

Non-English Speaking Participants

Purpose

The purpose is to outline the policies and procedures for non-English speaking participants involved in research.

Definitions

Interpreters work live with research participants. They verbally convey (in another language) information that is spoken, or they read aloud (in another language) materials which are written in English. Individuals providing interpretation during a project are considered to be engaged in research activities due to their interaction with participants.

Translators work with written documents, converting them from English into another language. As they do not interact with participants, they are not considered to be engaged in research activities, provided that their only activity is the translation service itself.

Translator or Interpreter Certification provides evidence of qualification to furnish services due to the ability to read, write and speak a language other than English. It is required for any project involving the written translation of English language documents into another language, or live interpretation of documents or communication between an investigator and participant. The certification form enables the translator to assert that the tone, meaning, and content of any translated documents remain consistent with the approved, English versions, or that the individual has the appropriate knowledge and experience to provide live interpretation services.

Policies

Federal regulations require that information given to a research subject (participant) or legally authorized representative of the subject “be in language understandable to the subject or the representative.” Accordingly, for research

intended or likely to involve subjects who are not fluent in English, any informed consent forms, parental permission (consent) forms, child assent forms or scripts, advertisements or other subject documents must be translated into a language understood by the subjects.

The principal investigator (PI) or another research team member must be fluent in the subjects' or representatives' language in order to answer questions, obtain informed consent, and conduct any interventions or interactions, unless an outside interpreter will be utilized for these tasks.

Interpreters

Interpreters working with participants directly are considered to be engaged in research activities and must complete one basic, human research course through the [Collaborative Institutional Training Initiative \(CITI\)](#). For more information, please see the Mandatory Training policy page.

Interpreters of de-identified audio recordings do not interact with participants and are not considered to be engaged in research activities. Therefore, they are not required to complete ethics training, provided that this specific type of interpretation is their only activity.

Deaf or Hard of Hearing

As English is often not the primary language of many deaf and hard of hearing participants, they would not be expected to have high proficiency in written English. Thus, English versions of consent documents must be written at an appropriate reading level (unless a waiver is requested and granted). Informed consent forms and other research materials must be approved by the Institutional Review Board or Exempt Review Committee, and then be interpreted live by an individual fluent in the particular sign language used by the participants (e.g., American Sign Language). If the interpreter is not a member of the research team, he/she will be subject to the same training policy as mentioned under the Interpreter section above.

Deaf or hard of hearing participants should be able to provide a signature on an English informed consent form after a study has been explained to them in their own language, unless a waiver of documentation of informed consent is requested and granted. Please see our Informed Consent, Parental Consent and Child Assent policy.

Procedures

When involving participants who speak a language other than English, the following procedure must be followed:

1. The investigator must clearly describe in the application who will be recruiting participants and how.
 2. The investigator must clearly describe in the application who will be obtaining informed consent of participants and how (e.g., written form in the other language, oral explanation, etc.).
 3. The investigator must clearly describe in the application how informed consent will be documented (e.g., signature to be collected on a form or to be waived).
 4. The investigator must clearly describe in the application who will be performing research interactions or interventions (if applicable).
 5. The English versions of the documents must first be submitted to and approved by the Institutional Review Board (IRB) or Exempt Review Committee (ERC). The readability must be appropriate for the target population.
 6. The investigator must then submit to the IRB or ERC:
 1. The documents written in the other language, unless waived (exception: deaf or hard of hearing participants)
 2. A completed Translator/Interpreter Certification form
This form must be signed by a translator or interpreter who will affirm that he/she is qualified to translate or interpret. Please see the [IRB](#) or [ERC](#) web pages for the appropriate form.
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Related Policies

- Informed Consent, Parental Consent and Child Assent
 - International Research
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History

12/03/2013 - Updated

05/25/2018 - Updated training requirements, procedures and related policies