

According to [45 CFR 46.116\(a\)\(3\)](#), informed consent must be conducted in a “language understandable to the subject or the legally authorized representative.” As such, there are times when it will be necessary for researchers to translate research documents, including informed consent documents, into a language other than English.

PIs wishing to conduct research with individuals for whom English is not their first language, must first submit all research documents (i.e., consent form, recruitment materials, measures, debriefing forms, etc.) to the IRB in English. The reason for this is that (1) the IRB may require revisions to the research documents, and it does not make sense to translate the research documents until the English language versions have received final approval and (2) the IRB must approve the individuals who will be completing the translations. PIs who plan to use a certified translator should include the name of the translator/company in their application. Once all changes have been made, the protocol will be granted conditional approval. Full approval will only be granted either when (1) the translated and back-translated documents have been received by the IRB and reviewed for consistency or (2) a certificate of translation from a certified translator has been received by the IRB.

Information to Include in the Protocol

Except as noted below, in **Waiver or Alteration of Informed Consent**, the consent document must include all the required elements of a standard consent form and informed consent must be obtained in writing. The PI must provide the names and qualifications of the individuals who will be doing the initial translation as well as the back-translation (see **Research Document Translation Requirements** for more on this). In addition, the PI must discuss any Cultural or other issues unique to the population that may influence the risk/benefit ratio of the study and how those issues will be addressed within the protocol and the consent procedures. The IRB reserves the right to consult with an outside expert on the specific culture included in the study if needed. If the study will be conducted in person or involves interviews, the PI will need to make clear to the IRB that all individuals conducting the research procedures can do so in the participant’s primary language. For example, if participants will be Spanish-speaking, then a Spanish-speaking investigator must be present during recruitment, consenting, and data collection to answer any questions participants may have or address concerns. Any individual who will be involved in implementing the research procedures must have completed CITI training or equivalent.

Research Document Translation Requirements

Once the protocol has received conditional approval, the PI may have the research documents translated. See the table below for the required qualifications of the translator based on the review category.

When Using Non-Certified Translators: All documents must be translated into the language in which the study will be conducted and then back translated into English. The individual conducting the back-translation CANNOT be a member of the research team because they should NOT have seen the original, English-language version of the documents prior to completing the translation.

When using Certified Translators: If the research documents are translated by a Certified Translation Company, then, in lieu of back-translated documents, the PI may submit a Certificate of Translation. This certificate should come from the Translation company on company letterhead. The PI will still be required

to submit the translated documents in addition to the Certificate of Translation before full approval can be granted. It is the PI's responsibility to locate a translation company and ensure that it is reputable.

Qualifications of Translator's Based on Review Category

	Initial Translation	Back-Translation	Accelerated Review (Exempt) Categories	Standard Review (Exempt and Expedited) Categories	Full Board
Fluent or Native Speaker <i>May be a member of the research team</i>	Yes	No	Yes	Yes	No
Fluent or Native Speaker <i>Not a member of the research team</i>	Yes	Yes <i>*Must be two different from the individual doing the initial translation</i>	Yes	Yes	No
Certified Translator <i>Not a member of the research team</i>	Yes	Yes <i>*Certificate of translation also accepted</i>	Yes	Yes	Yes

Next Steps Following Back-Translation of the Documents

The primary responsibility for ensuring equivalence between the original, translated and back-translated documents falls on the Principal Investigator. As such, before submitting the documents for review, the PI is expected to conduct a side-by-side comparison of the original and back-translated documents and identify any issues or concerns with the translation (e.g., typos that may represent incorrect translations; lack of clarity; changes in meaning; etc.). If issues are identified, then the PI must have a discussion with the translator and back-translator to resolve those issues. The PI must document how the discussion affected the translation and the back-translation. Any changes made to the translated and back-translated documents because of this discussion must also be indicated using track-changes or highlighting.

Once the PI is satisfied that the translation is correct, they will then submit the translated and back-translated documents along with the summary of the discussion regarding adjustments to the translations to the IRB. The IRB reviewer will compare the original English-language version to the back-translated version to ensure equivalence. The IRB may require that the documents be translated by a different translator if there are significant discrepancies between the original English-language and back-translated versions of the documents.

To facilitate the IRB's review of the original and back-translated versions, PIs are asked to submit the [Table for Submitting Original and Back-Translated Versions of Research Documents](#) with the revised documents. PIs must also submit clean copies of the research documents that will be used with participants.

Waiver or Alteration of Informed Consent and Documentation of Consent

According to [45 CFR 46.117\(c\)\(1\)\(iii\)](#), PI's may request a waiver or alteration of informed consent and/or from obtaining documentation of written informed consent if the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained. In this case, PI's must submit a short form written informed consent document stating all the required elements of informed consent as well as a written summary statement that will be presented orally to participants or their legally authorized representatives. In this case, the consent process must be witnessed, and the witness must sign both the short form consent document and the summary indicating that all elements were addressed with the subject. If appropriate, the participant or legally authorized representative could be asked to sign the short form document. A copy of both documents must be provided to participants or their legally authorized representatives.