The procedures used in seeking and obtaining informed consent should be designed to communicate with the subject population in terms they can understand. Information about a research project must be presented in such a way that enables each person to voluntarily decide whether or not to participate as a research subject. Thus, the information must be conveyed in language understandable to those being asked to participate as subjects in the research (45 CFR 46.116).

If you are recruiting non-English speaking subjects or subjects from a foreign culture, the IRB requests information as part of the IRB application (Research Description (Form B), Informed Consent section) regarding a plan for evaluating the level of English comprehension, and the threshold for providing a translation, or why such an evaluation would not be necessary.

If translation of an informed consent document into the subject’s native language is necessary, the IRB requests a copy in English, and an equivalent copy in the applicable language.

As part of your IRB application submission, the IRB asks for contact information for someone who can act as a cultural consultant for your study. The person should be familiar with the culture or subject population and/or be able to verify, if applicable, that the translated documents are the equivalent of the English version of documents submitted. The consultant should be able to provide comments/suggestions for the IRB regarding consent procedures and appropriateness of the research for the culture. The consultant should not have any direct involvement with the study.

If you do not know of someone who would be willing to act as your cultural consultant, the Office of Research Integrity (ORI) will try to find someone to fill this role, however, this may delay the approval process for your protocol.

In 2005, ORI staff consulted with the UK Hospital on Hispanic patient populations, and determined the local Spanish-speaking population was significant enough to justify providing a Spanish translation of the IRB informed consent form (ICF) templates for UK investigators. This service allows investigators to start with a core translation, requiring only adjustments based on their research, and minimizes their translation costs. Templates translated into Spanish to use as a guide for developing the consent/assent/parental permission document are available in the IRB application [Med-Template] [Nonmed-Template].

ORI has a Research Participants web page providing information about research for potential participants. It includes a section “Information about Research – in Spanish”: Información sobre la investigación - en Español. When recruiting Hispanic populations, these resources may be useful references for explaining clinical trials, research subject rights, and the rights of parents, in language understandable to the potential Spanish-speaking participant.

If you have foreign culture experience and/or speak a foreign language and would be interested in volunteering your time to serve as a consultant for the IRB, please provide your name, address, telephone number, e-mail, and a brief description of your experience, to Judi Kuhl at Judi.Kuhl@uky.edu, and ORI will add you to its list as a potential cultural consultant.

Next, in the Informed Consent Process Educational Series…
- To Re-Consent or Not To Re-Consent, That is the Question…
- Informed Consent/Assent Process Resources at your Fingertips
- and more!…