



Consenting Limited-English-Proficiency (LEP) Subjects

A Spectrum Health IRB Guidance Document

Purpose

This document provides guidance on how researchers should obtain and document informed consent from a subject who cannot read, speak, or understand the English language proficiently.

Regulatory Guidance and Definitions

- 45 CFR 46.116 & 21 CFR 50.20: General Requirements for informed consent
- 45 CFR 46.117(b)2 & 21 CFR 50.27(b)2: Documentation of informed consent
- FDA Information Sheet – A Guide to Informed Consent version 01/1998
- **Limited English Proficiency (LEP) Subject:** A person who is unable to communicate effectively in English because their primary language is not English, and they have not developed fluency in the English language.
- **Translation and interpreting** are two separate professions with different codes of ethics, educational requirements and certifications.
 - **Translator:** A professional who renders a written text from one language into another in writing.
 - **Interpreter:** A professional who renders a message orally, or in signed language, from one language into another.

Discussion

Anytime a researcher approaches a Limited English Proficiency (LEP) subject for participation, an evaluation of the ethical and legal ramifications should be made. If the subject does not clearly understand the information presented, the subject's consent will not truly be informed and may not be legally effective.¹

¹ FDA Information Sheet – A guide to informed consent 1/1998

Hospitals that receive federal dollars must provide some type of interpreting service for LEP patients seeking health care services at their institution.² Spectrum Health has interpreting services available to patients. Interpreters are available in-house and via contractors. Interpreters are available in person and over the phone. The interpreters at Spectrum Health are CCHI-certified and must fulfill continuing education requirements. Spectrum Health requires that only qualified interpreters be used when interpreting interactions between providers and patients/families. A bilingual family member may be present and interject but may not facilitate communication.

Scheduling a Spectrum Health-assigned interpreter requires advanced notice. If you will need more than one interpreter present (necessary when consenting with a translated short form and English long form) or assistance with a language of limited diffusion, even more advanced notice, at least 48 hours, will be needed to schedule interpreting services for availability. You will need to schedule for an interpreter to be present for a consent discussion in person or on the phone. Remember, if the study has more than one interaction with LEP subjects (e.g. follow-up visits, telephone calls, etc.), the researchers have an obligation to have interpreting services available for each subsequent interaction.

Process

Consenting with a **Short Form (Long form only in English, not translated into the subject's stated primary language)**

- Verify you have IRB approval to recruit LEP subjects and to use a Short Form for the particular study. If not, submit a modification to the IRB to request approval.
- Verify you have a Spectrum Health-assigned interpreter and an IRB-approved Short Form available in the subject's primary language. If not, contact the IRB for further information. IRB-Approved Short Forms are available on the IRB website in Spanish, Bosnian, Vietnamese, Italian, French, Korean, and Arabic.
- Contact the Spectrum Health Language Services Department and arrange for **two** interpreters to be present for the consent conversation. One interpreter will conduct the interpretation and the other will serve as a witness to the interpretation.
- The person obtaining consent (IRB approved study personnel) should bring the Short Form in the subject's stated primary language and **three copies** of the English IRB-approved long informed consent form to the consent discussion.
- Provide both the interpreter and the interpreter serving as the witness a copy of the English IRB-approved long informed consent to follow along during the consent process.
- The person obtaining consent should read the IRB-approved English consent out loud a few sentences at a time. The interpreter interprets what is read into the subject's primary language. The interpreter serving as the witness follows along to ensure nothing is skipped over and everything is presented in the subject's primary language. At any time, the subject may ask questions to the interpreter, that are then interpreted back into English to the person obtaining consent to answer, and so forth until all questions are answered. This process can take several hours depending on the length and complexity of the informed consent document.

² Federal Register, Vol. 65, No. 159. August 16,2000 - Improving Access to Services for Persons With Limited English Proficiency

- Assess understanding of what is involved with the study and the risk (e.g. by asking open ended questions) using the interpreter to facilitate questions and answers. The person obtaining consent (IRB approved study personnel) is responsible for evaluating the subject's comprehension of the consent content. If there is a doubt regarding the subject's comprehension, he/she should not be enrolled. The subject's autonomy should not be jeopardized due to a language barrier.
- If the subject decides to participate, the subject signs and dates the Short Form consent. This is the **only** document he/she signs. By signing the Short Form, he/she is concurring all the required elements of consent listed on the Short Form, including participation is voluntary and right to withdraw at any time, were interpreted to him/her from English into his/her primary language, and he/she consents to study participation.
- The person obtaining consent (IRB approved study personnel) signs and dates the English IRB-approved long informed consent form.
- The interpreter signs attesting to the fact that (s)he has interpreted everything said to the best of their ability and the interpreter witnessing the interpretation signs and dates, as witness to the interpretation, the Short Form consent document AND the English IRB-approved informed consent form.
- The person obtaining consent (IRB approved study personnel) should document in the subject enrollment note the full name and title of the person who provided interpreting service AND of the person who served as a witness to the interpretation.
- Provide a copy of the signed and dated Short Form consent **AND** signed and dated IRB-approved English long informed consent form to the subject and place a copy in the medical record. The copy of the signed English IRB-approved long informed consent form can be used as a reference by the subject when interacting with other medical providers or family members who speak and read English.
- File the original signed and dated Short Form consent **AND** signed and dated English IRB-approved long informed consent form together with the study regulatory documents.

Consenting with a **Translated** (long) Consent

- Verify the translated informed consent form in the subject's primary language has IRB approval.
- Contact the Spectrum Health Language Services Department and arrange a date and time to conduct the consent process with the help of a Spectrum–Health assigned interpreter.
- Bring both the English and translated IRB-approved informed consent forms. The English version will serve as a reference for the person obtaining consent.
- Verify through the interpreter that the subject has read the translated consent or provide adequate time for the subject to read the translated consent.
- Assess understanding of what is involved with the study and the risk (e.g. by asking open-ended questions) engaging the interpreter to facilitate questions and answers. The person obtaining consent (IRB approved study personnel) is responsible for evaluating the subject's comprehension of the consent content. If there is a doubt regarding the subject's comprehension, he/she should not be enrolled. The subject's autonomy should not be jeopardized due to a language barrier.
- The subject signs and dates on the translated IRB-approved long informed consent form.
- The person obtaining consent signs and dates on the translated IRB-approved long informed consent form.

- If there is a signature line for an interpreter on the consent form, they would sign and date, but the IRB does not require this signature line and date. A witness or interpreter signature on the consent is not required when the subject is able to read the consent for themselves.
- The person obtaining consent (IRB approved study personnel) should document the full name and title of the interpreter who facilitated the informed consent discussion in the study enrollment note.
- Provide a copy of the signed and dated, translated IRB-approved long informed consent form to the subject. It is recommended, but not required, to provide a copy of the unsigned English IRB-approved informed consent form for the subject to use as a reference when interacting with other medical providers or family members who speak and read English.
- File the original, signed and dated, IRB-approved translated long informed consent form with the study regulatory documents.

Assent Forms

- When studies require the use of an assent form follow the same translation process (translated long informed consent form or use of short form).

Translating Consent Documents

Spectrum Health has a translation service for translating documents into other languages. The contact information and form are available on the IRB website. You must wait until you have an English IRB approved informed consent form before submitting for translation. The IRB-approved Microsoft Word version should be submitted with the IRB stamped pdf version. There could be a cost for translation. Depending on the language, length of the consent, and complexity, the cost can vary significantly. For more information regarding cost for translation contact language.services@spectrumhealth.org.

The IRB recommends that if you anticipate LEP subjects, the cost of translation be built into the study budget when negotiating contracts with sponsors, submitting grant applications, or receiving agreements from the internal departments to absorb the cost. The sponsor for a study may provide translated documents. However, the IRB will require proof of the translator's professional experience and credentials at the time of submission. For industry sponsored clinical trials, the company will often arrange services and cover the cost of translation. However, all translated documents, regardless of the source, must be IRB approved prior use with any potential subject. Spectrum Health Language Services Department will not proofread non-Spectrum Health translations nor attest to their accuracy.

Conclusions

- Verify you have IRB approval to include LEP subjects in your research study.
- Secure Spectrum Health interpreting services during the consent process.
- Contact the Office of the IRB if you have any questions.