



Informed Consent with Non-English Speakers Policy/ Procedure

Internal Approval

SVP, Research

EVP & Chief Scientific Officer, Research

Scope

The Department of Health and Human Services (HHS) regulations (45 CFR 46.116 and 45 CFR 46.117) and U.S. Food & Drug Administration 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.

This policy outlines the informed consent process with non-English speakers and provides procedures concerning the use of interpreter services, documentation and required signatures when using translated consents, short form method of consent, and requesting funds for consent translation.

Policy Statements

Exclusion of Non-English Speaking Individuals

The Institutional Review Board (IRB) prohibits the exclusion of non-English speaking individuals from research protocols, unless there is a sufficient justification for the exclusion.

1. 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.

2. Justifications for excluding non-English speaking participants usually include scientific and methodological limitations based on the lack of appropriate validated instruments, surveys or assessments.
 - a. 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.
 - b. 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.

Short Form Consent

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 in the following situations:

1. **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.
2. **Greater than Minimal Risk:** the IRB will consider whether the short form is appropriate for use on a case-by-case basis when the research has been determined by the IRB to:
 - a. represent greater than minimal risk research,
 - b. has potential for benefit that is not available outside the context of the research, and
 - c. there is insufficient time to obtain a translated version of the consent
 - d. this situation is an occasional exception, not the rule.
3. **Low Literacy:** The IRB will also permit use of the short form when consenting low literacy English speaking adult subjects.

Interpreter Services

The Institutional Review Board (IRB) requires that the interpreter comes from the pool of experienced interpreters obtained through Interpreter Services.

1. Only in very exceptional circumstances should other individuals serve in this capacity.
2. IRB approval to use someone outside of Interpreter Services is granted on a case-by-case basis and only after consultation with Interpreter Services.

Procedures

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

1. Investigators are obliged to consider the potential that study populations may include non-

English speaking individuals and plan for this while developing their protocols. 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).

2. When subjects/families do not speak English, use of a translated consent is always preferred.
3. 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.
4. In addition, an interpreter is usually required during the informed consent process and ongoing interactions with the subject.

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.

1. Investigators need to contact interpreter services as soon as they anticipate a need for an interpreter. This will permit planning for appropriate staffing.
2. 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.
 - a. 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

1. 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.
2. 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.
3. 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 Process

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.

Short Form Process with an Interpreter Present

ALL the following requirements must be completed:

1. The Principal Investigator or research team member, with the assistance of the Interpreter, must:
 - a. Orally present the approved English version of the consent form to the subject in a language understandable to the subject.
 - i. The English version of the consent (also referred to as the "long form") serves as the summary of what is verbally presented to potential subjects and their families.
 - b. Provide the subject a written translation of the short form consent document.
 - i. The short form is an attestation that the elements of consent have been presented orally in a subject's native language.
2. The entire consent process must be witnessed by an individual who is fluent in both English and the subject's language.
 - a. The interpreter may serve as the witness.
 - b. 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.

Short Form: Documentation Requirements

1. The English version of the consent form must be signed by:
 - a. The investigator or research team member authorized by the IRB to obtain consent
 - b. The witness to the consent process.
2. The translated short form must be signed by:
 - a. The subject/parent/guardian
 - b. The witness to the consent process
3. Assent, IF REQUIRED: the research team member must indicate one of the following:
 - a. Minor subject signs and dates the short form, or
 - b. Reason assent was not obtained
4. The subject must be given copies of both the 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 (English and short form consent) placed in their medical record, if appropriate.

Short Form with Remote Interpreter (VRI iPad)

Technology)

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

1. It is always preferred to have an interpreter present during a research informed consent process; however, Interpreter Services will triage some requests for the use of remote services.
2. This decision depends on availability of in-house interpreters and the specific language requested.
3. 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.
4. The IRB has a required checklist that should be completed and filed with the research record when a remote interpreter is utilized. See IRB Checklist: *Use of Remote Interpreters & VRI iPad Technology for Short Form Consent Method*
5. When interpreters are present in the room and a short form is used, they can sign the English consent and short forms as a witness. However, when the interpreter is remote, wet signatures on the consent forms are not possible and the following extra steps are required.

Short Form with Remote Interpreter: Process

1. Research team member: Call the remote interpreter using the VRI iPad or by phone to start the consent process.
 - a. Use the English consent (long form) as a guide for discussion.
2. Before the consent process begins, the research team member needs to 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:

- a. you were present by phone or live video during the consent process;
- b. the information was presented in the language you were told was
- c. understood by the subject/parent/guardian; and
- d. 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?" Yes/No.

- a. If **NO**, the research team member may want to ask what the concern is and try to resolve it.
 - i. If they do not agree, you should not enroll the subject until you can find another interpreter who is able to serve this role.

- b. If **YES**, proceed.
 - i. 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 remote interpreter present the research team member 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? Yes/No*
 - i. If **YES**, continue to next question.
 - ii. If **NO**, the consent process must continue until a yes response is received.
 - b. *Do you have any questions? Yes/No*
 - i. If **YES**, all questions must be answered before moving on
 - ii. If **NO**, continue to obtain signatures.

Short Form with Remote Interpreter: Documentation Requirements

1. Subject/parent/guardian signs, dates and specifies the relationship to child on short form.
2. The person obtaining consent (PI/Coordinator), signs the English consent form ("long form").
3. 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:
 - a. The witness signature line on the short form.
 - b. The witness signature line on the English consent.
4. Assent, *IF REQUIRED*: the research team member must indicate one of the following:
 - a. Minor subject signs and dates the short form Reason assent was not obtained
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. File together 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*
7. Reminder: The informed consent process lasts throughout the entire study!
 - a. Keep a record of all updates, changes and discussions with the subject/parent/guardian.
 - b. All pertinent notes, concerns and questions should be documented, even after the consent form has been signed.

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 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

- Department of Health and Human Services Regulations (HHS 45 CFR)
 - §46.116: General requirement for informed consent
 - §46.117: Documentation of informed consent
- U.S. Food & Drug Administration CFR – Code of Federal Regulations Title 21
 - 50.25: Elements of Informed consent
 - 50.27 Documentation of informed consent
- IRB Checklist: Use of Remote Interpreters & VRI iPad Technology for Short Form Consent Method

Approval Signatures

Step Description

Approver

Date

Applicability

Boston Children's Hospital- Policies & Procedures