

Translated Documents Guidance

Consent documents and subject materials may be translated after the English versions have been approved by COMIRB. Whether these are translated immediately, or after the short form process has been used three times for a given language, the following items should be submitted to COMIRB as an amendment:

- Translated documents.
- Certificate of translation from a medical translation service OR a copy of the CV of an individual on the study team demonstrating they are a native speaker of the target language, or a certified medical translator.
- Stamped English copies of the approved consent form that is being translated, for general comparison purposes: version date and general formatting must match exactly. For subject materials, the clean English copies of these documents should be provided.

If the amendment contains only the translated and English documents, with no other changes to study materials, the amendment can be approved administratively.