Department: UAMS Institutional Review Board
Policy Number: 15.4
Section: Consent
Effective Date: August 25, 2004 ; July 28, 2008
Revision Date:

SUBJECT: 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. If English is not the subject's primary language, the consent process must be translated into a language the subject can understand. If an investigator anticipates the enrollment of non-English speaking subjects, the PI must make sure that an appropriate translation and translators are available to communicate with the non-English speaking subject. IRB must approve all consent procedures BEFORE the procedures are implemented.

Regulatory Guidelines.

45 CFR 46.116
21 CFR 50.2

Use the Short Form

A short form written consent document stating that the elements of informed consent required by §46.116 and UAMS Policy 15.1 have been presented orally to the subject or the subject's legally authorized representative (someone who can communicate on behalf of the individual).

When this method is used, there shall be

(1) A consent document that states that the elements of disclosure required by regulations had been presented orally to the participant or the participant's legally authorized representative.

(2) A written summary that embodies the basic and appropriate additional elements of disclosure.

(3) A witness to the oral presentation

(4) For participants who do not speak English, the witness is conversant in both English and the language of the participant.

(5) The IRB shall approve a written summary of what is to be said to the subject or the representative (someone who can communicate on behalf of the individual).

(6) Only the short form itself is to be signed (and dated for FDA-regulated research) by the subject or the representative.

(7) The witness shall sign (and date for FDA-regulated research) both the short form and a copy of the summary.

(8) The person actually obtaining consent shall sign (and date for FDA-regulated research) a copy of the summary.

(6) A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.