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| **Adult Translational Research Unit (ATRU)** | **Title: Research Interpreter & Translation Services** | **SOP Number:**  **ADMIN 010** | **Origin Date: 4/1/2024**  **Revision Date: 7/2/2024** |

**PURPOSE**:

The **MCW Office of Research (OOR)/IRB** and **CTSI Adult Translational Research Unit (ATRU)** now supports investigators in expanding access of research protocols to subjects with limited or non-English proficiency through the **MCW Research Language Services Core**. The inclusion of subjects in research who are not fluent in spoken or written English ensures that the burdens and benefits of research are justly distributed. They may also be included because the area of research necessitates involving limited or non-English proficient subjects, for example international projects. Investigators must assure that the limited or non-English speaking subjects fully understand their role in the project and provide voluntary informed consent. This procedure outlines the investigator responsibilities when enrollment of non-English or limited-English proficient research subjects is unexpected or anticipated.

**SCOPE:**

Applies to *all* **MCW, Froedtert Hospital, Children’s Wisconsin and CTSI Partner Institutions** faculty and staff

involved in human research.

**DEFINITIONS:**

**Back-Translation**

A 3 step process of taking a translated version of a file or document and having an independent translator, with no prior knowledge of the original content, translate it back into the original source language.

**Language Interpretation**

The conversation of one spoken language into another

**Language Translation**

The conversation of one written language into another

**Limited English Proficient (LEP)**

Individuals who do not speak English as their primary language and who have a limited ability to read, speak, write, or understand English

**Non-English Proficient (NEP)**

Individuals who come from another language background and do not yet speak any English

**RESPONSIBILITIES/SERVICE LINES:**

**David R. Friedland, MD PhD**

Medical Director

CTSI Adult Translational Research Unit

dfriedland@mcw.edu

**Renee N. Dex, RN, BSN**

Research Nurse Manager

CTSI Adult Translational Research Unit

[rdex@mcw.edu](mailto:rdex@mcw.edu)

**Jennifer Brown, CCRP**

Program Director

MCW Office of Research (OOR)

jlbrown@mcw.edu

**POLICY & PROCEDURE(S):**

**RECRUITMENT AND ENROLLMENT OF NON-ENGLISH OR LIMITED ENGLISHPROFICIENT SUBJECTS**

**Unanticipated Enrollment of LEP and/or NEP Subjects**

* On occasion, an opportunity to enroll a subject with limited or no proficiency in English may arise, but translated documents have not been previously approved for this project by the IRB. In these cases, federal regulations allow the use of a ‘short form’ in a language the subject understands to document that all required elements of informed consent were presented orally.
* If the investigator/study team expects to enroll more subjects who speak that language, the investigator/study team must follow the policy outlined below under **Anticipated Recruitment & Enrollment of LEP and/or NEP Subjects** (below).
* Projects that require reading or written responses from the subject, such as diaries and surveys, may not be appropriate under this procedure. Investigators/study teams/support services should carefully consider and plan how these documents will be translated and made available to the subject.
* Before enrolling a **LEP or NEP** subject under unexpected circumstances, the investigator/study team must:
* Submit an AME if the project requires the subject to speak English as an eligibility criterion.
* The AME must be approved before an **LEP or NEP** subject may be enrolled - If the project is industry-sponsored, the Sponsor’s approval of this change must also be provided with the AME.
* Assure that a summary *in English* of what is to be presented to the subject is available and approved by the IRB. Typically, this will be the IRB-approved consent form *in English*.
* Download a copy of the ‘short-form’ which are available/approved *in several different languages* on the **MCW Human Research Protections Program (HRPP), Office of Research (HRPP)** website.
* Request interpreter services fromthe**MCW Research Language Services Core** to set up an audio, video, or in-person appointment with a **LanguageLine Solutions** or **ATRU/CTO Bi-Lingual Staff** who is fluent in the language. The interpreter must be available during the entire consenting process. Federal research regulations do not allow a family member or friend to serve as the interpreter.
* Assure there is an adult witness to the entire oral presentation. The witness may not be the individual conducting the consent process or the interpreter. The witness may not be a project member, or an adult family member and must be fluent in both English *and* the language of the subject. The function of the witness is to certify that an adequate oral presentation was made to the subject or legal representative and voluntary consent was obtained.
* Develop a plan for ongoing communication during the research project, including for follow-up assessments, questions, adverse events, emergencies, and the ongoing ‘consent’ process for this **LEP or NEP** subject.
* **Froedtert Health (FH) Language Services** may provide interpreter services for FH patients who are in a research project only when their care and treatment is also part of clinical care. For research only visits, the project team will need to obtain these services through the **MCW Research Language Services Core**.
* CW HRPP supports the use of LanguageLine Solutions - Document Translation (DT) for written document translation for research. Interpretive services for pediatric patients & families should utilize **CW Language Services.**
* Investigators should incorporate the following when conducting the consent process when unexpectedly enrolling a **LEP or NEP** subject:
* The (English-speaking) project staff member going through the consent process with the subject and the interpreter should be sure that the *entire contents* of the consent form are reviewed and discussed.
* Informed Consent must begin with a concise and focused presentation of the key information to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research. The information must be organized and presented in a way that facilitates comprehension. The entire consent form in English does not necessarily need to be read to the subject word for word; however, if any federally required elements of informed consent (45 CFR 46.116) are missed, the entire consent process is invalid. For a list of required elements, see **IRB SOP: Informed Consent Document for Human Subject Research**.
* The project staff member going through the consent process should allow the subject time and opportunity to ask questions, and to think over the implications of project participation in accordance with **IRB SOP: Informed Consent Process for Human Subject Research**.
* Investigators/study team must obtain the subject’s signature to document the consent process.
* In addition, the following required signatures and additional steps in the consent process must be completed:
* The language specific ‘short form’ should be signed by the subject (or the subject’s LAR), the interpreter, and an adult witness.
* An English **MCW IRB Consent Form** should be signed by the witness and the individual conducting the informed consent discussion.
* The rationale for the use of the witness ‘Subject Has Limited English Proficiency’ should be selected under the witness signature box. A copy of the ‘short form’ and the English consent form must be provided to the subject. The originals should then be stapled together and filed Document the short form consent process followed in Sections A & B in your regulatory file (e.g. using a memo or note to file) and in the subject’s medical record if the project is FDA-regulated.
* Submit an AME to describe the plan for ensuring continued consent and communication with the subject during the project. If additional enrollment of **LEP or NEP** subjects is expected, the project should be amended at this time, following the process outlined in **Anticipated Recruitment & Enrollment of LEP and/or NEP Subjects** (below).
* Report the unexpected enrollment of **LEP or NEP** subjects in the next **Continuing Progress Report (CPR)** and include a description of the process that was followed and the plan to ensure the continued understanding of the project by the subject.

**Anticipated Recruitment & Enrollment of LEP and/or NEP Subject**

* When project is anticipated to recruit and enroll **LEP or NEP** subjects, investigators/study teams must identify in the **eBridge SmartForm** the target populations, the language(s) and must specify who will provide the translation and interpretation and their qualifications.
* In addition, the **eBridge SmartForm** must include the following:
* A description of the subject population, the procedures for eliciting informed consent, and the plan for ensuring continued consent and communication with the subjects during the project. The **IRB SOP: Informed Consent Process for Human Subject Research** must be followed.
* The consent form, questionnaires, surveys or other documents that subjects are expected to read and/or complete must be translated into a language that is understandable by the subject.
* The English and translated versions of the documents must be uploaded to the **eBridge SmartForm**.
* **Translator’s Declaration** and **Back-Translator’s Declaration** (if applicable) must be completed, signed, and uploaded in support of the translated consent form(s) and recruitment materials to be use if the investigators/study team is not utilizing **Language Line Solutions** through the **MCW Research Language Services Core**. All Spanish translated IRB Templates have been back-translated to accommodate NIH-Funded research.
* Projects Enrolling *Only* Non-English Speaking Subjects:
* Investigators must provide the proposed consent form and other documents in English and in the language of the subjects.
* Investigators must provide the **Back-Translator’s Declaration** (if applicable) for the consent form(s) and recruitment materials if the investigators/study team is not utilizing **LanguageLine Solutions** through the **MCW Research Language Services Core**. All Spanish translated IRB Templates have been back-translated to accommodate NIH-Funded research.
* Investigators must provide a consent form in a language understandable to the subject. The consent form must follow **IRB SOP: Informed Consent Document for Human Subject Research.**
* Both the translated **MCW IRB Consent Form**, the **Back-Translator’s Declaration** (if applicable) and the English version must be reviewed and approved by the **MCW IRB** before use.
* Consenting Process
* Project team members conducting consent must be familiar with the project and fluent in *both* English and the subject’s primary language, *OR*
* In addition to the project team member conducting consent, there must be a second individual (not a family member) who is fluent in *both languages* and who will be present to interpret for the subject to facilitate any questions and answers.
* Investigators should ensure that an individual who is familiar with the project and fluent in *both languages* is available by phone, or in-person to answer questions during the conduct of the project.
* To ensure that the translated documents convey the same meaning as the original in English, the completed **Translator’s Declaration** and **Back-Translator’s Declaration** (if applicable) for the consent form(s) and recruitment materials must be uploaded to the **eBridge SmartForm** if the investigators/study team is not utilizing **LanguageLine Solutions** through the **MCW Research Language Services Core**. All Spanish translated IRB Templates have been back-translated to accommodate NIH-Funded research.
* Questionnaires, Surveys, & Other Documents
  + When a project involves questionnaires, surveys, or other documents that subjects are expected to read and/or complete, subjects must be provided the document in their own language. The document must convey the same meaning as the original English version. Otherwise, responses of non-English proficient subjects will not be comparable to responses of those who are proficient in English.
  + Investigators/study teams must describe the process for administering the questionnaires, surveys, or other documents in the **eBridge SmartForm**.

**Who Can Serve as an Interpreter?**

* Enrolling Subjects at **Froedtert Health/MCW** Locations:
* No minor under the age of 18 may serve as an interpreter.
* Family members cannot serve as an interpreter for a subject.
* A native/fluent speaker who holds the equivalent of a high school education may serve as an interpreter
* An individual who holds a degree in the language of the target population(s) may serve as an interpreter
* The translator for the project’s consent form and/or other documents, must be a certified or credentialed (fluent) translator (Example: LanguageLine Solutions)
* Enrolling Subjects at **Community/Mobile** Locations (Non-MCW/Froedtert):
* No minor under the age of 18 may serve as an interpreter.
* Family members cannot serve as an interpreter for a subject.
* A native/fluent speaker who holds the equivalent of a high school education may serve as an interpreter
* An individual who holds a degree in the language of the target population(s) may serve as an interpreter
* The translator for the project’s consent form and/or other documents, must be a certified or credentialed (fluent) translator (Example: LanguageLine Solutions)
* If selecting an interpreter from the community from which subjects will be recruited, a plan to ensure confidentiality must be described in the **eBridge SmartForm**.

**REFERENCES:**

* 45 CFR 46.102(c)
* 45 CFR 46.116
* 21 CFR 50.3(1)

**ASSOCIATED SOPS:**

* IRB SOP: Informed Consent Process for Human Subject Research
* IRB SOP: Informed Consent Document for Human Subject Research
* IRB Form: Translator Declaration IRB Form: Back-Translator Declaration

**APPROVALS:**

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|  | Clinical and Translational Science Institute of Southeastern Wisconsin | |
| Signature:  A close-up of a signature  Description automatically generated  Date: 5/20/2024 | Signature:  Black text on a white background  Description automatically generated  Date: 5/20/2024 |
| Approved By: David Friedland, MD | Approved By: Renee N Dex, RN, BSN |
| ATRU Medical Director | ATRU Research Nurse Manager |
| Author: Renee N. Dex, Research Nurse Manager | |
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