II3F GD2 Use of Short Form to Obtain Consent from Non-English Speaking Participants

When the majority of subjects in a study are English speakers but a portion of the subjects will not be able to understand a consent form written in English, a short form can be used in to obtain consent. A short form is a written document stating that the elements of informed consent required by 45 CFR 46.116 have been presented to and understood by the subject or the subject's legally authorized representative. Use of a short form helps to ensure equal access for all eligible individuals.

If the majority of the anticipated subjects to be enrolled do not speak English or will be unable to understand a consent form written in English, the consent form must be translated into a language understandable to the subjects (see II3F GD1 Inclusion of Non-English Speaking Participants in Research).

When the person obtaining consent is assisted by a translator, the translator may serve as a witness. The subject must be given copies of the short form document and the summary.

Federal Regulation Concerning Short Forms

Adapted from 45 CFR 46.117(b)(2)

A short form is a written consent document stating that the elements of informed consent required by 45 CFR 46.116 have been presented orally to the subject or the subject's legally authorized representative.

When this method is used, the subject or her or his representative must be given an oral summary of the research before the subject or her or his representative signs the short form. The IRB must approve both the written summary of what will be said and the short form. In some cases, the English version of the consent form may be used for the summary.

There must be a witness to the oral presentation and the witness signs both the short form and a copy of the summary. The person actually obtaining consent also signs the copy of the summary. Following the oral presentation, the subject or her or his representative sign only the short form. A copy of the summary and the short form must be given to the subject or her or his representative.

Required and Protocol-Specific Elements for Short Form

Note: The language provided below is the regulatory language, taken from the regulations. The short form must be written at a reading level appropriate to the subject population.

Consent to Participate in Research

You are being asked to participate in a research study.

Before you agree, the investigator must tell you about (i) the purposes, procedures, and duration of the research; (ii) any procedures which are experimental; (iii) any reasonably foreseeable risks, discomforts, and benefits of the research; (iv) any potentially beneficial alternative procedures or treatments; and (v) how confidentiality will be maintained.

Where applicable, the investigator must also tell you about (i) any available compensation or medical treatment if injury occurs; (ii) the possibility of unforeseeable risks; (iii) circumstances when the investigator may halt your participation; (iv) any added costs to you; (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 and a written summary of the research.

You may contact _____ phone number_____ any time you have questions about the research.

You may contact _____ phone number_____ if you have questions about your rights as a research subject or what to do if you are injured.

Your participation in this research is voluntary, and you will not be penalized or lose benefits if you refuse to participate or decide to stop.

Signing this document means that the research study, including the above information, has been described to you orally, and that you voluntarily agree to participate.

_____ _____
Signature of Participant Date

_____ _____
Signature of Witness Date