IRB Standard Operating Procedures		
SOP#: 15 Revision#:	**Title: Translation for Studies Conducted in a Language Other than English**	**Effective Date: January 26, 2021**
Approved By:	**Institutional Review Board**	**Approval Date: January 26, 2021**

PURPOSE

To describe Institutional Review Board (IRB) Policy for the translation of study documents into a language other than English.

DEFINITIONS

Human subject - a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information.

IRB - an institutional review board established in accord with and for the purposes expressed in the federal regulations for the protection of human research subjects.

Minimal risk - the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Qualified Translator - An individual who demonstrates a high level of proficiency in at least two languages and has the appropriate training and experience to interpret with skill and accuracy.

Research - systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge

POLICY

This policy ensures that prospective participants have sufficient information to provide informed consent to participate in research. It is necessary to convey information regarding the research in a language the prospective participants understand. If the research targets a particular group that does not speak and/or read English, the recruitment materials (e.g. approach letters, informed consent documents, etc.) and project documents used with participants must be

translated into the language understood by the targeted group (45 CFR 46.116-117; 21 CFR 50.20). As researchers often wish to conduct research with participant groups who do not speak or read English fluently, the IRB has developed a policy regarding the use of translated documents.

RESPONSIBILITIES

Execution of SOP: Researchers, IRB

PROCEDURE

The requirements regarding obtaining IRB approval for translated documents varies depending on the level of risk of the research. Researchers should describe in their Project Information Form whether translated documents and which language(s) will be appropriate for the prospective participants. However, as the IRB often requires researchers to revise project documents, translated documents should not be submitted to the IRB until the IRB indicates that the English version is acceptable. Regardless of the level of risk, it is recommended that English versions of documents be approved prior to translating, minimizing the number of iterations of translations. All final translated documents must be submitted to the IRB.

Translations for Minimal Risk Research

The qualifications of the translator should be provided (e.g. native speaker, academic degrees, certified translator, etc.) to the IRB, using the Translation Certification form, when foreign language versions of project documents are provided. The translations should be consistent to the English versions in both content and format. Translators must sign the Translation Certification form indicating that they have carried out the translation to the best of their ability.

Translations for More than Minimal Risk Research

For projects involving greater than minimal risk to participants, the IRB requires that the researchers either use certified translators (with a letter of certification from the translator or translation service) or that a “back-translation” by a different translator than the one who performed the original translation be provided. The back-translation (back into English) serves to ensure that the non-English version contains all of the key elements of the English version. The translated documents (forward and back), as well as documentation of the qualifications of each translator, must be submitted to the IRB for final approval.

Use of a Qualified Translator

The IRB requires the use of a qualified translator. Rather than limiting researchers by having very specific qualifications for translators, the term “qualified” is left open so that researchers have flexibility and the IRB can make a case by case determination as to whether the qualifications of the translator/verifier are sufficient based on the project and the specific project documents.

For example, the IRB would not expect researchers to use someone who is a native Spanish speaker but has no medical background to translate a complicated clinical trials consent form. If this person does not have a good understanding of medical terminology, then they might not provide an adequate translation of the informed consent. On the other hand, a medical student, physician, experienced nurse, etc. who is a native speaker would typically be appropriate for translating the informed consent. If the project involves a survey (e.g. about how they view the services they receive, what toothpaste they use, etc.) where the risks are minimal and the research design is very simple, then a native speaker without a scientific/medical background would probably be qualified to translate the informed consent form.

The OIRB requires a Translation Certification form be submitted with all foreign-language translations of consent forms, recruiting materials and other project documents. This form attests to the validity of the translation and includes a statement of the English and foreign-language qualifications of the translator.

The IRB may invite a consultant to review the translated materials to determine cultural appropriateness.

Author Reference

NEIU IRB

University of New Mexico SOP#506.1

45 CFR 46.116-117 21

CFR 50.20

Contact Information

Please direct questions or concerns about this policy to:

Contact	Phone	E-Mail
IRB Office	773-442-4675	irb@neiu.edu
Dean of the College of Graduate Studies and Research	773-442-6012	gradstudies@neiu.edu

Disclaimer

The University reserves the right to modify or amend sections of this IRB SOP at any time at its sole discretion. This IRB SOP remains in effect until such time as the Responsible Officer calls for review. Requests for exception to any portion of this policy, but not to the policy statement, must be presented in writing to the Responsible Officer.