CARILION CLINIC INSTITUTIONAL REVIEW BOARD
Standard Operating Guidelines

Title: 5.5: Informed Consent Process: OBTAINING CONSENT FROM NON-ENGLISH SPEAKING SUBJECTS	
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Primary Sponsor: Human Research Protections Office	**Approved By:** Director of the Human Research Protections Office

Objective:

To describe the process researchers and their staff should use to obtain and document informed consent from non-English speaking subjects and require an interpreter and translated consent materials.

General Description:

The governing principles of human subject research—respect for persons, beneficence, and justice—require that researchers not exclude subjects based solely on their inability to read, speak, or understand English. Investigators need to communicate directly with subjects and conduct a reliable process to ensure the following:

- Study participation is voluntary, as indicated by free and truly informed consent (respect for persons); and
- All sections of the consent, including, but not limited to, study schedules, procedures, and risks, are accurately communicated. Subjects have ongoing opportunities to express concerns and ask questions to minimize risks to subjects (beneficence); and
- There are fair procedures and outcomes in the selection of research subjects so that risks and benefits of research are shared in society (justice).

Federal regulations enforced by the Office for Human Research Protections (45 CFR 46.116) and the Food and Drug Administration (21 CFR 50.20) state that informed consent "shall be in language understandable to the subject or the representative," and 45 CFR 46.117, along with 21 CFR 50.27, describe how the informed consent is to be documented.

Differences between Interpretation and Translation:

An interpretation is a verbal interaction between two parties and the person serving as interpreter is fluent (can speak, read, and write) in English and the language of the subject.

A translation is the process of translating a written document (e.g., consent form) from one language into another, assuring the language of the translated document has the same meaning as the written document in the first language.

Medical Interpreters

The use of an interpreter is required for all consent processes involving non-English speaking subjects.

The medical and technical information discussed during the initial consent discussion, as well as ongoing, study-related information, can be very complex and should be communicated to non-English speaking subjects through an interpreter with training and understanding in medical terminology. In addition, an individual with a professional commitment to maintain strict confidentiality should handle the private medical issues discussed with subjects.

An interpreter must be sufficiently fluent in both English and the potential research subject's, or Legally Authorized Representative's (LAR's), language to effectively facilitate communication between parties. The interpreter should be a member of a qualified professional interpretive service.

It is preferred that the interpreter is physically present with the subject, or LAR, and the person obtaining consent. Consult Carilion Clinic Interpreter Services for availability. There may be special circumstances where the interpreter is unable to be physically present. In circumstances when in-person interpretation is not possible, external medical translator services, such as Language Line (LL) utilized at Carilion Clinic, may be used. Write the interpreter's ID# in place of the signature for the interpreter on the consent document. In addition, write a detailed note in the research record regarding the consent process. Include the use of the specific external interpretation service, the interpreter's ID#, and interpreter's name.

Investigators should discuss the following topics with the interpreter before participating in an interpreter-mediated consent discussion.

- How will the interpreter incorporate cultural considerations into the consent information?
- How transparent will the interpreted conversation be? With multiple people communicating (e.g., subject, investigator/person obtaining consent, and interpreter), will everything said by each person be translated?
- How will the investigator and interpreter determine whether the subject truly understands the consent information?
- Informed consent is an ongoing process. How will the investigator ensure that the subject will understand ongoing study-related communication? If the subject has questions about continuing in the study, how will that be communicated to the researchers?

When using the full translated consent approved by the IRB, a research team member who is fluent in English and the language of the participant, and is capable of interpreting medical information, may obtain consent and serve as the interpreter. No witness or separate interpreter is needed.

Family members/friends of the participant may not serve as the interpreter unless they have appropriate medical interpretation qualifications.

Procedure:

There are two methods for obtaining and documenting informed consent for research subjects who do not read, speak, or understand English:

1. The **preferred method** is to provide IRB approved fully translated consent forms.

2. For the occasional and unanticipated non-English-speaking subject, an **alternative "Short Form" method** is allowed [21 CFR 50.27(b)(2) and 45 CFR 46.117(b)(2)].

Informed consent is an ongoing process throughout a study. For non-English speaking subjects, IRB approval is required for the consent process and the research team members who are obtaining consent. The investigator should also address the means for providing continued, qualified interpretive services.

Translated IRB approved Consent Documents (Preferred Method)

As part of the IRB submission process, investigators should estimate the likely proportions of non-English speaking people who may be encountered as eligible subjects for a proposed study. The consent form and other written research materials must be translated into a language understandable to the subject.

The IRB requires the use of a written consent document that has been translated by a qualified translator into a language understandable to the subject, which contains all necessary elements for obtaining legally effective informed consent.

The IRB will accept translated documents when a Certificate of Translation is provided to verify the translations are accurate. Those who translate the material are to provide a brief description of their qualifications for serving in this role when completing the certificate of translation. It is acceptable for a research team member to translate the document(s) if they have appropriate skills. A Certificate of Translation document is available on the Carilion Clinic IRB website.

The translation should take place after the IRB has approved the English version of the consent. The translated documents and the Certificate of Translation should be submitted to the IRB for approval.

The cost of translating written consents is the investigator's responsibility.

Short Form Consent Process (Alternative Method)

When the study team expects to enroll only a few (3 or less) non-English speaking subjects, the IRB permits oral presentation of informed consent information. A Short Form written consent document and a written summary of what is to be presented orally must be used. The Short Form indicates that elements of informed consent have been presented orally in the language of the subject. The Short Form is written in the subject's (or LAR's) language.

Please follow the requirements below when enrolling non-English speaking subjects using the Short Form process:

1. IRB must approve the English full consent document, Short Form consent in the subject's language, and English Short Form.
2. The English full consent document may serve as the summary; therefore, a separate summary document is not necessary.
3. The person obtaining consent (research team member) and interpreter must be present during the entire consent discussion.
4. An impartial witness must be present during the entire consent process. The interpreter may serve as the witness. The witness must be fluent in the language of the subject and in English. Adult family members may serve as the witness. The research team members cannot serve as the witness.
5. The person obtaining consent and interpreter/witness will sign/date the English full consent document.
6. The non-English speaking subject (or LAR) and interpreter/witness will sign/date the Short Form consent in the subject's language.

7. A copy of the signed/dated Short form and English full Consent will be given to the subject (or LAR).
8. A detailed note about the consent process will be included in the research record.
9. The English version of the short form that is available is for translation purposes only and should not be used to obtain any signatures.

Short Form Consent Process Additional Information:

Research Team Members Fluent in English and the Subject's Language:

- The bilingual research team member conducts the consent process in the subject's language and explains all elements of consent using the English full consent document as the summary of what is said to the participant.
- There must be a separate individual present to observe the entire consent process who signs as the impartial witness.

Bilingual Witness Unavailable:

- In the rare instance that the interpreter is unable to act as the witness (e.g., Research Team Member Interpreting) and the impartial witness is not fluent in both languages, then the witness must verify with the interpreter that the English consent has been fully explained to the potential subject in their language, that all questions have been satisfactorily addressed, and the subject agrees to participate. A detailed note should be included in the research record regarding the special circumstance.

Both Consent Processes- Signature Overview
Each person should sign the consent form they understand.

- The non-English speaking subject signs the translated consent (or the Short Form) in their language.
- The person obtaining consent, if fluent in only English, signs the English full consent.
- The interpreter/witness, who understands both languages, will sign both the translated full consent in the subject's language (or Short Form) and English full consent.
- If the person obtaining consent is acting as the interpreter, they sign both the translated consent in the subject's language (or Short Form) and the English full consent.

Subject Unable to Read

Please note that when a subject or the subject's LAR is unable to read, an impartial witness will be present during the entire consent discussion. The consent signature indicates that the

witness attests that the information in the consent document was accurately explained to the subject, or LAR, and that consent was freely given.

Re-consent

If re-consenting subjects, or LAR, with revised consent forms is required, the same process must be followed. A translated consent addendum may be used to document ongoing consent in response to study changes, if appropriate.

Health Insurance Portability and Accountability Act (HIPAA) Authorization

If HIPAA applies to the study, researchers should request an "Alteration of the HIPAA Authorization" in the Carilion IRB application. The alteration means that when using the Short Form Consent Process, the participant or LAR do not need to sign the HIPAA Authorization. This includes when there is a separate HIPAA Authorization or one embedded in full consent.

Ethical and Legal Considerations

As part of each consent discussion, investigators have an ethical and legal obligation to assess the subject's understanding of the consent information to ensure that the consent is truly "informed." When the investigator and subject do not share a language, the investigator must depend on the accuracy of the translated consent documents and the working relationship with the medical interpreter. The investigator's familiarity with the subject's culture ("cultural competency") or lack of familiarity affects communication.

For research that is relying on an external IRB, the process for consenting non-English speaking subjects set forth by the sponsor will be evaluated on a case-by-case basis.

A detailed note should be included in the research record regarding the consent process.