

Revisions to the MCW IRB SOPs for Recruitment & Enrollment of Non English Speakers

Effective December 2, 2024, the following documents have been revised and posted to the MCW HRPP website with regards to the recruitment, consenting, enrollment, and continued engagement of non English speaking subjects:

IRB SOP: Recruitment and Enrollment of Non English Speakers v7

IRB Form: Translator and Interpreter Certification Form v3

IRB Form: Backtranslation Certification Form v2 (RETIRED)

Background

Over the past 2 years, the MCW HRPP Office conducted background research and an extensive literature review to benchmark best practices for research involving non English speaking subjects. This effort led to improvements and revisions that enhance procedural clarity and support researchers, staff, and subjects within the MCW HRPP research community.

Information and findings include:

Translation vs. Interpretation: Understanding the differences and importance of both processes in research. Translation involves the written conversion of text from one language to another, while interpretation deals with spoken language conversion.

Key Considerations for Translation: The literature emphasizes the need for accurate, culturally appropriate translations that consider tone, cultural context, and language variations. It highlights that no single translation method is perfect and that processes are often underreported, leading to variability in methods and institutional regulations.

Commonly Used Translation Methodologies:

- **Back Translation:** While commonly used, it often fails to capture cultural nuances and contextual differences.
- **Collaborative and Iterative Translation:** Encouraged for its accuracy and cultural relevance, involving multiple rounds of translation and review by a team of translators and researchers.
- **Pretesting and Cognitive Interviewing:** Ensuring translations are comprehensible and culturally appropriate through feedback from the target population.

Current Process

The current process describes the engagement of non English speakers as "unanticipated" vs. "anticipated." Additionally, the current approval process required the submission of two amendments for using the ShortForm, a plan for continued engagement and confidentiality of subjects, and reporting the use at the next CPR.

Recruitment and enrollment of non English speakers also require back translation of the consent form and study documents. Final IRB approval is contingent upon providing the English, Translated, and Back Translated versions of subject documents, along with completed Translator and Back Translator Declaration Forms.

Summary of revisions:

1. Removal of Back Translation Requirement:

- Back translation

Over the next few months, the MCW HRPP Office will provide tailored education, additional guidance documents, and other learning opportunities on this topic.

Please contact the MCW HRPP Office with any immediate questions. Thank you for your ongoing collaboration and support throughout this transition!