

**Department:** UAMS Human Research Advisory Committee  
**Policy Number:** 17.7  
**Section:** Special Populations  
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**SUBJECT: Non-English Speaking**

Subjects who do not speak English should be presented with a consent document written in a language understandable to them. Where informed consent is documented in accordance with 45CFR46.117(b)(1), the written consent document should embody, in language understandable to the subject, all the elements necessary for legally effective informed consent.

Alternatively, 45CFR46.117(b)(2) permits oral presentation of informed consent information in conjunction with a short form written consent document (stating that the elements of consent have been presented orally) and a written summary of what is presented orally. A witness to the oral presentation is required, and the subject must be given copies of the short form document and the summary.

When this procedure is used with subjects who do not speak English, (i) the oral presentation and the short form written document should be in a language understandable to the subject; (ii) the HRAC-approved English language informed consent document may serve as the summary; and (iii) the witness should be fluent in both English and the language of the subject.

At the time of consent, (i) the short form document should be signed by the subject (or the subject's legally authorized representative); (ii) the summary (i.e., the English language informed consent document) should be signed by the person obtaining consent as authorized under the protocol; and (iii) the short form document and the summary should be signed by the witness. When a translator assists the person obtaining consent, the translator may serve as the witness.

The HRAC must receive all foreign language versions of the short form document as a condition of approval under the provisions of 45CFR46.117(b)(2). Expedited review of these versions is acceptable if the protocol, the full English language informed consent document, and the English version of the short form document have already been approved by the convened HRAC.