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| **TRANSLATION GUIDE INTRODUCTION** |
| This guide describes the Institutional Review Board’s (IRB) policy regarding translation of research related documents when enrolling non-English speaking participants.  Prospective participants need sufficient study-related information to provide informed consent to participate in research. Researchers must convey information regarding the research to participants through methods that will be effective and appropriate for the participant population. If the research targets a particular group that does not speak and/or read English, the recruitment materials, informed consent (guardian and/or assent) documents, and project documents used with participants must be translated into the language understood by the targeted group (45CFR46.116-117; 21CFR50.20).  Teachers College, IRB developed a translation of research related documents policy as researchers often wish to conduct research with participant population who do not speak or read English fluently. |
| **Researchers fluent in English and the other language may translate documents when the IRB staff determines that it is unlikely for significant changes to be requested but before the IRB approves the study. Alternatively, researchers can translate the participant documents after all approvals are completed and submit the translated documents and verification form as an amendment.**   * Study-related information that is given to a subject or a subject’s legally authorized representative must be in a language understandable to the subject or representative. * Language should be culturally sensitive to the population to whom the documents are being presented. * Reading level should be at maximum of a 6th grade level. * Translated documents provided to subjects must be approved by the IRB prior to use. * For new studies enrolling only non-English speakers, full study approval will not be granted until the translated documents are reviewed and approved by the IRB. * The translated versions must reflect the approved English documents. |

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| All translated documents that will be used to interact with participants should be included with the IRB submission including (*but not limited to*):   * + Verbal consent or assent scripts   + Written informed consent, parent permission, or assent documents   + Information sheets to participants   + Recruitment materials   + Study measures (e.g., surveys, questionnaires, interview questions, etc.)   + Other documents as requested at the discretion of the IRB   Please note that in addition to documents provided to subjects, letters that are not written in English, such as international ethics committee letters or site permission forms, are to be accompanied by an English translation when submitted to the IRB for review and approval. |
| **Requirements Regarding Obtaining IRB Approval for Translated Documents**  The requirements regarding obtaining IRB approval for translated documents varies depending on the level of risk of the research. Researchers should describe in their IRB Application whether translated documents and which language(s) will be appropriate for the prospective participants. If the researcher is a native speaker/writer of the language, they may translate the materials, but they must seek an impartial individual certifying the accuracy of the translated documents. The IRB may invite a consultant to review the translated materials to determine cultural appropriateness.   * If a **native speaker**, the researcher must disclose in the IRB application:   + They are a native speaker and able to speak/read/write in that language.   + They plan to translate all documents in the language appropriate for the prospective participants.   + They will seek an impartial individual certifying the accuracy of the translated documents (who is not the translator of the documents or a member of the research team).   + They will ask the impartial individual to sign the “Translation Verification Form.” * If **not** a **native speaker**, the researcher must disclose in the IRB application:   + They are a not a native speaker but they will seek the translation expertise of someone who is able to speak/read/write in that language.   + The plan regarding who will translate all documents in the language appropriate for the prospective participants.   + They will seek an impartial individual certifying the accuracy of the translated documents (who is not the translator of the documents or a member of the research team).   + They will ask the impartial individual to sign the “Translation Verification Form.”   TC IRB asks researchers to revise project documents wish translated documents submitted to the IRB after 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. |
| **MINIMAL RISK RESEARCH** |
| **Translations for Minimal Risk Research**  For projects 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 when non-English language versions of project documents are provided. The translations should be consistent to the English versions in both content and format. Translators must seek an impartial individual to sign the “Translation Verification Form,” indicating that they have carried out the translation to the best of their ability. |
| **MORE THAN MINIMAL RISK RESEARCH** |
| **Translations for More than Minimal Risk Research**  For projects involving greater than minimal risk to participants, the IRB requires that the researchers either use qualified (or 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), and documentation of the qualifications of each translator, must be submitted to the IRB for final approval. |
| **QUALIFIED TRANSLATOR** |
| **Use of a Qualified Translator**  The IRB requires the use of a qualified translator. The IRB requires a “Translation Verification Form” be submitted with all non-English 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 non-English language qualifications of the translator.  Rather than limiting researchers by having very specific expectations 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 participant documents.  On the other hand, a medical student, physician, experienced nurse, etc. who is a native speaker would typically be appropriate for translating the participant documents. 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 participant documents.  Each protocol is reviewed on a case-by-case basis, and IRB reviewers may ask for supplemental information to verify the accuracy of translated documents.  **A copy of the “Translation Verification Form,” can be found in Mentor IRB/Documentation.** |