Human Research Protection Program Departmental Policy and Procedure

3.4 Informed Consent of Subjects with Limited English Proficiency

Responsible Office: Human Research Protection Program Department (HRPPD)

Effective Date: May 12, 2026

I. Policy Statement

a. The federal regulations on informed consent require the information be presented in a language understandable to the subjects. Where informed consent is documented in accordance with 46.117(b)(1), the written consent document should embody, in language understandable to the subject, all the elements necessary for legally effective informed consent.

b. UT Southwestern Medical Center is located in a culturally diverse area. Investigators are encouraged to recruit and include all segments of the community in research, including individuals whose primary language is not English.

c. The UTSW HRPP strongly encourages the use of a full consent form translated into the participant's language whenever possible. When all of the participants in a study (i.e., the target population) are anticipated to be non-English speaking, a full translated consent is required.

d. Researchers should prepare both English language and translated consent forms for proposals that include non-English-speaking subjects. The IRB may consult with language experts or require a "back-translation" into English. In such cases, the investigator may be asked to provide documentation to verify the accuracy of the translation and back- translation.

e. If a non-English-speaking subject is encountered unexpectedly, the subject cannot be enrolled until the IRB has reviewed and approved the consent process and the process for documentation of consent.

f. In studies where written consent is indicated, and a potential subject

understands English but does not read or write English, a witness should document that the subject understands the research and the consent process and has consented to participate.

II. Scope

a. This policy and procedure applies to all human subjects' research involving subjects with limited English proficiency (LEP).

III. Procedures For Policy Implementation

a. Potential subjects who do not speak English should be presented with a consent document written in a language understandable to them. The UTSW IRB, however, recognizes that not every eventuality can be planned for ahead of time in every protocol.

b. Investigators must deliver all information regarding informed consent/assent to potential subjects or their legally authorized representatives in the subject's native language(s) or one that the subject understands. The investigator must provide the IRB and prospective subjects a translated version of the consent form (long form or short form as approved by the IRB).

c. Investigators may use interpreter services to obtain consent in a language understandable to the participant or the participant's legally authorized representative.

d. Documenting Informed Consent of individuals with limited English Proficiency (LEP). There are two possible methods which may be used:

    i. Full translation of the long consent

        1. When all of the participants in a study (i.e., the target population) are anticipated to be non-English speaking, a full translated consent is required.

        2. The IRB may require a full translated consent if more than an occasional non- English speaking subject is enrolled throughout the

conduct of the study.

3. The IRB requires that appropriately translated consent documents be submitted to the IRB for review and approval prior to their use in enrolling participants.

ii. Short Form

1. Short Form - Federal regulations permit oral presentation of informed consent information in conjunction with a short form written consent document (stating that the elements of consent have been presented orally) and a written summary of what is presented orally.

a. IRB may permit informed consent in this manner for some or all of the subjects (see 21 CFR 50.27(b)(2)) or 45 CFR 46.117(b)(2).

b. This method of consent may be used if subjects do not speak English and a translated long consent document is not available.

c. A witness to the oral presentation is required, and the subject must be given copies of the short form document and the summary.

e. PI Responsibilities

i. Full translation of the long consent

1. The PI must obtain appropriate translation.

2. The PI must provide appropriate verification of the translation.

a. Verification may include a statement from the PI of the procedures used to verify the translation or by providing a certificate of translation from a professional translation company.

3. The PI is responsible for ensuring appropriate resources (translators, language phones, etc.) are available to communicate with the subjects at recruitment, enrollment (informed consent) and all future encounters. The PI should provide a description of the plan to

communicate with LEP subjects in the research protocol.

ii. Short Form

1. The PI must obtain appropriate translation. The HRPP has Short Form translations available in numerous languages on the website. If the language needed for the research is not available, it is the PI's responsibility to obtain the translated consent.
2. If the PI does not use one of the templates provided by HRPP, appropriate verification of the translation must be provided.
    a. Verification may include a statement from the PI of the procedures used to verify the translation or by providing a certificate of translation from a professional translation company.
3. The PI is responsible for ensuring appropriate resources (translators, language phones, etc.) are available to communicate with the subjects at recruitment, enrollment (informed consent) and all future encounters. The PI should provide a description of the plan to communicate with LEP subjects in the research protocol.
4. Short Form Procedures:
    a. The oral presentation must be in a language understandable to the subject. The short form should also be in a language understandable to the subject, however it may be in English if translation would represent an unreasonable delay that could be detrimental to the potential participant; researchers may not avoid translating the short form out of mere convenience or to reduce study expenses.
    b. The short form must be submitted to the IRB for review and approval. If the researcher uses the English version but anticipates additional non-English speaking subjects, then the researcher

should have the long or short consent forms translated and submit the form to the IRB for review and approval.

c. The IRB-approved English language informed consent document may serve as the summary, and the interpreter must be conversant in both English and the language of the participant. The witness's role is to document that the consent process occurred appropriately, that the participant understood the research, and that consent was voluntarily given; bilingual fluency is not required. When the person obtaining consent is assisted by an interpreter, the interpreter may serve as the witness.

d. Signature Requirements:

    i. Short Form (in participant's language):

        1. Signature of participant or legally authorized representative (required by OHRP/FDA)
        2. Signature of witness (required by OHRP/FDA)

    ii. English Informed Consent Document or summary:

        1. Signature of person obtaining consent (OHRP)
        2. Signature of witness (required by OHRP/FDA)

e. A copy of the summary is given to the subject or the subject's LAR, in addition to a copy of the short form.

f. The PI is responsible for keeping the original signed informed consent form and, according with the requirements specified in the UTSW Records Retention Policy and the study procedures as approved by the IRB

f. IRB Review and Approval

i. Long Form translation

1. The IRB may utilize administrative review procedures in approving translations of such documents if the English language consent/assent document has already been approved by the IRB, and a qualified individual has verified the accuracy of the translation

2. The HRPPD staff may identify a cultural consultant to review the study and informed consent/assent document for accuracy and cultural appropriateness. If the HRPPD staff is unable to identify an individual to serve as a cultural consultant, the investigator may provide a cultural consultant for review of accuracy of the informed consent form and cultural appropriateness. The cultural consultant must not have any affiliation with or investment in the research.

3. The HRPP staff ensures that the consultant does not have a conflict of interest. (See 6.4 IRB Member And Consultant Conflict Of Interest)

ii. Short Form

1. Use of the short form in lieu of the long translated consent form requires IRB approval.

2. The PI may request to use a short form written consent document stating that the elements of informed consent have been presented orally to the subject or the subject's legally authorized representative.

3. The IRB must approve a written summary (typically the long English consent is used as the summary) of what is to be said to the subject or the subject's legally authorized representative (LAR) which embodies the basic and appropriate elements of disclosure.

4. The IRB reviews the request and may approve the short form option for documentation only if all of the requirements outlined in 45 CFR

46.117(b), and as applicable, 21 CFR 50.27(b) are met.

IV. Definitions

See glossary of human research terms

V. References

a. 21 CFR 50: Protection Of Human Subjects

b. 45 CFR 46: Protection Of Human Subjects

c. 45 CFR 164: Security And Privacy (HIPAA Privacy Rule)

d. 21 CFR 56: Institutional Review Boards

VI. Revision and Review History

a. Revision Date: May 2026; Author: HRPP; Description: Clarified requirements for witness signature while using Short Form consenting procedures

b. Revision Date: June 2021; Author: HRPP; Description: Separated policy from P&P manual. Updated references to AVPHRA and IRB Director. Minor administrative edits.

c. Revision Date: January 2019; Author: HRPP; Description: Revision to reference 2019 common rule

d. Revision Date: August 2017; Author: HRPP; Description: New Policy Development

e. Revision Date: March 2012; Author: IRB Office; Description: IRB Written Procedures