



MCW Office of Research Standard Operating Procedure

RECRUITMENT AND ENROLLMENT OF NON-ENGLISH OR LIMITED ENGLISH-PROFICIENT 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 subjects with limited or non-English proficiency. The inclusion of 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 limited or non-English proficient subjects, for example international projects. Investigators must assure that the limited or non-English speaking subjects fully understand their role in the project and provide voluntary informed consent.

This procedure outlines the investigator responsibilities when enrollment of non-English or limited-English proficient research subjects is unexpected or anticipated.

DEFINITIONS:

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

LEP: Limited-English proficient

NEP: Non-English proficient

Legally Authorized Representative (LAR): "An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research." (45 CFR 46.102 (c)) (21 CFR 50.3(1))

PROCEDURES:

Unanticipated enrollment of LEP and/or NEP Subjects:

1. On occasion, an opportunity to enroll a subject with limited or no proficiency in English may arise, but translated documents have not been previously approved for this project by the IRB. In these cases, federal regulations allow the use of a "short form" in a language the subject understands in order to document that all required elements of informed consent were presented orally.
2. If the Investigator expects to enroll more subjects who speak that language, the investigator must follow the policy outlined below under "Anticipated Recruitment".
3. Protocols that require reading or written responses from the subject, such as diaries and surveys, may be not appropriate under this procedure. Investigators should carefully

consider and plan how these documents will be translated and made available to the subject.

4. Before enrolling a LEP or NEP subject under unexpected circumstances, the Investigator must:
 - a. Submit an amendment if the protocol requires the subject to speak English as an eligibility criterion. The amendment must be approved before an LEP or NEP subject may be enrolled. (If the project is industry-sponsored, the Sponsor's approval of this change must be provided with the amendment).
 - b. Assure that a summary in English of what is to be presented to the subject is available and approved by the IRB. Typically, this will be the IRB-approved consent form in English.
 - c. Download a copy of the "short-form" from the MCW HRPP website. The HRPP has provided approved short-forms in several different languages on the HRPP website. If a different language is required, contact the HRPP Office for assistance.
 - d. Obtain the services of a hospital-approved interpreter (certified medical interpreter) who speaks that language. The interpreter must be available during the consenting process. Federal research regulations do not allow a family member or friend to serve as the interpreter.
 - e. 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. The witness may be a project member, or an adult family member. He/she must be fluent in both English and the language of the subject. 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.
 - f. 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 this one LEP or NEP subject.
 - i. Froedtert Hospital Language Services will provide interpreter services for FH patients who are in a research project only when their care and treatment is also part of clinical care.
 - ii. For research only visits, the research staff will need to schedule interpreter visits using an outside agency.
5. Investigators should incorporate the following when conducting the consent process when unexpectedly enrolling a LEP or NEP subject
 - a. The (English-speaking) project staff member going through the consent process with the subject and the interpreter should be sure that the entire contents of the consent form are reviewed and discussed. The informed consent must begin with a concise and focused presentation of the key information to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research. The information must be organized and presented in a way that facilitates comprehension. 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. For a list of required elements, see *IRB SOP: Informed Consent Document for Human Subject Research*.
 - b. 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*.

6. Investigators must obtain the subject signature to document the consent process. In addition, the following required signatures and additional steps in the consent process must be completed:
 - a. The language specific short form should be signed by the subject (or the subject's LAR), the interpreter, and an adult witness.
 - b. The English IRB Approved Consent Form should be signed by the witness and the individual conducting the informed consent discussion.
 - i. To link the two consent forms, document below the signatures on the English consent form that a short form was used. For example, "This consent form was used in conjunction with a short form in Spanish signed by the subject."
 - ii. A copy of the short form and the English consent form must be provided to the subject. The originals should then be stapled together and filed
 - c. Document the short form consent process followed in Sections A & B in your regulatory file (e.g. using a memo or note to file) and in the subject's medical record if the project is FDA-regulated.
 - d. Submit an amendment to describe the plan for ensuring continued consent and communication with the subject during the project. If additional enrollment of LEP or NEP subjects is expected, the project should be amended at this time, following the process outlined below in Anticipated Recruitment.
 - e. Report the unexpected enrollment of LEP or NEP subjects in the next continuing progress report (CPR) and include a description of the process that was followed and the plan to ensure the continued understanding of the project by the subject.

Anticipated Recruitment and Enrollment of LEP and/or NEP subjects:

1. When project is anticipated to recruit and enroll LEP or NEP subjects, the Investigator must identify in the eBridge SmartForm the target populations, the language(s) and must specify who will provide the translation and interpretation and their qualifications. In addition, the eBridge SmartForm must include the following:
 - a. a description of the subject population, the procedures for eliciting informed consent, and the plan for ensuring continued consent and communication with the subjects during the project. The *IRB SOP: Informed Consent Process for Human Subject Research* must be followed.
 - b. The consent form, questionnaires, surveys or other documents that subjects are expected to read and/or complete must be translated into a language that is understandable by the subject.
 - c. The English and translated versions of the documents must be uploaded to the eBridge SmartForm.
 - d. If the *Translator's Declaration* and *Back-Translator's Declaration* apply, these must be completed, signed, and uploaded for the consent form(s) and recruitment materials.

For Projects enrolling only non-English Speaking subjects:

1. The Investigator must provide the proposed consent form and other documents in English and in the language of the subjects.
2. The Investigator must provide the *Back-Translator's Declaration* for the consent form(s) and recruitment materials.

Informed consent process

1. 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*. Both the translated consent form, the back translation and the English version must be reviewed and approved by the IRB before use.

2. When conducting the consent process, Investigators should ensure:
 - a. Project team members conducting consent 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, there must be a second individual who is fluent in both languages (not a family member) and who will be present to translate questions and answers for the subject.
3. Investigators should ensure that an individual who is familiar with the project and fluent in both languages is available by phone or in person to answer questions during the conduct of the project.

Questionnaires and other documents

1. When a project involves questionnaires, surveys, or other documents that subjects are expected to read and/or complete, subjects must be provided the document in their own language. The document must convey the same meaning as the original English version. Otherwise, responses of non-English proficient subjects will not be comparable to responses of those who are proficient in English.
2. Investigators must describe the process for administering the questionnaire or survey in the eBridge SmartForm.

Interpreter and translation services:

For Projects which will enroll Froedtert Hospital patients

1. When enrolling subjects at Froedtert Hospital, the following must be observed when identifying who can serve as an interpreter for a project:
 - a. No minor under the age of 18 can serve as an interpreter.
 - b. Family members cannot serve as an interpreter for a subject
2. The translator for the project's consent form and/or other documents, must be a certified or credentialed translator.

Projects conducted in the community at large (not enrolling from Froedtert Hospital)

1. The following qualifications must be observed when identifying who can serve as an interpreter for a project:
 - a. No minor under the age of 18 can serve as an interpreter.
 - b. Family members cannot serve as the interpreter
 - c. 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.
2. When identifying who may serve as a translator or conduct the back-translation for the project consent form and/or other documents, the following qualifications must be indicated:
 - a. A native speaker who holds the equivalent of a high school education
 - b. An individual who holds a degree in the language of the target population(s)
 - c. A certified or credentialed translator.
3. The translated documents must also be back-translated into English by a certified or credentialed translator, or other credentialed person (e.g. foreign language degree) acceptable to the IRB. The back-translated documents must be provided in the IRB submission. The translation and back-translation cannot be performed by the same individual.
4. To ensure that the translated documents convey the same meaning as the original in English, the completed *Translator's Declaration* and *Back-Translator's Declaration* forms for the consent form(s) and recruitment materials must be uploaded to the eBridge SmartForm.

REFERENCES:

45 CFR 46.102(c)

45 CFR 46.116

21 CFR 50.3(1)

SUPPORTING DOCUMENTS:

IRB SOP: Informed Consent Process for Human Subject Research

IRB SOP: Informed Consent Document for Human Subject Research

IRB Form: Translator Declaration

IRB Form: Back-Translator Declaration

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