with an oral presentation of the information in the participants preferred language, using a professional interpreter, and the process documented in the consent note.

iii. When obtaining assent from a non-English speaking older minor, if there is a translated long form and the IRB has approved a process that allows older minors to provide their assent on the long form, then the older minor may read and indicate their assent on the translated long form. In general, IRBO has provided guidance that age 12 and above is an "older minor" who should be able to understand the written ICD; however, first check the protocol if age for this group is noted. Otherwise, verbal assent should be obtained and documented as above.
iv. If this is a deviation from the protocol, it does not need to be promptly reported to the IRB using an RNI form but may be reported at the time of continuing review.

9. How will the IRB be notified of the use of the short form consent/process?
    a. By submitting an RNI in PROTECT within 7 days of the short form being signed. Select "use of short form" option.
    b. The requirement to report the use of the short form applies to all NIH participants:
        i. Regardless of the IRB of record.
        ii. Does not apply to external sites/centers where CCR is the Coordinating Center.
    c. For a modification that involves a reconsent and the translated IC document approved is not ready by the time of a participant's next visit/time of required reconsent, the short form consent/process should be used and an RNI submitted.

10. What happens once the ICD is translated into the participant's language if the short form process was used?
    a. The participant needs to receive a copy of the ICD. There is no need to reconsent the participant (i.e., have them sign the ICD in their native language), but rather share the document with them.
        i. If the participant is off study at the time the translated ICD is available: until such time that the IRB issues guidance otherwise, the decision to provide off study participants with a copy of the translated ICD will be left to the PI/treating investigator.
    b. Upload the translated ICD to CRIS. Instructions will follow shortly from HIMD on the documentation required when uploading. In the meantime, contact OEC.
    c. Document in CRIS how the participant received the ICD and when.

11. What if I need a short form in a language for which a short form does not exist?
    a. If the specific study to which the individual will be consented is known:
        i. Greater than minimal risk studies: PSO will submit the request for translation of the long study consent for the specific study.
        ii. Minimal risk studies: PSO will consult with OCD and determine if to submit a request for a short form translation or if to submit a request for translation of the ICD.
    b. If the study to which the individual will be consented is not yet known and/or the long form ICD will take too long to be translated, PSO will request that a short form be translated ASAP. The individual cannot be consented/enrolled until the short form is translated.

12. What if a study includes participant-facing questionnaires, handouts, etc.?
    a. These may also need translation based on the risk of the study and the type of information or questionnaire being used (e.g., a safety information handout will likely require translation;

a questionnaire validated in English where completion is optional/not required for non-English speaking participants would not require translation).

b. The CRC will be asked to help PSO identify those studies that include these materials when a request for translation is submitted through the portal.

What about special considerations for IRB approved modifications/amendments?

13. *For IRB approved modifications that <u>do not require reconsent</u> of participants:* If the protocol already has an IRB non-English ICD approved, how will the PSO know to proceed with translation(s) of the ICD(s) into the other language(s) once the IRB approves the modification of the English ICD?

    a. In general, PSO will not automatically proceed to request a translation of any ICD(s) upon IRB approval of a modification. While exceptions will be made in some cases with prior approval from OCD (e.g., studies with expected enrollment of Spanish-speaking participants where a Spanish ICD is already available; revised ICDs that involve minimal revisions; studies with high accrual ceilings), PSO will first contact the study team upon IRB approval of every modification that includes a revised ICD(s) prior to requesting translation.
    b. *Within 2 business days of IRB approval of the revised ICD(s),* PSO will notify the PI/CRC of the IRB approval. PSO will include information regarding any prior language(s) into which the revised ICD(s) was translated at the time of the last modification (i.e., current/ active non-English ICD(s) on the CC consent website).
    c. *Within 3 business days of being notified by PSO of an IRB approval that involves a revised ICD(s),* the CRC/designee will be required to follow-up with PSO to confirm if the study involves expected enrollment of participants in any of the previously translated languages. If not, any ICD posted in another language will be deactivated, and the CRC/team will need to contact PSO to request ICD translation request at the time a new non-English speaking participant in the unanticipated language(s) is identified.

       Note: At the time of the submission of a modification that involves a revised ICD(s), PSO will indicate in the PROTECT study application submitted with the MOD to "deactivate" (i.e., mark as "not active") any previously translated ICD(s) where the revised translated consent is not being submitted concurrently with the revised English consent. This is the indication to PSS to deactivate/remove an ICD(s) on the CC consent website. After confirmation by the CRC/designee of any required translations, PSO will indicate in a new MOD to "(re-)activate" (i.e., mark as "active") the revised translated ICD(s) when submitting to the IRB for approval. Similarly, this is the indication to PSS to activate an ICD(s) on the CC consent website.

14. *For IRB approved modifications that <u>do require reconsent of participants</u>:* What about modifications to ICD approved by the IRB that require reconsent of participants (or other method of written notification – e.g., letter)?

    a. *Within 2 business days of IRB approval of the revised ICD(s) that require reconsent,* PSO will notify the PI/CRC of the IRB approval. PSO will include the IRB's determination for which participants require reconsent (e.g., on active treatment, all in follow-up, etc.).
    b. *Within 3 business days of being notified by PSO of an IRB approval that requires reconsent,* the CRC/designee will be required to check PRES and submit to PSO a request through the portal the list of each non-English language for participants who require reconsent per the IRB's determination.

   i. Since PRES only started collecting consent language in 2021, the CRC will need to go into PRES and update the non-English language for any participant still on study at the time the modification (greater than minimal risk studies) or for all participants ever consented to the study (minimal risk studies).

c. When PSO receives the listing of languages required:
   i. Greater than minimal risk studies: PSO will submit the request for translation of the revised ICD in each/every language required.
   ii. Minimal risk studies: PSO will consult with OCD and determine for what language(s) to submit a request for ICD translation, or if to advise the study team to use the short form consent/process.

d. When PSO receives the translated ICD(s) from the library, the PSO Manager/designee will submit each translated ICD ASAP as received as a new modification to the IRB (i.e., if multiple translated ICDs are needed, PSO has been advised by the IRB not to wait to submit all at once to the IRB).
   i. If the revised translated ICD is not IRB approved by the time of the participant's visit at which reconsent is required, proceed with the short form/process (including submission of an RNI).

Resources:

- OHSRP Policy 301 Informed Consent
- OHSRP Guideline-Enrolling Non-English Speaking Subjects
- OHSRP Presentation from 2/1/24: *An overview of IRB expectations when non-English speaking persons enroll in research: The importance of ensuring comprehension.*