Informed Consent with Non-English Speakers

Purpose

This policy outlines the informed consent process with Non-English Speakers. Guidance is provided concerning:

1. Use of Interpreter Services
2. Documentation and Required Signatures When Using Translated Consents
3. Short Form Method
4. Requesting funds for consent translations

Policy

The Department of Health and Human Services (HHS) 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 protocol 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.

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.

Investigators are obliged to consider the potential that study populations may include non-English speaking individuals and plan for this while developing the protocol. 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 (i.e. communication: in person, telephone, mail, or email).

When subjects/families do not speak English, use of a translated consent is always preferred.

Short Form Consent

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 (i.e., 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.

Procedure

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

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 (IRB) 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 is granted on a case-by-case basis and only after consultation with Interpreter Services.

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

Documentation 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 (e.g. by phone), should be documented with a signed and dated note to file or notation on the consent document. This documentation should be clear.

If the investigator/research team speaks the subject's language and is authorized to serve as the interpreter, then documentation, such as a signed and dated note to file or notation on the consent document should be added to clarify this.

Short Form Method

The IRB 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 them with a translation of the informed consent document in a timely manner.

Circumstances: Minimal Risk and Greater than Minimal Risk

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:

a. Minimal Risk: When the research has been determined by the IRB to represent minimal risk, investigators can 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/institutional-review-board/information-for-researchers/informed-consent***.

b. Greater than Minimal Risk: When the research has been determined by the IRB to represent greater than minimal risk 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 is an occasional exception, not the rule.

The IRB will also permit use of the short form when consenting low literacy English speaking adult subjects. For further information, see the IRB policy: ***General Information: Informed Consent and Parental Permission*** and ***Special Considerations: Assent and Parental Permission***.

Short Form Process with Interpreter Present

When a "short form" is used to document informed consent, the consent process must include an oral presentation of the English informed consent in a language understandable to the potential subject.

The English consent serves as the summary of what is verbally presented to potential subjects and their families. It may be referred to as the "long form."

The short form is an attestation that the elements of consent have been presented orally in their native language. The subject then signs the "short form."

The informed consent process for enrolling subjects using the "short form" consent document is outlined below. Note, ALL the following requirements must be completed.

1. The Principal Investigator or study staff, through the Interpreter, must:
   a. orally present the approved English version of the consent form to the subject in a language understandable them and
   b. 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 subject's language. 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:
   a. the investigator or study staff authorized by the IRB to obtain consent and
   b. the witness to the consent process (see two above), and
   c. the translated "short form" must be signed by the subject.

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.

5. The original signed English version with the original signed "short form" should be placed in the subject's research record and a copy of both placed in their medical record, if appropriate.

Please note: The IRB has a checklist on the IRB website that may be used to assist investigators in the short form process when the interpreter is present.

Short Form with Interpreter REMOTE (VRI iPad Technology)

Due to the increasing numbers of non-English speaking patients, Interpreter Services have contracted with remote interpreters to provide assistance as needed. This process is facilitated using iPad dedicated for this purpose.

It is always preferred to have an interpreter present during a research informed consent process; however, the Interpreter Services department will triage some requests for the use of remote services. This decision depends on availability of in-house interpreters and the specific language requested.

If a research consent form has been fully translated into the subject's language, remote interpreters may be used to assist in the process, as is the current practice process. A note in the research record should indicate an interpreter was used during the informed consent process.

Requirements for REMOTE Interpreter Use

If a short form is approved by the IRB and the REMOTE Interpreter (VRI iPad Technology) is utilized, there are regulatory requirements that must be followed to assure compliance.

The IRB has a required checklist that is found on their website should be completed and filed with the research record when a remote interpreter is utilize. See: ***Use of Remote Intepreters & VRI iPad Technology for Short Form Consent Method***

When interpreters are present in the room and a "short form" is used, they can sign the English consent (long) and short forms as a witness. However, when the interpreter is remote, actual signatures on the consent forms are not possible and the following extra steps are required.

REMOTE Interpreter Process

1. Call the remote interpreter using the VRI iPad or by phone to start consent session, using English consent (long form) as a guide for discussion.

2. Before the consent session begins state the following:

   "Because you are not here and unable to sign documents we need to ask if you will allow us to sign on your behalf by writing your name and ID# on the consent forms in a section that says witness. We want to let you know that the term witness has a very limited definition when used for this purpose. It means 1) you were present by phone or live video during the consent process; 2) the information was presented in the language you were told was understood by the subject/parent/guardian; and 3) the subject/family was given the opportunity to ask questions while you were present. The consent form includes this definition. *Will you agree and allow me to sign on your behalf by writing your name and ID# on the consent forms?"*

   - If yes, proceed.
   - If no, you may want to ask what the concern is and try to resolve it. If they will not agree, you should not enroll the subject until you can find another interpreter who is able to serve this role. Conduct the consent process with the VRI iPad interpreter using the English consent as a guide for content during the discussion.

3. After the consent discussion, with the interpreter still on the line, the person obtaining the consent, must ask the remote interpreter to ask the subject/family/guardian the following two questions:

   a. *Did you understand the information about the research?*

      - If yes, continue to next question.
      - If no, the consent process must continue until a yes response.

   b. *Do you have any questions?*

      - If yes, all questions must be answered before moving on
      - If no, continue to obtain signatures.

4. Obtain the following:

   a. Subject/parent/guardian signs, dates and specifies the relationship to child on short form
   b. The person obtaining consent (PI/Coordinator), signs the English consent form ("long form")
   c. The person obtaining consent (PI/Coordinator) records the Interpreter name and ID# on both short and the English Consent (long) form and writes "As authorized by [insert interpreter's name]" on:
      - The witness signature line on the short form.
      - The witness signature line on the English consent.

   d. If the IRB required ASSENT, must check one of the following:
      - Minor subject signs and dates the short form
      - Reason assent was not obtained
      - N/A: assent not required for this study

5. Provide the subject/parent/guardian:
   a. A copy of the signed and dated short form document and
   b. A copy of the signed and dated English consent (long form).

6. The informed consent process lasts throughout the entire study! Keep a record of all updates, changes and discussions with the subject/parent/guardian. All pertinent notes, concerns and questions should be documented, even after the consent form has been signed.

7. Attach/combine together and file the:
   a. Signed English consent (long form)
   b. Signed short form and
   c. Required checklist: ***Use of Remote Interpreters & VRI iPad Technology for Short Form Consent Method***

Requesting funds for consent translations

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 can 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.

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.

Related Content

IRB Policies

General Information: Informed Consent and Parental Permission

Special Considerations: Assent and Parental Permission

Required Checklist

Use of Remote Interpreters & VRI iPad Technology for Short Form Consent Method

Document Attributes

Title	**Informed Consent with Non-English Speakers**		
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