



MCW IRB Committee Procedures

RECRUITMENT AND ENROLLMENT OF NON-ENGLISH OR LIMITED ENGLISH-PROFICIENT 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 when enrollment of non-English or limited-English proficient research subjects is identified in the recruitment plan or occurs unexpectedly.

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))

PROCEDURE:

Unexpected Recruitment and Enrollment of Limited English or Non-English Proficient Subjects

1. On occasion, an opportunity to enroll a subject with limited or no proficiency in English may arise and 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. When this occurs, Investigators must follow *IRB SOP: Recruitment and Enrollment of Non-English or Limited English Proficient Subjects* to ensure consent has been obtained in a meaningful way from the subject.
3. All unexpected enrollments of LEP subjects must be reported at the next continuing progress report (CPR) for the project. The IRB Committee or designated reviewer should review the enrollment and subsequent plan the Investigator has included to ensure the continued understanding of the project by the subject along with continuing the consent process. The plan should address the following:
 - a. Does the Investigator identify a qualified interpreter to ensure understanding by the subject regarding consent form changes and required visits?
 - b. Are there any materials such as questionnaires, diaries, or surveys which may need translation into the subject's primary language?
 - c. Does the Investigator anticipate additional enrollment of subjects who have limited English proficiency?

4. If the Investigator has not provided a plan in the CPR to address these issues, the IRB Committee should request the Investigator to provide the plan prior to re-approving the project.
5. If the Investigator indicates additional subjects who are LEP may be enrolled into the project, the IRB Committee may request the Investigator to amend the project to identify this change and follow the *IRB SOP: Recruitment and Enrollment of Non-English or Limited English Proficient Subjects* in providing the appropriate translated documents and identification of qualified interpreters.

Anticipated Recruitment and Enrollment of Limited English or Non-English Proficient Subjects

Investigators who plan to recruit and enroll subjects who are LEP or NEP must identify the target populations and languages in the eBridge SmartForm application for the IRB Committee or designated reviewer to review the Investigator's plan to consent and provide language appropriate documents for these subjects.

The IRB Committee or designated reviewer should review the following items to ensure they are appropriate to the design of the project:

1. The plan and procedures for eliciting and ensuring ongoing consent with the subjects. This would include identification of an interpreter for the process and providing their qualifications. Interpreters should not be:
 - a. A minor or anyone under the age of 18 and;
 - b. Family members of the subject
2. If an interpreter is being selected from the target community, Investigators must describe a plan to ensure confidentiality of subjects who are participating.
3. All translated documents including but not limited to: Informed Consent Form, questionnaires, surveys, diaries, recruitment materials, advertisements should be uploaded to the eBridge SmartForm application. These documents should be translated into a language understandable by the target population.
4. The translated consent form and recruitment materials should include the *IRB Form: Translator Declaration Form*, to indicate the translators' qualifications and to attest they have completed a true and accurate translation.
5. Back-translations of the consent form and recruitment materials must be provided for the IRB review to ensure the accuracy and appropriate wording of the translated documents proposed to be used. The back translation should include the *IRB Form: Back-Translation Declaration Form* to indicate the translators qualifications and to attest they have completed a true and accurate back-translation.
6. For projects enrolling only non-English speaking subjects, Investigators must provide the consent form and other documents in English and in the language of the subjects, and the completed back translator form for the consent form(s) and recruitment materials.
7. The IRB Committee member or designated reviewer should note in applicable reviewer checklist if the Investigator has submitted a complete plan or if any of the above items are not included or addressed when reviewing the eBridge SmartForm application.
 - If any items are missing, the IRB Committee or designated reviewer should request them as modifications before issuing final approval.

REFERENCES:

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

SUPPORTING DOCUMENTS:

IRB SOP: Recruitment and Enrollment of Non-English or Limited English Proficient Subjects

IRB Form: Translator Declaration Form

IRB Form: Back-Translation Declaration Form

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