

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 is no longer a requirement. Instead, study teams must provide the English and Translated version of all subject-facing documents along with the *Translator and Interpreter Certification Form*. Additionally, a plan for continued engagement and confidentiality of subjects for the entirety of the project is required.

2. Clear Guidance for Use of ShortForm to Consent Non-English Speakers:

- Before using the ShortForm, project teams must submit a Protocol Deviation as a Reportable Event. After approval of the RE and use of the ShortForm, an amendment updating all required eBridge Sections and documents must be submitted. This RE, use of the ShortForm, and AME must be reported at the next CPR.

3. New Translation/Interpretation Certification Form:

- The *Translator and Interpreter Certification Form* must be used to certify the accuracy and appropriateness of translations and interpretations. The form must be completed, signed, and uploaded to the eBridge SmartForm.

4. Document Restructuring:

- Expanded definitions, updated formatting, and new sections for clarity. This includes separating the use of ShortForm procedures from planned enrollment procedures and adding new sections for projects with reliance.

What is NOT Changing

- **Translation Requirements:** All subject-facing documents, including consent forms, recruitment materials, questionnaires, surveys, and diary prompts, must still be translated into a language the subject can understand. These documents' English and translated versions must still be uploaded to the eBridge SmartForm and any other requirements noted in the SOP.
- **Planning for Inclusion:** Study teams are still encouraged to plan ahead for the intentional recruitment and enrollment of non-English-speaking subjects. This includes developing a plan for translation and interpretation for the entirety of the project (recruitment through completion of all activities); and providing all necessary forms and requirements outlined in the SOP.
- **ShortForm Use:** Using the ShortForm to consent non-English speakers will still require IRB approval and adherence to submission and reporting procedures. Use of the ShortForm continued to have limitations and must be used in accordance with the guidelines outlined in the SOP.
- **Institutional Policies:** Projects conducted at Froedtert Hospital, Children's Wisconsin, and/or Versiti must still adhere to the policies outlined in the SOPs for each institution. Adherence to specific process requirements and qualifications for translators/interpreters will continue. Project and confidentiality plans must be described in the eBridge SmartForm as currently required.

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!