

---

# Yale University Institutional Review Boards Guidance

---

## 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 to ensure that the burdens and benefits of research are justly distributed or because the areas of research necessitates involving non-English speaking participants, for example international studies. Irrespective of the reason, investigators must take care to ensure that the non-English speaking participants fully understand their role in the study and provide voluntary informed consent. This document provides guidance for investigators who wish to enroll non-English speaking participants.

---

#### 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. A list of Spanish translators is appended below.

Some key points:

- On-line translation programs are not always 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.
- “Textbook” translations may not be readily understandable to participants. Translations should be into the appropriate dialect for the participant population.
- Read the original document carefully to eliminate repetitious material or text that does not need to be translated. Finalize the original before having it translated.
- 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 proof read 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 proof reader, 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

Ideally, the research team will include individuals fluent in the language spoken by potential participants. If, however, an investigator is not fluent in a potential subject’s language, an interpreter should be available 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 translator 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 and benefits to the potential subject.

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

## **Yale-New Haven Hospital Interpreter Service**

The Yale-New Haven Hospital Interpreter Service is cost-free to the hospital research community provided that the study has a treatment component and that the principal investigator has a Yale School of Medicine approved protocol and translated consent form. The Yale-New Haven Hospital Interpreter Service does not provide translation of consent forms but can assist in the consent discussion. The PI may call the Service for a hospital translator to be present to translate the consent form verbatim, or to help to answer subject questions in the subject's own language and effectively participate in the consent process. The translation should be scheduled in advance, which the PI may do by calling 688-7523. On most day and early evening shifts, there are translators scheduled to be on-duty, but they are mainly present for clinical and emergency patients. Therefore, it is advisable to schedule translations in advance given that it takes time for the process to occur. The translators 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 conduct 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 translators.
- For confidential interviews, the interpreter must be willing to maintain the confidentiality of the information provided by the participant and should be asked to sign a confidentiality agreement.
- The sensitivity of the data may necessitate that an interpreter can not 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.

## **Appendix A**

Yale-New Haven Hospital Recommended Translation Resources for Spanish (as of June 22, 2006)

1. Laura Gingold                      Languages: Spanish & English  
Email: [laura.gingold.translations@gmail.com](mailto:laura.gingold.translations@gmail.com)  
Phone: 011.54.11.4776.3661  
(Buenos Aires, Argentina. Best to contact via Email)

2. Kimberly Vilar                      Languages: Spanish & English  
Email: [kimvilar@hotmail.com](mailto:kimvilar@hotmail.com)  
Phone: (202) 558-2301

3. Eduardo H. Berinstein              Languages: Spanish & English  
Email: [sayitinspanish@rcn.com](mailto:sayitinspanish@rcn.com)  
ATA Certified English > Spanish  
Phone: (617) 734-9515 or (617) 632-6961

4, Norma Turconi Languages: Spanish & English  
Email: [norma.turconi@gmail.com](mailto:norma.turconi@gmail.com)

5. Hispanicare Languages: Spanish & English  
Website: [www.hispanicare.com](http://www.hispanicare.com)  
Phone: (866) 378-2646

A guide to selecting translation services can be found at the American Translators Associate web site at [www.atanet.org/Getting\\_it\\_right.pdf](http://www.atanet.org/Getting_it_right.pdf).

**References:**

Department of Health and Human Services, *Institutional Review Board Guidebook*, Introduction and Chapter III, [www.hhs.gov/ohrp/irb/irb\\_glossary.htm](http://www.hhs.gov/ohrp/irb/irb_glossary.htm)  
Department of Health and Human Services, Policy Guidance; Informed Consent – Non English Speakers, <http://www.hhs.gov/ohrp/humansubjects/guidance/ic-non-e.htm>