Obtaining consent from non-English speaking subjects

Informed Consent Process Series

CARILION CLINIC

Governing Principles

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.

Federal regulations state that informed consent “shall be in language understandable to the subject or the representative (45 CFR 46.116; 21 CFR 50.20; 45 CFR 46.117).

Key Definitions

Interpretation

- Verbal interaction between parties
- Interpreter must be fluent (can speak, read, and write) in both English and subject's language
- Real-time communication facilitation

Translation

- Converting written documents between languages
- Must preserve exact meaning across languages
- Applies to consent forms and all materials

Medical Interpreter Requirements

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

Who Can Serve as Interpreter

- Must be from qualified professional interpretive service
- Must understand medical terminology
- Must maintain strict confidentiality
- Family/friends cannot serve as interpreters unless professionally qualified

Interpreter Options

- In-person interpretation (preferred)
  - Consult Carilion Clinic Interpreter Services for availability
- External services when in-person is not possible
  - Language Line (LL) utilized at Carilion Clinic may be used

Documentation

- Write the interpreter's ID# in place of the signature for the interpreter on the consent document if the interpreter is not present in person
- Write a detailed note in the research record regarding consent process
  - Include the use of specific external interpretation service, the interpreter's ID#, and interpreter's name

Pre-consent discussion with medical interpreters

- Cultural considerations for research subject
- Transparency of interpreted conversation
- Methods to verify subject understanding
- Plan for ongoing communication with subject
- Process for subject’s questions

Procedures: Two Primary Methods

1. Preferred: Translated IRB approved Consent Documents

- For anticipated non-English speaking subjects
- Full translation of all materials
- IRB approval required

2. Alternative: Short form

- For occasional/unanticipated cases
  - Less than or equal to 3 subjects
- Oral presentation with written summary
- Specific witness requirements

Translated IRB approved Consent Documents (Preferred Method)

Preparatory Steps

1. Estimate proportion of non-English speaking eligible subjects
2. Obtain IRB approval for English version first
3. Have qualified translator prepare materials
4. Submit Certificate of Translation to IRB
5. Obtain IRB approval of translated documents

*Cost of translating written consents is the investigator's responsibility.

Consent Process with Translated Documents

1. Address how to effectively communicate with potential participant to obtain informed consent
   - Investigator or research team member if fluent in participant's language

   OR
   - Use of an interpreter
2. Document process in research record
3. Provide copies of signed documents to subject

Note: Sponsored studies will usually provide translated standard documents, but the research team should plan to have any site specific documents translated by Carilion Interpreter Services.

Research Team Member & Translated IRB approved Consent Documents

When using the full translated consent approved by IRB (preferred method), a research team member who is…

- Fluent in English *and* the language of the participant;
- Capable of interpreting medical information

may obtain consent and serve as interpreter. In this situation, no witness or separate interpreter is needed.

Short Form Method

Pre-Consent Requirements

1. Obtain IRB approval for the following:
   - English full consent document
   - Short Form in subject's language
   - English Short Form by Carilion Clinic IRB requirements

Required Personnel

1. Person obtaining consent (research team member)
2. Qualified interpreter
3. Impartial witness (interpreter may serve as witness)
   - Adult family members may serve as witness
   - Research team members cannot serve as witness

Step-by-Step Process

1. Ensure all required personnel present
2. Conduct oral presentation using English consent as summary
3. Have interpreter translate all communications
4. Allow time for questions and clarifications
5. Obtain required signatures

Short Form Signature Requirements

Who Signs What

- Research team member obtaining consent and interpreter/witness will sign & date the English full consent document
- Non-English speaking subject (or LAR) and interpreter/witness will sign & date the Short form consent in the subject's language
- Copy of the signed/dated Short form and English full consent will be given to the subject (or LAR)

*English version of the short form is for translation purposes only and should not be used to obtain any signatures.

Documentation

- Detailed notes in research record
- Interpreter information
- Consent process description

Both Consent Processes- Signature Overview

Each person should sign the consent form they understand.

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

Subject Unable to Read

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 Procedures

- Follow same process as initial consent
- May use translated consent addendum, if appropriate
- Document all elements
- Maintain ongoing interpretation services

HIPAA Authorization

- Request “Alteration of HIPAA Authorization” in IRB application
  - Alteration means that when using the Short Form Consent Process, the participant (or LAR) do not need to sign the HIPAA Authorization
  - Includes when there is a separate HIPAA Authorization or one embedded in full consent
- Document in research record

Ongoing Obligations

- Assess subject understanding
- Ensure truly informed consent
- Maintain cultural competency
- Document all processes thoroughly
- Provide continuous communication through interpretive services

Questions or need help?

Contact IRB office:

IRB@carilionclinic.org

References

Carilion Clinic Institutional Review Board. (2024). Standard operating guidelines for informed consent process: obtaining consent from non-English speaking subjects (SOG-5.5).