



UNIVERSITY OF
SOUTH ALABAMA

IRB SOP 705
Translation and Interpretation

Purpose

This Standard Operating Procedure (SOP) document describes the policies and procedures affiliated with translation and interpretation in human subject's research.

Scope

This SOP applies to IRB members, IRB staff, Investigators, and other relevant study personnel who may be responsible for implementing this procedure.

Definitions

Interpreter: refers to a person who reads aloud (in another language) materials written in English, or who conveys (in another language) information that is spoken in English.

Translate: refers to converting materials written in English into materials written in another language

Back translation: refers to the practice of translating materials from one language to another language and then (in a separate action) translating the materials back into the original language. The purpose is to evaluate the quality and integrity of the translation.

Policy

- 1.0 For research intended, or likely, to involve subjects who are not fluent in English, any consent, assent, and parental permission forms must be translated or interpreted into a language understood by the subjects.

- 2.0 The USA IRB expects that translated documents will meet the following requirements. Researchers are required to inform the IRB how they will ensure that these translation requirements will be met. A qualified translator/interpreter should be able to ensure that the tone, meaning, and content of the translated documents remain consistent with the IRB-approved English version
 - 2.1 Linguistically accurate;
 - 2.2 At an appropriate reading level for the subject population; and
 - 2.3 Culturally sensitive for the locale in which they will be used.
- 3.0 Signed Translation Certification from all persons providing translation services
- 4.0 Translated or interpreted materials may not be used until they have been approved by the IRB.

Procedures

- 1.0 Obtaining translation or interpretation
 - 1.1 The researcher's IRB materials should describe the translation or interpretation process, including any criteria that will be used to identify the translator or interpreter. This may, for example, involve the use of a certified translation service.
 - 1.2 The following should be considered when selecting a translator or interpreter:
 - 1.2.1 The vocabulary of the materials (e.g., how complex and specialized)
 - 1.2.2 The background, experience, and language proficiency of the translator or interpreter
 - 1.2.3 The risks to subjects that might reasonably be expected with poor translation or interpretation
 - 1.2.4 Local cultural context and issues
 - 1.3 Sources of translation
The USA IRB does not require researchers to use a specific translation service. Possibilities include but are not limited to:
 - 1.3.1 The American Translators Association maintains two online directories, at: <http://www.atanet.org/onlinedirectories/>
 - 1.3.2 Directory of Translation and Interpreting Services (by individuals)
 - 1.3.3 Directory of Translation and Interpretation companies
 - 1.3.4 Native speakers who have demonstrated proficiency in English, including knowledgeable members of the research team, academics at other institutions, bi-lingual tribal leaders, etc.
 - 1.3.5 Graduate students or instructors in foreign language programs.

- 1.4 IRB review and approval of translated materials
It is unlikely that an IRB member will be proficient in the translated language. Therefore, the IRB's review focuses on whether the translation method is appropriate, based on consideration of the factors described in section 1.2 (above).
- 1.5 IRB review and approval of interpretation
The IRB evaluates the researcher's selection (or criteria for selection) of an interpreter. The IRB considers the factors described in section 1.2 (above).
 - 1.5.1 Privacy, confidentiality, and accuracy of translation/interpretation should be considered if family members or friends will be asked to interpret.
 - 1.5.2 How will the researcher and interpreter determine whether the subject truly understands the consent information?
- 1.6 The IRB has the authority to require revisions or additions to the consent process to ensure that non-English speaking subjects are adequately informed and are providing truly voluntary consent.
- 1.7 Stamping translated materials
The USA IRB will return any approved consent form (whether in English or translation) with the IRB approval stamp.

Regulated Documents:

45 CFR 46.116; 21 CFR 50.20

University Related Documents:

[SOP 702: Consent Documentation](#)

Related Forms:

Translation Certification Form (Located in IRBNet Forms and Templates)

History:

Effective Date:

Revisions: January, 2019

Responsible Office:

Office of Research Compliance and Assurance