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OBTAINING AND DOCUMENTING INFORMED CONSENT OF SUBJECTS WHO DO NOT SPEAK ENGLISH

The Department of Health and Human Services (DHHS) regulations (45 CFR 46.116 and 45 CFR 46.117) and Food and 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 using signed consent forms. Given the diversity of patients seen in our hospitals, investigators may encounter a non-English speaking patient who is interested in participating in a research study. When presented with this situation, investigators should carefully consider the ethical and legal ramifications of enrolling a subject when there is a language barrier. It is neither ethically justifiable to exclude potential subjects in a research study solely on the basis of language spoken nor ethically justifiable to obtain consent of subjects who do not have a clear understanding of the consent document or who do not have the opportunity to freely ask and receive answers to their questions. Without this understanding and opportunity, consent may not be truly informed and may not be legally effective. In order to address these considerations, when enrolling subjects who do not speak English in research, the subject must be provided with **BOTH**:

- a written consent document in a language understandable to them, AND
- a-qualified interpreter fluent in both English and the subject's spoken language

Depending upon the research, the *written* consent document can be either:

- a written translation, in the subject's language, of the entire English version of the consent form approved by the Mass General Brigham IRB Office, OR
- a written translation of the so-called 'short form' consent document

A translated consent form should be used when enrollment of non-English speaking subjects is anticipated or planned. A short form written consent document may be used for incidental and unexpectedly encountered non-English speaking potential subjects. The 'short form' should generally only be used when the research involves no more than minimal risk to subjects or, if more than minimal risk, presents the prospect of direct benefit to individual subjects.

USE OF A WRITTEN TRANSLATION OF THE ENTIRE ENGLISH VERSION OF THE MASS GENERAL BRIGHAM IRB-APPROVED CONSENT DOCUMENT (LONG METHOD)

. When investigators can reasonably expect that more than an incidental number of subjects speaking the same non-English language will be enrolled (), the use of a written translation of the *entire* English version of the consent form is required. The Mass General Brigham IRB must approve all written translated versions of the consent form and recommends that the written translation be done by an in-house medical interpreter from Interpreter Services or other qualified person or service recommended by Interpreter Services. Investigators must also arrange for a medical interpreter fluent in both English and the subject's spoken language to be present, or available by phone or videoconference, during the consent process. The IRB may approve exceptions as described in the Use of Interpreters section below.

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USE OF A WRITTEN TRANSLATION OF THE 'SHORT FORM' CONSENT DOCUMENT

The request to use short forms to enroll non-English speaking subjects must be reviewed and approved by the IRB. Although it is always preferable, and in some cases required by the Mass General Brigham IRB, to use a written translation of the *entire* Mass General Brigham IRB-approved English version of the consent form (see above), a translated version of a 'short form' consent document can be used to document informed consent when a non-English speaking individual is unexpectedly encountered and a written translation of the Mass General Brigham IRB-approved consent form is not available. The 'short form' 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 benefit to individual subjects. The 'short form' attests that the elements of consent have been presented orally. When the 'short form' is used to document informed consent, the consent process must include the text of the English version of the consent form presented orally in a language understandable to the potential subject. A medical interpreter must be present either physically, by phone or videoconference to interpret, in the subject's language, the researcher's oral presentation of the English version of the consent form.

The short form consent document has been pre-translated in multiple languages and made available to the research community by the IRB. These documents are located on Research Navigator. If the study team encounters a non-English speaker who speaks a language into which the short form has not been translated, contact the IRB (partnersirb@partners.org).

The consent process for enrolling subjects using the 'short form' consent document is outlined below. **ALL** of the following requirements must be completed:

1. The Principal Investigator (or other member of the study staff with PI-delegated and IRB approved responsibility for obtaining informed consent) must present the Mass General Brigham IRB-approved *English version of the consent form* orally to the subject through a medical interpreter and fluent in English and the language understandable to the subject;
2. The subject must be given a written translation of the *'short form'* consent document in the language understandable to him/her to read and must have the opportunity to ask and receive answers to questions;
3. The entire consent process must be witnessed by an individual who is fluent in English. The witness attests that the information in the consent form was presented to the subject and the subject was given the opportunity to ask questions. The interpreter may serve as the witness to the consent process, if they are willing to do so.
4. The witness must be independent of the study team and cannot be a family member of the subject.
5. The Mass General Brigham IRB-approved *English version of the consent form* must be signed by the investigator obtaining informed consent **and** the witness to the consent process (see 3 above);
6. The written translation of the *'short form'* must be signed by the subject **and** the witness to the consent process (see 3 above).

DOCUMENTATION OF LONG METHOD AND SHORT FORM:

1. The consent process should be documented in the study records and the subject's medical record, if the information is relevant to their medical care. Information about who was present (in-person/remote), and whether subject had questions and time to consider participation should be included.
2. If informed consent takes place remotely, there must be a process in place to obtain signatures from the appropriate parties and the procedure documented in the protocol.
3. Long Method: The subject must be given a signed copy of the translated consent form. The consent document should be placed in the subject's research record.
4. Short Form: The subject must be given signed copies of **both** the English version of the consent form **and** the short form consent document. 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.
5. The consent documents should be placed in the subject's medical record, if the information is relevant to their medical care.
6. The research record should document the use of an interpreter.
7. The following signatures are required:

Long Method

Involved Parties	Signature Required
Subject	Translated Consent Form
Person obtaining consent	Translated Consent Form

Short Form

Involved Parties	Signature Required
Subject	Short Form
Person obtaining consent	English Consent Form
Witness	Short Form and English Consent Form
Interpreter	None (unless the Interpreter serves as witness)

OPTIONAL PROCEDURES

A short form consent document cannot be used to obtain informed consent for optional research procedures. A fully translated consent form in the subject's native language must be submitted to the IRB for review if participant consent for optional procedures is needed. If there is insufficient time to translate the consent form, study teams cannot obtain consent for optional procedure using the short form. In this case, study teams should document in the study records that optional procedures were not presented to subjects. Once the study team has had the opportunity to translate the consent form, they may go back and obtain consent for optional procedures from participants.

AFTER INITIAL CONSENT

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. Research teams are expected to include an appropriate interpreter for subsequent study visits to ensure that subjects have an opportunity to ask questions and receive relevant study information.

USE OF INTERPRETERS

For both written translation and short form use, the IRB requires that the interpreter come from the pool of experienced medical interpreters available through Interpreter Services. The IRB will consider approving an exception to the requirement to use an interpreter from Interpreter Services on a case-by-case basis.

If the Principal Investigator or a member of the research team with a medical background is a native fluent speaker of the participant's language and their qualification to interpret is described in the protocol and approved by the IRB, they may serve as the interpreter.

For minimal risk studies, a study staff member or healthcare professional may serve as the interpreter. If you would like to use this option, provide a description (in the "Informed Consent" section of the Detailed Protocol or Site Addendum attachment) of the individual and their credentials which make them an appropriate person to provide this translation.

USE OF TRANSLATOR SERVICES

Individuals who translate study documents must be qualified to perform the translation. A translator's attestation of accuracy should be submitted in Insight.

For more than minimal or minimal risk studies that are a) FDA regulated, b) industry-funded, or c) involve multiple sites, the written translation may be done by a translator from MGB Interpreter Services or other qualified person or service. Documentation of certified translation, such as the certificate or similar indication of translation certification must be included with the translated documents when submitting to the IRB for review and approval. More than minimal risk studies involving a single site must follow the above process.

For single site minimal risk studies that are not FDA regulated or industry funded, written translations may be performed by an individual considered by the Principal Investigator to be qualified to perform the translation. The qualifications of the translator must be described and presented to the IRB (e.g., native speaker, certificate of translation, training and/or experience in medical translation). The IRB will assess whether the translator's background is appropriate based on the study risks and complexities of study procedures.

Minor changes to IRB approved translated consent form may be made by bilingual coinvestigators for minimal risk studies with prospective IRB approval. These changes may include minor corrections to the consent form, advertisements, data collection forms, recruitment letters or other study documents. The IRB

Chair or designee will determine whether the changes qualify as minor or major modifications. The qualifications of these individuals must be described to the IRB.

The IRB may use its discretion and allow other bilingual study staff to translate approved study documents.

TRANSLATED STUDY DOCUMENTS

All documents that will be used with participants must be translated. These may include:

- Verbal consent scripts
- Written informed consent documents
- Assent forms
- Information sheets
- Recruitment materials
- Surveys/questionnaires/interview guides
- Instructional materials
- Other documents as requested at the discretion of the IRB

In the interest of efficiency, it is recommended that the foreign language translations be submitted to the IRB by amendment after initial approval of the English versions.

MINIMAL RISK STUDIES WITH AN INFORMATION SHEET

The IRB can request a translation of the English Information sheet if the study team expects to enroll individuals who do not speak English. If there are limitations to obtaining a translation, the reasons should be documented in the protocol. The Principal Investigator (or other member of the study staff with PI-delegated responsibility for obtaining informed consent) must present the Information Sheet orally to the subject through an interpreter fluent in English and the language understandable to the subject. This process should be described in the protocol. Study teams should document all the relevant circumstances surrounding the consent process in the subject's study records. Refer to the Use of Interpreters and Use of Translator Services above.

STUDIES CONDUCTED AT NON-US SITES WHERE MGB IS ENGAGED IN THE RESEARCH

Foreign language consent documents which are approved by the local ethics committee should be submitted to the MGB IRB along with an English translated copy.

FREQUENTLY ASKED QUESTIONS

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 a documentation of informed consent process checklist/clinic chart/progress note/ or 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?

Yes. A medical interpreter must be present either physically or by phone or videoconference to interpret, in the subject's language, the researcher's oral presentation of the English version of the consent form.

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?

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.

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 Research Navigator: https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Translation-Resources.pdf (Mass General Brigham 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 research proposal budgets.

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, with prior IRB approval. When the investigator is truly fluent in the language understood by the subject AND English, they may obtain informed consent with prior IRB approval. Consideration should be given to how the investigator acquired their language skills; for example, did they receive medical training in that language. When a bilingual investigator obtains

informed consent using the 'short form' written consent document, there must be an independent witness to the presentation who is fluent in English. 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 Mass General Brigham IRB to obtain informed consent for a particular study.

Why does the Mass General Brigham 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

Researchers could also use medical interpreter services coordinated by the hospitals' Interpreter Services (e.g., use of Interpreter Phone on a Pole or IPOP).

Does the Mass General Brigham IRB ever grant an exception to the requirement to use a medical interpreter from Interpreter Services?

Yes. The Mass General Brigham IRB 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?

Please contact Interpreter Services at your hospital to request a medical interpreter.

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 their 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 'short form' consent process be documented?

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 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 subject records or clinic chart/progress note/other source document as applicable.

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 Mass General Brigham IRB 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, when applicable, addition elements of informed consent will be described to them orally and that their participation is voluntary. The Mass General Brigham IRB 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 Research Navigator: https://partnershealthcare.sharepoint.com/sites/phrmApply/aieipa/irb/Pages/Non-English-Consent.aspx#Short Forms

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, they must give their 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?

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. Submit translator's attestation of accuracy as an "Other" attachment in Insight.