MCW IRB Committee Procedures

RECRUITMENT AND ENROLLMENT OF NON-ENGLISH SPEAKING SUBJECTS

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

Applies to: Institutional Review Board Committees

PURPOSE: This procedure outlines what the IRB committees should consider and evaluate when reviewing projects enrolling 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 the 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.

PROCEDURE:

Enrollment of Non-English Speakers Using the MCW IRB ShortForm

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. This 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 policy 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.

The IRB Committee or designated reviewers reviewing a submission utilizing the ShortForm should evaluate the Investigator and project team's plan(s) for translation of all subject-facing documents and interpretation for the subject for the entirety of the project.

Unique situations and project-specific questions for projects who are recruiting, consenting and enrolling non-English speakers may be discussed with the HRPP Office, IRB Chair and/or forwarded to the Full Committee.

Protocol Deviation for Use of the ShortForm

Before utilizing the ShortForm to enroll a non-English speaking subject, Investigators and project teams must submit a protocol deviation as a Reportable Event (RE). Research teams must submit a RE each time they use a ShortForm to enroll a non-English speaking subject.

1. The IRB Committee and/or designated reviewer will review and evaluate the RE to confirm the following elements are met:
    a. The RE must explain the context of the consenting and 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.
        i. Identify the documents intended for use with the initial subject must be provided with the RE.
        ii. Additional details are described below in "Informed Consent Process Utilizing the ShortForm"
    b. The RE must also indicate that an Amendment (AME) with all required SmartForm, protocol, and document changes will be submitted after use (consent & enrollment) with the ShortForm.
    c. If the project is industry-sponsored, the Sponsor's approval of this change must be provided with the RE.
2. The RE must be acknowledged before the non-English speaking subject is consented and enrolled with the ShortForm.

Informed Consent Process Utilizing the ShortForm

When reviewing the RE for the use of the ShortForm, the IRB Committee and/or designated reviewer should ensure Investigators have included and accounted for the following:

1. Assure that a summary in English of what is to be presented to the subject is available and approved by the IRB.
    a. Typically, this will be the MCW IRB-approved consent form in English.
        i. If not, confirm there is a plan for ensuring all federally required language is included.
        ii. *IRB SOP: Informed Consent Document for Human Subject Research* contains a list of required elements.
2. A plan for an English-speaking project team member and interpreter to ensure that the consent form's contents are reviewed and discussed with the subject.
    a. 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.
    b. The information must be organized and presented in a way that facilitates comprehension.
    c. The planned consent process is in accordance with the *IRB SOP: Informed Consent Process for Human Subject Research.*

Reviewing the Amendment After Use of ShortForm

Investigators must submit an AME following the initial RE to describe the plan for ensuring continued consent and communication for the duration of the project for the consented non-English speaking subject.

1. The AME should include all translated subject facing materials, updated SmartForm and protocol (if applicable).

OR

2. A detailed rationale explaining why it is not appropriate to provide the subject the translated subject-facing material in their spoken language.

a. In addition, the AME must also include one of the following:
    i. A plan for providing a copy of the approved English Consent Form translated into the spoken language of the subject. The translation of the consent form must follow the translation policies for subject-facing documents in IRB SOP: Recruitment and Enrollment of Non-English Speaking Subjects.

    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.
3. If additional enrollment of non-English speaking subjects in a specific language population is expected, the project should be amended following the process outlined under *IRB SOP: Recruitment and Enrollment of Non-English Speaking Subjects* section *Planning For Inclusion of Non-English Speakers.*
4. The AME must be approved before additional non-English speaking subjects in the specific language population are enrolled.

Reviewing CPRs After Use of the ShortForm

1. Investigators must report the protocol deviation for use of the ShortForm in their next Continuing Progress Report (CPR).
    a. IRB Committee should confirm the CPR in section 14 includes the following:
        i. Call out the use of the ShortForm in that reporting period.
        ii. Reference the previous submitted RE (protocol deviation)
        iii. Reference the submitted AME describing the plan for continued consent and communication with non-English speaking subject(s)

Planning for Recruitment and Enrollment of Non-English Speakers:

When a project will recruit, consent and enroll non-English speaking subjects, Investigators must plan and prepare accordingly and describe how they will carry out these activities in the eBridge SmartForm.

The IRB Committee or designated reviewer should review the protocol and eBridge SmartForm to identify who the target populations are, the respective language(s) that research will be conducted in, and who will provide ongoing translation and/or interpretation for the duration of the project, along with their qualifications.

The Protocol (if applicable) eBridge SmartForm must include the following:

1. A description of the subject population, the procedures for eliciting informed consent, the process for conducting project activities, and the process of administering project documents.
2. The plan for ensuring continued consent and communication with the subjects for the entirety of the project.
3. Uploaded translations of ALL subject-facing documents in the subjects' spoken/preferred language.

The qualifications of Translators and Interpreters will also be assessed by the IRB Committee and/or designated reviewer.

Translation of Subject-Facing Documents

When reviewing a submission that involves non-English speakers, the IRB Committee or designated reviewer ensure the Investigator and project team has completed the following steps and requirements:

1. The English and translated versions of all subject-facing documents must be uploaded to Section 52.

2. 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 that the subject can understand.
3. 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.
    a. The C2 Checklist for the submission may provide additional project-specific context.
    b. Reach out to the HRPP Office to discuss unique situations and project-specific questions regarding recruiting and enrolling non-English speakers.
4. To ensure a certified and accurate translation has taken place, the IRB Committee or designated reviewer should confirm one of the following two options has been completed 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, 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.
        iii. The Office of Research website, under Research Resources, has a list of MCW-supported translation/transcription vendors.
5. Please note that MCW HRPP does not require or recommend back translation as a translation methodology given that back translation does not always result in a valid or accurate translation.

<u>Interpretation for Non-English Speakers</u>

1. For projects conducted within Froedtert Health, Versiti or Childrens Wisconsin clinical space, Investigators must follow the applicable institutional requirements in use of interpreter services and described in Section 12 of the eBridge SmartForm.
2. For projects conducted in the community at large
    a. The IRB Committee or designated reviewer should confirm that the interpreter identified for the project meets the following qualifications:
        i. No minor under the age of 18 can serve as an interpreter.
        ii. Family members cannot serve as interpreters.
        iii. If an interpreter is selected from the community from which subjects will be recruited, a plan to ensure confidentiality must be described in the eBridge SmartForm.

        OR

        iv. Alternatively, a professional service/company may be used for interpretation, and this must be detailed in the eBridge SmartForm and protocol (if applicable).
            a. A certificate or confirmation of interpretation must be provided.
    b. To ensure an appropriate and accurate interpretation process has taken place, Investigators must choose one of the following two options as a certification of interpretation:

i. A completed and signed copy of the *Translator and Interpreter Certification Form* must be uploaded to the eBridge SmartForm.
ii. Provide confirmation that interpretation will be conducted by a professional service/company. This confirmation must be uploaded to the eBridge SmartForm and support all subject-facing interactions for the duration of the project.
    1. A professional interpreter may also complete the *Translator and Interpreter Certification Form*.

c. A list of MCW-supported translation/Interpreter services can be found on the Office of Research website, under Research Resources.

Informed Consent Process Non-English Speakers

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 in English will be provided for the IRB Committee or designated reviewer to review.
2. When reviewing the planned consent process, IRB Committee or designated reviewer should ensure one of the following two measures are in place:
    a. Project team members who consent subjects must be familiar with the project and fluent in both English and the subject's primary language.

    OR

    b. In addition to the project team member conducting consent, a second individual who is fluent in both languages (not a family member) must be present to interpret for the subject and facilitate any questions and answers.
3. The IRB Committee or designated reviewer should ensure the Investigator or project team's plan includes having an individual familiar with the project and fluent in both languages available by phone or in-person to answer questions for the duration of the project.

Projects with Reliance and Non-English Speakers

Projects involving an sIRB must reach out to MCW IRB Reliance before recruiting and enrolling non-English speakers.

The procedures below outline the steps that must be followed when MCW serves as the sIRB and 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; Investigator and project teams may follow those operating procedures and utilize the relying site's templates.
    b. Another option is for relying sites to adhere to MCW's policies and utilize MCW's consenting templates for all engagements with non-English speakers.

2. When MCW is relying on an external IRB:
    a. Investigator and project teams must adhere to MCW's policies and procedures for all engagement of Non-English Speakers.
    b. The MCW ShortForm and Informed Consent templates must be used to consent subjects.

REFERENCES:

45 CFR 46.102 (c)
21 CFR 50.3(1)

SUPPORTING DOCUMENTS:

IRB SOP: Informed Consent Document for Human Subject Research
IRB SOP: Informed Consent Process for Human Subject Research
IRB SOP: Recruitment and Enrollment of Non-English Speaking Subjects
IRB Form: Translator and Interpreter Certification Form

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