Short Form Consent
Guidance

Definitions:

Short Form: A modified consent form written in a language understandable to the subject (or legally authorized representative) that sets out the basic requirements for informed consent.

Witness: An individual, ideally the translator, that is fluent in both English and the language of the subject (or legally authorized representative) that attests that the oral presentation of the long form English consent document was conducted. The witness is present during the entire consent interview.

Written Summary: A document accompanying a short form that provides an account of what is presented orally during the consent interview. An IRB-approved English language long form consent document may serve as a written summary.

Translator: An individual who must be fluent in both English and the language of the subject (or legally authorized representative) who translates the discussion between the investigator/research team and the subject (or legally authorized representative). The preferred individual would be affiliated with the institutional translation services department or a commercial translation service; however a member of the research team or someone else (excluding family members) fluent in both languages may serve in this role.

When to Use the On-Line Pre-Approved Short Form Consent:

The short form consent is typically used when the prospective subject or his/her legally authorized representative does not speak English and there is not enough time to translate the approved written English consent form into a language understandable to the subject

The Person Obtaining Consent using a short form consent process requires the assistance of a ***Translator*** and the presence of a ***witness***.

- ***Who can be the Person Obtaining Consent?***
  - The Person Obtaining Consent is a member of research team who is IRB approved to obtain consent, as long as that person is not also serving as the translator and witness. (One person cannot serve all three roles of Witness, Person Obtaining Consent and Translator.)

- ***Who can be the Translator?***
  - The Translator must be fluently bilingual and preferably a hospital Translator whenever possible.
  - If a member of the IRB approved study team is fluently bilingual in the subject's language, the study team member can act as the Translator and Person Obtaining Consent, but cannot also act as witness.
  - The translator cannot be a family member or person closely associated with the potential research subject.

- ***Who can be the Witness?***
  - The Witness is a person who attests to the oral presentation and is conversant in both English and the subject's language.

- The witness may be the Translator (including the hospital Translator), study staff, a family member, or other person.
- A member of the IRB approved study team acting as Translator *and* Person Obtaining Consent cannot also act as witness.

Before starting the consent process, verify whether the Translator will also be able to serve as a witness (one person cannot serve all three roles of Witness, Person Obtaining Consent and Translator.)If not, you will need to obtain another person to act as the witness.

Signature Requirements
If the subject agrees to take part in the study, the following signatures are required:

Short Form (translated) must be signed and dated by:
i) Subject or the subject's Legal Representative
ii) Person Obtaining Consent
iii) Witness (see above)
iv) Translator

If a study includes additional studies in which the subject must provide specific consent for that procedure, the "Addendum- Short Form Consent to Participate in a Research Study" must also be translated and reviewed with the subject. The following signatures are required on the form.

Summary Form (English) must be signed and dated by:
Attach the additional "Short Form Consent to Participate in a Research Study" signatures page addendum to the IRB approved English long form.

i) Person Obtaining Consent
ii) Witness (see above)
iii) Translator