

Title:	Use of Interpreter Services and Translated Documents
Responsible Office:	Institutional Review Office (IRO)
Responsible Official:	Karen Hansen, IRO Director
	<i>Signature/date</i>
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POLICY STATEMENT

It is the policy of Fred Hutchinson Cancer Research Center (FHRC) that all documents translated/interpreted from English to another language must receive IRB review and approval before use, to assure that the rights and welfare of research participants are adequately protected.

DEFINITIONS

Translation: Conversion of a written document from one language to another.

Interpretation: Facilitating oral communication in more than one language; performed by an interpreter.

Interpreter: A person who translates orally for individuals conversing in different languages.

Legally authorized representative: A person authorized either by statute or by court appointment to make decisions on behalf of another person. In human subjects research, an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research [Federal Policy §____.102(c)].

REFERENCES

21 CFR 50.20

21 CFR 50.27

21 CFR 50.25

21 CFR 50.27(b)(2)

45 CFR 46.117(b)(2)

21 CFR 56.111(b)

OHRP, Policy Guidance, November 9, 1995

(<http://www.hhs.gov/ohrp/humansubjects/guidance/ic-non-e.htm>)

FDA Information Sheets: Frequently Asked Questions: Informed Consent Process

PRINCIPLES/OVERVIEW

At FHRC, investigators may encounter research participants who are not English speakers or may engage in research studies that target individuals who are not English speakers. It is the

Center's responsibility to ensure that non-English speakers are presented with the same opportunity to participate in a research activity as are English speakers. This involves the presentation (written or oral) of the informed consent information in a language understandable to the non-English speaker.

The FHCRC IRB must review and approve any translated documents that were previously IRB approved versions in English. The FHCRC IRB must also review and approve the process of using the short form.

INDIVIDUALS AFFECTED BY THIS POLICY

The contents of this policy apply to Institutional Review Office (IRO) staff, IRB members, employees of FHCRC and investigators from other institutions who submit research studies to the FHCRC IRB for review and approval.

PROCEDURES

1. Use of Translated Documents

When the study's subject population targets a particular group that does not speak or read English, the FHCRC follows these steps in the review and approval of translated/interpreted documents:

- a. For new studies: The English and non-English version of each document are submitted to the IRB as part of the new application and reviewed by the full IRB Committee at a convened meeting. However, the IRB acknowledges the cost of translation services so the IRB will allow the translated documents to be submitted after the English version of the documents are reviewed and approved by the IRB. The translated document(s) must be submitted along with a completed protocol modification form. See Section b below for detailed information regarding the use of the *protocol modification form*.
- b. For ongoing studies: A completed *protocol modification form* is submitted along with the IRB approved English version and the translated document(s). See *IRB Policy 2.5 Modification to Ongoing Activities* for specific procedural instructions for modifications. The IRB Chair or designee will review the modification. The IRB Chair or designee will make the final determination if the modification is a "Major" or "Minor" modification. The IRB Chair or designee will follow the modification review process as outlined in *IRB Policy 2.5 Modification to Ongoing Activities*.

For translated document submitted as a modification, if approved by the IRB Chair or designee, the IRB staff will follow the same processing requirements as noted in the processing section in *IRB Policy 2.5 Modification to Ongoing Activities*.

- c. Methods of Translation

The written translated document(s) submitted for review and approval must be translated in one of two ways:

- Single back translation: The translated document is translated back into English. The person providing the back translation must be different from the person providing the original translation.
- Double translation: Two individuals independently translate the document from English into another language and an arbitrator reviews both translated documents. The arbitrator decides if there are differences between the two translated documents. Changes to documents will be made, if applicable.

The IRB Chair or designee will review and determine if any other translation methods are appropriate depending on the nature of the study. A consultant to the IRB may be invited to provide comments to the IRB Chair or designee. See *IRB Policy 1.3 IRB Committee Structure* for specific information regarding the use of consultants.

- d. The IRB encourages but does not require the use of certified translators.
- e. The person providing the translation service completes the *Translation Certification Form*. The completed and signed *Translation Certification Form* is submitted to the IRB with the translated documents. If the translator is not certified, a written summary of his/her qualifications must be included on this form.
- f. The IRB may invite a consultant to review the translated document to determine cultural appropriateness. See *IRB Policy 1.3 IRB Committee Structure* for information regarding the use of consultants to the IRB.

2. Use of Interpreters and the Short Form Written Consent Document

When the research study unexpectedly encounters a potential research participant who does not speak or read English, a short form written consent document in the language of the research participant or the research participant's legally authorized representative is used. The short form documents that the elements of informed consent required by 45 CFR 46.116 (or, for FDA-regulated studies, 21 CFR 50.25) were presented orally to the research participant by the interpreter and the investigator leading the content discussion.

- a. The IRB must approve a written summary of what is to be discussed with the research participant or legally authorized representative. The IRB-approved English language informed consent document may serve as the written summary used for discussion with the research participant.
- b. The person providing the interpretation service completes the *Interpretation Certification Form*. The completed and signed form is submitted to the IRB for studies that require this service. If the interpreter is not certified, a written summary of his/her qualifications must be included on this form.
- c. When the interpretation service occurs at the Seattle Cancer Care Alliance (SCCA), the investigator must follow the *SCCA Informed Consent: Use of Interpreters in the Informed Consent and Assent Process for Research Protocol*.
- d. A witness, proficient in English and in the research participant's language, must be present throughout the consent process. When the person obtaining consent is assisted by an interpreter, the interpreter may serve as the witness.
- e. At a minimum, the following signatures are required:
 - The research participant/representative signs the short form.
 - The witness signs the short form and the summary.
 - The person obtaining the consent signs the summary.

Additional signature/documentation procedures may be followed as appropriate:

- It is acceptable for the research participant or legally authorized representative to sign the written summary (e.g., the IRB-approved English language informed consent document) provided the research participant or legally authorized representative has also signed the short form document that is written in the research participant's native language.

If the IRB-approved English language informed consent document is used for signatures and it does not provide space for a witness signature, a witness attestation form may be used.

- The process of obtaining consent for a patient who does not speak or read English may be documented in the medical record and as required by facility maintaining the medical record.
- f. Copies of the short form and the summary will be given to the research participant or legally authorized representative.
- g. IRB Approved Short Form Templates

An IRB-approved English short form and its approved translations are posted to the IRO website and may be used as described in this policy. Any new translation must receive IRB approval before use. Expedited review of a foreign-language version of the short form is acceptable provided that the protocol, the English version of the informed consent document, and the English version of the short form have already been approved by the IRB Committee. The IRB Staff follows the *Screener: Short Form to process any new translation request of the short form* . Approval documentation is found in IR 6418.

SUPPORTING DOCUMENTS

Translation Certification Form

Interpretation Certification Form

SCCA Informed Consent: Use of Interpreters in the Informed Consent and Assent Process for Research Protocol

Sample Short Form: Consent to Participate in Research

[IRB-approved short forms]

SCCA Witness Addendum to Informed Consent Document

Screener: Short Form