**GUIDE 622 – for Informed Consent Process for Non-English Speakers and Person with Limited Literacy**

The University of Hawaii (UH) is located in a culturally diverse state.  Investigators are encouraged to recruit and include all segments of the community in research, including individuals whose primary language is not English.

Participants who do not speak English should be presented with a consent document written in a language understandable to them, and which embody all the elements necessary for legally effective informed consent.

The UH HSP strongly encourages the use of a full consent form translated into the participant’s language whenever possible. When all of the participants in a study (i.e., the target population) are anticipated to be non-English speaking, a full translated consent is required.

 When a full-length form embodying all elements of consent is required by the IRB to document consent, the IRB requires that appropriately translated consent documents be submitted to the IRB for review and approval prior to their use in enrolling participants.

Investigators may use language translators or interpreter services to obtain consent in a language understandable to the participant or the participant's legally authorized representative.  The IRB may utilize expedited review procedures in approving such documents if the English language consent document has already been approved.

**Short Form Consent Process**

Federal regulations permit the use of a short form consent process (45 CFR 46.117(b)(2) and 21 CFR 50.27(b)(2))with the prior approvalof the IRB.

Short Form of Consent Documentation

If the short form of consent documentation is used, the investigator must follow the following procedures[[1]](#footnote-1):

1. The short form of consent document states that the required and appropriate additional disclosures have been orally presented to the participant or the LAR;
2. A written summary must embody the required and appropriate additional disclosures;
3. The investigator orally presents the required and appropriate additional disclosures to the participant or the participant's LAR;
4. A witness must be present during the oral presentation;

1. If the participant or the LAR does not speak English, the witness must be conversant in English and the language that the participant or the LAR speaks;
2. The participant or the LAR signs the consent document;
3. The witness signs the consent document and a copy of the written summary;
4. The person obtaining the consent signs the copy of the written summary;
5. A copy of the signed consent document and the signed written summary is given to the participant or the LAR.

### Oral Presentation in Conjunction with Short Form Written Consent

If the Investigator adopts the approach of short form written consent, the consent process must meet the requirements for short form written consent.[[2]](#footnote-2) This consent process includes:

1. Oral presentation of informed consent information;
2. A short form of written consent document stating that the elements of consent have been orally presented;[[3]](#footnote-3) and
3. A written summary of what is orally presented.

The language requirements of this consent process are:

1. The oral presentation and the short form written document should be in a language readily understandable to subjects;
2. The English informed consent document approved by the IRB may serve as the summary;
3. The witness should be fluent in both English and the language of the subject.

When an interpreter assists in the consent process, the interpreter may serve as the witness to the consent process.

At the time of consent,

1. the subject (or the subject’s LAR) should sign the short form;
2. the person obtaining consent as authorized under the protocol should sign the summary ; and
3. the witness should sign the short form document and the summary .

A copy of the summary and the short form must be given to the subject or the subject's LAR.[[4]](#footnote-4)

The short form written consent document must be in a language understandable to the subject.[[5]](#footnote-5) The Investigator must submit to the IRB for review all foreign language versions of the short form.[[6]](#footnote-6) The Investigator should also submit any other translated documents presented to subjects.  The IRB may review these documents with outside experts to ensure that translation is appropriate.  These translated versions may be approved under expedited review if the study, the English version of the full informed consent document, and the English version of the short form document have already been approved by the convened IRB.

### When the Participants Only Speak Oral Languages or Cannot Read

At times, a study involves participants who only speak oral languages or cannot read. This does not change the requirement that the informed consent information must be presented in language understandable to the subject.  When an oral presentation of informed consent information is used with subjects who only speak oral languages or cannot read,

1. the oral presentation should be in a language understandable to subjects, and
2. the English informed consent document approved by the IRB may serve as the summary.

At the time of consent, the IRB will require that:

1. The summary be signed by the person obtaining consent as authorized under the protocol; and~~/or~~
2. The summary be signed by the witness.

If an interpreter assists in the consent process, the interpreter may serve as the witness to the consent process. The Investigator must submit to the IRB for review all English language versions of information presented to subjects.

### HSP Guidance on Interpretation

#### "Interpret" v. "Translate"

These two terms are often used interchangeably.[[7]](#footnote-7) The major difference is that an interpreter relays a message orally while a translator works with written words. So in the context of the informed consent process, "interpret" and "interpreter" should be used.

#### Interpreter Protocol

The following are guidelines for interpreters.

1. **Interpret in the First Person.** Avoid "he said" or "she said." Speak as if you were the Investigator or the participant.
2. **Positioning and Eye Contact.** Use positioning and eye contact to help bridge the communication between the Investigator and the participant.
	1. **Positioning.**
		1. One option is to place yourself between them.
		2. Another option is to stand beside either one of them to stimulate eye contact between them.
	2. **Eye Contact.**
		1. The interpretation process should promote eye contact between the Investigator and the participant. So sometimes avoiding eye contact with either can encourage eye contact between them.
		2. Any eye contact or avoidance of it should not be in a way that seems disrespectful.
3. **Existing Translation.** Use of existing translation promotes consistency among different interpreters and different participants, and prevents waste of time due to unfamiliarity with the material.
4. **No Side Conversations.** Side conversations are impolite and waste time. If either the Investigator or the participant initiates a side conversation with you, you can offer to talk more after the consent process and inform the other person about the side conversation so that the other person understands what is going on.

#### Investigator Protocol

The following are guidelines for Investigators.

1. **Address the Participant Directly.** Address the participant directly as if the participant understood everything.
2. **Speak in a Moderate Pace and Short Segments.** Speak in a pace and segments that allow the interpreter to properly convey your message.
3. **Cue Interpreter.** The interpreter may not know when to begin speaking. Give the interpreter a clear cue, such as a pause, quick look, nod, or hand gesture.
4. **No Side Conversations.** Again side conversations are impolite and waste time. If the interpreter initiates a side conversation, politely offer to talk more after the consent process.

*The IRB has and follows written policies and procedures requiring appropriate protections for prospective participants who cannot give consent or whose decision-making capacity is in question. (AAHRPP Element II.4.B)*

If you have questions, contact the UH Human Studies Program at 808.956.5007

1. 45 C.F.R. § 117(b)(2). [↑](#footnote-ref-1)
2. 45 C.F.R. § 46.117(b)(2). [↑](#footnote-ref-2)
3. For a sample of short form written consent document, see OHRP Guidance on Non-English Speaker, supra note 89. [↑](#footnote-ref-3)
4. 45 C.F.R. § 46.117(b)(2). [↑](#footnote-ref-4)
5. OHRP Guidance on Non-English Speaker, supra note 89. [↑](#footnote-ref-5)
6. Id. [↑](#footnote-ref-6)
7. See Interpretation Guidelines, National Health and Nutrition Examination Survey (NHNES), Ctrs. for Disease Control & Prevention, 2 (Nov. 2006), http://www.cdc.gov/nchs/data/nhanes/nhanes\_07\_08/interpretation\_guidelines.pdf. [↑](#footnote-ref-7)