Obtaining and Documenting Informed Consent of Subjects Who Do Not Speak or Read English

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Background:

Federal Regulations require that information given to a subject as part of the consent process be in language understandable to the subject. Documentation of informed consent by use of an IRB-approved written consent signed by the subject or the subject’s legally authorized representative (LAR) is required unless the IRB has determined that the criteria for waiver of written informed consent is met.

If the research will be conducted in a foreign country, please also see the Investigator Guideline on International Research.

1. Q: What are the requirements for obtaining and documenting informed consent of subjects who do not speak or read English?

Research investigators may seek informed consent only under circumstances that provide the prospective subject sufficient opportunity to consider whether or not to participate in a research study and that minimize the possibility of coercion or undue influence. Informed consent information must be presented in a language understandable to the potential subject and should embody all the necessary elements for legally effective informed consent.

If it is likely that the research population will include non-English speaking participants, the IRB-approved informed consent must be translated into the native language of the subject population, with a back-translation of the document, if appropriate (see below). Translations must be performed by a qualified third party, and must be submitted for IRB review following approval of the final version of the English consent document.

If a qualified translator performs the translation of the original English consent into the native language of the subject population, no back-translation is required; otherwise, a back translation will need to be included in your submission to the IRB, even if the researchers are fluent in the native language. The back-translation should be done by a qualified third party, fluent in both English and the native language, but unfamiliar with the nature of the study and its procedures.

If the research is conducted in a foreign country, and involves direct interactions with participants, it is important that the individuals who will be interacting with participants in these studies be fluent in the native language of the subjects, whether it is merely to be ready to answer questions that might arise during the consent phase, or to conduct in-depth interviews. The investigator should explain in the protocol who will be interacting with participants, and again describe their qualifications and experience in that language and culture.

2. Q: Is a translated consent required for studies where the population is unlikely to include non-English-Speaking participants

No. An alternative may include a short form written consent in a language understandable to the subject stating that the elements of informed consent required by the Federal Regulations have been presented orally to the subject or the subject's LAR. When this method is used an individual who is fluent in both
English and the language of the subject must witness the oral presentation. The IRB-approved English-language consent can serve as the written summary of what is to be said to the subject or the LAR. All English and Non-English consent forms, including the short form (See Q3 below), and recruitment materials must be reviewed and approved by the IRB prior to their use.

3. Q: If you are primarily seeking consent from subjects who do speak and read English, but unexpectedly want to enroll someone who does not speak or read English, what is required?

Federal regulations allow the use of a “short form” translated into the subject’s native language. The IRB approved “short form” is available on the IRB website written in Spanish or Hindi. The “short form” is a generic consent form that states general requirements required under the regulations such as, the subject is being asked to participate in research; they can refuse to participate without penalty, contact information for the IRB, etc. Based on an analysis of the population in Gainesville, the IRB has already approved short forms in Spanish and Hindi.

In addition to the use of the “short form”, the study staff must include the following when consenting a non-English speaking study subject:

- **Interpreter:** Have a competent interpreter fluent in English and the subject’s native language.
- **Summary:** the competent interpreter should present an IRB approved written summary of the protocol. The IRB approved Informed Consent form written in English can serve as the written summary.
- **Researcher:** A member of the research team who is approved by the IRB to obtain informed consent should participate in the process, answer questions, and seek informed consent.
- **Witness:** A witness who is fluent in English and the subject’s native language must witness the informed consent discussion. The competent interpreter may serve as the witness.

If the subject gives consent to participate, the following must occur:

- The subject (or LAR) must sign and date the “short form”
- The witness should sign and date (a) the “short form” and (b) the IRB approved Informed Consent written in English
- The person obtaining consent should sign and date the IRB approved Informed Consent written in English
- Give the subject copies of the “short form” and the IRB approved Informed Consent written in English.

We advise that you make a research note to file to document that the above process occurred.

4. Q: What if you need a “short form” for a subject who speaks a language other than Spanish or Hindi?

- You will need to have the “short form” translated by a qualified third party. This should include a back-translation to English to verify the translation is appropriate.
• Obtain IRB approval: the IRB must review and approve this translated document. Submit a minor revision to your study. If this is the only change made the IRB should be able to quickly review and approve the revision.

5. Q. Are there any other consent modifications that may be required?

Yes. In studies conducted in foreign countries, participants may not have access to, or experience with, phones or email, for example; or it may be impracticable to have them phone an international number to contact a supervisor or the IRB office. In such cases, the PI should explain how participants will be provided with appropriate contacts for any questions about the research, or their rights as participants. In some instances, it would be helpful to have a member of the local community act as a liaison in this capacity.

6. Q. What if the population is illiterate?

Particularly in certain international settings, potential participants may be illiterate. Obviously, neither a written informed consent document nor signed documentation of consent makes sense in such cases. Oral consent scripts, with a waiver of documentation of informed consent (i.e. no signed consent) may be proposed under these circumstances.

7. Q. Is a back-translation needed if the consent process is oral?

No, but you should confirm and/or document that the person to be obtaining consent is fluent in both English and the target language.

8. Q. Are there cultural considerations involving informed consent?

Yes. It is not uncommon for expectations and concepts about research to be different among different cultures and communities. This may be especially true among non-English speaking populations in foreign countries. Please see the Investigator Guideline on International Research.

These cultural differences can mean a reluctance to sign any form, which can be seen as a potential threat in cultures where signatures are not the norm for economic or contractual social agreements. It is appropriate in such cases for the researcher to request a waiver of the requirement for signed documentation of consent, and obtain oral consent for participation.

In other cases, consent from a community or tribal leader may be needed in addition to, or potentially as an alternative to, the consent of individual members. Such circumstances should be described clearly in the submission so the IRB can assess the appropriateness of the consent process.

Similarly, participant attributes that may define your target population – or that are disclosed as part of your research – a disorder, disease, ethnic or religious identification, sexual orientation, and the like, may be benign in our culture, but stigmatizing and potentially very harmful in another culture. In such cases, any additional steps that will be undertaken to protect the privacy of individuals or the confidentiality of this information, both during recruitment and in other phases of the research, should be explicitly described.
In general, you should explain in the protocol (or the International Addendum) (a) how you will be able to identify such cross-cultural issues in your work (have you become familiar with the conventions or that culture? Do you have a local collaborator who is sensitive to these kinds of issues?), (b) any potential for such problems in your project, and (c) the steps that will be taken to minimize any additional risks that these may create.

For social and behavioral sciences research, a helpful resource for thinking about these kinds of issues is the American Anthropological Association’s [statement about ethnographic research and IRBs](https://www.americananthropologicalassociation.org/irb).