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
- 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.

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

Hospitals that receive federal dollars must provide some type of interpretation 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, via contractors and are available in person and over the

¹ FDA Information Sheet – A guide to informed consent 1/1998
² Federal Register, Vol. 65, No. 159. August 16, 2000 - Improving Access to Services for Persons With Limited English Proficiency
phone. The interpreters at Spectrum Health are certified and also have additional training in understanding medical terminology. Spectrum Health requires only their certified interpreters are used when interpreting health related concerns at their facilities. A bilingual family member may be present and interject, but may not serve as an official interpreter.

The use of Spectrum Health interpretations requires advanced notice. If you will need more than one interpreter present or assistance with a rare language, even more advanced notice, at least 48 hours maybe even more, will be needed to schedule interpreting services to be available. 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**

- Verify you have IRB approval to recruit LEP subjects and to use of a Short Form for the particular study. If not, submit a modification to the IRB to request approval.
- Verify you have an 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, and Vietnamese.
- Contact 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 (e.g. investigator or coordinator) should bring the Short Form in the subject’s primary language and **three copies** of the English IRB-approved 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 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.
- 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 is responsible for evaluating the subject’s comprehension of the consent content not the interpreter. 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 explained to him/her verbally in his/her primary language and he/she consents to study participation.

- The person obtaining consent signs and dates the English IRB-approved informed consent form.
- The interpreter witnessing the interpretation signs and dates the Short Form consent document AND the English IRB-approved informed consent form certifying the oral presentation was interpreted fully and accurately. The witness serves as the link between the two consent documents.
- The person actively serving as the interpreter does not sign and date either consent document. However, this person still serves a very important role in the consent process. Thus, the person obtaining consent should document in the subject enrollment note who provided interpreting service AND who served as a witness to the interpreting service.
- Provide a copy of the signed and dated Short Form consent AND signed and dated IRB-approved English informed consent form to the subject and place a copy in the medical record. The copy of the signed English IRB-approved 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 informed consent form together with the study regulatory documents.

Consenting with a Fully-Translated Consent

- Verify the translated informed consent form in the subject’s primary language has IRB approval.
- Contact Spectrum Health Language Services Department and arrange a date and time to conduct the consent process with an interpreter present.
- 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) using the interpreter to facilitate questions and answers. The person obtaining consent is responsible for evaluating the subject’s comprehension of the consent content not the interpreter. 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 informed consent form.
- The person obtaining consent signs and dates on the translated IRB-approved 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 should document the name of the interpreter who facilitated the informed consent discussion in the study enrollment note.
- Provide copy of the signed and dated, translated, IRB-approved informed consent form to the subject. It is recommend, 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 informed consent form with the study regulatory documents.

**Translating Consent Documents**

Spectrum Health has a translation service for translating documents into other languages. The contact information and form is 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 is a cost. Depending on the rarity of the language, length of the consent, and complexity, the cost can vary significantly.

The IRB recommends if you anticipate encountering 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 IRB does not require researchers to use Spectrum Health translating service. Another service provider may be used. However, the IRB will require proof of the translator’s professional experience and credentials. 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.

**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.