Department:	**UAMS Institutional Review Board**
Policy Number:	**15.4**
Section:	**Consent**
Effective Date:	**August 25, 2004**
Revision Date:	**July 28, 2008; January 24, 2011; September 1, 2015; February 15, 2016; August 6, 2020; August 15, 2022**

SUBJECT: **Non-English-Speaking Research Subjects and when Short Form of Consent Documentation is allowed**

POLICY

Federal regulations allow consent to be documented using either a full written informed consent form or a short form written informed consent form stating the required elements of informed consent have been presented orally to the subject or the subject's legally authorized representative. While the UAMS IRB typically will prefer the use of a full written consent form, there are occasions where the use of a short form is appropriate, including occasions where potential subjects do not speak English well.

PROCEDURE

A. If an Investigator anticipates the enrollment of non-English speaking subjects at the time of initial submission, or if during the course of the study it becomes apparent that non-English speaking subjects will routinely be encountered, the Investigator must submit:
   1. A consent process description that addresses how the Investigator will ensure that the initial consent process and ongoing communications will be in a language understandable to the subject or LAR, such as use of institutional interpreter services, bilingual staff, etc.
   2. A translated consent document;
   3. Translated copies of any other documents that will be provided to subjects, such as brochures, questionnaires, diaries, as applicable;
      a. Note that translated materials should not be submitted for review until after the IRB approves the English version of those materials.
   4. Certification of translation. This must include the name and credentials or qualifications of the person or company who translated the documents and a certification that the document is an accurate translation. Certifications that the documents have been back translated are encouraged, although not required.

B. The IRB will review this proposed consent process in accordance with its usual procedures for review and approval of initial submissions or modifications.

C. When a non-English-speaking potential subject is encountered unexpectedly, the study team may consider developing a consent process that uses a short form consent document and written summary of the complete information presented to the subject. The approved English-language consent form may be used as the summary.
   1. The study team must obtain the IRB's concurrence or approval to use the short form consent process prior to implementing it.
   2. If there is time to submit a modification for approval, the study team must include in its modification a description of the consent process encompassing the following elements:
      a . A short form in the language of the subject or LAR stating that the elements of disclosure required by regulations have been presented orally to the subject or the subject's legally authorized representative.
      b. The short form shall be signed and dated by the subject/LAR and a witness.
      c. The witness must be conversant in both English and the language of the subject/LAR and may serve as the translator for the consent process.
      d. The witness must be present for the entire oral presentation of the consent.
      e. The written summary must embody the basic and appropriate additional elements of disclosure. The approved English-language consent form meets this requirement.
      f. The written summary shall be signed and dated by the person obtaining consent, and the witness.
      g. If the approved summary document does not include a witness signature line, the witness may sign anywhere in the signature block, and add a notation clarifying that is the witness signature.
      h. A copy of the signed short form and signed summary shall be given to the subject or LAR.

3. IRB approval of the short form and associated consent process must be obtained prior to using a short form, if the short form consent process is submitted as a modification through the e-system.
4. If there is no time to submit a modification for approval, e.g. the potential subject is at the site, or one is expected shortly but the IRB e-system will not allow a modification to be submitted, the study team must contact the IRB office for direction if a short-form consent process is contemplated.
    a. An IRB expedited reviewer may, at their discretion, discuss the proposed consent process with the study team via email and allow the use of the short form consent process for that one subject. The email discussion shall serve as alternative documentation that the short form was discussed and approved in a manner consistent with the review and approval of a modification using expedited procedures (see F.3 below).
    b. The IRB may require a modification to be submitted as soon as possible indicating the short form consent was used for the subject with the IRB's concurrence, and to obtain consent for future uses of the short form process, if appropriate.

D. Investigators wishing to routinely document consent using a short form consent for reasons other than recruitment of subject(s) who do not speak English well must obtain IRB approval prior to implementation of this process.

E. Any short form consent process must:
1. Use a short form document written in language understandable to the subject or the subject's legally authorized representative (LAR).
2. The investigator must submit a written summary of what is to be said to the subject for IRB approval.
3. Involve a witness to the oral presentation of information to the subject/LAR.
4. The subject/LAR shall sign the short form. The witness shall sign the both the short form and a copy of the summary. The person obtaining consent shall sign the copy of the summary.
5. A copy of the summary and of the short form shall be given to the subject or the subject's LAR.

F. In its review, the IRB:
1. Must determine that the consent process and procedures for documentation are appropriate and that the requirements of this policy are met prior to approving the use of the short form of consent documentation.
2. May consider the likelihood of additional non-English speaking subjects and determine whether to place a limit on the number of subjects who may be enrolled using the short form of consent documentation.
3. May use expedited review procedures for the translated short-form consent 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 IRB, or if the study qualifies for expedited review.
4. Will post full-board-approved translated short form templates on the IRB's website as they become available. The approved templates must be used exactly as is, with the only allowable changes highlighted.

REFERENCES

45 CFR 46.116(a)(3) and 46.117(b)(2)
21 CFR 50.20 and 50.27(b)(2)
OHRP guidance titled *Informed Consent of Subjects Who Do Not Speak English (1995)*
FDA information sheet titled *A Guide to Informed Consent.*
OHRP/IRB Director Personal Correspondence (August 6, 2020; archived with policy revision)
AAHRPP Elements II.3.F and III.1.F
Short form consent templates available at the UAMS IRB's website