

Informed Consent of Non-English Speaking Research Subjects

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Objectives

- **Regulations**

- What does the Common Rule have to say?

- **PI makes a determination**

- Is there a likelihood that non-English speaking subjects will enroll?

- **Investigator Procedures**

- What is the procedure for non-English speaking subjects?

- **The Short Form Process**

- When can you use it?

Common Rule



§46.116 General Requirement for Informed Consent

“...An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative....”

§46.117 Documentation of Informed Consent

“(b)(2) A short form written consent document stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject’s legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or representative....”

PI Makes a Determination:

- **The PI must determine whether there is a likelihood that non-English speaking subjects will enroll in their research:**
 - Based on factors such as research design and requirements
 - Patient demographics
 - Local area demographics
- **If non-English speaking subjects are anticipated to enroll, the IRB approved consent form for the research must be translated into the language of these subjects.**

PI Makes a Determination:

(continued)

- **While the research is being conducted, if a non-English speaking subject is encountered that speaks a language which the PI did not anticipate and in which the IRB approved consent has not been translated, the PI may either have the IRB approved consent form translated or use the short consent form.**
- **If the PI, subsequently anticipates that more non-English speaking subjects will be encountered, then the PI must translate the IRB approved consent form.**

Investigator Procedures

- 1. After the IRB has approved the English version consent form for a protocol, the PI must have the form translated into the languages of the anticipated non-English speaking subjects and it must be reviewed and approved by the IRB.**
 - PI may use the UCD translation services
 - PI may use an outside agency, such as a sponsor, but evidence of the translator's qualifications must be provided to the IRB.

Investigator Procedures

(continued)

2. When an anticipated non-English speaking subject is encountered, the person obtaining consent may either consent the subject directly if he or she speaks the same language as the subject or may use the services of an interpreter to relay information to the subject.
3. After the consent process, all forms are signed as usual and the subject is provided copies of all forms.

Investigator Procedures

(continued)

- When an unanticipated non-English speaking subject is encountered the PI may either:
 - Translate the English version consent (remember to get IRB approval) OR
 - Use the Short Form consent process

Short Form Consent Process

- **To use this process, the person obtaining consent must have:**
 - **A witness**
 - The witness must be present during the consenting process and must be fluent in English and the language of the subject. The witness may serve as the interpreter. The witness may not be a family member or close personal friend of the subject.
 - **An English version of the IRB approved consent form.**
 - **A short form consent form, and Experimental Bill of Rights, both translated into the subject's language.**
 - IRB copies of these documents translated into various languages are on the IRB Administration website.

Short Form Consent Process

(continued)

- **The person obtaining consent must orally present all material outlined in the IRB approved consent form to the subject.**
 - The consent forms do not have to be read word for word.
 - The person obtaining consent may present the information directly to the subject if he/she speaks the same language as the subject. Or
 - The person obtaining consent will present the information to the interpreter who will then convey the information to the subject.

Short Form Consent Process

(continued)

- **After consent is obtained, the person obtaining consent, the witness and subject must sign both forms:**
 - the IRB approved English version of the consent form and
 - the translated short form.
- ▶ **Don't forget: The subject also signs the translated Experimental Bill of Rights. The subject is then provided a copy of all forms.**

Report of Short Form

- **At the annual renewal, the IRB will require investigators to report on each use of the short form process.**
 - **“identify the language and number of subjects consented in that language, utilizing the Short Form during the past year.”**

Contact Information

- **IRB Admin General Phone Number: 916-703-9151**
- **Modifications: 916-703-9161**
- **IRB Admin Website:**
<http://www.research.ucdavis.edu/IRBAdmin>
- **UC Davis Interpreting Services: 916-734-2321**