Short Form Guidance

When can the short form be used?

* The participant or LAR does not speak/understand English; AND
* The participant of LAR speaks only a language(s) that was not anticipated in the study population or location; AND
* An approved translated consent form in participant's language has not been approved by the IRB; AND
* There is not adequate time for preparation and IRB review and approval of a translated consent form

How must the short form be used?

* An oral translation of the approved English language consent form should be presented in a language understood by the prospective participant.
* There must be a translator. Children's IRB policy is to encourage the use of professional or certified translators as we do for written translations. Exceptions may be made, however, on a case-by-case basis depending on availability of professionals.
* There must be a witness to the oral presentation. The witness must be fluent in both English and the language of the presentation. The translator may also serve as the witness.
* Unless provided on our website, the IRB must receive all foreign language versions of the short form document as a condition of approval. Expedited review of these versions is acceptable if the protocol, the full English language informed consent document, and the English version of the short form have already been approved by the convened IRB. If the foreign language version cannot be written by a certified or professional translator, the researchers must also submit an English back-translation of the short form.

What signatures are required?

* The participant signs and dates the short form (receives a copy of the signed short form and a written summary of what is to be said to the participant). In cases in which a short form is being used, the English language informed consent document may serve as this written summary. The Children's IRB, however, reserves the right to require the PI to provide the protocol translated into the participant's primary language.
* The study staff obtaining consent signs and dates a copy of the written summary (and any additional documentation that is required by the IRB). The study staff retains the original signed copy of the short form and written summary and the participant receives a copy to take home.
* The witness signs the short form and the summary.
* The translator signs nothing unless serving as the witness too.

What has to be given to the IRB?

* The IRB must receive all foreign language versions of the short form and written summary.

What the Federal Regulations have to say about the short form:

(2) A short form written consent document stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

***For studies that are reviewed by the NCI CIRB, the CIRB short forms must be used.**

Helpful Links:

CHOA IRB Short Forms

OHRP Guidance: Obtaining and Documenting Informed Consent of Subjects Who Do Not Speak English