McLaren HEALTH CARE

RESEARCH TRANSLATION REQUIREMENTS FOR NON-ENGLISH SPEAKERS GUIDANCE DOCUMENT

OVERVIEW

All research participants (or their Legally Authorized Representative [LAR]) if they are unable to consent for themselves) must be able to understand enough about a research study and the elements of consent in order to be able to make an informed decision regarding participation. This means the consent and study materials must be presented in a language the potential participant or LAR can understand.

Non-English speaking subjects are those whose primary language is not English and with the limited ability to read, write, speak or understand English.

When enrolling non-English speaking subjects, investigators must:

- have a plan to manage communications with the person during all phases of study participation.
- the Investigator's plan to manage non-English speaking participants in a study must be described in the iRIS application. This must include a plan for translation at study visits and/or follow-ups, etc.

The requirements for consent and translation of documents will depend on whether or not it is known in advance that non-English speakers will be eligible for the study.

DEFINITIONS

Non-English Speaking - Non-English speaking subjects are those whose primary language is not English and with the limited ability to read, write, speak or understand English.

Interpreter – person who accompanies researchers to convey verbal information to another person in their native language.

Translator – person who coverts written materials from English to another language.

Legally Authorized Representative (LAR) – an individual/judicial/body or body authorized under applicable law to consent on behalf of prospective subject to the subject's participation in the procedure (s) involved in the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure (s) involved in the research.

Short Form - (a written document, in the participant's native language, stating that the elements of informed consent required by 45 CFR 46.116 and/or 21 CFR 50.25 have been presented to and are understood by the subject or the subject's LAR)

I. Non-English Speakers – Known in Advance (Expected Enrollment)

When it is known, or is likely, that non-English speaking participants will be eligible for enrollment, then an IRB approved translation of the consent (containing all of the elements of informed consent), HIPAA document, and other study related documents is required ***prior*** to recruitment of non-English speakers.

Submission Process for Non-English Speakers Known in Advance

1. Submit the ICF, HIPAA document, and all other study related documents in English to the IRB.
2. Once IRB approval is obtained, submit the documents to the translator.
3. Submit a modification to the IRB for approval of the translated version of relevant documents (with certification of translation).
4. In the iRIS application, the Investigator must describe the plan to manage non-English speaking participants throughout the course of the study, including the qualifications of the interpreter.

II. Non-English Speakers – Not Known in Advance (Unexpected Enrollment)

When it is not known in advance, or expected, that non-English speaking participants will be eligible for enrollment, obtaining consent from someone not fluent in English requires:

1. Use of the written Short Form. The Short Form consent is available on the MHC HRPP website in some languages. Use of the short form requires IRB approval ***prior*** to the enrollment of subjects.
2. A written summary (generally the IRB-approved English ICF).

Submission Process for Not Known in Advance

1. Submit a modification to the IRB for approval of the Short Form, stand-alone HIPAA document, written summary (generally the IRB-approved ICF) and all other study related documents (in English and translated language) with certification of translation.
2. In the iRIS application, the Investigator must describe the plan to manage non-English speaking participants throughout the course of the study, including the qualifications of the interpreter.

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III. Who should be present for the Consent Discussion:

1. **Consenter** – Principal Investigator or designee (authorized by IRB)
2. **Interpreter** – must be fluent in both English and the subject's language and be unbiased (the interpreter may also serve as the witness). The interpreter may be a member of the research team. The interpreter may not be a family member.
3. **Witness** to Oral Presentation (may not be a member of the research team).
4. **Research Subject**, or LAR (if appropriate)

SUMMARY: DOCUMENTATION AND RECORD KEEPING FOR NON-ENGLISH SPEAKERS IN RESEARCH

	Subject and/or LAR	Interpreter	Witness (the interpreter may serve as witness)	Principal Investigator or designee (authorized by IRB)
Sign and date	• Translated Full ICF or short form • stand-alone HIPAA (if applicable)	Nothing (document use in study file, e.g. checklist)	• Short form • Full English ICF or summary	• Full English ICF or summary
Receives signed and dated copy	• Translated Full ICF[1] or short form • Full English ICF • Stand-alone HIPAA (if applicable)	Nothing	Nothing	• Both forms must be maintained in subject research files (staple together)

[1] If the study is FDA regulated, and the short form is used for incidental enrollment of NES's, FDA guidance has indicated that the subject must get a translated version of the full consent form soon after enrolling in the study (1-2 weeks).

For assistance on interpretation and translation services, please feel free to contact the MHC Research Integrity office at (248) 484-4950.