

<b>Guidance Document</b>	Translated Documents
<b>Effective Review</b>	Health Sciences and Non-Medical REB (Delegated & Full Board)
<b>Version Date</b>	October 25, 2023

## Introduction

- Considering the scope and objectives of their research, researchers should be inclusive in selecting participants. Researchers shall not exclude individuals from the opportunity to participate in research because of attributes such as culture, **language**, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, gender, or age, unless there is a valid reason for the exclusion. (TCPS2-Article 4.1)
- Study materials (i.e., informed consent) should be available in languages understandable to the participants (or substitute decision makers (SDMs)) in order to provide free and informed consent for research studies. (TCPS2-Article 2.1).

## Process for Investigators

- Translated materials are to be submitted for review and REB approval prior to use in enrolling non-English speaking participants unless formal translation services (clinical trials) or other 3<sup>rd</sup> party translators (e.g., trusted family member of the participant/SDM) are available contemporaneously.
- If applicable, study documents originally written in other languages must be translated into English and the translation must be submitted for ethical review.
- The study team must provide the translated study documents with an attestation that is signed by the translator to say that this has been completed. The translated documents will be approved by the REB and the attestation will be acknowledged.
- See **APPENDIX A** for translation attestation guidelines.
- The translation of study documents should be completed by a qualified person other than the study team when at all possible.
- After the documents are approved by the REB, the study team will provide the document(s) to the appropriate participants in the research study.
- If a translator is being utilized during the consenting process, the translator must be impartial, and the consent form must include the signature and printed name of the translator.

## **Process for the REB**

- Translated copies of the study documents will be approved after the REB has approved the English version of the consent form. A copy of the translator's signed and appropriate confirmation (attestation) of the accuracy of the translation must accompany this. If the translated documents are standardized versions in other languages, attestations need not accompany these documents.
- If there are REB board members fluent in both English and the language of the translated documents, the board can call upon those board members to review the study and confirm the translations.
- There must be a level of scrutiny for translations/attestations proportional to the level of risk of the research and language proficiency of the researcher. The REB always reserves the right to request additional information from the researcher or translator, as needed.
- The use of translated study documents in research projects will be reviewed by the REB on a case-by-case basis due to the number of variables that could be present when considering how, when, and why translated documents and attestations may be required and/or used.

## APPENDIX A – Translation Attestation Guidance

When study documents are required in a language other than English to meet the needs of participants, Western’s REBs require an attestation from the person or service who did the translation. This typically takes the form of a signed letter\*. Below are the elements that must be in an attestation document as well as some optional text that is helpful, but not required.

- Date
- Name of the translator
- Affiliation of translator
- Contact information of translator or service
- Credentials of the translator (a statement that they are fluent in English and language of translation and any applicable professional/personal qualifications)
- Statement confirming that the translated documents are accurate and complete representations of the English versions as noted.
- Names and version dates of English documents that have been translated. This is often best submitted as a table or list.
  - Please note that the naming convention for the translated documents should remain as well as the version dates/version numbers of the English documents.
- Signature of translator
- **Optional:** Study title, Principal Investigator’s name, & REB#

Please note that Western’s REBs **do not** require translated documents to be submitted in the first iteration of an application. Study materials will be reviewed, and recommendations issued. Translating documents prior to at least initial REB review is generally not necessary. Study materials are best translated as the last element to initial review or as an amendment post-approval of English documents.

*\*When a study team member on a NMREB application is fluent in English and the language of translation, instead of a separate letter, an attestation can be made within the WREM form alone.*