Guidance when enrolling Non-English-Speaking Participants:

Documents must be translated from English into the required language by a certified translation service or credentialed individual.

The Principal Investigator will submit either a letter of certification of accuracy from the translation agency or a Certificate of Translation Form (located on the IRB website) for documents translated by a credentialed individual via eIRB.

When to Use the Pre-Approved Short Form Consent and Sub-Study Signature Page Addendum located on the IRB Website:

Short Form Consent:

The short form consent is typically used when the subject (or legally authorized representative) does not speak English and there is not enough time to translate the approved long form written English consent into a language understandable to the subject.

Sub-Study Signature Page Addendum:

If a study includes additional sub-studies for which the non-English speaking subject must provide specific consent to participate (for instance, an optional biopsy or PK study), the sub-study signature page addendum must also be translated into the appropriate language, reviewed with the subject or legal representative and signed and dated.

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. Signatures indicate that the elements of informed consent have been presented orally to the subject or subject's legal representative.

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 study documents into the language of the subject (or legal representative). The individual should be certified by a professional organization or institution as being fluent in the required language. It is the responsibility of the Principal Investigator to ensure that translators are fully qualified to fulfill this role.

Interpreter: 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). This would preferably be an individual who has been certified by a professional organization or institution as being fluent in the required language, however a member of the research team or someone else (excluding family members) fluent in both languages may serve in this role. It is the responsibility of the Principal Investigator to ensure that interpreters are fully qualified to fulfill their role.

Witness: An individual that is fluent in both English and the language of the subject (or legally authorized representative) who attests that the oral presentation of the written summary was a true representation of the contents of the document. The witness is present during the entire consent interview. This individual may be a member of study staff, a family member, or another individual who

is fluent in the required language.

Who can serve in these roles? *

The following persons may serve in multiple roles for the consenting process:

Note: A member of the study staff acting as both interpreter and the person obtaining consent cannot also act as a witness.

The Interpreter may also serve as one these roles, but not both:

- The witness
- The person obtaining consent (IRB-approved study team member)

The Person Obtaining Consent may also serve as one of these roles, but not both:

- The interpreter (if they are an IRB-approved study team member)
- The witness

The Witness may also serve as one of these roles, but not both:

- The interpreter,
- The person obtaining consent (IRB-approved study team member)

Before starting the consent process, verify whether the Interpreter will also be able to serve as a witness; if they will not, another person who speaks the language will be needed to act as the witness.

Required Signatures:

The following signatures are required on the short form(s):

Short Form Consent must be signed and dated by:

- The Subject or Legal Representative*
- Witness

* *The subject or legal representative will receive a signed copy of the short form*

Written Summary (Long Form English Informed Consent) must be signed and dated by:

- The Person Obtaining Consent
- The Witness (**It is acceptable for the Witness to sign and date the bottom of the long form if there is no Witness signature line is available**)

* *The non-English speaking subject (or legal representative) does not sign the long form English consent.*
* *The subject or legal representative will receive a signed copy of the long form English consent.*

The Sub-Study Signature Page Addendum is to be used when the written summary includes optional sub-studies and must be signed and dated by:

- Person Obtaining Consent
- Witness

* *The subject or legal representative will receive a signed copy of the short form.*
** *All parties must date their signatures for FDA-regulated and VA research.*