

INSTRUCTIONS FOR USING “SHORT FORM” CONSENT DOCUMENTATION

Federal regulations for the protection of human subjects require that informed consent information be presented “in language understandable to the subject” and, in most cases, that informed consent be documented in writing (45CFR46.116 and 117). If an investigator *expects* to enroll non-English speaking subjects, the KUMC Human Subjects Committee (HSC) requires the use of a foreign-language translation of the informed consent document.

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

In such cases, the investigator may use a written “short form” in the subject’s native language as written documentation of the consent process, along with an oral translation of the complete English version of the informed consent document. The **translator** may be a qualified hospital/clinic staff member or a professional translator. Family members are not allowed to serve as translators for research consent. The family member may or may not understand medical terminology and may have a biased viewpoint about the potential subject’s participation in the study.

The written “short form” indicates that the elements of informed consent required by the regulations have been presented orally to the subject. The HSC must have approved the content of what is to be orally presented to the subject; therefore, the HSC-approved consent form must be the basis of the oral translation.

A **member of the study team** must be present during the consent process with the translator. The presence of a study team member ensures that any questions about the study can be answered by a knowledgeable individual.

When this method of obtaining consent is used, there must be a **witness** to the oral presentation. The witness must be fluent in both English and the subject’s language. *The translator may serve as the witness.*

The requirements for documenting the informed consent process using a short form are:

1. A Spanish version of the Short form is available by contacting the HSC office at humansubjects@kumc.edu or (913) 588-1240. The HSC# and PI name should be added prior to printing the form. If another language is needed, the HSC Office will make arrangements for translation.
2. The **subject** must sign the “Short Form.” Note: the subject does **not** sign the English version because it is not in the subject’s language. The subject/participant signature lines on the English consent should be marked through and left unsigned, with an explanatory note written on the signature page.
3. The **witness** must sign both the “Short Form” and the copy of the English version of the informed consent document. The witness may use signature lines designated for a witness, if they are present on the document. Otherwise, name and signature lines for the witness can be added by hand.

4. The **study team member** must sign the English informed consent document as the authorized person obtaining consent under the protocol. Use the signature lines marked “Person obtaining consent.”
5. A signed copy of both the “Short Form” and the English informed consent document is given to the subject.
6. A signed copy of both the “Short Form” and the English informed consent document is retained with the subject’s research records.

Please refer to the next page for the text of the Short Form consent in English.

HSC# _____ PI: _____

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 investigator must tell you about (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 it is applicable, the investigator 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 investigator 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 Human Subjects Committee 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 (KUMC).

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 Translator/Witness to Consent

Signature of Translator/Witness to Consent

Date