Department: **UAMS Institutional Review Board**
Policy Number: **15.4**
Section: **Consent**
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SUBJECT: Non-English-Speaking Research Subjects

The changing demographics in the United States and the State of Arkansas present potentially challenging issues with regards to diverse ethnic populations who do not speak the English language. In addition to their genotypic and phenotypic diversity that can affect research outcomes, a Principal Investigator must also be cognizant of the unique problems associated with obtaining inform consent in non-English-speaking research subjects. A precept of human research is that the participating individual must understand all of the proposed research procedures that will be conducted with a potential adult research subject. This precept is further extended to children who are capable of assenting to research even though not of legal age. Heretofore, informed consent or assent has been achieved using a document written in English at the eighth-grade education level. Now with the ever increasing immigration of non-English-speaking persons to the United States, the need arises to anticipate enrolling of such subjects in research studies using consent/assent documentation in the native language of the potential subject.

Regulatory Guidelines.
45 CFR 46.116
21 CFR 50.2

Ethical Considerations. Short consent forms that provide only information that a subject will have research procedures explained to them orally open up areas for both potential misunderstanding on the part of the research subject and liability for the investigator and institution. There may be differences in what was perceived by the research subject during the oral explanation and what the investigator is attempting to convey. Particularly, when an intermediary such as a translator is used to relate complex medical and scientific concepts, there is fertile ground for misunderstanding. Moreover, from an ethical point of view, why should not a non-English-speaking research subject be afforded information comparable to what an English-speaking subject receives in a written consent form?

Consenting Process.

a. Short Consent Form. This type of consent form is a standardized version approved by the UAMS IRB and is meant to accommodate the urgent enrolling of a non-English-speaking research subject in an IRB approved research protocol. Use of this form is intended to be a bridge between the need to enroll the non-English-speaking research subject under extenuating circumstances and the reasonable period of time when a translation of the approved English consent form can be provided the research subject for re-consenting. Therefore, it is anticipated that the short form will only be utilized once and thereafter, all subsequent non-English-speaking subjects will have access to the translated English consent form approved by the IRB. Emergency exception to a one-time use of a short form can be granted by the IRB Chair or designee.
b. Consenting with the Short Form. Presenting the short consent form to a potential research subject must be done in the presence of a certified translator who speaks the subject's native language in addition to English. The Principal Investigator should complete the blank areas of the standardized short consent form which is in the research subject's native language. These blank lines are to be completed in English. The short form will explain that the translator is to convey to the potential

research subject all elements contained in the approved English consent form. Further, the short form will inform the potential research subjects that any questions concerning the research or its potential risks and benefits will be answered by the research team and that in a reasonable period of time they will be provided a translated version of the English consent form being used to provide an oral translation at the time of consenting. Further, the potential subject will be told that they will be asked to later sign a translated consent form in their native language (re-consenting). The Principal Investigator or designee must be present during the period of dialog with the potential research subject and translator to answer any questions concerning the study. Signatures lines must be appropriately executed to complete the consent process. The translator may sign as the witness that the research subject has understood the elements of the English consent form as explained to them orally in their native language.

c. IRB Notification of Consent Obtained With A Short Form. The PI must notify the IRB within 5 calendar days that a short consent form has been used to enroll a non-English-speaking research subject. Further, the Principal Investigator must initiate the process for acquiring a translation of the approved English consent form in the research subject's native tongue. Once that translation has been accomplished, a copy of the translated consent form along with a letter from the translator certifying the accuracy of the translation must be provided to the IRB. Upon receipt of these documents, the IRB Chair or designee can provide expedited review and approval of the translated consent form.
d. Re-consenting With The Translated Consent Form. Upon receiving IRB approval of the translated consent form, the Principal Investigator must use all due effort to contact the research subject and have the person sign the translated consent form in their native language. Such signing must be done in the presence of a certified translator who must also sign the consent form as a witness. The Principal Investigator or designee must be present during this re-consenting process to provide answers to any questions that arise.

Modifications To The Originally Translated Consent Form. During the course of performing a human research protocol there may arise changes in the protocol and/or consent process requiring modifications to the originally translated consent form. The PI can choose to handle this situation in one of two different ways:

a. Add An Addendum. An appropriate passage that explains the changes in the body of the native language consent form may be added as an addendum to the previously approved translated consent form. Such an addendum must be submitted to the IRB for approval along with a letter from the translator certifying the accuracy of the translated passage prior to use. This addendum must contain a signature line for the research subject to sign and enter date and time. Each addendum must contain the title of the protocol to which it will be attached, the Principal Investigator's name, the institution's name, and the sponsor's name. Bold letters at the top of this document must identify it as an Addendum.
b. Add Appropriate Translated Passages To The Translated Consent Form. The preferred method is to add appropriate changes into the body of the originally translated version of the approved English consent form. This method would be patterned after that used for modifications to an English language consent form wherein the Principal Investigator would submit a highlighted version of the proposed changes to the previously approved consent form. The difference is that with this method, as with method a) above, a letter from the translator certifying the accuracy of the translation must be provided for IRB approval.