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

August 2024

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

1. When is a translated consent required per the new NIH IRBO policy (effective March 1, 2024)?
    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 from the time of implementation of the NIH IRBO policy (i.e., March 1, 2024).
        ii. After the use of 3 short form consents in a particular language from March 1, 2024, 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.

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 to determine the "Risk Level".
    b. This information will also soon be available in CCR's PINS and/or PRES systems.

4. When and how 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 (preferably) 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 (or at ~3 weeks prior to the scheduled appointment/planned date of consent).

- 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: If the potential/planned consent involves multiple non-English speaking participants (e.g., enrolling 3 Amharic-speaking family member participants at the same time), the IRB considers this a "single" use/ count for the use of a short form in that language.

c. CCR PSO Manager/PSO designee will submit the request to the NIH Library. Clinical Research Coordinators (CRCs) and other study team members must not submit requests for translations of ICDs.

5. What if the research team could not let PSO know in advance about a non-English speaking participant and 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 unanticipated use of a short form consent/process for a new participant to any CCR study using the portal.
   b. If PSO was already notified of the (then potential) participant in the past and is already working on a translation but the translation was not IRB approved/available in time that a short form was used, or the decision was reached for a minimal risk stud that a translation was not required, you do not need to notify PSO again for this same instance that a short form was used.

6. When and how will the NIH IRB be notified of the use of the short form consent/process?
   a. The NIH IRB must be notified within 7 days after the use of a short form consent for any CCR study.
   b. Submit an RNI in PROTECT:
      i. Select "use of short form" option
      ii. Provide the justification for using the short form consent process in the description of the event and include justification of the use of the short form regardless of the risk level of the study.
      iii. For minimal risk studies, inform the IRB if the translated consent will be provided to the participant.
      iv. For greater than minimal risk studies, indicate that the translated consent will be provided to the participant.
   c. The requirement to report the use of the short form applies to ALL NIH participants regardless of the IRB of record.

   NOTE: Does not apply to external sites/centers where CCR is the Coordinating Center.

7. 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.

8. What happens once the ICD is translated into the participant's language if the short form process was used?
    a. The PSO Manager will submit to the IRB for approval. See 11b.
    b. Once approved, the participant needs to be provided a copy of the ICD. There is no need to reconsent the participant (i.e., have them sign the ICD in their preferred 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.
    c. Upload the unsigned translated ICD to CRIS, selecting the document type "Translated Protocol Consent." HIMD will add the patient identifiers to the bottom left of the ICD.
    d. Document in CRIS how the participant received the ICD and when.
    e. Follow up with IRB via a comment in the appropriate RNI that the participant was provided the translated ICD.

9. 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.

10. 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 IRB approved modifications that have an existing ICD in the participant's preferred language?

11. What happens if the IRB approves a modification of the ICD that **does not require reconsent** of existing participants and the protocol already has previously approved non-English ICD(s)?
    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 the PI (e.g., studies with expected enrollment of Spanish-speaking participants; 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 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.
        i. If translation of the ICD is needed for the expected enrollment of non-English speaking participants (e.g., most often Spanish-speaking individuals), PSO will proceed to request translation from the NIH Library and notify the team when IRB approved.
        ii. If translation of the ICD is not needed for the expected enrollment of participants:
            - The last IRB approved version of any ICD posted in another language will remain on the CC consent website in case of an unanticipated future consent of a participant in that language.
            - The CRC/team will need to contact PSO to request ICD translation per #4 above at the time a new non-English speaking participant in the unanticipated language(s) is identified to request the translated ICD be updated to the currently approved English version.
            - If the decision is made to consent the individual prior to an updated translated version being available (see 1.a.ii above), the PI/consent designee must follow the procedures in 12e below.

12. What happens if the IRB approves a modification of the ICD that **does require reconsent** of existing participants (or other method of written notification – e.g., letter) and the protocol already has previously approved non-English ICD(s)?

    Step 1

    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 a request to PSO 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).

Step 2

a. While waiting for IRB approval of the translated modified consent, DO NOT use the short form process. Wait to reconsent participants with the revised translated consent form.

b. However, if the information in the modified consent needs to be provided to participants emergently or it is in the best interest of the participant to be informed of the changes before the translated version is available and approved by the IRB (such as information about new risk(s) and/or urgent or new research procedure that cannot wait for the translated version):

i. The research team should verbally inform the participant of the changes using a qualified medical interpreter.

ii. Document in CRIS this discussion including the participant's willingness to continue study participation.

c. Reconsent once the translated consent is available. The participant's signature must be obtained on the revised translated consent document.

13. What happens if the IRB approves a modification of the ICD, and a NEW non-English speaking participant needs to enroll **AND** there is already an existing non-English ICD in the participant's preferred language *but it is not current/the same version as the English ICD*?

NOTE: Effective June 27, 2024, IRB's policy is that any previously approved non-English ICD version remains posted on the CC consent website because it is the IRB's stance that using a prior version of an ICD in a non-English speaking individual's language is more informative to the individual than using the short form process. However, if there is a modification to the English ICD, it is not CCR's policy to automatically update each non-English consent version with each modification (i.e., as there may be no reconsents required or anticipated future enrollments in that same language).

a. Notify PSO per #4 above.

b. If it is in the best interest of the participant to enroll prior to the modified version of the translated consent being available, do not use the short form process but follow the steps below:

i. Document informed consent using the existing version of the translated consent document.

ii. Using a qualified medical interpreter, verbally inform the participant of the pending changes to the informed consent.

iii. Document this process and what information the participant was verbally told in the consent note in CRIS.

iv. When the modified version of the translated consent document is available, provide it to the participant and reconsent them at that time, obtaining the participant's signature on the updated version of the translated consent document.

v. Document IC process in CRIS.

Resources:

- OHSRP Policy 301 Informed Consent
- OHSRP Guideline-Enrolling Non-English-Speaking Subjects (version 06.27.2024)
- OHSRP Presentation from 2/1/24: *An overview of IRB expectations when non-English speaking persons enroll in research: The importance of ensuring comprehension.*