UTSW HRPP Guidance on Enrolling and Consenting Non-English Speaking Subjects

This document is intended to be used in conjunction with HRPP Policy 3.1 Informed Consent Requirements, 3.4 Informed Consent of Subjects with Limited English Proficiency and 6.2 IRB Approval of Research

Executive Summary

- Study teams should consider whether inclusion of non-English speaking subjects is appropriate for each study
- Short forms will be approved for new studies to enroll an occasional* non-English speaking subject
- If more than an occasional* non-English speaking subject will be enrolled, a short form may be approved for new studies while the full translation is pending
- The UTSW HRPP will confirm short forms are used appropriately at annual review
- Using short forms with more than occasional subject may require a fully translated consent be IRB approved and may be considered non-compliance

**generally meaning three or less over the course of the study*

1. Requirements for inclusion of non-English speaking subjects.

a. Research studies must have a plan for equitable recruitment, selection, and inclusion of subjects, which includes non-English speaking populations, or otherwise justify the rationale for exclusion of these subjects.

i. In some studies, inclusion of vulnerable populations (including non-English speaking subjects) may not be appropriate because risks may be unreasonable in relation to anticipated benefits to the subjects. In these studies, appropriate inclusion and exclusion criteria ***with justification*** should define the subject population and provide an explanation for excluding non-English speaking subjects.

ii. Examples of such justification include (but not are limited to):

- The study has no potential benefit and current standard of care (SOC) treatment is acceptable (*risk benefit ratio concerns)*;
- Study includes procedures which requires the ability to communicate quickly and in real-time (*safety and/or scientific concerns)*; or
- Study includes instruments which are not validated in a non-English language (*scientific concerns)*

b. When enrolling non-English speaking subjects, investigators must have a plan to manage communications with the participant during ***all phases*** of study participation, including: recruitment, consent discussions and enrollment, and during study visits or unexpected contact (phone calls or follow-up).

2. Which consent should be used?

a. Short Form**:** If the Principal Investigator (PI) and/or the IRB anticipate an ***occasional**** subject speaking the same non-English language to be enrolled, the IRB may approve a short form in the subject's language to ensure equal access to research studies.

i. Short forms must be IRB approved for each applicable language on a research study and stamped by the HRPP staff prior to its use. Short forms are available on the UTSW HRPP Forms website in 37 languages including translation certificates.

i. The IRB will re-evaluate the use of any approved short forms during annual reviews (during Continuing Review or Annual Update) and may require a fully translated consent document to be submitted. Use of the short form for more than an ***occasional**** subject may be considered noncompliance.

**Occasional generally means three or less over the course of the study.*

b. Fully Translated Consent**:** If the PI and/or the IRB anticipate that more than an ***occasional**** subject speaking the same non-English language will be enrolled, the IRB will require a fully translated consent document be prepared and approved.

i. Investigators are advised to have the translation completed after UTSW IRB approval of the English informed consent document has been issued.

ii. A non-English short form may be approved as part of the initial application to prevent delay of enrollment of non-English speaking subjects.

iii. Performance sites may prohibit the use of short form consents, and/or require fully translated consent documents to be available prior to issuing performance site approval. Contact the appropriate performance site research office for additional information.

3. Use of short form consent during modifications to fully translated consents

a. When the English consent is modified, any prior approved version of a fully translated non-English consent document is no longer valid and should not be used to consent new subjects.

i. Include a short form for each non-English language in the modification submission (with the modified English consent) to request the use of the short form while the full translation is pending. The approved short form will be uploaded on top of the fully translated document.

ii. If a short form is not included, the HRPP staff will overwrite the full translation of the non-English document with a blank document to ensure an invalid form is not used to consent subjects.

iii. If the IRB requires re-consent as part of the modification approval, non-English speaking subjects enrolled on the study must be re-consented as well. A short form and the newly modified and approved English consent document may be used to document re-consent in the interim until the fully translated consent document becomes available. The fully translated non-English consent document should be provided to subjects once it is approved by the IRB; however additional re-consent is not necessary.

4. How to document the consent process

The below section includes guidance on the signature processes only. Consent processes using a short form or a fully translated form should allow subjects ample time to consider participation, ask questions, and make a voluntary decision to participate or decline participation.

a. <u>Utilizing a Short Form and English Summary</u>

i. The non-English short form and an approved English consent (i.e., English summary) must be verbally presented to the subject.

ii. A witness who is fluent in both languages must be present during the entire consent conference.

1. The witness must be unaffiliated with the study. If using an interpreter, the interpreter may serve as the witness.

iii. The subject must receive a copy of the short form and the approved English consent.

iv. Signatures:

1. The study subject will sign the short form

2. The person obtaining consent will sign the approved English consent

3. The witness will sign the short form and the approved English consent (if the witness is from a interpreter service over the phone, obtain the interpreter's unique ID and write this on the line)

(Hint: Each person will sign the forms he/she can read. The subject understands the non-English language and signs the short form; the person obtaining consent understand English and signs the approved English consent; and the witness understands both languages and signs both).

b. <u>Utilizing a Fully Translated Document</u>

i. Use of an interpreter or an interpreter service may help ensure the non-English speaking subject is able to understand the study and his/her role in it.

ii. Signatures:

1. The study subject will sign the non-English fully translated consent (first line/box)
2. The person obtaining consent will sign as person obtaining consent (second line/box)
3. The interpreter or interpreter service is not required to sign when a fully translated consent document is used; if a signature line for interpreter is present, this should be completed (if using a phone interpreter service, obtain the interpreter's unique ID and write this on the line)