MCW Office of Research
Standard Operating Procedure

RECRUITMENT AND ENROLLMENT OF NON-ENGLISH SPEAKING SUBJECTS

Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: Faculty and Staff involved in human research

PURPOSE:
The IRB supports Investigators in expanding access of research protocols to non-English speaking subjects. Including subjects in research who are not fluent in spoken or written English ensures that the burdens and benefits of research are justly distributed. They may also be included because the area of research necessitates involving non-English speaking subjects (e.g. international-based projects or within a specific community). Investigators must assure that the non-English speaking subjects fully understand their role in the project and provide voluntary informed consent.

This procedure outlines the investigator's responsibilities when enrollment of non-English speaking subjects.

DEFINITIONS:

Consent: refers to an explicit agreement to participate in a certain action, particularly and especially after thoughtful consideration.

ShortForm: Both a document and a process to consent non-English-speaking subjects when a fully translated consent form is unavailable. The document is a template provided by the MCW IRB and found on the Office of Research website. The process involves presenting consent information orally and having a bilingual witness. Signatures from the subject, the person obtaining consent, and the witness must be obtained as part of this process. Consenting via this process and utilizing the ShortForm document is regulated under 45 CFR 46.116 and 46.117 and requires MCW IRB approval.

Non-English Speakers: individuals who do not speak or understand English as their primary language and may require communication or documentation in their native language for full comprehension.

Interpretation: Interpretation is the physical process of converting spoken language from one language (the source language) into another (the target language), ensuring accurate communication of meaning, style, and cultural nuances. Interpreters work bi-directionally, meaning they interpret both to and from the source and target languages, with methods varying by setting and context.

Certified Interpreter: An interpreter who has passed a formal certification process by a recognized body, meeting rigorous standards in language proficiency, interpreting skills, and professional ethics. At MCW, a certified interpreter must provide proof of certification to engage in research activities.

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 Translation/Interpretation Certification Statement and should be completed by the Principal Investigator (PI) and the identified translator(s) and/or interpreter(s) of the project. This form must be uploaded to eBridge for all projects proposing to recruit and enroll non-English Speaking subjects. One form must be provided per translator and/or interpreter.

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

PROCEDURES:

Enrollment of Non-English Speakers Using the MCW ShortForm Consent Process
On occasion, an opportunity to enroll a non-English speaking subject may arise but translated documents have not been previously approved by the IRB. In these cases, federal regulations allow the use of a ShortForm Consent in a language the subject understands. The MCW ShortForm documents that all required elements of informed consent were presented orally.

If the Investigator expects to enroll more subjects who speak that language, the investigator must follow the steps outlined under "Planning for Recruitment and Enrollment of Non-English Speakers."

Please note that projects that require reading or written responses from the subject, such as diaries and surveys, may not be appropriate under this procedure. Investigators should carefully consider and plan how these documents will be translated and made available to the subject.

Please contact the MCW HRPP Office for project-specific questions on recruiting and enrolling non-English speakers.

ShortForm: Protocol Deviation for Use of the Short Form

1. Before consenting a non-English speaking subject with the MCW IRB ShortForm, the Investigator must:
    a. Submit a protocol deviation as a Reportable Event (RE) for IRB review.
        i. A RE must be submitted each time the ShortForm is used to consent a non-English speaking subject.
        ii. The RE must be acknowledged before the non-English speaking subject is consented with the ShortForm.
        iii. The RE must explain the context of the enrollment taking place, the process that will be followed to consent and enroll the subject, and the plan for continued communication and engagement with the subject.
            1. The documents intended for use with the initial subject must be provided with the RE.
        iv. The RE must also indicate that an amendment with all required SmartForm, protocol, and document changes will be submitted after enrollment with the ShortForm (see section *ShortForm: Amendment for Continued Consent and Communication*).
            1. If the project is industry sponsored, the Sponsor's approval of this change must be provided with the RE.
        v. Lastly, this protocol deviation must be reported at the next CPR (see section *ShortForm: Continuing Progress Reports and Use of the ShortForm*).

ShortForm: Accessing the ShortForm

1. Download a copy of the "ShortForm" from the MCW HRPP website.
    i. The MCW HRPP has provided approved Short Form Consent documents in several languages. These are posted on the MCW HRPP website.
        a. If a different language is needed, contact the HRPP Office for additional resources.

ShortForm: Interpretation For Non-English Speakers When Using the ShortForm

Before consenting a non-English speaking subject with the MCW IRB ShortForm, the Investigator must:

1. Obtain the services of a certified interpreter who speaks the subject's language.
    a. The interpreter must be available during the consenting process.
    b. The interpreter must also fulfill any additional requirements set forth by any other affiliated institution (i.e.: Froedtert Health, Children's Wisconsin, Versiti, etc.)
    c. Federal research regulations do not allow a family member or friend to serve as the interpreter.
2. Assure there is an adult witness to the entire oral presentation. The witness may not be the individual conducting the consent process or the interpreter.
    a. The witness may be a project member, or an adult family member.
    b. The witness must be fluent in both English and the language of the subject.
    c. The function of the witness is to certify that an adequate oral presentation was made to the subject or legal representative and voluntary consent was obtained.

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.
3. A copy of the ShortForm and the English consent form must be provided to the subject.

ShortForm: Amendment After Use of ShortForm

1. Each time a subject is consented with the MCW IRB ShortForm, Investigators must submit an amendment to describe the plan for ensuring continued consent and communication for the duration of the project.
    a. If additional enrollment of non-English speaking subjects is expected, the project should be amended following the process outlined under the section:

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:
    i. A plan for providing a copy of the approved English Consent Form translated to the spoken language of the subject. The translation of the consent form must follow the translation policies for subject-facing documents outlines under the section: *Planning for Recruitment and Enrollment of Non-English Speakers*.

    OR

    ii. A detailed rationale explaining why it is not appropriate to provide the subject a copy of the consent form in their spoken language.

2. *FDA Guidance: Informed Consent (2023)* recommends that Investigators obtain a translated version of the IRB approved English Consent Form promptly for FDA regulated projects to provide a copy of the written consent document (21 CFR 50.27).

ShortForm: Continuing Progress Reports and Use of the ShortForm

1. Investigators must report the protocol deviation (RE) for use of the ShortForm in the next Continuing Progress Report (CPR).
2. The CPR should reference the use of the ShortForm and reference the previously submitted RE and amendment describing the plan for continued consent and communication with non-English speaking subject(s) as part of the progress of research at the site since the last CPR.

Planning for Recruitment and Enrollment of Non-English Speakers:

When a project will recruit and enroll non-English speaking subjects, Investigators must plan and prepare accordingly.

To begin this process, Investigators must create a protocol and study design that upholds the principles of the Belmont Report and supports intentional engagement and enrollment of non-English speakers for the entirety of the project.

To do this, the Investigator should:

1. Identify the needs and languages spoken by the target population.
2. Engage with community leaders and organizations to understand cultural nuances, build authentic trust,
3. Allocate budget and resources for translation and interpretation services.
4. Review relevant regulations and institutional policies for enrollment of non-English speakers.
5. Develop outreach strategies to inform and engage non-English speaking communities for the duration of the project and beyond.
6. Complete any necessary trainings or background work on cultural competency and effective communication with non-English speakers.

In addition, the Protocol and eBridge SmartForm must include the following:

1. A description of the subject population, the procedures for eliciting informed consent, and the process for conducting project activities and administering study documents.
2. The respective language(s) that research will be conducted in.
3. Identification of who will provide ongoing translation and/or interpretation for the duration of the project, along with their qualifications.
4. The plan for ensuring continued consent and communication with the subjects for the entirety of the project.

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. A Certificate of Translation or other official documentation confirming that a professional serve/company will provide interpretation.
        i. A list of MCW supported translation/transcription vendors can be found on the MCW Office of Research website, under Research Resources.

Planning For Inclusion of Non-English Speakers- Informed Consent Process

Investigators must provide a consent form in a language understandable to the subject. The consent form must follow the *IRB SOP: Informed Consent Document for Human Subject Research.*

1. The consent form in the subjects' language and an English version must be reviewed and approved by the MCW IRB before use.
    a. When conducting the consent process, Investigators should ensure appropriate interpreter services are available.
        i. The Interpreter must be fluent in both languages and available by phone or in-person to answer questions for the consent process and for the duration of the project.
    b. Additionally, the interpreter may be:
        i. A project team member familiar with the project and fluent in both English and the subject's primary language

        OR

        ii. A Certified or Qualified Interpreter fluent in both languages and available for the length of the entire study.

Planning For Inclusion of Non-English Speakers- Other Things to Note

1. Investigators should consider if it may be most efficient to obtain initial approval first, and then submit an amendment adding Non-English Speaker enrollment (along with all required translations).
2. Please note that Non-English Speakers may **not** be consented, enrolled or begin study activities until their engagement and all related materials have been reviewed and approved by the IRB.

Planning For Inclusion of Non-English Speakers- Projects with Reliance

Projects involving a single IRB (sIRB) review require investigators to reach out to MCW IRB Reliance team before recruiting and enrolling non-English speakers.

However, the procedures below outline the steps that must be followed when MCW serves as the sIRB, or when MCW is relying on an external IRB:

1. When MCW serves as the sIRB:

a. If a relying site requires adherence to their own site's policies and use of their templates; study teams may follow those operating procedures and utilize the relying site's templates.
    i. PLEASE NOTE: This scenario requires confirmation from MCW IRB Reliance. Therefore, study teams must reach out to MCW IRB Reliance prior to utilizing the relying site's policies/documents and enrolling Non-English Speakers.

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

Effective Date:	12/02/2024
Version number:	7.0
Previous Version/date:	6.0; 07/01/2023
Responsible Office:	HRPP Office
Approval Date:	12/02/2024
Approved By	
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