

Introduction

The Marquette University (MU) Institutional Review Board (IRB) emphasizes the importance of using translated documents to ensure ethical and responsible research practices when recruiting and consenting human subjects. The purpose of this guidance document is to inform researchers about the significance of translations, best practices for their implementation, and IRB submission requirements.

Why Translations Matter

- **Informed Consent:** A core principle of human subjects research is informed consent. Participants must fully understand the research process, risks, and benefits before agreeing to participate. Translated documents allow non-English speaking individuals to comprehend the study details and make informed decisions about their involvement.
- **Ethical Considerations:** Including translated documents demonstrates respect for potential participants from diverse backgrounds. It eliminates language barriers and promotes inclusivity in research endeavors.
- **Data Integrity:** Misunderstandings due to language barriers can compromise data quality. Translated documents ensure participants understand instructions and respond accurately, leading to reliable research findings.
- **Regulatory Compliance:** Federal regulations often mandate the provision of translated documents when enrolling non-English proficient (LEP) subjects. The IRB can help researchers navigate these regulations.

Documents Requiring Translation

- **Recruitment Materials:** This includes advertisements, flyers, and information sheets that explain the research study.
- **Consent Form:** This is the most crucial document requiring translation. It details the study procedures, potential risks, and participant rights.
- **Assent Forms:** For research involving children, translated assent forms should be provided to ensure their understanding.
- **Study Materials:** Depending on the research design, surveys, questionnaires, and other data collection instruments may require translation.

Translation Best Practices

- **Professional Translation:** Utilize qualified translators with expertise in scientific and medical terminology relevant to your research field.

- **Back-Translation:** For critical documents like consent forms, consider a back-translation process where the translated document is translated back into English by a different translator to ensure accuracy.
- **Culturally Appropriate Language:** Translations should be culturally appropriate and use language understandable to the target audience.

IRB Submission Requirements

- **Certification of Translation:** MU IRB requires a certification statement. Researchers can use the form, “Certification of Translation,” found on the IRB website under Forms, to verify and certify the translation of study documents.
- **IRB Review:** Professional translation of research materials can be costly, and it is the responsibility of the researcher to cover these costs. MU IRB recommends holding off on translating any materials into another language until the MU IRB has approved the study based on the English language materials.
- **Who Can Translate:** The researcher may choose to contract a professional translation company or a professional translator. Additionally, a member of the research team who is fluent in both languages may be able to certify and attest to the accuracy of the translation of research materials. Note, MU IRB may require someone other than a team member to translate/interpret given the level of risk to human subjects in the study.

Conclusion

Research studies purposefully recruiting subjects who do not speak or understand English must adequately provide informed consent or partake in study activities, all documents that will be presented to them (e.g., consent forms, study information sheets, recruitment materials) must be translated into their primary language. By incorporating translated documents, researchers can ensure informed consent and ethical treatment, to facilitate data collection.