Wayne State University
Institutional Review Board (IRB)

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Research Translation Requirements for Non-English Speakers

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. Implementation will require either a written translation or oral presentation by a person who is fluent in both English and the other language. 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.

Non-English Speakers – Known in Advance

If it is known, or is likely, that eligible participants will include non-English speakers, then an IRB approved translation of the consent and other relevant study documents is required ***prior*** to recruitment of non-English speakers.

Two options are permissible for translations of written documents:

1. **Certified** translation from English to non-English by a translator who is fluent in both languages (back translation is not required) OR
2. **Two-way process** where a forward translation of the consent from English to non-English by a translator who is fluent in both languages AND then a back translation into English by a different translator who is also fluent in both languages (this person must not have seen the original English consent form).

- For option one, proof of certified translation must be submitted for approval.
- For option two, both the forward and backward translations must be submitted for approval.

Non-English Speakers – Not Known in Advance

When it is not known in advance, or expected, that non-English speaking research participants will be eligible for enrollment, obtaining consent from someone not fluent in English requires use of the written Short Form AND a verbal translation of the English consent by a translator. The Short Form consent is available in 18 languages on the IRB website and use of any of these does not require prior IRB approval. If a different language is needed, IRB approval of the Short Form in the new language is required prior to use. Also, when a study involves 4 - 6 uses of the Short Form in any one language, the English version of the study's consent must be translated into that language, and submitted as an amendment for IRB approval.

Person Obtaining Consent – Must be a member of the research team who has completed required CITI training. If not also serving as translator or witness, may be fluent only in English.

Translator – Must be fluent in both languages, gives oral presentation of consent content, can be anyone including a member of the research team, but can not also serve as the witness.

Witness – Must be fluent in both languages, confirms that understandable consent content was presented. Can be anyone including a member of the research team, but this person cannot also serve as the translator.