**607 – Guidelines for Using a Short Form**

Per 45 CFR 46.117(b)(2) and 21 CFR 50.27(b)(2), oral presentation of informed consent information combined with the use of a short form written consent document and a written summary of what is presented orally is permitted for participants who do not speak or read English.

**What to include in your IRB Application:**

1. Intention to use the short form consent process. This should be noted and explained in the “consent” section of the protocol application. The Investigator must agree to follow the procedures specified in the application for use of the short form consent process.
2. Summary Form (Modified English consent form):

This summary form is modified version of the English consent form that includes a signature section for the witness. The following witness signature section should be added on the last page under the Person Obtaining Consent (POC) section:

*The witness must sign below only if the consent is provided as a summary form and accompanied by a short form foreign language consent.*

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*Signature of Witness Date*

1. Short Form Consent written in the language of the potential participant(s).
2. If HIPAA applies, request an “Alteration of HIPAA Authorization”:

This should be noted and explained in the “consent” section of the protocol application. The alteration means that when using the Short Form Consent Process, neither the potential participant nor their legally-authorized representative should sign the HIPAA Authorization (whether there is a separate HIPAA Authorization or one embedded in the Summary Form).

**Contents of the Consent Documents**

* The Short Form Consent states that the elements or disclosure required by regulations have been presented orally to the participant or the participant’s legally authorized representative.
* The Summary Form includes the basic and required additional elements of disclosure.

**Interpreters and Witnesses**

The short form consent process requires the assistance of an interpreter (who speaks the participant’s primary language and English fluently) and the presence of a witness.

**Who can be an interpreter?**

* Preferably, a hospital interpreter whenever possible
* A family member of the potential participant can act as an interpreter only if the potential participant has declined to use the hospital interpreter.
* If a member of the study staff speaks the potential participant’s language, the staff member can act as the Interpreter and Person Obtaining Consent (POC), but should not also act as the witness.

 **Who can be a witness?**

* A person who attests to the oral presentation and is conversant in both English and the potential participant’s language.
* The witness may be the interpreter (including the hospital interpreter), study staff, a family member, or other person.

Before starting the consent process, verify whether the interpreter will also be able to serve as a witness. If not, you will need to obtain another person to act as the witness.

***Note: A member of the study staff acting as the interpreter AND Person Obtaining Consent cannot also act as the witness.***

**Signature Requirements**

For a participant utilizing the short form process to fully consent to participating in the study, the following signatures need to be collected:

***Short Form (translated) must be signed and dated by both:***

1. Participant, or the participant’s LAR, and
2. Witness

***Summary Form (English) must be signed and dated by both:***

1. Person Obtaining Consent and
2. Witness

***Note: If the participant or the LAR is non-English speaking, the POC must ensure that any questions or options presented by the consent form are documented and initialed by the POC on the Summary Form, per the participant’s wishes, as they are understood during the consent process.***

**Providing Copies of Consent**

* A copy of the signed short form will be given to the participant or the legally authorized representative.
* A copy of the signed summary will be given to the participant or the legally authorized representative

**Additional Information**

For more information on the use of short form consent and its consenting process, visit: <http://www.hhs.gov/ohrp/policy/ic-non-e.html>.