



## Informed Consent with Non-English Speakers

### Policy

#### A. Informed Consent/assent/parental permission in other Languages

The Department of Health and Human Services (DHHS) regulations ( [45 CFR 46.116](#) and [45 CFR 46.117](#)) and FDA regulations ( [21 CFR 50.25](#) and [21 CFR 50.27](#)) require that informed consent information be presented in language understandable to the subject, and in most situations, that informed consent be documented in writing. Investigators should carefully consider the ethical/legal ramifications of enrolling a subject when there is a language barrier. If subjects do not clearly understand the consent document or freely ask and receive answers to their questions, then their consent will not be truly informed and may not be legally effective.

The Institutional Review Board prohibits the exclusion of non-English speaking individuals from research protocols unless there is a sufficient justification for the exclusion. In particular, if a research protocols offers a potential for direct benefit that may only be available within the context of the research, the exclusion of non-English speaking individuals becomes ethically problematic. Investigators are obliged to consider the potential that study populations may include non-English speaking individuals and plan for this while developing the protocol. Investigators need to plan for the inclusion of non-English speaking subjects. This will entail consideration of how to communicate clearly during the initial recruitment and informed consent process, and for enrolled subjects, throughout all stages of the research study (in person, telephone, mail or email communication).

When subjects/families do not speak English use of a translated consent is always preferred. The IRB will allow the use of the short form for minimal risk research. Exceptions can be made on a limited basis to allow the use of a short form for research which is greater than minimal risk. If researchers can reasonably expect that more than an incidental number of subjects speaking the same non-English language will be enrolled (for example, if the investigator is targeting a non-English speaking group), translation of the entire English version is required. In addition an interpreter is usually required during the informed consent process and ongoing interactions with the subject.

Justifications for excluding non-English speaking participants usually include scientific and methodological limitations based on the lack of appropriate validated instruments, surveys or assessments. In some situations use of another language may confound the research results or not permit appropriate analysis of the data especially when protocols are designed with a small sample size. It is an investigators' obligation to determine whether there are appropriate alternate assessments, instruments or surveys that could be utilized for non-English speaking participants prior to excluding them.

In order to ensure the inclusion of non-English speaking individuals in research, the following guidelines are provided.

### 1. Corporate Sponsored Research:

When research is sponsored by a corporate entity, the clinical trial agreement negotiated between the company and Boston Children's Hospital should include a provision for the sponsor to cover the costs of translating consents and other important research documents. This cost could be included as a line item within a budget or if there is uncertainty as to whether non-English speakers will be eligible, it may be included as a provision, if needed, in the agreement.

### 2. Federally Funded Research:

When research is federally funded it is permissible to include the translation of research documents and the potential use of an interpreter as direct expense in a budget. Investigators should include these costs in their budgets.

### 3. Use of Interpreter Services:

Interpreter Services is available to assist when recruiting and interacting with a non-English speaking individual. They also may assist during the short form consent process and serve as the witness to the fact that the consent form was explained and the subject had the opportunity to ask questions. Investigators need to contact interpreter services as soon as they anticipate a need for an interpreter. This will permit planning for appropriate staffing.

The Institutional Review Board requires that the interpreter comes from the pool of experienced interpreters obtained through Interpreter Services. Only in very exceptional circumstances should other individuals serve in this capacity. Approval to use someone outside of Interpreter Services needs to be granted on a case by case basis and only after consultation with Interpreter Services. For questions about obtaining the assistance of Interpreter services please page #0335 for Spanish, and #0120 for other languages through the page operator at 617-355-6363.

Because informed consent is an ongoing process, issues related to the subject's ability to understand and ask questions should continue to be considered throughout the study, and not just at the time of initial consent. For example, it is recommended to arrange for a medical interpreter to be available at subsequent study visits to ensure that subjects have an opportunity to ask questions and receive relevant study information.

### 4. Documenting the consent/assent/parental permission process and required signatures when using translated consent forms:

When a consent form is translated into another language the investigator/research team member obtaining consent and the subject/parent should sign on the appropriate signature lines of the translated consent form. In many of these cases an interpreter will also be present to assist in the consent process.

The involvement of the qualified interpreter in-person or remotely (eg by phone), should be documented with a signed, dated note to file, or notation on the consent document, to make this clear. If the investigator/assistant speaks the language and is authorized (see above) to serve as the interpreter, documentation, such as a signed, dated note to file or notation on the consent document should be added to make this clear.

### 5. Use of Short Form Method of Consent:

The IRB allows the use of a short form method of consent when the research has been determined by the IRB to represent minimal risk. For greater than minimal risk research when the research has potential for benefit that is not available outside the context of the research and there is insufficient time to obtain a translated version of the consent, the IRB will consider whether the short form may be used on a case by case basis, however investigators must get permission from the IRB for an individual patient or a protocol in

general. See the following section below for a detailed description of and additional documentation required when using the Short Form method of consent.

## **B. Short form method of consent/assent with non-English speakers**

The Institutional Review Board realizes that with increasing numbers of non-English speaking subjects and family members, investigators cannot always anticipate the interest of a particular non-English speaking individual and provide him/her with a translation of the informed consent document in a timely manner. However to exclude individuals on the basis of not speaking English is not ethically justifiable.

Under these circumstances and in accordance with the regulations, a translation of the "short form" (which attests that the elements of consent have been presented orally) can be used to document informed consent in writing. Boston Children's Hospital will allow the use of the "short form" for non-English speaking individuals\* only in the following situations:

- 1) The research has been determined by the IRB to represent minimal risk. For these protocols investigators will be able to access the short forms in the appropriate language and utilize it without the need to notify the IRB. Short forms may be found at <http://www.childrenshospital.org/research-and-innovation/research/research-administration/office-of-clinical-investigation/information-for-researchers/informed-consent> .
- 2) For greater than minimal risk research when the research has potential for benefit that is not available outside the context of the research and there is insufficient time to obtain a translated version of the consent, the IRB will consider whether the short form is appropriate for use on a case by case basis, however investigators must get permission from the IRB. (This situation should be an occasional exception, not the rule)

\*The IRB will also permit use of the short form when consenting low literacy English speaking adult subjects. See separate guidance titled "General Information: Informed Consent and Parental Permission" for more information.

When a "short form" is used to document informed consent, the consent process must include an oral presentation of the English informed consent in language understandable to the potential subject. The English consent serves as the summary of what is verbally presented to potential subjects and their families. The subject then signs a "short form" which is available in his/her native language. The short form is an attestation that the elements of consent have been presented orally. Short form consent templates translated into many languages are available on the IRB's website.

The informed consent process for enrolling subjects using the "short form" consent document is outlined below. **ALL** of the following requirements (1, 2, 3 and 4) must be completed

- 1) The principal investigator or assistant, through the Interpreter, must orally present the approved English version of the consent form to the subject in a language understandable to him/her, and the subject must be given a written translation of the "short form" consent document to read;
- 2) The entire consent process must be witnessed by an individual who is fluent in both English and the language understandable to the subject. The interpreter may serve as the witness. (In this context the term witness is used only to attest to the fact

that the information was presented in a language understandable to the subject/family and the subject/family had the opportunity to ask questions);

- 3) The approved English version of the consent form must be signed by the investigator or study staff authorized by the IRB to obtain consent and the witness to the consent process, and the translated "short form" must be signed by the subject and the witness to the consent process (see 2 above); **AND**
- 4) The subject must be given copies of both the approved English version of the consent form and the translated version of the "short form" consent document. The original signed English version with the original signed "short form" attached should be placed in the subject's research record and a copy of both placed in his/her medical record, if appropriate.

## Related Content

IRB Policies:

"General Information: Informed Consent and Parental Permission"

"Special Considerations: Assent and Parental Permission"

## Document Attributes

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