



Consent Document Translation Affirmation Form

Principal Investigator Name:

Project Title:

Language of Translated Consent (e.g., Spanish):

This submission is for approval of:

- The initial submission of a consent document
- A modification to an already approved consent document dated

The UNTHSC OPHS and IRB require that all consent documents be submitted in English for review and approval. In addition, any consent documents that will be translated into another language must be back-translated to English to assure clarity of the translated information. Different individuals **MUST** perform the translation and back-translation of the consent document. The PI can perform the translation but *cannot* perform the back translation. In addition, the back-translator must perform the back-translation without first seeing the English version of the consent document.

You are required to submit:

- The English version of the consent document in distribution-ready format (letter head)
- The translated version of the consent document in distribution-ready format
- The back-translated version of the consent document (indicate “back-translation” at the top of page)
- The signed affirmation of translation/ back translation

TRANSLATION AFFIDAVIT: I hereby certify that I have performed the translation of the attached consent document for the reference project on behalf of the Principal Investigator indicated above, and that this is a true and correct statement regarding the translation of the English Consent Form for the above named project into the _____ language.

Signature of Translator

Date

Printed Name of Translator

BACK TRANSLATION AFFIDAVIT: I affirm that I have performed the back-translation of the attached consent document for the above referenced project on behalf of the Principal Investigator indicated above, and that this is a true and correct statement regarding the translation of the _____ language consent form back to the English language.

Signature of Back-Translator

Date

Printed Name of Back-Translator