Marshfield Clinic

Informed Consent of Non-English Speaking Subjects

1. SCOPE

1.1. System Wide

2. DEFINITIONS & EXPLANATIONS OF TERMS

2.1. Human Subjects

- A living individual about whom an investigator conducting research obtains: 1) data through intervention or interaction with the individual or interaction with the individual or 2) identifiable private information.

2.2. Legally Authorized Representative

- An individual, judicial body, 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 research.

2.3. Research

- An activity that involves a prospective research plan, which incorporates data collection, either quantitative or qualitative and data analysis to answer a research question: " a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" (see 45 CFR 46).

3. PROCEDURE BODY

This document outlines the requirements for obtaining informed consent from potential human subjects who do not speak English so that they can participate in human subjects research. This document should be referenced in conjunction with the document, "Informed Consent for Research".

3.1. Federal Regulations and Guidance

a. Department of Health and Human Services (DHHS) regulations at 45 CFR 46.116 and 46.117, and Food and Drug Administration (FDA) regulations at 21 CRF 50.20 and 50.27, require that the elements of informed consent be presented in a language understandable to a potential subject, and in most cases, that informed consent be documented in writing. DHHS Office of Office for Human Research Protection (OHRP) encourages using informed consent documents in languages understandable to subjects when possible.

b. DHHS OHRP

- OHRP recognizes that it is the responsibility of Institutional Review Boards (IRBs) to determine whether a separate translated document containing the elements of informed consent is needed, or whether a short form process is appropriate.
- When an IRB approves the use of a short form process for non-English speaking subjects, OHRP guidance state that:
  - The IRB must receive all foreign language versions of the short informed consent document as a condition of approval under 46 CFR 46.117(b)(2). Expedited review of the version is acceptable if the convened IRB has already approved the protocol, the English language document containing informed consent elements, and the English version of the short informed consent form document.
  - The short form informed consent document and the oral presentation should be in the language understandable to the subject.
  - The IRB-approved English language informed consent document may serve as the summary.
  - A witness to the process is required. The witness should be fluent in both English and the language of the subject, and the interpreter may serve as witness.

c. FDA Guidance

- The FDA has stated that when the study subject population is expected to include non-English-speaking subjects, an IRB should ensure that a translated consent document is prepared and the translation is accurate.
- FDA guidance also states that if a non-English speaking subject is unexpectedly encountered, an investigator should carefully consider the ethical and legal ramifications of enrollment when a language barrier exists. If the subject does not clearly understand the information presented, consent will not truly be informed, and may not be legally effective.

3.2. When Enrollment or Non-English Speakers is Expected to Exceed 25% of Local Study Population

a. When the percentage of non-English speaking subjects is expected to exceed 25% of the local study population, the Marshfield Clinic Research Foundation (MCRF) IRB will require a separate consent document in the subject's native language.

b. When MCRF IRB requires a translated consent document with all required informed consent elements, the PI is responsible for arranging for the translation.

c. FDA guidance requires MCRF IRB to ensure that the translation is prepared accurately and thus, the translated document must be submitted to MCRF Office of Research Integrity & Protections (ORIP) for IRB approval with a validation certificate or a back translation from an independent translation service. The PI is responsible for the costs of these services. The IRB will review the validation certificate or back translation through expedited review.

d. When a translated document containing all elements is used, a translator may be present to facilitate communication. Translation services may be scheduled through the Marshfield Resource and Information Center. The interpreter may not be a family member of the subject. Translation must be provided to the subject free of charge.

e. Investigators may not enroll any subject if the investigators feel the language barrier, even through the assistance of an interpreter, is so significant that legally effective consent cannot be obtained.

3.3. When Enrollment of Non-English Speakers is Not Expected to Exceed 25% of Local Study Population

a. Due to the low number of non-English speaking individuals in the potential subject population, MCRF IRB normally approves the use of the Hmong short-version and Spanish short-version informed consent documents with oral presentation for studies in which enrollment of Hmong and Spanish-speaking subjects is not expected to exceed 25% of the local study population.

3.4. Short Form Process

a. For Hmong or Spanish speakers

- Please see 3.3.a above for how to obtain the short-version documents, and 3.4.c below for details on how to present them.

b. For Languages other than Hmong or Spanish

- Potential subjects who speak foreign languages other than Hmong and Spanish may not participate in research until a translated version of the English consent form or a short informed consent document is approved by the IRB.
- The IRB-approved English-version short informed consent document, the foreign-language short informed consent document, and the back translation or certificate will be submitted to MCRF IRB for expedited review.
- The PI may begin using the translated short form and oral consent process once IRB approval is received.

c. Presentation of Short Form

- The MCRF IRB-approved English summary document must be read in the subject's language to the prospective subject, in its entirety, through a translator.
- Translation services may be scheduled through the Marshfield Resource and Information Center. The interpreter may not be a family member of the subject. Translation must be provided to the subject free of charge.
- The IRB-approved document in the subject's language must be used to document informed consent. The SP Code, PI name and study title must be inserted in English at the top of the short informed consent document before beginning the informed consent process.
- The subject must sign the short-form informed consent document.
- The person obtaining the consent must sign the IRB-approved summary.

- A witness, fluent in both English and the language of the subject, must be present. The witness must be able to attest to the accuracy of the presentation, the apparent understanding by the prospective subject and the voluntary decision to participate. The interpreter may serve as the witness. The witness may not be a family member of the subject. The witness must sign the short-form informed consent document and the summary document.
- The subject must be given copies of the signed short informed consent document and the summary.
- The IRB has the authority to recommend a videotape recording of the consent process.

d. Investigators may not enroll any subject if investigators feel the language barrier, even through the assistance of an interpreter, is so significant that legally effective consent cannot be obtained

3.5. Considerations at Time of Continuing Review

a. At the time of continuing review, the IRB will ask for specific information about the subject's enrolled, including a count of the number of subjects enrolled who could not speak English, a summary of problems with communications encountered during the consent process and as the study progressed, and the manner in which those problems were resolved.

b. Based on the percentage of non-English speaking subjects enrolled, and the risks and complexity of the research, the IRB may determine at the time of continuing review that additional protections for future subjects are required.

3.6. Non-English Speaking Minor Subjects

a. For potential subjects who are less than 18 and do not speak English, investigators must follow, "Assent of Children," as well as the procedures for obtaining informed consent set forth above.

4. ADDITIONAL RESOURCES

4.1. References:

- Assent of Children
- Informed Consent for Research
- Informed Consent: Obtaining and Documenting Informed Consent of Non-English Speakers (OPRR Memo 1995)
- FDA: Guide to Informed Consent (1998)

4.2. Supporting documents available:

- IRB Consent – Short Form (Hmong version)
- IRB Consent – Short Form (Spanish version)
- IRB Consent – Short Form Child Assent Required (Hmong version)
- IRB Consent – Short Form Child Assent Required (Spanish version)

5. DOCUMENT HISTORY

Version No.	Revision Description
1.0	New Document in Document Control transferred from Policy & Handbook Library.- #699.7
2.0	Add hyperlink to IRB Forms and other applicable policies referenced in this document.

6. DOCUMENT PROPERTIES

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