INSTRUCTIONS FOR USING "SHORT FORM" CONSENT DOCUMENTATION

Federal regulations for the protection of human participants require that informed consent information be presented "in language understandable to the participant" and, in most cases, that informed consent be documented in writing (45CFR46.116 and 117). If an investigator *expects* to enroll non-English speaking participants, the KUMC institutional review board (IRB) requires the use of a foreign-language translation of the informed consent document.

However, there may be times when a non-English speaking participant is unexpectedly found to be eligible for enrollment. In this case, investigators will not have an IRB-approved written translation of the consent form in the participant's native language.

In such cases, the investigator will use **two** documents to obtain informed consent:

1. A "Short Form" written in the participant's native language. The short form is typically one-page and tells the individual about research in general but is not study-specific.
2. The IRB-approved English consent form. The English consent will be presented orally by a qualified interpreter as outlined below.

The following individuals must be involved in the consent of a non-English speaking participant:

The principal investigator or other study team member must be present during the consent process. The presence of a study team member ensures that questions about the study can be answered by a knowledgeable individual.

The **interpreter** facilitates the informed consent dialogue between the potential participant and the study team. The interpreter may be present in person or by phone/computer. The interpreter must be qualified by professional training or by certification (when consenting heath system patients). Family members are not allowed to serve as interpreters for research consent. The family member may or may not understand medical terminology and may have a biased viewpoint about the potential participant's involvement in the study.

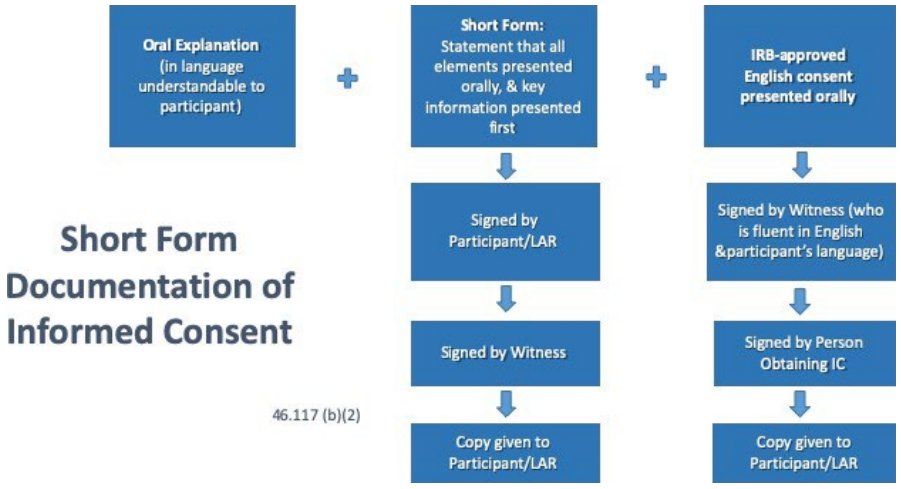
The **witness** must be fluent in both English and the participant's language, observes the consent process, and confirms the potential participant was provided information in their own language. The witness also confirms the participant had opportunity for questions and observes the decision to participate or decline. The interpreter can serve as the witness; however, professional interpreters typically are not allowed to act in both functions. **The witness cannot be a member of the study team**. The witness can be a health care professional, family member or other fluent adult.

The **participant or their legally authorize representative (LAR)** considers the information presented and decides whether or not to join the study.

The Table and Figure describe how individuals work together and sign the study documents.

Working together to administer consent to a non-English speaking potential participant

Individuals	Role	Documents Signed*
PI and Study team members	Explains the study in its entirety, aided by the interpreter; Answers the potential participant's questions through the interpreter	English, IRB-approved consent form
Qualified Interpreter fluent in both English and the potential participant's language	Reviews the Short Form with the potential participant; Orally interprets the English, IRB-approved consent form to the participant; Asks questions to the study team on behalf of the participant	If the interpreter is also the witness, he/she signs the English, IRB-approved consent form and the relevant foreign language Short Form *If the interpreter is not physically present, the study team records the interpreter's ID# on the English, IRB-approved consent form.*
Witness to the consent (may be the interpreter or another individual, fluent in both languages)	Observes the consent process; Confirms that the Short form and the English consent were explained to the participant and observes the potential participant's decision on whether to join the study	English, IRB-approved consent form and the relevant foreign language Short Form
Potential participant/LAR	Considers the study, asks questions and decides whether to participate	Relevant foreign language Short Form



Please note that obtaining informed consent in the participant's language is only the beginning of the research. To involve non-English speaking participants, investigators must ensure that all aspects of the study can be conducted in the participant's language. For example, instructions about drug dosing, interviews about symptoms, quality of life surveys, assessments of adverse events and all other communications must be presented to the participant in a way that provides for participant comprehension and safety as well as supplying the study with valid data.

If a study team wants to enroll a non-English speaking participant and a translated consent form is not available, please follow these steps:

1. For studies under an external IRB, contact their representative and proceed as instructed.

   For studies under the KUMC IRB:

2. For sponsored studies, confirm that the sponsor is willing to provide an interpreter at each study visit and that all participant-facing documents can be translated.
3. Print the appropriate Foreign Language Short Form. Short Form Versions are available in more than a dozen languages. If another language is needed, contact the IRB Office to make arrangements for a translation.
4. Add the IRB Approval # and PI name to the document header before obtaining signatures.
5. Conduct the informed consent discussion, including all parties listed above.
6. Provide the original signed version of both the Foreign Language Short Form and the IRB-approved English informed consent document to the participant. The English version should be provided for future reference even though the participant does not sign it.
7. Retain the signed copy of both the Foreign Language Short Form and the IRB-approved English informed consent document with the participant's research records.
8. Arrange for a full translation of the English consent form into the participant's language. Submit the translated consent in the eIRB study as a study modification.
9. Obtain participant's signature on the translated consent form at the earliest convenience.
10. Ensure an interpreter will be present at future study visits.

Contact **Interpreter Services at (913) 588-1564** for assistance finding an interpreter. For questions about how to obtain legally effective consent, you may email the **IRB office or call (913) 588-1240.**

Please refer to the next page for the English content
of all Foreign Language Short Form Consent documents in English

The text on this page displays the English content that is professionally translated for each foreign language short form.

CONSENT TO PARTICIPATE IN RESEARCH

You are being asked to participate in a research study. Participating in research is different from getting standard health care. The main purpose of research is to benefit future patients and society in general. Research studies may or may not benefit the people who participate.

Before you agree, the researcher must tell you: (i) why the study is being done and what you have to do during the study; (ii) which parts of the study are research and how long you will be in the study; (iii) any likely risks, discomforts, and benefits of the research; (iv) other treatments you can have if you decide not to join the study; and (v) who can see your study records and how your records will be kept private.

When applicable, the researcher also must tell you: (i) how to get care and who would pay for it, if you have an injury or harm caused by being in the research; (ii) the possibility that there are unknown risks in the research; (iii) reasons the researcher might stop your participation; (iv) any added costs to you for being in the research; (v) what happens if you decide to stop participating; (vi) when you will be told about new findings which may affect your willingness to participate; and (vii) how many people will be in the study.

If you agree to participate, you must be given a signed copy of this document. You will also get a copy of the consent form for this study written in English.

Please contact the investigator, Dr._____at phone number_____any time you have questions about the research or if you are injured or have any problems during the research.

You may contact the KUMC Institutional Review Board at (913) 588-1240 if you have questions about your rights as a research participant.

Research is voluntary, and you may change your mind at any time. There will be no penalty if you decide not to participate, or if you start the study and decide to stop early. Either way, you can still get medical care and services at the University of Kansas Medical Center.

If you sign this document, it means that the English version of the research consent form has been orally translated for you, that you have had your questions answered, and that you voluntarily agree to participate in the research.

_____
Printed Name of Research Participant

_____ _____
Signature of Research Participant Date

_____
Printed Name of Interpreter/Witness to Consent

_____ _____
Signature of Interpreter/Witness to Consent Date