Guidance
Consent of Subjects with Limited English Proficiency

Reminder
If the IRB has approved use of the short form in a particular language for an unexpected enrollment, it is expected that any future enrollments of subjects who speak that same language will utilize fully translated, IRB approved consent documents (as per the preferred method) since enrollments in that language are no longer unexpected.

Consent of Non-English-Speaking Subjects
Institutional Review Boards (IRBs) are charged with the responsibility of protecting the rights of human subjects. One key element of this is the review and approval of informed consent processes and forms to be used in a research study to ensure a subject's rights and voluntary participation are safeguarded.

Ensuring that prospective subjects fully understand a research study - the purpose, the risks and benefits, what will happen to them, etc., can be challenging in the best of circumstances, particularly with complex and high-risk studies. When a potential subject does not speak English, this creates an even greater challenge to obtaining truly informed consent.

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." A subject with limited English proficiency is one unable, or has limited ability, to verbally comprehend the spoken English language or read and comprehend documents written in English.

The following is per Children's Wisconsin policy, Federal regulations, and guidance from OHRP. 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.

- **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 (the IRB approved English informed consent document may be used as the 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).

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Reminders for Both Methods

- The IRB must approve the enrollment of non-English speaking subjects.
    - Investigators must specify in the study application if subjects with limited English proficiency will be included.
    - Investigators should provide a description of how the investigator and study team will communicate with subjects with limited English proficiency.
    - Because informed consent is an ongoing process, investigators should provide a description of how a potential subject with limited English proficiency will have questions and concerns, as well as their continued agreement to participate in the research, assessed and addressed.
- Use a qualified interpreter (one with training and understanding regarding medical terminology), fluent in both English and the subject's language, to present the study summary/full consent document to the subject and facilitate discussion, questions and answers.
    - The interpreter should not be a family member of the subject.
    - If the person obtaining consent is fluent in both English and the language understandable to the subject, they must go through CW language services for vetting and establishing themselves as an interpreter.
    - For assistance with obtaining an interpreter, contact Children's Wisconsin Language Services.
- It is the investigator's responsibility to judge subjects' comprehension of the consent information, including whether participation is voluntary and the right to withdraw at any time.
    - If there is any doubt about a subject's comprehension due to a language barrier, that subject should not be enrolled.
- Per OHRP, it is the responsibility of the IRB of record to determine which procedure (i.e. preferred method or short form method) to obtain and document the consent of subjects with limited English proficiency is appropriate. In some circumstances, the IRB of record may not approve the use of the short form.

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- For example, the IRB of record may feel the study is too complex, or it may determine that limited English proficient subject enrollments are expected and thus may require fully translated material.

- **HIPAA Authorizations:** When a translated HIPAA in the appropriate language is available this should be used. If investigators are having the full consent translated into another language, this should also be done for the HIPAA Authorization unless this is embedded into the consent form. Children's currently has a HIPAA Authorization translated into Spanish. In cases where the short form consent process is used and there is no fully translated HIPAA in the subject's language, the following should be done:

  - Interpreter should read the current English HIPAA Authorization to the subject in the subject's language. If this language is embedded in the approved consent, this is included as part of the verbal translation of the English consent/summary. If it is not included, the separate HIPAA Authorization form should be verbally translated by the interpreter.

  - Make a note directly on the HIPAA Authorization Form that the form was verbally translated and by whom. Have the subject sign the HIPAA Authorization Form.

Preferred Method Process
Ideally, 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 IRB of record must first approve all other aspects of the study, except for translated material, with no further modifications required.

  - This prevents having to re-translate documents if there are modifications required to the English versions.

  - Include all materials, in addition to the informed consent documents, that will be translated and provided to non-English speaking subjects (such as patient brochures, information sheets, advertisements, patient diaries or data collection tools, surveys, etc.).

- Investigator then submits, **via an amendment**, the translated documents for IRB review and approval.

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- Investigator must include a certification of translation.
- Two way, or "back" translation is not required.
- If an amendment is submitted because a short form was previously approved (and therefore enrollments of subjects with limited English proficiency are no longer unexpected) and fully translated documents are being submitted, the most current IRB approved English versions of the consent documents should be used for the translation and the amendment should indicate which versions were translated.

- Consent should be obtained using the IRB approved translated documents which the subject or subject's legally authorized representative is able to read and comprehend, and an interpreter should be available to assist with questions and discussion.
- Consent is documented by having the subject or the subject's legally authorized representative sign the IRB approved translated consent document.
- A copy of the translated, signed consent form is given to the subject/subjects legally authorized representative.

Short Form Method Process
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. There are templates available in several languages with accompanying certifications.

The IRB must approve the written summary of what is to be said to the subject and the short form before consent is obtained and the subject enrolled. The investigator may use the IRB approved English version of the informed consent document as the study summary.

- When a potential subject with limited English proficiency is identified, the investigator should submit a reportable event (planned protocol deviation) in the electronic submission system requesting use of the short form for a particular subject.
  - Typically, this should be requested **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.

- Include the short form template with study title, investigator's name and contact information included.

- Reference the effective date of the IRB approved English consent form that will be used as the summary.

- **Note**: Regarding studies under the oversight of an external IRB of record (not MCW): When a reliance is established, IRBs may have a different processes for approving the use of the short form. The investigator must determine what the process is for the reviewing IRB of record.

  - The process for using the short form for studies overseen by the NMDP can be found here: Relying on the NMDP and in the Manual for Sites Relying on the NDMP – page 14.

  - The process for studies overseen by the NCI CIRB (primarily Children's Oncology Group studies) can be found here: CIRB Short Form Q and A.

- **In all cases in which the investigator finds a need to use the short form process, in addition to the IRB of record, the CW HRPP must also be informed of and acknowledge this use before the subject is enrolled. This should be submitted as a Reportable Event – Planned Protocol Deviation in the electronic submission system.**

- There must be a **witness** to the translation and consent discussion facilitated through a qualified interpreter.

  - Per regulation, 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 translator may serve as the witness. This reduces the burden of finding another party who is not family of the subject and who is fluent in both languages to witness the discussion.

- Consent is documented with signature on IRB approved informed consent documents:

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- **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).

***Helpful Hint**: each person signs the document that is written in the language understandable to the individual.*

- A copy of the signed summary and short form is given to the subject or subject's legally authorized representative.
- CW HRPP allows use of the short form **one time** in a study for a subject with limited English proficiency speaking a particular language. Consequently, future enrollments for individuals speaking that language are expected to utilize fully translated documents.