



IRB Guidance Document and Form

Translation Certification Requirements

Purpose:	The purpose of this document is to provide guidance along with the required forms when documents must be translated from English to a second language and/or a second language to English during the course of an IRB review/approval.
Who This Applies To:	All investigators whose project(s) require translation services.
Date Created:	December 3, 2018
Update Log:	September 08, 2023 – minor edits

CU IRB Translation Certification Instructions

If your project requires translation either from English to non-English or non-English to English the translator and the Principal Investigator (PI) must complete the Translation Certification Form below, and include it with all translated documents (i.e., consent forms, recruitment materials, international approval letters, etc.). All materials must be included with the study submission in Cayuse.

The Translation Certification Form is required regardless of review type (i.e., exempt, expedited or full board) or form type (i.e., initial, renewal, or modification) when documents require translation during the review and/or approval of a project involving human subjects or human subject determinations. Situations where documents would require translation certification are when:

- Research is conducted in languages other than English, *AND/OR*
- Documents are required to be translated to English for purposes of CU IRB review.

Translation certification provides the CU IRB assurance that the individual completing the translation has the appropriate knowledge and skills to perform the translation and the translated document(s) is equivalent in meaning when compared with the original document.

MISCELLANEOUS CONSIDERATIONS:

- **Timing of Translation and Translation Certification:** It is strongly recommended to delay translation of documents from English to non-English until AFTER the IRB has reviewed and confirmed that no additional changes to the English version of the document would be required. Delaying translation until after such a review will help avoid having to consult a translator more than once.
- **Submission of Documents:** The IRB recommends translated documents along with the Translation Certification Form be submitted via a Modification after English documents (i.e., consent and recruitment, etc.) have been confirmed to be in the final form. All documents should be submitted as attachments within Cayuse.
- **Modification of Documents:** Each time a document (which has been subsequently translated to non-English) is amended in English, the new English version must be translated into non-English. The research team must provide a track-change English version of the document to the translator as reference in performing the new translation. Two copies (a clean copy and track changes copy) of the resulting translation must be submitted to the IRB for review along with the track change English copy and Translation Certification Form. A new Translation Certification Form must be submitted for ALL revised documents, even if the original translator completed the most recent translation.
- **Multiple Translators:** If multiple translators will assist in the translation of approved documents, a Translation Certification Form must be completed by each translator. A single Translation Certification Form can be used for multiple documents translated by a translator.
- **Qualification Limitations:** Conversational interpretation experience per qualifications may require additional review or documentation on a case-by-case basis.

If there are any questions regarding the process, in general, please feel free to contact the IRB office irb@chapman.edu or 714-628-2833.

CU IRB Translation Certification Form

CU IRB #: _____

CU IRB Study Title: _____

Principal Investigator (PI): _____

Original Language: _____

Translated Language: _____

Translator First and Last Name: _____

Translator Contact information
(i.e., email, phone and/or mailing
address): _____

Qualifications of Translator
(i.e., certifications, life experiences,
education, years of experiences,
registrations, etc.): _____

Date of Translation: _____

Description of Documents Translated
(i.e., participant consent form,
parental consent form, child assent
form, adolescent assent form, email
script, flier, etc.): _____

Translator Certification:

I certify that I am fluent in _____ (original document language) and
_____ (translated document language), and that the above described information
and attached/corresponding document(s) is an accurate translation.

Translator Signature: _____

Date: _____

PI Certification:

By signing this form, I certify that I understand it is my responsibility as Principal Investigator to ensure that IRB-approved study documents, e.g., recruitment materials and consent forms, are accurately translated in a language understandable to study participants.

PI Signature: _____

Date: _____