MUSC Human Research Protection Program (HRPP)

Guidance Document — Working Reference

Informed Consent for Research Participants with Limited English Proficiency (LEP)

Applies to:	All MUSC HRPP-reviewed human participants research (biomedical and behavioral) enrolling or potentially enrolling non-English-speaking participants or legally authorized representatives (LARs)
Authoritative sources:	U-IRB-HRPP 7.5 – Research Involving Non-English Speaking Participants (eff. 03/20/2025); MUSC IRB "Guidance for Non-English Speaking Consent Process" (12/18/25); HRPP 6.1 – Consent Process
Regulatory basis:	45 CFR 46.116 & 46.117 (Common Rule); 21 CFR 50.27(b)(2) (FDA)
Owner:	MUSC HRPP / Office of Research Integrity (ORI)

1. Purpose

This document translates MUSC's policy (U-IRB-HRPP 7.5) and frequently asked questions into IRB guidance for study teams, IRB coordinators, and IRB members.

Consent must be obtained using language that the participant or LAR understands. This requires either a written translation of the consent document or an oral presentation by a person fluent in both English and the participant's language, per 45 CFR 46.116 and 46.117 and 21 CFR 50.27(b)(2).

The IRB **requires** written translation of the long form consent document into the relevant non-English language(s) when a study team is recruiting participants likely to speak and read a non-English language and to have Limited English Proficiency (LEP).

Use of the short form process is only appropriate when a Principal Investigator (PI) does not anticipate encountering non-English speaking individuals for their study. If a PI expects to enroll more than one participant speaking the same non-English language, it is best in most cases to use a translated full form and anticipate this from beginning.

For FDA regulated studies, FDA Informed Consent: Guidance for IRBs, Clinical Investigators, and Sponsors advises fully translating the long form consent document, either before the consent process takes place, or after a short form consent process is used.

2. Definitions

- **Translator:** An individual fluent in both English and the participant's/LAR's language who translates study documents in writing. Should be certified by a professional organization or institution. The PI is responsible for ensuring translators are qualified.

- **Interpreter:** An individual fluent in both English and the participant's/LAR's language who interprets the live discussion between the research team and the participant/LAR. Preferably certified; maybe a research team member or another qualified individual but may not be a family member. The PI is responsible for ensuring interpreters are qualified.
- **Witness:** An individual fluent in both English and the participant's/LAR's language who attests that the oral presentation of the written summary accurately reflected the document's contents, and who is present for the entire consent interview. May be study staff, a family member, or another qualified individual.
- **Person Obtaining Consent**: The IRB-approved study team member conducting the consent discussion.
- **Short Form:** A document, in a language understandable to the participant/LAR, stating that the required elements of consent were presented orally. Only the short form is signed by the participant/LAR.
- **Written Summary:** The document (typically the IRB-approved English long form) that accompanies the short form and reflects what is presented orally during the consent interview.

3. Who Can Serve in Multiple Roles

A member of study staff acting as both Interpreter and Person Obtaining Consent cannot also serve as Witness.

The Interpreter may also serve as one of the following, but not both:

- Witness
- Person Obtaining Consent (if an IRB-approved study team member)

The Person Obtaining Consent may also serve as one of the following, but not both:

- Interpreter (if an IRB-approved study team member)
- Witness

The Witness may also serve as one of the following, but not both:

- Interpreter
- Person Obtaining Consent

Before starting the consent process, verify whether the Interpreter will also be able to serve as a witness; if they will not, another person who speaks the language will be needed to act as the witness.

4. Consent Form Option #1: Long Form Written Consent Document

4.1 Translation Process

The consent form for non-English-speaking participants/LARs must be identical in content and format to the English version, except that it is translated into a language understandable to the participant or LAR.

4.2 Certification of Translation

The PI must submit, via eIRB, either:

- A letter of certification of accuracy from the translation agency; or
- A completed Certificate of Translation Form (available on the IRB Forms website) if the translation was completed by a credentialed individual.

4.3 Consenting Process When Using the Long Form

A person knowledgeable about the study, its procedures, and its scientific basis must be available — by telephone, electronic platform, or in person — to answer questions before the participant signs the translated consent form. If that knowledgeable person is not fluent in both English and the participant's primary language, a second person fluent in both languages must be present to interpret questions and answers for the participant or LAR. See HRPP 6.1 for the general consent process.

5. Consent Form Option #2: Short Form Written Consent Document

Permitted under 45 CFR 46.117(b)(2) and 21 CFR 50.27(b)(2): a short form stating that the required elements of consent were presented orally to the participant/LAR, with a witness present. The short form is typically used when there is not enough time to translate the approved long form into a language the participant understands.

An IRB-approved short form template is available on the MUSC IRB website for this purpose.

The short form process must still be IRB approved for the study prior to use.

5.1 When Long Form Translation Becomes Required After Short Form Use

If the study is greater than minimal risk, has a duration of more than 60 days, AND requires multiple visits, the PI must submit an IRB amendment translating the long form consent into the participant's language within 120 days of enrollment. The participant must be provided a copy of the translated long form once approved.

5.2 Written Short Form Consent — Content & Signatures

- Content: A statement that the basic elements of consent (per 45 CFR 46.116) were presented to the participant/LAR in an understandable language.
- Signed and dated by: the Participant or LAR, and the Witness.
- The participant/LAR receives a signed copy of the short form.
- The participant/LAR does NOT sign the long form English consent (written summary).

5.3 Written Summary (Long Form English Consent) — Content & Signatures

- Content: The basic elements of consent to be presented orally. Where an English consent form exists for English-speaking participants, the Written Summary content must match it.
- Signed and dated by: the Person Obtaining Consent, and the Witness.
- If no witness signature line exists on the long form, it is acceptable for the witness to sign and date at the bottom of the document.
- The participant/LAR receives a signed copy of the long form English consent (written summary), in addition to the signed short form.

6. Sub-Study Signature Page Addendum

If a study includes optional sub-studies requiring separate consent from a non-English-speaking participant (e.g., an optional biopsy or PK sub-study), the Sub-Study Signature Page Addendum must also be translated into the appropriate language, reviewed with the participant/LAR, and signed and dated.

- Signed and dated by: the Person Obtaining Consent, and the Witness.
- The participant/LAR receives a signed copy.

7. HIPAA Authorization

Where a study also requires HIPAA authorization, the authorization must likewise be understandable to the LEP participant, following the same translated long form or short form logic described above.

For research involving targeted populations that have limited English proficiency, the use of a written translation of the approved long form consent/authorization document is required. The translated consent/authorization must be approved by the IRB.

If the IRB approves the use of a short form consent, researchers should use the Spanish translation of the stand-alone HIPAA authorization for Spanish speakers.

8. Required Signatures — Summary Table

Document	Signed and Dated By	Participant/LAR Signs?	Participant/LAR Receives Copy?
Option #1 Long Form Consent			
Translated Long Form (Option #1, no short form used)	Participant/LAR (per standard consent signature practice)	Yes	Yes
Option #2 Short Form Consent			
Short Form	Participant/LAR* + Witness	Yes	Yes
Written Summary (Long Form English Consent)**	Person Obtaining Consent + Witness	No	Yes

**** The participant or legal representative will receive a signed copy of the short form.***
*****The non-English speaking participant(or legal representative) does not sign the long form English consent. The participant or legal representative will receive a signed copy of the long form English consent.***

*****All parties must date their signatures for FDA regulated and VA research***

9. Questionnaires for Non-English-Speaking Participants

Questionnaires must be translated so that responses from non-English-speaking participants are comparable to those of English-speaking participants, and must convey the same meaning as the original English version.

9.1 Self-Administered Questionnaires

Must be the same as the English version in content and format, except translated into a language understandable to the participant.

9.2 Verbally Administered Questionnaires

Option 1: Translation of the Questionnaire

The questionnaire is translated in writing and administered to the participant by a person fluent in the participant's language.

Option 2: Verbal Administration Without Written Translation

A written translation is not required, provided the questionnaire is administered verbally by a bilingual person fluent in both English and the participant's language.

10. Other Documents and Scripts

For research involving non-English-speaking participants that uses verbal scripts or documents other than the consent form and questionnaires, investigators must describe in their IRB submission the measures they will take to ensure the information in these materials is conveyed to participants accurately and in an understandable way.

11. IRB Submission Requirements

- Short Form
    - The IRB must approve a study's use of short form consent documentation prior to its use. If not approved at a study's initial review, the study team can add a short form process via an amendment. eIRB application: In the IRB application check non-English speak on the participant demographic section and describe your proposed consent process on the consent process page. Include the short form and the stand-alone HIPAA authorization form.
- Long Form:
    - Certificate of Translation Form or translation agency certification letter: submitted via eIRB for all translated documents (long form, short form if modified, sub-study addendum, questionnaires).
    - Amendment for long form translation triggered by short form use: required within 120 days of enrollment when the study is greater than minimal risk, exceeds 60 days in duration, and involves multiple visits.
    - Interpreter/translator qualifications: PI is responsible for verifying that the translation/interpretation entity is certified or credentialed in the required language; not separately submitted to the IRB unless requested.

12. Reliance

Most studies use the SMART IRB framework in which a blended policy approach is followed. The reviewing IRB must approve the process but also taken into account the relying institutions/IRB local context considerations and policy.

The easiest way to remember: The Relying IRB's policy dictates *if* you can do something based on local laws, language restrictions and institution policies (i.e. Gatekeeper)

The Reviewing IRB's policy dictates *how* you execute the process providing the actual templates, timelines and study protocols.

Quick Decision Summary

Scenario	Pathway	Key Action
LEP participant identified with time to translate before consent	Long Form (Option #1)	Translate long form; submit Certificate of Translation via eIRB; ensure knowledgeable/bilingual person available per Section 4.3
LEP participant identified, insufficient time to translate long form	Short Form (Option #2)	Amendment to add short form process (if not already completed); Use IRB-approved short form template; witness required; complete required signatures per Section 5
Study using short form is >minimal risk, >60 days, multiple visits	Convert to Long Form	Submit amendment translating long form within 120 days of enrollment; provide participant a copy once approved
Study includes optional sub-study requiring separate consent	Sub-Study Addendum	Translate addendum; review with participant/LAR; obtain required signatures
Study includes questionnaires	Translate or verbally administer	Self-administered: must be translated. Verbal: translate, or administer verbally via bilingual person (no written translation required)

RESOURCES

45 CFR 46.117(b)(2)

HHS Guidance: Informed Consent of Participants Who Do Not Speak English (1995), available at https://www.hhs.gov/ohrp/regulations-and-policy/guidance/obtainingand-documenting-infomed-consent-non-english-speakers/index.html

FDA Guidance: Informed Consent (2023), available at https://www.fda.gov/regulatory-information/search-fda-guidancedocuments/informed-consent