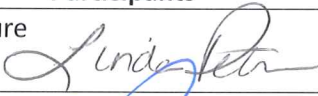



Standard Operating Procedures		
SOP #506.0 Revision 0	TITLE: Translation for Non-English Speaking Participants	Effective Date: 12/1/2015
Approved By: OIRB Director	Signature 	Date 12/3/2015
Approved By: IRB Chair	Signature 	Date 12/7/15

PURPOSE

To describe Institutional Review Board (IRB) policy with regard to translation of study related documents when enrolling non-English speaking participants.

REVISIONS FROM PREVIOUS VERSION

None

POLICY

In order to ensure that prospective participants have sufficient information to provide informed consent to participate in research it is necessary for the researchers to convey information regarding the research to participants through methods that will be effective for the participant population. If the study population targets a particular group that does not speak and/or read English, the recruitment materials (e.g. approach letters, informed consent document) must be translated into the language understood by the targeted group (45CFR46.116-117; 21CFR50.20). 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, OIRB Staff.

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 their consent forms, translated consent forms should not be submitted to the IRB until the IRB indicates that the English version of the consent form is acceptable. Regardless of the level of risk, it is recommended that English versions of consent forms be approved prior to translating, minimizing the number of iterations of translations.

Translations for Minimal Risk Research

For studies involving minimal risk to participants (“no foreseeable risks involved in participating in this research beyond those experienced in everyday life”), 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 consent forms 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 studies 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. The OIRB requires a translation certification form be submitted with all foreign-language translations of consent forms, recruiting materials and other study materials. This form attests to the validity of the translation and includes a statement of the English and foreign-language qualifications of the translator.

Rather than limiting researchers by having very specific qualifications for translators, the term “qualified” is left wide 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 study and the specific study 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 doesn’t have a good understanding of medical terminology then he/she 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 study 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 study design is very simple then a native speaker without a scientific/medical background would probably be qualified to translate those consent forms.

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

REFERENCES

45 CFR 46.116-117
21 CFR 50.20