



Investigator Guidance: Translation Requirements

Individual subjects and sometimes significant portions of the subject population, may not comprehend the spoken English language or read and comprehend documents, such as those for informed consent, that are written in English. If possible, such individuals should not be excluded from research that may have potential benefits. If they are to be included, their ability to engage in the consent process and make informed decisions about participation in research and its risks and benefits must be protected. To accomplish this, informed consent documents should be presented to prospective subjects in a manner and language that they can understand. The same is true for other research related documents such as interviews or surveys.

NOTE – The IRB may, at its discretion, approve translated versions of documents, questionnaires or other materials published in peer reviewed journals or materials previously approved by the UM IRB.

To determine what consent documents should be used for individuals considered by investigators to be potential subject, the following requirements apply:

- 1) Informed consent documents should be written in a manner that is understandable to the people being asked to participate. Every effort should be made to express a scientific concept/idea in lay terms at an approximate 8th grade reading and comprehension level.
- 2) If a potential subject cannot read English but can read another language, any written consent that is obtained should be in that alternative language. Any amendments or addenda to the consent form must also be in that language
- 3) If a potential subject cannot read English but he/she fully comprehends spoken English, the consent form may be read to the subject in English. The subject's ability to understand English should be noted in writing, and signatures of the subject, the person who obtains consent, and a witness should be obtained
- 4) If a potential subject cannot read either English or the available alternative language, and does not fully comprehend spoken English but does fully comprehend the alternative language when spoken, the consent form that has been translated into the alternative language should be read to the subject. The subject's ability to understand the alternative language should be noted in writing, and the signatures of the subject, the person who obtains consent, and a witness should be obtained

Exceptions to the above requirements may be made in situations when:

- 1) A subject requires rapid entry into a study for his/her well-being but the study does not have a consent form fully translated in writing to the subject's language
- 2) Investigators are uncertain whether non-English speaking subjects might be enrolled in a study, or believe that the majority of subjects are English speakers and that there might be only a small number of subjects (less than five) who will not understand English.

- 3) A waiver of written consent has been approved by the IRB. In this case, consent must be obtained verbally from all participants in whichever language was understood
- 4) A waiver of consent (written and verbal) has been approved by the IRB

In situation 1 and 2 (above), regulations [45 CFR 46.117(b)(2) and 21 CFR 50.27(b)(2)] permit the use of a short form in the subject's language together with a summary document in English. The "short form" consent document may be generic but it must affirm that the required elements of informed consent have been presented orally to the subject or the subject's legally authorized representative and that a witness fluent in both English and the subject's language was present to observe the process. When the person obtaining informed consent is assisted by a translator, the translator may serve as the witness. [ref. [HRP-090 – SOP – Informed Consent Process for Research](#), §5.2]

Translation Process

If a researcher intends to enroll subjects who do not adequately read the English language, informed consent documents should be translated into a language comprehended by the potential subjects.

The English version of approved study documents, including informed consent documents, should be approved by the IRB before the documents are translated into languages other than English. This will avoid duplicate work in case modifications have to be made to the English versions before they are approved by the IRB.

Once the English documents have been approved by the IRB, the investigator may create documents in other language(s) intended for use. The translated documents must be approved by the IRB before they may be used. Documents are eligible for IRB approval if translated as follows [NOTE – Only for studies whose management has been outsourced to Western Institutional Review Board (WIRB), the applicable translation policy is that defined by WIRB]:

- 1) The translation may be made by a certified translator approved to conduct such business by the university. Such translations must be accompanied by a signed translator certification statement including the date of the translation. This process may be used all studies but it is **required for studies involving an IDE or IND**. This requirement for certified translations for FDA research involving drugs or devices is consistent with the FDA requirement that a translated document be accompanied by an "Affidavit of Accuracy"
- 2) The translation may be made by a "back translation" method (see below) for submission to the IRB. This process may be used for all **studies that do not involve an IDE or IND**.
- 3) The translation may be made by a qualified translator. Included in these qualifications is that the translator be fluent (i.e. can speak, read and write) in the language. The translator must attest that the translated informed consent accurately reflects the IRB-approved English informed consent and provide the date of the translation. The translator must also submit to the HSRO a signed statement describing his/her qualifications to make this translation from one specific language into another. **This process may be used only for studies that are approved by the IRB as 'exempt'**. [NOTE – The signed statement should define that the translation is true, accurate, and correct "to the best of my knowledge and ability".]

Back-Translation Process

For studies not involving an IDE or IND, a “back-translation” of IRB-approved documents is permitted. This process requires:

- 1) A “forward” translation from the IRB-approved English document to the target language by a translator who is fluent in both languages.
- 2) A “back” translation of the “forward” translation into English. This must be done by a translator fluent in both languages who is someone different from the translator who provided the “forward” translation. The back translator must create the translation independent from the “forward” translation and must attest to the fact that he/she has not seen the original English consent form
- 3) Review and approval of both the forward and back translations for accuracy and completeness by the IRB

"Forward" and "back" translations should each be made by qualified translators. Included in these qualifications is that the translators are fluent (i.e. can speak, read and write) in the target language.

The "forward" and "back" translators must each attest that the translation he/she made was done independent of the other translation, is accurate and provide the date of the translation. The "back" translator must also attest to the fact that he/she did not see or refer to the English document when making his/her translation.

Each translator must also submit to the HSRO a signed statement describing his/her qualifications to make this translation from one specific language into another. *[NOTE – The signed statement should define that the translation is true, accurate, and correct "to the best of my knowledge and ability"]*

The "forward" and "back" translations, the IRB-approved English documents and the information from the translators should be submitted to the HSRO for forwarding to the IRB for review and approval. The IRB Chair or designee may approve the translated documents or may refer them to the convened IRB for review and approval.