**SMARTFORM TEMPLATE LANGUAGE - TRANSLATION SERVICES**

**Section 12.4** - **Are the subjects for this project limited to those who speak and read English?**

*Note: The short-form consent procedure (see HelpText) may be used for one or two subjects (by language) who do not speak English fluently, but if more are encountered or targeted, the IRB requires a translation plan for documents, interviews, and emergencies.*

This study may enroll subjects that [Enter Language, e.g. Spanish] is their primary language. In this case, because the study staff is not fluent in [Language], there must be a second individual who is fluent in both languages (not a family member) who will be present (via telephone, video call, or in-person) to interpret questions and answers for the participant.

Informed consent, ongoing safety assessments, and clinical data for this study may be obtained by utilizing certified language assistance services through **LanguageLine Solutions,** which is supported/managed by the MCW Office of Research/CTSI ATRU, to ensure effective communication with non-English speaking research participants.

**LanguageLine Solutions** eliminates cultural and language access barriers to communication and provides research staff one-touch instant access to accurate audio/video interpretation and translation supported by 20,000+ certified interpreters in more than 240+ top languages, 24/7/365. All language assistance services/tools are confidential, secure, and HIPAA-compliant.

**LanguageLine Translation Interpretive & Translation Services**

Interpreters must be unbiased and impartial and have an obligation to preserve accuracy and correct any error of interpretation during the process in order to maintain the authenticity of the translation. All final products/documentation should be reviewed for accuracy, completeness, and cultural or linguistic nuances to ensure that the final context has the same meaning and intent as the original source material.

* Spanish Interpretative Services (In-Person/Over-The-Phone) - **ATRU/CTO Bi-Lingual Staff**
* Interpretative Services (Over-The-Phone/Video) - **LanguageLine Solutions**
* Document Translation - **LanguageLine Solutions**

*Memory text of the MCW IRB Templates are only available in Spanish.*

*All Spanish translated****IRB Templates****have been Back-Translated to accommodate* ***NIH-Funded****research.*

*CW HRPP supports the usage of LanguageLine Solutions - Document Translation (DT) for written document translation for research. Interpretive services for pediatric patients & families should utilize CW Language Services.*

**Section 39.5 - Describe the circumstances under which consent will be obtained, including where the process will take place.**

*All study related information must be presented in the primary language of the subject.*

*The short-form consent procedure (see HelpText) should be used for enrollment of subjects that are non-English or Spanish-speaking.*

For [Enter Language, e.g. Spanish]-speaking subjects, the informed consent form has been translated via **LanguageLine Solutions** and will be presented in the [Language]. Study staff must have a fluent translator available (via telephone, video call, or in-person) during the consenting process and must follow MCW SPOs on enrolling non-English speaking subject(s) and the Informed Consent process.

As the Informed Consent process is an on-going discussion between the subject and the person designated to consent, subjects will be encouraged to ask questions while the study information is being presented. During this interchange, the consenting process will be done orally by the PI or his/her designee. A translator will be available via telephone, video call, or in-person for [Language]-speaking patients. Individuals who are properly trained to consent subjects will make sure that the informed consent process is done in a manner to solicit sufficient feedback to ensure that subjects have understood the information presented in the consent form.