



Human Subjects Protection Update

1. Use of the Short Forms For Non English Speaking Research Subjects During the Consenting Process

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COMMITTEE ON CLINICAL INVESTIGATION

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Eunice Newbert

Melyssa Sueiro

CONTACT US:

**333 Longwood Ave.
4th Floor
Boston, MA 02115**

**Tel: 617-355-7052
Fax: 617-730-0226**

Use of Short Forms For Non English Speaking Research Subjects During the Consenting Process

The Committee on Clinical Investigation realizes that with increasing numbers of non-English speaking subjects and family members, investigators cannot always anticipate when a non-English speaking individual will be eligible for a study and therefore it may not be possible to translate an informed consent document in a timely manner. However; to exclude individuals on the basis of not speaking English is not ethically justifiable.

In accordance with both HHS and FDA regulations, the committee has agreed to allow the use of a "short form" which attests that the elements of consent have been presented orally. Short forms have been prepared in several languages and will be available on the Clinical Investigation website.

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.
- 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 if the short form may be used, however investigators must get permission from the IRB. (This situation should be an occasional exception, not the rule)

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);

4. The subject/family 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.

The following document provides detailed questions with corresponding answers that provide further information about the use of the short form.

Why is this change being implemented?

It has been noted that there are an increasing number of non-English speaking subject eligible for research protocols. While it is always best to provide subjects with a translated consent, this may not always be feasible. While some sponsors agree to pay the cost of translating the consents and the Clinical Investigation office has some funds to translate consents, these resources are limited. The regulations have always permitted the use of a short form. We have determined that for minimal risk studies the option of a short form should be available to investigators. For protocols that carry greater than minimal risks, the IRB still feels it is essential that families receive a fully translated document.

What is a short form?

A short form is a brief document that attests that the elements of consent have been presented orally. It does not contain study specific information and is available in several different languages. In order to approve the use of a short form, the IRB must also approve a summary of what will be orally presented to the families. The IRB has agreed that the English version of the full consent document will serve as this summary and that information in the written English consent will be presented orally to the potential subject and family.

When can a short form be used?

- 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.
- 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)

When can a short form NOT be used?

- 1) For greater than minimal risk research where there is no potential for benefit or
- 2) For greater than minimal risk research, the research has potential for benefit that is not available outside the context of the research and there is sufficient time to obtain a translated version of the consent

In these cases, translation of the entire English version of the consent is required.

How will I know if my protocol qualifies as minimal risk and is thus eligible to use the short form?

Protocols submitted to the IRB from this point forward will have wording included in the approval letter indicating whether or not a short form may be used.

For existing protocols, please consult your original protocol approval letter to determine the IRB designated risk category. If you have any questions about the current risk category based on previous amendment submissions, please call or email the office to determine protocol eligibility.

What languages have short forms?

At the current time, the short form is available in the following languages:

- Albanian
- Arabic
- Chinese
- French
- Haitian Creole
- Portuguese
- Spanish
- Vietnamese

What if my protocol qualifies for use of a short form and I need a translated short form for a language that is not available on the CCI website?

In this situation, please call the IRB office. If possible we will try to arrange to have the English short form translated into the appropriate language, especially if we are receiving multiple requests for the same language. However, it may not be feasible to have the short form prepared in a new language in a timely manner.

Where do I find the short forms?

Short forms in 8 different languages will be posted on the Clinical Investigations website under the section "Information for Investigators " and then "Informed Consent".

Are there any special requirements when I use a short form?

All of the following requirements (1, 2, 3 and 4) must be completed when using a short form:

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);
4. The subject/family 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.

How and When is Interpreter Services needed?

Interpreter services are needed to provide an oral presentation of the consent to the subject. It is important that Interpreter Services be provided with as much advance notice as possible so they can accommodate the request and be available for you

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

Who can provide an oral presentation of the English consent form to the subject?

The Committee on Clinical Investigation requires that the interpreter comes from the pool of experienced interpreters available through Interpreter Services whenever possible. Only in very exceptional circumstances will the IRB allow other individuals to serve in this capacity. Approval to use someone outside of Interpreter Services needs to be granted on a case by case basis by the IRB and only after consultation with Interpreter Services. It is important that Interpreter Services be provided with as much advance notice as possible so they can accommodate the request.

Do I need a witness when I use the short form?

As mentioned above a witness is required when a short form is used. 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

Can the witness be a parent or family member?

The witness must be someone who understands English and the respective language fluently. When an interpreter is required the interpreter can serve this role. Only in exceptional circumstances should other individuals to serve in this capacity, during which the CCI should be consulted.

What if I have a non-English speaking patient eligible for a more than minimal risk study, enrollment is time-sensitive and there is no time to translate the consent?

We will handle these requests on a case-by-case basis, therefore please call our office should this situation arise. It is possible we will allow the use of an interpreter, if the protocol offers potential for direct benefit and there are no alternatives for the subject. In these cases we may also arrange to have the written consent translated at a later date.

Signatures:

If I use the short form,

What does the patient/parent/legally authorized representative sign?

The short form only

What does the Principal Investigator sign?

The English version of the consent form and the short form

What does the witness sign?

The English version of the consent form and the short form

What forms do I give the subject/family?

The subject/family must be given copies of both the approved English version of the consent form and the translated version of the "short form" consent document

It seems that involvement of a non-English speaker in research where there is no consent translation is too complicated, should I just exclude them from my research?

No, Excluding individuals on the basis of not speaking English is not ethically justifiable. This violates the Belmont principle of justice, which assures equitable subject selection in research.

Is there anything I need to think about after obtaining consent with the use of a short form?

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

Please feel free to contact the Clinical Investigation office at 57052 with questions or for information at any time.