Consent/Parental Permission/Assent of Subjects with Limited English Proficiency

Please refer to the detailed Guidance - Consent of Subjects with Limited English Proficiency for additional information

Federal regulations from the Department of Health and Human Services (HHS), Office for Human Research Protections (OHRP), and the U.S. Food & Drug Administration (FDA) state that informed consent "shall be in language understandable to the subject or representative." The FDA further advises, "When the study subject population includes non-English speaking people or the clinical investigator or the IRB anticipates that the consent interviews will be conducted in a language other than English, the IRB should require a translated consent document to be prepared and assure that the translation is accurate."

A subject with limited English proficiency is one unable, or with limited ability, to verbally comprehend the spoken English language or read and comprehend documents written in English. For individuals who speak languages other than English, or who possess limited English proficiency (LEP), informed consent may require an interpreter and a translated consent form.

"From an ethical and participant-centered perspective, considerations of access and justice support the inclusion of people with LEP in research, which are reflected in the regulatory requirement for institutional review boards (IRBs) to ensure equitable participant selection (21 CFR 50.27 (b)(2)). Underlying this principle is the idea of sharing the benefits of research equitably across groups and members of society, and that people should not be denied access to research based on medically or scientifically irrelevant characteristics, such as limited proficiency in English."

"Another consideration stems from the importance of enrolling diverse and representative study populations, which ensures that the research conclusions can be generalized widely across all segments of society. While LEP is not itself a scientifically relevant variable, it can overlap with such features, including increased co-morbidities and polypharmacy, due to the unfortunate fact that individuals with LEP are more likely to be economically vulnerable and more susceptible to negative social determinants of health."

- *Research Equity and Enrolling Non-English Speakers*

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Careful forethought is needed to anticipate logistical challenges and balance the importance of fostering diversity with the costs of translation services. When planning research, investigators should consider the potential for subjects with limited English proficiency that may be a part of the population being studied. If enrollment of subjects with limited English proficiency is anticipated, certified full translations of all recruitment material, patient information, and informed consent documents should be incorporated into the budget and study design.

The following is per Children's Wisconsin policy, Federal regulations, guidance from OHRP, and the FDA. There are two methods by which to obtain and document a subject's informed consent to participate in a research study.

Preferred Method

The Preferred Method is to provide consent forms written in a language understandable to the subject or the subjects legally authorized representative.

- The IRB of record must first approve all other aspects of the study, except for translated material, with no further modifications required. The translations should be based on the currently IRB approved assent/parental permission/consent documents. These translated documents should then be submitted **as an amendment**.
    - This prevents having to re-translate documents if there are modifications required to the English versions.
- CW HRPP requires that a certificate of translation be included with the submission of translated documents
- CW does NOT require back translations of any translated documents.
- Subject/parents should sign the fully translated assent/parental permission/consent documents and should be provided with a copy for their reference.
- An interpreter should be used for the discussion, even when there are translated documents, to assist with getting the potential subject/family questions answered.
    - If the investigator or a member of the study team is fluent in the language of the potential subject, they may be able to work with CW Language Services to be approved as a translator (written materials) or interpreter (verbal interactions).

- Translated documents MUST be kept up to date as there are modifications to the study and any of the study documents.
- CW HRPP office does not require a particular translation service to translate documents.

Short Form Method

The Short Form Method should only be used for the **occasional and unexpected** enrollment of a non-English speaking subject when no prospectively IRB approved translated consent documents in the appropriate language are available. The investigator may use oral translation of an IRB approved study summary to explain the study to obtain consent, and an IRB approved "short form" to document consent (if one is available in the appropriate language).

- CW HRPP allows use of the short form **one time** per language in a study for a subject with limited English proficiency. After that use, it is no longer unexpected that subjects who speak a particular language may be enrolled, and for future enrollments in that language it is expected that fully translated documents will be used.
- There are a number of short form consent template available. The "short form" essentially states that the elements of informed consent have been presented orally to the potential subject or the subject's legally authorized representative and the subject agrees to participate in the study. However, they do not cover any specifics about the particular study in which the subject will be enrolled. This information must be covered via an IRB approved study summary.
    - At CW, it is allowable to use the current IRB approved parental permission/consent document as the summary for use in the consent discussion.
- When a potential subject with limited English proficiency is identified, the investigator should submit an amendment requesting use of the short form for a particular subject.
    - Typically, this should be requested via an amendment immediately **after** there is an unexpected, identified subject for which no fully translated consent documents are available at the time of enrollment.

If this is being requested **before** a potential non-English speaking subject is identified, these requests must provide sufficient rationale for why the IRB should approve use of this method prior to identification of a specific non-English speaking subject. These requests will be assessed case by case.

- There must be a witness to the consent discussion done through an interpreter.
    - Per regulations, this witness must be fluent in both English and the subject's language.
    - The witness must be present for the entire discussion, not just the signature.
- Per OHRP, the interpreter may serve as the witness. This reduces the burden of finding another party who is not family of the subject and fluent in both languages to witness the discussion.

- Consent is documented with signature on IRB approved informed consent documents:
    - **Subject** or subjects legally authorized representative signs the short form.
    - **Person obtaining** informed consent signs the IRB approved English consent document (summary).
    - **Witness** signs both the short form and the IRB approved English consent document (summary).
    - In stituations where signature of the child is required to document assent, the minor should also have/sign a document in a language understandable to them. If the minor is fluent in English, they should document their assent on an approved assent or the approved parental permission form. If the child is limited in English proficiency, they should sign the short form.
- A copy of the signed summary and short form is given to the subject or subject's legally authorized representative.

Reference: Research Equity and Enrolling Non-English Speakers By Luke Gelinas, PhD, Senior IRB Chair Director. September 27,

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