

OBTAINING AND DOCUMENTING INFORMED CONSENT OF NON-ENGLISH SPEAKING SUBJECTS

FREQUENTLY ASKED QUESTIONS

When must a written translation of the entire English version of the consent form be used to obtain and document informed consent?

When investigators can reasonably expect that more than an incidental number of subjects speaking the same non-English language will be enrolled (for example, if the research is targeting a non-English speaking group), the use of a written translation of the entire English version of the consent form is required. Investigators are also generally expected to use a written translation of the entire English version of the consent form for research that involves more than minimal risk and no direct medical benefit to subjects.

Is an interpreter required for the consent discussion when a written translation of the entire English consent form is used?

Yes. Because the consent process involves more than simply reading the consent form, an interpreter must be in attendance, either physically or by phone or video conference (see next FAQ) so that the subject can ask and receive answers to any questions they might have about the research.

When a medical interpreter is used in conjunction with the translated version of the English version of the consent form, can the medical interpreter participate by phone or videoconference?

Yes. The medical interpreter may participate by phone or videoconference because they are not required to sign the consent form. However, participation of the medical interpreter by phone or videoconference should be documented in the translated consent document and a clinic chart/progress note/other source document. The investigator should be sure that the connection is clear and that technical problems do not interfere with the consent discussion.

When informed consent is obtained using the 'short form' written consent document, can the medical interpreter interpret by phone or videoconference?

No. In order to fulfill the regulatory requirements for documentation of informed consent using the 'short form' written consent document, the medical interpreter must be able to sign the English version of the consent form and the 'short form' written consent document in the subject's language.

How do I get research consent forms and other study-related documents translated into other languages?

Interpreter Services has provided a list of resources which can be found on the PHRC website:

http://intranet.massgeneral.org/phrc/translation_resources.htm (PHS internal only link).

Interpreter Services can also serve as a liaison with approved outside vendors who have agreed to be contacted for translation services. Prices vary. Funds to pay for translation of research consent forms and other study documents should be built into your research proposal budgets.

When can the 'short form' written consent document be used to obtain and document informed consent of a subject who does not speak English?

A translated version of a 'short form' written consent document can be used to document informed consent when a non-English speaking individual is unexpectedly encountered and a written translation of the entire PHRC-approved consent form is not available. The 'short form' written consent document should generally only be used when the research involves no more than minimal risk to subjects or, if the research involves more than minimal risk, presents the prospect of direct medical benefit to individual subjects.

Can a family member serve as the interpreter when using the 'short form' written consent document or the translated version of the entire English consent form?

Generally, no. Family members may not be impartial and are not professionally trained medical interpreters. Family members may not have knowledge of medical terminology or the confidence to

ask for clarification, and subjects may not feel comfortable revealing certain sensitive personal or medical information through family members. Also, rather than interpret, family members often tend to speak for the subject, removing the subject from the decision-making process. Consequently, misunderstandings may inadvertently occur. Professional, trained medical interpreters should perform this important task.

Can study staff members who are bilingual serve as the interpreter?

Generally, no. The interpreter must be impartial and be independent of the study. However, an independent bilingual member of the clinical staff may act as the interpreter when a medical interpreter from Interpreter Services is not available and the consent discussion cannot be rescheduled.

Can a bilingual investigator* obtain informed consent using the 'short form' written consent document or a translated version of the entire English consent form?

Yes. When the investigator is truly fluent in the language understood by the subject AND English, s/he may obtain informed consent. Consideration should be given to how the investigator acquired his/her language skills; for example, did s/he receive medical training in that language. When a bilingual investigator obtains informed consent using the 'short form' written consent document, there must ALSO be an independent witness to the presentation who is fluent in English and the language understood by the subject. Whenever the investigator obtains informed consent in another language, this should be appropriately documented in the study records. *Note: Investigator refers to a member of the study staff approved by the PHRC to obtain informed consent.

Why does the PHRC (IRB) require that investigators use a medical interpreter from the hospitals' Interpreter Services?

The medical interpreters available through Interpreter Services are qualified by training and experience to interpret oral presentations of medical information to patients in clinical settings. Medical interpreters are tested and trained on the following:

- Oral and written fluency in English and at least one other language
- Interpreting skills and cultural competencies
- Medical terminology
- National Standards of Practice for Medical Interpreters
- National Interpreters' Code of Ethics
- Department and Hospital Policies and Procedures
- HIPAA

Does the PHRC (IRB) ever grant an exception to the requirement to use a medical interpreter from Interpreter Services?

Yes. The PHRC will consider exceptions on a case-by-case basis. Investigators desiring an exception must submit a formal request for approval of a protocol exception.

How do I request a medical interpreter?

To schedule a medical interpreter in advance, call (617) 726-6966 (MGH) / (617)732-6639 (BWH), identify the appointment as being for research and have the following information ready:

- Subject's medical record number
- Date, time and location of appointment
- Expected length of appointment
- Cost center (fund#) number for interpreter charges
- Contact or beeper number for coordination

Are the services of medical interpreters available 24/7?

Yes. Contact information is available on the Interpreter Services website.

BWH Interpreter Services at 617-732-6639

http://www.bwhpikenotes.org/Patient_Family_Care/Patient_Care_Services/Interpreter_Services/Contacts.aspx (PHS internal only link)

MGH Interpreter Services at 617-726-6966 or mghinterpreters@partners.org

<http://www2.massgeneral.org/interpreters/index.asp> (PHS internal only link)

What does it cost to use a medical interpreter?

Currently (January 2010) face-to-face interpretation costs approximately \$30/hr with a 2-hour minimum.

Will the hospital or the IRB cover the cost of using medical interpreter services or obtaining written translations of study documents?

No. Your study fund will be billed for this service. The IRB cannot pay for this. Build these funds into your research proposal budgets in future. Consider asking your sponsor for additional funds to cover this important service, which is necessary to enroll subjects from among the diverse populations we see at our hospitals.

In the 'short form' consent process, will the medical interpreter perform a sight translation of the English version of the consent form?

No. The investigator is responsible for presenting the information in the English version of the consent form orally to the subject. The interpreter will interpret the investigator's presentation. The investigator should direct his/her presentation to the subject, not to the interpreter.

In the 'short form' consent process, must the investigator present the entire English version of the consent form to the subject?

Yes. The investigator must present all of the information in the English version of the consent form. Investigators should present the information in simple lay terms (not "medicalese") and should encourage questions from subjects and family members.

Should the use of a medical interpreter/bilingual investigator during the consent process be documented anywhere in addition to the signed consent documents?

Yes. To further document and facilitate clarification of any future questions regarding the consenting process, the investigator should include the following information in a clinic chart/progress note/other source document:

- that **XX** study was presented orally to the subject in specify language through a medical interpreter OR by me because I am fluent in specify language and English;
- the subject's questions were answered (if any);
- subject agreed to participate and signed the 'short form' written consent document;
- a copy of the English version of the consent form signed by the investigator and interpreter/witness was given to the subject; AND
- a copy of the 'short form' written consent document signed by the subject and the interpreter/witness was given to subject.

This note should be signed and dated by the person obtaining consent.

When the 'short form' written consent document is used to obtain informed consent, which consent document does the subject sign?

The subject signs the 'short form' written consent document.

When the 'short form' written consent document is used to obtain informed consent, which consent document does the investigator obtaining informed consent sign?

The investigator obtaining informed consent signs the English version of the consent form.

When the 'short form' written consent document is used to obtain informed consent, which consent documents are signed by the medical interpreter or the witness fluent in both English and the language understood by the subject?

The medical interpreter signs the statement specific to medical interpreters in the English version of the consent form AND the interpreter line in the 'short form' written consent document. When a bilingual investigator obtains informed consent, the witness fluent in both English and the language understood by the subject signs the non-interpreter witness statement in the English version of the consent form AND the non-interpreter witness line in the 'short form' written consent document.

When the 'short form' written consent document is used to obtain informed consent, copies of which of the signed consent documents are given to subjects?

The subject must be given signed copies of BOTH the PHRC-approved English version of the consent form AND the written translation of the 'short form' consent document.

When the ‘short form’ written consent document is used to obtain informed consent, which of the original signed consent documents are retained in the subject’s research records?

The original signed English version of the consent form WITH the original signed written translation of the ‘short form’ document attached should be placed in the subject’s research record.

When informed consent is obtained by a bilingual investigator using the ‘short form’ consent document, should the bilingual investigator sign the ‘short form’ written consent document?

No. The investigator should sign the English version of the consent form and the witness should sign the ‘short form’ written consent document AND the English version of the consent form.

When the entire English version of the consent form is translated into the language understood by the subject, do both the subject and investigator sign the translated consent form?

Yes. The translated consent form must be signed by both the subject AND investigator obtaining informed consent. A witness signature is not required; however, a medical interpreter must be available to interpret the consent discussion / questions and answers about the research. Participation by the medical interpreter in the consent process should be documented in the translated consent document and a clinic chart/progress note/other source document.

Can informed consent be obtained from a non-English speaking subject if there is a medical interpreter present BUT there is no ‘short form’ written consent document translated into the language understood by the subject on the PHRC website?

No. In order to obtain and document informed consent of subjects who do not speak English, you must have a ‘short form’ written consent document in the subject’s language. The ‘short form’ explains that informed consent is being obtained for research and that the basic and, when applicable, addition elements of informed consent will be described to them orally and that their participation is voluntary. The PHRC will have the ‘short form’ written consent document translated in additional languages upon request. Timeframe for completion of the translation will vary depending upon available resources. Available ‘short form’ written consent documents can be found on the PHRC website: <http://healthcare.partners.org/phsirb/nonengco.htm#BulletIII>.

Can a family member who speaks English provide informed consent for a non-English speaking subject who is legally competent to give informed consent to participate in research?

No. When a subject is legally competent to give informed consent to participate in research, s/he must give his/her own consent.

Can the Medical Interpreter Waiver Form (for informed consent discussions) ever be used for research?

No. The Medical Interpreter Waiver form can only be used for informed consent discussions for clinical care, not for research.

Must a medical interpreter be used for study visits or follow-up phone calls?

Yes. You will need to enlist the services of medical interpreters in these settings. When you think about enrolling someone who does not speak English, consider carefully whether you can accomplish this throughout the study. On occasion, safety issues may preclude enrolling non-English speakers.

Must study questionnaires/instruments, information sheets, and other study documents be translated into the subject’s language?

Generally, yes. Investigators are expected to provide subjects with a written translation of all study documents that are given to subjects to ensure that they can follow study directions and participate safely in the study.