

Short Form Consent Instructions

• These instructions are for use by the research team and should not be shared with the subject. If the subjects can read and understand English, Do not use the Short Form Consent.

• If a translated version is not available in the appropriate language, the Principal Investigator must request to have the IRB-approved Short Form Consent translated into the language the subject understands. Please ensure that subjects are consented with an IRB approved study specific Short Form Consent by submitting with the initial submission documents.

- 1. Complete the following open fields in the document:
 - a. Principal Investigator's name
 - b. Study Title
 - c. Contact Name and phone number of the person whom can answer questions about the research.
 - d. Contact Name and phone number of the person whom can answer questions about your rights as a research subject or what to do if you are injured.

2. Present the attached Short Form Consent to the potential research subject in a language s/he understands.

3. The Subject/Legally Authorized Representative must sign and date the Short Form Consent version appropriate for his/her language, if applicable.

Interpreter/Witness:

• An interpreter must read the IRB-approved English version of the full Informed Consent Document to the potential subject in his/her chosen language; the full Informed Consent Document serves as a written summary of the research.



- An individual who is fluent in both English and the potential subject's language must witness the consent process.
- The witness must be unaffiliated with the study.
- The witness must sign and date the Short Form Consent and the IRB-approved consent document.
- The interpreter may serve as a witness.
- If the interpreter is also the witness, the interpreter must complete the Witness and Interpreter signature sections on the Short Form Consent.
- If the medical or technical information in the consent document is complex, the interpreter must have an understanding of this information.

Person Obtaining Consent:

- The Person Who Obtained Consent must sign and date the IRB-approved English consent document.
- The English version of the consent document **may** not have a separate signature section for the witness, so s/he will sign below the Person Who Obtained Consent.

4. The subject must receive a copy of the signed and dated Short Form Consent and the IRB-approved English consent document as a written summary of the research.

5. The research staff must make an entry on the consent document or in the research records documenting the use of the short form consent.

6. The research team will file the original signed and dated IRB-approved English consent document, the original signed and dated Short Form Consent and the translated version of the full Informed Consent Document, when and if a translated version becomes available in the subject's study records.