



Short Form Consent Process Guidance for Interpreters and Witnesses

If a non-English speaking subject is unexpectedly encountered, it is still possible to obtain informed consent, even when a translated consent form is unavailable. The process is called a *short form consent* and consists of an oral presentation of a study summary containing the information in the consent form presented in the subject's native language and accompanied by a translated short form consent document (Common Rule 45 CFR 46.117, FDA regulations 21 CFR 50.27).

How is the information presented to the prospective participant?

In the short form consent process, the investigator presents the consent information to the subject (parent/guardian) using an interpreter. The interpreter must be fluent in both English and the native language of the subject (parent/guardian).

Who serves as a witness to the short form consent process?

Either the interpreter or a second individual (fluent in both languages) can serve as the witness. However, the witness cannot be otherwise involved in the study.

How is consent documented?

Consent is then documented on both a Short Form Consent form written in the subject's native language and on a Study Summary Document.

The witness signs the Short Form Consent Document and the Summary Document.

What is the witness attesting to when they sign the study documents?

With his/her signatures, the witness documents the following:

- The information in the Summary Document as well as any additional information conveyed by the person obtaining consent was presented to the subject in a language preferred by and understandable to the subject; and
- The subject's questions were interpreted and the responses of the person obtaining consent were presented in a language preferred by and understandable to the subject.
- At the conclusion of the consent conference, the subject was asked in a language preferred by and understandable to the subject if s/he understood the information in the Summary Document as well as any additional information conveyed by the person obtaining consent (including responses to the subject's questions) and responded affirmatively.