

Guidance Document	Translated Documents
Effective Review	Health Sciences and Non-Medical REB (Delegated & Full Board)
Version Date	July 30, 2018

Introduction

- Taking into account 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 on the basis 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) 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.
- 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 study documents translated, back translated, 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.
- The translation of study documents should be completed by someone other than the study team who has the ability to complete such a translation.
- After the documents are approved by the REB, the study team will provide the document 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 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 to the English versions 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.