**Consent with Non-English Speaking Subjects**

Federal regulations require that informed consent information be presented “in language understandable to the subject.” If an investigator *expects* to enroll non-English speaking subjects, the HSC requires the use of a foreign-language translation of the informed consent document. However, there may be times when a non-English speaking subject is unexpectedly found to be eligible for enrollment. In this case, investigators will not have an HSC-approved written translation of the consent form in the subject’s native language.

When such circumstances arise, the investigator may use a written "short form" in the subject’s native language as written documentation of the consent process, along with an oral translation of the complete English version of the informed consent document. The translator may be a qualified hospital/clinic staff member or a professional translator. Family members are not allowed to serve as translators for research consent. The family member may or may not understand medical terminology and may have a biased viewpoint about the potential subject’s participation in the study.

The written “short form” states that the elements of informed consent required by the regulations have been presented orally to the subject. The HSC must have approved the content of what is to be orally presented to the subject; therefore, the HSC-approved consent form becomes the basis of the oral translation. Currently, the HSC Office has a “short form” consent in Spanish, Russian, Somali, Vietnamese and Arabic. Other languages may be requested.

A member of the study team must be present during the consent process with the translator. The presence of a study team member ensures that any questions about the study can be answered by a knowledgeable individual.

When this method of obtaining consent is used, there must be a witness to the oral presentation. The witness must be fluent in both English and the subject’s language. The translator may serve as the witness.

In summary, the individuals involved in a “short form” consent process are:

- the potential subject
- the translator
- the witness (who may also be the translator)
- a member of the study team

**It is important to note that simply finding a translator to verbally translate a research consent form is not compliant with federal regulations.** The verbal process must be accompanied by the written short form.

For specific directions on how to obtain legally effective consent in these circumstances, please consult the document entitled “Instructions for Using Short-Form Consent Documentation.” Researchers also may call the HSC office at (913) 588-1240 for assistance.