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**Title: Obtaining Short Form Consent**

**Date of Last Revision: 04-12-2017**

**Audience: UCI Researchers, IRB Members, HRP Staff**

Because the Orange County area is a diverse region of many cultures and languages, investigators who enroll research subjects in Orange County must consider the likelihood of encountering eligible subjects with limited English proficiency. The purpose of this guidance is to explain how researchers should obtain and document informed consent for subjects who are non-English speakers and require an interpreter and translated consent materials. In addition, this guidance explains some of the factors that IRB Members should consider when reviewing a request to use the Short Form consent process.

**Regulatory Requirements:**

Federal regulations enforced by the Office for Human Research Protections (45 CFR 46.116) and the Food and Drug Administration (21 CFR 50.20) state that informed consent "shall be in language understandable to the subject or the representative," and 45 CFR 46.117, along with 21 CFR 50.27 describe how the informed consent is to be documented. In addition, for all studies that pose a real or foreseeable risk of biomedical harm, California state law (Health and Safety Code section 24172) requires that the Experimental Subject's Bill of Rights be provided to all subjects "written in a language in which the subject is fluent."

This guidance incorporates the federal and state regulatory requirements into the following two methods for obtaining and documenting informed consent for research subjects who do not read, speak, or understand English:

1. **PREFERRED METHOD:** The preferred method is to provide consent forms written in the subject's language. For biomedical research, the Experimental Subject's Bill of Rights must also be provided in the language in which the subject is fluent.
2. **SHORT FORM METHOD:** For the occasional and unanticipated non-English-speaking subject, an alternative "Short Form" method is allowed [21 CFR 50.27(b)(2) and 45 CFR 46.117(b)(2)]. The translated Short Form is a generic document and does not contain study specific language. A copy of the English language version of the Short Form has been included in this handout on page 5, for reference.

**Short Form Considerations:**

Per [UCI Human Research Protections policy](#), the Short Form method should not, in general, be used for Phase 1 clinical trials, clinical research that targets vulnerable subject populations such as children and pregnant women, and for 'true' placebo-controlled studies. Study specific justification must be provided in [Appendix Q](#).

The IRB must use its best judgment to ensure the protection of human research subjects when considering whether the use of the Short Form method for non-English speaking subjects is appropriate based on the researcher's justification and the specifics of the research.

**Example:** The IRB reviewed a request for Short Forms for all languages except English for prospective subjects diagnosed with Hepatocellular Carcinoma. IRB Members with medical expertise noted that research has shown that Asians / Pacific Islanders had higher incidence rates of this disease than other racial / ethnic groups. In addition, there has been a marked increase in incidence rates occurring among Hispanics. Accordingly, the IRB agreed that the researchers should anticipate enrollment of Asian and Hispanic subjects as part of this research study. The IRB, considering the population at UCI Medical Center, agreed that the researcher must translate their Consent Form into Spanish, Chinese and Vietnamese languages. For all other languages that may not be anticipated, the use of Short Forms was found appropriate.

## Overview of the Short Form Process:

1. The investigator requests a Short Form consent process by completing [Appendix Q](#) of the IRB application.
2. If IRB approved, researchers may download the applicable Short Form for use. The IRB does not stamp the Short Form as 'approved', however, Short Form approval is noted in the IRB Approval Letter. [Translations of the Short Form](#) are available on the IRB Application and Forms page under the heading, 'Human Research Protections / Foreign Language Translations.'
3. The investigator consents non-English speaking subjects using the translated Short Form and approved English consent document.
4. Only those study team members who are approved by the IRB to obtain informed consent from research participants may obtain Short Form consent (as noted in Section 2 of the IRB approved Protocol Narrative).
5. The subject will read the Short Form consent in his/her chosen language.
6. An interpreter, in the presence of the Lead Researcher or qualified Co-Researcher (approved by the IRB), will orally translate the English version of the IRB-approved consent document and will facilitate the question and answer phase of the informed consent process between the potential participant and the researcher.
7. A witness will be present during the oral presentation of the English version of the IRB-approved consent document.
  - a. Note: The witness must be an adult, fluent in both languages, who is not a member of the study team (i.e., is not listed in the protocol narrative). The interpreter may serve as the witness.
8. The following signatures will be obtained on the Short Form consent and the English version of the IRB-approved consent:
  - a. The subject will sign and date the Short Form consent; *and*
  - b. The witness and researcher will sign and date both the Short Form consent and the English informed consent document.
9. A copy of the English informed consent document and the Short Form consent will be given to the participant.
10. A copy of the Experimental Subject's Bill of Rights should also be provided to all research subjects considering participation in a medical experiment, per [California Health & Safety Code](#). These are available on the IRB Application and Forms page under the heading, 'Human Research Protections / [Foreign Language Translations](#).' Additional Experimental Subject's Bill of Rights translations may be requested by contacting the HRP office at 949-824-1558.
11. HIPAA: Authorization for the Use of Personal Health Information for Research may apply. Translated versions of this document are available on the IRB Application and Forms page under the heading, 'Human Research Protections / [Foreign Language Translations](#).'
12. Self-Certification of Surrogate Decision Makers for Participation in Research may apply. Translated versions of this document are available on the IRB Application and Forms page under the heading, 'Human Research Protections / [Foreign Language Translations](#).'
13. Once the subject has consented and eligibility is confirmed, the English version of the IRB-approved consent form must be translated into the subject's language by a professional or certified translator and provided to the subject within one month from the subject's initial consent.



#### 14. Requirements for Translations:

- a. *Greater than minimal risk studies:* a professional or certified translation of the consent/assent form(s) and recruitment material(s) is required for studies that pose more than minimal risk to subjects (i.e., studies that require full committee review), unless the IRB has granted a waiver of documentation of informed consent.
  1. For a professional translation the Lead Researcher (LR) must provide the qualifications of the individual who translated the informed consent documents and recruitment materials. The LR must include any credentials, certifications, education, native language fluency, etc.
  2. For a certified translation, a copy of the certification from the translator or translation service should be attached to the translation of any informed consent documents and recruitment materials.
- b. *Minimal risk studies:* Studies that are eligible for expedited review also require translation of the consent/assent forms; however, certified translation is not required. The IRB will accept documents translated by an individual fluent (i.e., can speak, read and write) in a given language. The qualifications of the individual performing the translation will be assessed by the IRB. A letter from the translator describing their qualifications must be provided with the translation documents. As noted above, the LR must include any credentials, certifications, education, native language fluency, etc.
- c. Differences between an interpretation and a translation: For purposes of research informed consent, an interpretation is a verbal exchange between two parties and the person serving as interpreter is fluent (can speak, read and write) in English and the language of the subject. A translation is the process of translating a written document (e.g., consent form) from one language into another, assuring the language of the translated document has the same meaning as the written document in the first language.

#### More About Translations:

**Cost of Translation:** The cost of translating written consents is the investigator's responsibility. These costs may be quite high, particularly for large studies where multiple translations are needed and/or studies with relatively complex consent information that may require additional time by a skilled professional. Investigators should include the costs of written translations as well as medical interpreter services on grants and contracts. Industry sponsors are often willing to pay the costs of translating consent forms.

**Translation Services:** The following translation companies are provided for convenience; the UCI HRPP does not endorse any translation service. Additions to this list are appreciated.

- [Accredited Language Services \(ALS\)](#)
- [Executive Linguist Agency, Inc.](#)
- [Global Language Solutions](#)
- [New World Language Services, Inc.](#)
- [Transperfect Translations](#)

#### Clinical Investigations and Biomedical Studies

The medical and technical information discussed during the initial consent discussion, as well as ongoing, study-related information, can be very complex and should be communicated to non-English speaking-subjects **through an interpreter with training and understanding in medical terminology**. In addition, an individual with a professional commitment to maintain strict confidentiality should handle the private medical issues discussed with subjects.

### **Working Effectively with Medical Interpreters:**

The field of medical interpretation is evolving and although protocols are being developed, standardized practices do not exist. Investigators may want to discuss some or all of the following topics with the interpreter before participating in an interpreter-mediated consent discussion.

1. Will the medical interpreter serve as patient/subject advocate as well as interpreting the consent material?
2. If the English version of the consent form is orally interpreted for the alternative "Short Form" method, how will the interpreter incorporate cultural considerations into the consent information?
3. How transparent will the interpreted conversation be? With three people communicating (subject, investigator and interpreter), will everything said by each person be translated?
4. How will the investigator and interpreter determine whether the subject truly understands the consent information?
5. Informed consent is an ongoing process. How will the investigator ensure that the subject will understand ongoing study-related communication? If the subject has questions about continuing in the study, how will that be communicated to the researchers?

### **The Informed Consent Discussion with Non-English Speaking Subjects:**

As with all consent discussions, sufficient time should be allowed for explaining each section of the consent and for the subject to ask questions. Working with an interpreter to explain complex topics such as randomization, placebo control, dosing schedules and invasive/noninvasive procedures may require additional time and/or subsequent discussions. See [How to Consent](#) for detailed information.

**IMPORTANT NOTE:** It is the investigator's responsibility to judge the subject's comprehension of the consent information including the understanding that participation is voluntary and that the subject has the right to withdraw at any time during the study. If the investigator doubts the subject's consent comprehension, he/she should not enroll the subject in the study. **The subject's autonomy must not be jeopardized due to a language barrier.**

**UNIVERSITY OF CALIFORNIA IRVINE  
CONSENT TO ACT AS A HUMAN RESEARCH SUBJECT- SHORT FORM**

Title of Study: \_\_\_\_\_

\_\_\_\_\_  
Name of Lead Researcher, Department & Telephone Number:

\_\_\_\_\_  
You are being asked to participate in a research study. Because the complete informed consent document is not translated into a language you understand, the English form will be translated for you verbally.

Before you agree to participate, the investigator must tell you about (i) the purposes, procedures, and duration of the research; (ii) any procedures which are experimental; (iii) any reasonably foreseeable risks, discomforts, and benefits of the research; (iv) any potentially beneficial alternative procedures or treatments; and (v) how confidentiality will be maintained.

Where applicable, the investigator must also tell you about (i) any available compensation or medical treatment if injury occurs; (ii) the possibility of unforeseeable risks; (iii) circumstances when the investigator may halt your participation; (iv) any added costs to you; (v) what happens if you decide to stop participating; (vi) when you will be told about new findings which may affect your willingness to participate; and (vii) how many people will be in the study.

If you agree to participate, you must receive a signed copy of this document and a copy of the complete informed consent document in English.

You may contact \_\_\_\_\_ at phone number ( ) \_\_\_\_\_ anytime you have questions about the research. You may contact the UCI Institutional Review Board at 949-824-6068 or 949-824-2125 or by email at [IRB@research.uci.edu](mailto:IRB@research.uci.edu) if you have questions about your rights as a research subject or what to do if you are injured.

Your participation in this research is voluntary, and you will not be penalized or lose benefits if you refuse to participate or decide to stop. Signing this document means that the research study, including the above information, has been described to you orally in a language you understand, you have had a chance to ask any questions that you have about the study, and that you voluntarily agree to participate.

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NAME OF SUBJECT	SUBJECT SIGNATURE	DATE
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NAME OF INVESTIGATOR	INVESTIGATOR SIGNATURE	DATE
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NAME OF WITNESS	WITNESS SIGNATURE	DATE
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