Yale University Institutional Review Boards

200 GD.2 Guidance on Inclusion of Non-English Speaking Participants in Human Research

Overview

Participants who are not fluent in spoken or written English are included in research studies (a) to ensure that the burdens and benefits of research are justly distributed or (b) because the area of research necessitates involving non-English speaking participants, for example, international studies. Federal regulations (45 CFR §46.116; 21 CFR 50.20) require that the information that is given to the subject or the representative shall be in language understandable to the subject or the representative. Ensuring this is the responsibility of the Principal Investigator/research team.

If an investigator is not fluent in a potential subject's language, an interpreter should be available ***both*** during the consent process and during the subject's participation in the research study as needed. A family member of a potential subject should **not** be used as the interpreter for that individual because he or she may have a conflicting interest relating to the study and may not be able to fully explain the study's risks, benefits and procedures to the potential subject.

Investigators must take care to ensure that non-English speaking participants fully understand their role in the study, provide voluntary informed consent, ***and have interpreter services available throughout their participation in the study to ensure the subject's continued understanding of study participation and his/her ongoing consent. This requires the use of an interpreter, either a bilingual staff person who has been approved as an interpreter, or a professional interpreter.***

This document provides guidance for investigators who wish to enroll non-English speaking participants. Providing research services to non-English speaking subjects may require the use of

- translators (those who create written documents)

  and/or

- interpreters (those to facilitate oral discussion).

Translation of Documents

Any written documents to be used with individuals who do not read English should be translated to a language understandable to the participant.

- ***IRB approval of the English language version of the consent document must be obtained before translation.***
- ***The translated consent or compound authorization document must be approved by the IRB before use with participants.***
- ***The IRB may require a back translation of the document.***
- ***If a fully translated consent/compound authorization document will not be used, the short form consent may be used in combination with the full consent or compound authorization document.***
- ***Short forms for use in studies under review by the NCI CIRB must be approved by the NCI CIRB and must be submitted for approval with a translator's certification.***

Some key points:

- On-line translation programs offering instant translation are generally not accurate or appropriate for research-related documents. Translations should be performed by a translator who has adequate understanding of the purpose of the document and the technical points to be covered in the documents. Certified professional translators, available through online search, provide language expertise.
- "Textbook" translations may not be readily understandable to participants. Materials should be translated into the appropriate dialect for the participant population.
- Talk to the translator. It is very important that the translator understand what the document will be used for. Also, in their careful reading of the text, the translator may find areas they have questions about.
- Let the translator proofread the typeset copy before printing.
- A professional translator translates into their primary language or has the material proofread by a native speaker, works with a proofreader, has specific training in translation, has experience both in translating and in the subject

area addressed by the document, and can provide you a sample of their work. All translators listed in the Appendix meet these criteria.

Use of Interpreters

Non-English-speaking research subjects must be afforded the opportunity to engage in discussion with an individual fluent in their native language in order to provide fully informed and ongoing consent to participate.

Ask the interpreter to communicate their concerns about the capacity of the subject to understand the information.

Assess the appropriateness of the questions and the level of exchange between the interpreter and the subject to help evaluate subject's understanding, based on the responses of the participant.

Ask the interpreter directly if there are any areas of particular concern, to identify cultural variations relevant to the research.

For studies involving Yale New Haven Hospital patients, interpreter services that may be used include the Yale New Haven Hospital Interpreter Service, hired interpreters approved by Yale New Haven Hospital Interpreter Services, or use of telephone interpretation services. Study personnel who are fluent in the language of the subject may conduct research conversations with the participant once they have been approved by Yale New Haven Hospital Interpreter Services. They do not serve as interpreters because they are not interpreting third party communication.

Yale-New Haven Hospital Interpreter Service

Yale-New Haven Hospital Interpreter Services is cost-free to the hospital research community provided that the study has a treatment component and that the principal investigator has either a Yale IRB-approved protocol and translated consent form, or has an IRB-approved short form translated consent document that indicates that a summary of the research will be orally presented in a language that the subject understands. In addition, the research team must have a contractual agreement with YNHH Interpreter Services to provide this service.

The Yale-New Haven Hospital Interpreter Service **does not** provide translation of consent forms. The PI may call the Service for a hospital interpreter to be present to assist in the consent process by providing interpretation of information being transmitted by the researcher as he/she reviews the consent form information with the subject, and to interpret questions from the subject related to the study in the subject's own language.

The consent process must always be conducted by a member of the research team.

Interpretation services should be scheduled in advance, which the PI may do by calling 203-688-7523. On most day and early evening shifts, there are interpreters scheduled to be on-duty, but they are mainly present for clinical and emergency patients. Therefore, it is advisable to schedule interpreters in advance, given that it takes time for the process to occur. The interpreters are stationed primarily within the hospital proper and adjacent clinics.

Hiring Interpreters for Study Interviews

If the investigator and participant are not fluent in the same language, an interpreter may be needed to facilitate communication related to interviews, focus groups or other verbal interactions with participants. The investigator should consider the following when selecting an appropriate interpreter:

- Relationship of the interpreter to the interviewee or to community. Selecting an interpreter from the community in which the interviews will take place may limit the confidentiality which can be promised to the participant and may inhibit a participant from speaking freely, limiting the integrity of the data. For confidential interviews, it is recommended that an interpreter from outside the community be used. In some cases, an area university may have students willing to serve as interpreters.(Note: YNHH Interpreter Services does not encourage use of interpreters from the community as they may not adhere to professional codes of conduct and may compromise PHI.)
- People serving as interpreters for subjects in research studies at Yale New Haven Hospital (YNHH) must be approved by YNHH Interpreter Services.
- For confidential interviews, the interpreter must be willing to maintain the confidentiality of the information provided by the participant and community interpreters should be asked to sign a confidentiality agreement.
- The sensitivity of the data may necessitate that an interpreter cannot be used. For example collection of data of

interest to factions in violent conflicts may make it difficult to ensure the confidentiality of information provided through an interpreter.

Telephone Interpreter Services

Telephone interpreter services are available through Yale New Haven Hospital Interpreter Services for those studies that qualify (as noted above). Except in an emergency, telephone interpretation is not intended for use for the consent process.

Commercial telephone interpreter services are available. See Appendix B for reference.

IRB Review and Documentation

Short Form Consent

Per federal regulation, a short form written consent document stating that the elements of informed consent required by 45 CFR § 46.116 have been presented orally to the subject or the subject's legally authorized representative may be used when a non-English speaking subject wishes to enter into a research study and the full consent document is not translated.

When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. The English Language version of the IRB approved informed consent or compound authorization may serve as the summary. The short form must also be approved by the IRB. Short forms available on the HRPP website do not need to be submitted for IRB review and approval. However, short forms translated into languages that are not listed on the HRPP website must be submitted to the IRB office via an amendment for acknowledgment prior to their use. In all cases, a possible inclusion of non-English speaking participants in research and the use of a short form must be described in the protocol application and approved by the IRB.

For studies that invoke HIPAA, where a compound authorization is used, the short form includes language indicating that HIPAA requirements have been included in the oral presentation. The short form may also be used in concert with a HIPAA Research Authorization Form (RAF) written in the language of the subject and acknowledged by the IRB. Translated HIPAA RAFs available on the HRPP website do not need to be submitted for IRB acknowledgment. In instances in which a translated RAF is not available, the IRB staff will make a determination to waive the requirement for written authorization.

Only the short form itself is to be signed by the subject or the representative (and, if applicable, the translated HIPAA RAF). However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A family member fluent in both languages may serve as witness, but may not serve as interpreter. The interpreter may serve as witness.

A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

Limitation on the Use of the Short form for consenting purposes:

If more than 2 study participants are enrolled using a short form translated into the same language, then the full consent form should be translated into that language for use the next time a subject speaking that language is to be enrolled.

	Subject (and/or his/her LAR)	**Interpreter**	**Witness** *The Interpreter may serve as Witness*	**Researcher**
Signs	**Translated Consent Document or Short Form** HIPAA Research Authorization Form (if used instead of a compound consent/authorization form)	**Nothing** Note: the use of interpreter should be documented in the study file; e.g. consent checklist	**The short form and the *full* consent document**	**The *full* consent document**
Receives	**A copy of the translated form (may be the short form)** **A copy of the full consent form (even if in English)**	**Nothing**	**Nothing**	**Both forms to be kept on file (signed short form and summary/full consent form)**

Federal Guidance

Per the Office of Human Research Protections (OHRP) regulations 45 CFR § 46.116, § 46.117

- Informed consent must be conducted with the researcher and an interpreter fluent in both English and the language of the subject.
- The subject signs a "short form" consent written in the subject's language
- The researcher signs the written summary (may use the English language consent form)
- The witness (person fluent in both languages) signs the short form and the written summary/informed consent document
- The subject receives both the signed short form and the written summary/informed consent document
- Copies of both forms are maintained in the research file

Per the Food and Drug Administration (FDA)

To meet the requirements of 21 CFR 50.20, the informed consent document should be in language understandable to the subject (or authorized representative). When the consent interview is conducted in English, the consent document should be in English. When the study subject population includes non-English speaking people or the clinical investigator or the IRB anticipates that the consent interviews will be conducted in a language other than English, the IRB should require a translated consent document to be prepared and assure that the translation is accurate. As required by 21 CFR 50.27, a copy of the consent document must be given to each subject. In the case of non-English speaking subjects, this would be the translated document. While a translator may be helpful in facilitating conversation with a non-English speaking subject, routine ad hoc translation of the consent document should not be substituted for a written translation.

If a non-English speaking subject is unexpectedly encountered, investigators will not have a written translation of the

consent document and must rely on oral translation. Investigators should carefully consider the ethical/legal ramifications of enrolling subjects when a language barrier exists. If the subject does not clearly understand the information presented, the subject's consent will not truly be informed and may not be legally effective. If investigators enroll subjects without an IRB approved written translation, a "short form" written consent document, in a language the subject understands, should be used to document that the elements of informed consent required by 21 CFR 50.25 were presented orally. The required signatures on a short form are stated in 21 CFR 50.27(b)(2): A short form written consent document stating that the elements of informed consent required by 50.25 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining the consent shall sign a copy of the summary. A copy of the summary shall be given to the subject of the representative in addition to a copy of the short form.

Appendix A

Yale-New Haven Hospital Recommended Translation Resources (as of April 2014)

1. Accents Perfect Translation & The Language Link of Connecticut http://www.aptranslation.com/
Email: languagelink@cox.net
354 Main St, Ste 8, Newington
860-561-5438

Languages: Multiple (Specializing in Spanish, French, Portuguese, German, Japanese, Russian and Chinese)
Certified and non-certified translation available

2. ABC Language Services
Email: info@abclanguageservices.com
http://www.abclanguageservices.com/
1880 Silas Deane Hwy, Suite 202
Rocky Hill
860-883-1012
Languages: Multiple: (Specializing in rare languages)

3. Eduardo H. Berinstein
www.ebtranslations.com
Email: eduardo@ebtranslations.com
Phone: (617) 734-9515 or (617) 632-6961
Languages: Spanish, Portuguese, Cape Verdean, French, Haitian Creole, Russian, Chinese,Vietnamese
ATA Certified English > Spanish

4. Lingua Tech International
Email: linguaint@aol.com
Phone: 937-832-3186
Languages: Multiple (Asian, European)

5. Interpreters and Translators Inc.
www.ititranslates.com
Email: info@ititranslates.com
Phone: 800-648-0686
Languages: Multiple (Asian, European)

Yale Approved Vendor, Transcription and Translation:

Verbal Link Transcription Services
2901 Ocean Park Blvd., Ste. 215

Santa Monica, CA 90405
Tel: (877) 267-0990
www.verbalink.com

A guide to selecting translation services can be found at the American Translators Association web site at http://atanet.org/

Appendix B

Telephone Translation Services

http://www.languageline.com/
http://www.certifiedlanguages.com/
http://www.ctslanguagelink.com/opi.php

References:

Department of Health and Human Services, Policy Guidance; Informed Consent – Non English Speakers, http://www.hhs.gov/ohrp/policy/ic-non-e.html
Food and Drug Administration, Guide to Informed Consent, http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm

Revision History

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