Qualified Interpreter: An interpreter with the necessary skills and experience to interpret accurately, often demonstrated through language proficiency, understanding of subject matter, and practical experience, but without formal certification. At MCW, a qualified interpreter must complete and sign the Translator and Interpreter Certification Form to engage in research activities.

Translator: Translators convert written text from one language to another, preserving style, tone, and meaning while adjusting for societal context and cultural nuances. Translators aim for seamless integration into the target language, but cultural nuances may be retained for specialized content.

Translation: The written process of converting the meaning of a text from a source language into an equivalent text of another target language(s). This involves accurately conveying the original document's content, style, and nuances into another language.

Certified Translation: A written translation that comes with a signed Certification Statement attesting to the accuracy and completeness of the translation. Certified translations are often used for official purposes, and in the United States, anyone can certify a translation without needing specific training or certification. Certifying translations for oneself or family members is discouraged and not permitted for research at MCW.

- See the Translator and Interpreter Certification Form for more information.

Translation/Interpretation Certification Statement: At MCW, a certification statement must include the translator/interpreter qualifications, an affirmation of the document's completeness and accuracy, identification of the translated documents and language, and identification of the activities that will be performed. The certification statement should also include the individual’s name, signature, and date. The certification statement can be modified as needed to meet specific project requirements.

- At MCW, the Certification Statement is embedded in the Translator and Interpreter Certification Form; completion of this Certification Form will serve as the Certification Statement.

Translator and Interpreter Certification Form: This form includes the

3. Develop a plan for ongoing communication during the research project--including for follow-up assessments, questions, adverse events, emergencies, and the ongoing "consent" process for the non-English speaking subject.

ShortForm: Informed Consent Process Utilizing the ShortForm

Investigators should consider and complete the following when consenting a non-English speaking subject with the ShortForm.

1. Preparing for the Informed Consent Process Utilizing the ShortForm:
    a. Assure that a summary in English of what is to be presented to the subject is available and approved by the IRB.
        i. Typically, this will be the IRB-approved consent form in English.
    b. The (English-speaking) project staff member reviewing the consent process with the subject and interpreter should ensure that the contents of the consent form are reviewed and discussed.
        i. The informed consent discussion must begin with a concise and focused presentation of the key information. This should assist a prospective subject in understanding the reasons why one might or might not want to participate in the research.
        ii. The information must be organized and presented in a way that facilitates comprehension.
        iii. The entire consent form in English does not necessarily need to be read to the subject word for word; however, if any federally required elements of informed consent (45 CFR 46.116) are missed, the entire consent process is invalid.
            1. For a list of required elements, see IRB SOP: Informed Consent Document for Human Subject Research.
    c. The project staff member going through the consent process should allow the subject time and opportunity to ask questions, and to think over the implications of project participation in accordance with IRB SOP: Informed Consent Process for Human Subject Research.
2. Investigators must obtain the subject's signature to document the consent process. In addition, the following required signatures and additional steps in the consent process must be completed:
    a. The ShortForm should be signed by the subject or the subject's Legally Authorized Representative (LAR) if applicable, the interpreter, and an adult witness.
        i. For more information as to who may serve as a LAR see IRB SOP: Legally Authorized Representatives (LAR): Who can Consent on behalf of an Adult Subject with Decreased Decisional Ability.
    b. The English IRB Approved Consent Form should be signed by the adult witness and the individual conducting the informed consent discussion.
    c. The rationale "Subject has limited English proficiency" should be selected under the witness signature box.

Planning for Recruitment and Enrollment of Non-English Speakers. This amendment must be submitted before additional non-English speaking subjects are enrolled.

b. The amendment must include one of the following:

5. Uploaded translations of ALL subject-facing documents in the subjects' spoken/preferred language.

Additional steps and requirements that must be planned for when recruiting, consenting and enrolling non-English speaking subjects are outlined below.

Planning For Inclusion of Non-English Speakers - Translation

Before a project consents and enrolls non-English speakers, the steps and requirements outlined below must be planned for and completed by the Investigators and project team.

1. All subject-facing documents, including the consent form, recruitment materials, questionnaires, surveys, diary prompts, or other documents that subjects are expected to read and/or complete must be translated into a language the subject(s) can understand.
2. The English and translated versions of all subject-facing documents must be uploaded to the eBridge SmartForm.
    a. Whether or not intervention materials are required for review and translation will be assessed on a project-by-project basis as this is project-dependent.
3. To ensure a certified and accurate translation has taken place, Investigators must choose one of the following two options as a certification of translation:
    a. A completed and signed copy of the Translator and Interpreter Certification Form must be uploaded to the eBridge SmartForm.
        i. The Translator and Interpreter Certification Form must be completed, signed, and uploaded in support of all subject-facing documents, including the consent form(s), recruitment materials, surveys/questionnaires, etc.

    OR

    b. Provide a certified translation by a professional translation service/company. A certificate of translation or confirmation of a certified translation must be uploaded to the eBridge SmartForm.
        i. This certification must support all subject-facing documents, including the consent form(s), recruitment materials, surveys/questionnaires, etc.
        ii. A professional translator may also complete the Translator and Interpreter Certification Form as a certification of translation.
            - A list of MCW supported translation/transcription vendors can be found on the Office of Research website, under Research Resources.
    c. MCW HRPP Office does not require or recommend back translation as a translation method given that back translation does not always result in a valid or accurate translation.

Planning For Inclusion of Non-English Speakers- Interpretation

1. For projects which will consent and enroll subjects from Froedtert Hospital, Children's Wisconsin, and/or Versiti, all procedures must adhere to the policies outlined in the SOPs for each institution.
2. For projects conducted in the community at large:
    a. The following qualifications must be observed when identifying who can serve as an interpreter for a project:
    b. No minor under the age of 18 can serve as an interpreter.
    c. Family members cannot serve as the interpreter.
    d. If selecting an interpreter from the community from which subjects will be recruited, a plan to ensure confidentiality must be described in the eBridge SmartForm.

    e. A professional service/company may be used for interpretation, and this must be detailed in the eBridge PRO SmartForm and study protocols.
3. In support of all interpretations for the project and to ensure an appropriate and accurate interpretation process has taken place, Investigators must upload one or both of the following documents to the eBridge PRO SmartForm:
    a. A completed and signed Translator and Interpreter Certification Form to the eBridge PRO SmartForm.
    b.

b. Another option is for relying sites to adhere to MCW's policies and utilize MCW's consenting templates for all engagement of Non-English Speakers.

2. <u>When MCW is relying on an external IRB:</u>

a. The study teams must adhere to MCW's policies and procedures for all engagement of Non-English Speakers.
    i. The MCW ShortForm and Informed Consent templates must be used to consent subjects.
    ii. Please note study teams must reach out to MCW IRB Reliance for project-specific questions and guidance when relying on an external IRB.

REFERENCES:

45 CFR 46.102(c)
45 CFR 46.116
21 CFR 50.3(1)
FDA Guidance: Informed Consent: Guidance for IRBs, Clinical Investigators and Sponsors (2023)

SUPPORTING DOCUMENTS:

IRB SOP: Legally Authorized Representatives (LAR): Who can Consent on behalf of an Adult Subject with Decreased Decisional Ability
IRB SOP: Informed Consent Process for Human Subject Research
IRB SOP: Informed Consent Document for Human Subject Research
IRB Form: Translator and Interpreter Certification Form

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HRPP Authorized Official:	Ryan Spellecy, PhD, Director, HRPP Human Research Protections Program (HRPP) Office of Research Medical College of Wisconsin