Translations and Consent for Non-English Speaking Patients

ORP Open Forum Table, SWOG Group Meeting

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Facilitators:

Dana Sparks (dsparks@swog.org) and Dacia Christin (daciac@crab.org)

Overview of focus of table discussion:

- Importance of plain language, translations, and cultural competence
- Newest non-binding consent guidelines containing recommendations for non-English speakers
- Use of interpreters in obtaining consent
- Use of short forms
- Development of institutional SoPs for non-English speakers participating in research
- Translations often available for SWOG studies
- Spanish-speaking ORP network

"The information that is given to the subject or the representative shall be in language understandable to the subject or the representative."

21 CFR Part 50 Subpart B §50.20

Non-binding consent guidelines (Aug 2023)

- Who should be present when consenting with a short form, and what should they sign?
  - Person responsible for obtaining consent: *long form in English*
  - Participant: *short form in other language*
  - Interpreter if person obtaining consent is not bilingual: *no signature unless acting as witness*
  - Witness (bilingual or sufficiently proficient, interpreter acceptable as witness): *long form in English and short form in other language*

- Documentation of informed consent for non-English speaking participant:
  - Consult with IRB and consider:
    - Documentation
    - Interpreter: modes, who, qualifications
    - Re-consenting

- Recommended use of interpreter throughout the course of research.

Use of interpreter (facilitator's recommendations)

- Verify with institution if interpreters are/need to be HIPPA compliant.
- Confirm interpreter is able to communicate about topic.
- Ask interpreter to clarify in their own words if a misunderstanding due to cultural differences might occur.
- Remember: Interpreter not responsible for obtaining consent; study team is.
- Direct communication at patient, not interpreter.
- Make eye contact with patient, not interpreter.
- Document use of interpreter.
- Use of family member as interpreter? AVOID

When can I use a short form in NCTN studies

- No long-form version is available (CIRB-approved Spanish translation often available).
- Eligibility criteria do not restrict language.
- Institutional policies allow use of short form.
- Institutional policies have been reported to CIRB.
- CIRB short form exists in a language the patient understands.
- Note: Possibly different short form for studies initiated before/after 1/21/2019.

Creation of SOPs or Internal Processes for Non-English-Speaking Patients

- Refer to newest guidelines for recommendations and consult with IRB.
- Guidelines/processes/training for use of translators connecting via video, in-person, interpreter line.
- Documentation when consenting a patient with LEP.
- NOTE: Possible to obtain approval from CIRB for your own translated short-form.

Example of process for obtaining IC from patients with limited English proficiency (CDC 2022)

INSTRUCTIONS FOR USE OF SHORT FORM IN OBTAINING INFORMED CONSENT

PURPOSE OF THE INFORMED CONSENT SHORT FORM

This form is an option for obtaining informed consent or parental permission for a patient who is being offered treatment under an expanded access investigational new drug protocol held by the Centers for Disease Control and Prevention (CDC).

The Informed Consent Short Form should be used when the required elements of informed consent are presented orally to a patient or the patient's legally authorized representative (LAR). The short form and applicable written summary are translated into the patient's preferred language. The short form describes the required elements of informed consent and specifies that those elements, as they pertain to the treatment, will be presented orally to the patient/LAR. Details pertaining to the specific treatment are included in the written summary.

Whenever possible, short form and written summary translations that are already approved by the CDC Institutional Review Board (IRB) should be used. The CDC IRB-approved short form(s) should be used as is with no changes, except to specify the following (in English):

1. Title of the Expanded Access Investigational New Drug (IND)
2. Name of Treating Physician and Contact Information
3. Emergency Contact Person/Institution and Contact Information

When a CDC IRB-approved informed consent short form translation is not available in the language needed, the English version of the CDC IRB-approved informed consent short form must be used for translation by a certified interpreter. If a certified interpreter is not available, another adult who is fluent in both English and the language needed may interpret, provided the patient (parent/LAR) is comfortable sharing medical information (i.e., the reason treatment is being offered). If a facility wishes to create a written translation of the short form, the CDC IRB-approved informed consent short form must be translated by a certified translator and the translation must be submitted to and approved by the CDC IRB prior to use.

HOW TO CONSENT WITH A SHORT FORM

The treatment provider presents the consent and written summary information to the patient (parent/LAR), using an interpreter as needed. The patient (parent/LAR) has an opportunity to ask questions. Consent/parental permission is then documented on both the Informed Consent Short Form in the patient's (parent's/LAR's) preferred language and on the written summary.

Responsibilities of the Interpreter

The interpreter must be fluent in both English and the preferred language of the subject (parent/LAR). When the treatment provider presents the consent information to the patient (parent/LAR), the interpreter presents the information in the subject's (parent's/LAR's) preferred language.

Witness to the Short Form Consent Process

Either the interpreter or a second individual (fluent in both languages) can serve as the witness. The witness cannot be otherwise involved in providing the treatment. The witness can be an adult family member, friend, a clinic nurse who is not involved in providing the treatment, or anyone else 18 years or older with whom the patient (parent/LAR) is comfortable sharing medical information (i.e., the reason treatment is being offered).

Attestation to the Short Form Consent Process

With their signatures, the person obtaining consent and witness attest to the following:

- The information in the Summary Document as well as any additional information conveyed by the person obtaining consent was presented to the patient in a language preferred by and understandable to the patient; and
- The patient's questions were interpreted and the responses of the person obtaining consent were presented in a language preferred by and understandable to the patient.
- At the conclusion of the consent process, the patient was asked in a language preferred by and understandable to the subject if s/he understood the information in the Summary Document as well as any additional information conveyed by the person obtaining consent (including responses to the patient's questions) and responded affirmatively.

Patient Copies

The patient (parent/LAR) must be provided copies of both the short form and the written summary.

Some Additional Support in Spanish

Translations often available for:

- Informed consent
- Trial summary
- PROs

Spanish-speaking ORP network

- Creation of online discussion forum in progress for Spanish-speaking ORPs
- Networking and peer support in Spanish
- Data encryption, privacy policies, mobile friendly
- Contact Dacia Christin for more information (daciac@crab.org)

Resources

- Centers for Disease Control and Prevention (CDC), Instructions for Use of Short Form When Obtaining Consent. Available at: https://www.cdc.gov/poxvirus/mpox/pdf/Short-Form-Instructions.pdf, n.d.

**This is an explanation of the CDC's process for obtaining informed consent using the short form. Although not cancer trial, it is intended to be illustrative of a solid consent process for non-English speaking patients and meets the latest non-binding guidelines.*

- Central Institutional Review Board (NCI), *Short Form Q&A.* Available at: Short Form Q & A | NCICIRB, March 14, 2022.

**This link contains important information and considerations when and if you can use Short Forms in the consent process. List of short form languages also available here.*

- NSABP, *Regulatory Briefs,* "II. Update on "Certified" Translators". Available at: Regulatory Briefs - Update on "Certified" Translators (ctsu.org), May 4, 2006.

**This link provides information about what a "certified" translation means. Please note that in the US, no standardized certification exists for translators.*

- Office for Human Research Protections, *Informed Consent of Subjects Who Do Not Speak English*. Available at: Informed Consent of Subjects Who Do Not Speak English (1995) | HHS.gov

**These guidelines provide OHRP recommendations for consent of patients with limited English proficiency.*

- U.S. Department of Health and Human Services, Food and Drug Administration, et al. *Informed Consent: Guidance for IRBs, Clinical Investigators, and Sponsors*. Available at: Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (fda.gov), Aug 2023.

**Non-binding guidelines for consent of non-English speakers described on pg. 46-50.*