**Non-English-Speaking Participants**

**Overview:**

When enrolling non-English speaking research participants, or seeking consent from non-English communicating parents/guardians, investigators must have a plan to manage communications with the participant during ***all phases*** of study participation.  This extends beyond recruitment, the consent process and initial enrollment, to include study visits as well as possible unexpected phone calls or follow-up questions. It is the investigator’s responsibility to be fully prepared to communicate with all participants during any phase of the study.

**Definitions:**

* **Back translation**: process of translating written materials from one language to another and then, in a separate process, translates the document back into the original language.  This process is performed to evaluate the quality and integrity of the information being translated.
* **Translator**: person who converts written materials from English to another language
* **Certified Translator**: a professional translator who has successfully completed a certification program or exam providing them with certified translator credentials
* **Interpreter**: person who accompanies researchers, in real time, to convey verbal information to another person in their native language
* **Medical Interpreter**: an interpreter who is familiar with medical terminology
* **Non-English speaking**: unable to communicate in the English language
* **Witness**: an individual who is fluent in both English and the necessary foreign language who will be physically present during the consent process to observe the process and sign consent forms

 **Determining Translation Requirement:**

It is required that consent forms and study related interventions be provided to subjects in the language which they understand. There are different requirements for who can translate documents, serve as an interpreter and serve as a witness for consent for exempt, expedited and full board review studies. These requirements are detailed in the tables below.

**Information at a Glance:**

Table 1: Who Can Act as the Translator?

* This individual must read, speak, and write the native language in English

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Exempt | Expedited— No Clinical Procedures | Expedited—Involves Clinical Procedures | Full Board |
| Fluent Study Team member | Yes | No | No | No |
| Non-Certified translator who is not part of the study team | Yes | Yes | No | No |
| Certified Translator who is not part of the study team | Yes | Yes | Yes | Yes |

### Table 2: Who can act as the Interpreter?

* Must read, speak, and write the native language and English
* Is available to answer Participants’ questions at any stage of the study.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Exempt | Expedited—No Clinical Procedures | Expedited—Involves Clinical Procedures | Full Board |
| Family member of participant | No | No | No | No |
| Fluent study team member | Yes | No | No | No |
| Bilingual individual who is not part of study team | Yes | Yes | No | No |
| Bilingual Clinical staff who is not part of the study team | Yes | Yes | Yes | Yes |
| Medical Interpreter who is not part of the study team | Yes | Yes | Yes | Yes |

### Table 3: Who Can act as the Witness?

* Must read, speak, and write the native language and English
* Must be physically present for the consent process

|  |  |  |  |
| --- | --- | --- | --- |
| Documentation | Expedited—No Clinical procedures | Expedited—Involves Clinical Procedures | Full Board |
| Fluent study team member | Yes | Yes | Yes |
| Family member of Participant | Yes | Yes | Yes |
| Bilingual Clinical Staff | Yes | Yes | Yes |
| The person acting as Interpreter | Yes | Yes | Yes |

### ****Frequently Asked Questions****

**Where can I find a Translator or Interpreter to hire?**

* The IRB does not endorse or recommend any specific translator or interpreter services.
* If your study requires a certified language professional, please first contact your Department Administrator to determine if your department has a preferred service provider.

**What if I end up with potential subjects who speaks a language other than English and I want to enroll them in the study, but I did not plan for this in my initial IRB application?**

* If at any point the study transitions to planning the enrollment of subjects that speak a particular non-English language, the IRB application must be modified and translated documents must be submitted before enrollment of these individuals can begin.