

Translation Procedures for Short Form, Long Form and Addendum

This OHRS Information Sheet provides guidance to investigators who plan to consent participants whose primary language is one other than those included in the current list of translated Short Form (and/or addendum) consents.

- When a study team identifies that the Short Form (and/or addendum) is missing in a language they need, the study team should employ a company or individual to translate the English Short Form document (and/or addendum) into the language needed. This is available on the OHRS website at: <http://www.dfhcc.harvard.edu/research/clinical-research-support/creation/forms-and-templates/consent-form-builder-and-templates/>
- The company or individual hired to do the translation should provide a certification of translation to the study team.
- The study team then submits the Short Form (and/or addendum) in the new language, along with the certification of translation to the IRB as an amendment to the protocol.
- The IRB then reviews the amendment (usually on an expedited basis) and approves the use of the translated Short Form (and/or addendum) and it is then posted on the OHRS website for all study teams to use.
- A copy of the certification of translation is required for the IRB to approve the amendment and is kept on file by OHRS.

If the investigator opts to translate a “long form” Consent Form document, please use the following procedures:

- The company or individual hired to do the translation should provide a certification of translation to the study team.
- The study team then submits the Consent Form in the new language, along with the certification of translation to the IRB as an amendment to the protocol.
- A copy of the certification of translation is required for the IRB to approve the amendment and is kept on file by OHRS.

The English Short Form Consent and current Certificates of Translation were last reviewed and approved by the IRB on August 3, 2017.