Fred Hutch Cancer Center

Institutional Review Board

Policy/Procedure

Title:	Use of Interpreter Services and Translated Documents
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Responsible Office:	Institutional Review Office (IRO)
Responsible Official / Approved By:	Meghan Scott, IRO Director

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POLICY STATEMENT

It is the policy of Fred Hutchinson Cancer Center (Fred Hutch) that non-English speaking participants are afforded the opportunity to participate in research when appropriate protections are in place. When non-English speaking participants are enrolled in research, translation and/or interpretive services must be used to facilitate the proper communication of information to participants. All documents translated from English to another language must receive IRB review and approval before use, to ensure that the rights and welfare of research participants are adequately protected. When translation of documents is not feasible, the investigator must receive IRB approval to use a short form consent process with non-English speaking participants.

DEFINITIONS

See *HRP-001 - SOP - Glossary of Terms and Acronyms* for full definitions of the following:

Impartial Witness

Interpretation

Interpreter

Legally Authorized Representative

Translation

Witness

PRINCIPLES/OVERVIEW

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 principal investigator's responsibility to ensure that non-English speakers are presented with the same opportunity to participate in a research activity as are English speakers. Any plan to exclude non-English speakers from the research must be justified and approved by the IRB.

At the same time, investigators should carefully consider the ethical and legal ramifications of enrolling participants when a language barrier exists. If the participant does not clearly understand the information presented, the participant's consent will not truly be informed and may not be legally effective.

Common justifications for excluding non-English speakers from participation may include:

- Early phase clinical trials without a prospect for direct benefit, that will enroll only a limited number of subjects;
- Studies without a prospect for direct benefit and with procedures that are greater than minimal risk;
- Assessment tools, surveys, questionnaires or psychological tests that are only available in English;
- Enrollment required in situations where translators will not be readily available (satellite clinics, after regular working hours, emergencies, etc.)
- Expectation based on experience that non-English speakers will rarely present to the clinic where enrollment will take place.

When non-English speakers will be enrolled in the research, the informed consent information must be presented (written or oral) in a language understandable to the participant.[1] The Fred Hutch IRB must review and approve any translated documents prior to their use. The Fred Hutch IRB must also review and approve the process of using a short form consent if non-English speaking participants are unexpectedly encountered during recruitment to the research.

INDIVIDUALS AFFECTED BY THIS POLICY

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

PROCEDURES

1. Use of Translated Documents

When a study targets a particular subject population that does not speak or read English, the materials a participant would see or hear during recruitment or during the study need to be translated, reviewed, and approved by the IRB. Materials may include, but are not limited to recruitment ads, flyers, or broadcasts; consent documents; study tools; letters; or other communications.

Fred Hutch IRB encourages, but does not require, the use of certified translators.

a. Methods of Translation

The written document(s), including transcriptions of spoken materials, submitted for review and approval must be translated in one of the following ways:

- Forward translation: The document is translated into the target language.

[1] HHS: 45 CFR 46.116; FDA: 21 CFR 50.20

- Back translation (optional): The document is translated into the target language, then the translated document is translated back into English. The person providing the back translation must be different from the person providing the original translation.

b. A translation certification must be provided with the translated documents. If a certification is unavailable, the person providing the translation service may complete *HRP-280 - FORM - Translation Certification*. The translation certificate or 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.

c. For new study submissions: The English and non-English version of each document, if available, are attached to the New Study submission in Hutch IRB for IRB review.

   However, the IRB acknowledges the cost of and time necessary for 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 with Modification as described below.

d. For ongoing studies: translated documents are submitted either for review of new translations of previously approved English versions, or because the English version of the document(s) underwent revisions and a re-translation of the documents is necessary. A Modification is submitted in Hutch IRB with a completed *HRP-252 - FORM - Modification Supplement,* along with the latest English version and the translated document(s). See *IRB Policy 2.5 Modification to Ongoing Activities* (025) for specific procedural instructions for modifications.

   i. The Designated Reviewer will review the Modification. The IRB Designated Reviewer will make the final determination if the modification is a “Major” or Minor” modification. The Designated Reviewer will follow the modification review process as outlined in *IRB Policy 2.5 Modification to Ongoing Activities* (025).

   ii. The Fred Hutch IRB expects previously approved translated documents to be updated (re-translated) whenever the English versions of those documents are modified.

   iii. If approved by the Designated Reviewer, the IRB staff will follow the same processing requirements as noted in the processing section in *IRB Policy 2.5 Modification to Ongoing Activities* (025).

e. The IRB Chair or designee will review and determine whether any other translation methods are appropriate, depending on the nature of the study.

f. The IRB may invite a consultant to review the translated document to determine cultural appropriateness. See *IRB Policy 1.3 IRB Committee Structure* (019) for information regarding the use of consultants to the IRB.

g. Once the IRB approves the translated materials, the investigator may use the materials for the research.

2. Use of Interpreters

a. Whenever a researcher interacts with a participant or the participant’s legally authorized representative (LAR) and does not speak that person’s language, an interpreter must be used to ensure information is properly communicated. An interpreter must be sufficiently fluent in both languages to effectively facilitate communication between parties. The interpreter should be a member of a qualified professional interpretative service. Family members of the participant shall not serve as interpreters except in exceptional circumstances, such as emergencies.

b. It is preferred that the interpreter is physically present with the participant or LAR and the person obtaining consent. However, there may be circumstances where the interpreter is unable to be physically present, and instead assists with the consent discussion remotely (i.e., phone, video conference, etc.). If the interpreter assists with the consent discussion remotely, the interpreter may only serve as a witness if a video conference is utilized so they can adequately observe the consent discussion.

c. If the participant or participant’s LAR is unable to read the translated consent document, the interpreter may serve as the witness as long as he/she is not a member of the research staff. Refer to *IRB Policy 2.11 Informed Consent* (017) for information about witnesses.

3. Short Form Consent

When researchers unexpectedly encounter a potential research participant who does not speak English (or who has limited English proficiency), a short form consent process can be used with approval from the IRB. A short form consent document captures 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.

Note: the Fred Hutch IRB has pre-approved a model short form consent document, including an English version and certified translated versions into a number of languages. They can be found on the IRO website at: https://extranet.fredhutch.org/en/f/irb/short-form-consent-other.html. A study team **must first obtain IRB approval to use the short form consent *process*** with an unexpected participant who does not understand English. If the consent plan originally approved on a new application did not include a short form consent process, submit a Modification in Hutch IRB, including *HRP-252 - FORM - Modification Supplement*. Once approved to use the short form consent process, any of the IRB pre-approved short forms posted on the IRO website can be used to consent participants.

If a language is encountered other than one of the languages with a pre-approved version, the English short form would need to be translated into the relevant language and receive IRB approval prior to use. Contact the IRO to assist with arranging a translated version of the short form. Expedited review of a foreign-language version of the short form is acceptable. The IRB Staff follows the *HRP-374 - WORKSHEET - Short-Form Consent* to process any new translation request of the short form. Approval documentation for the short form consent documents is found in File 6418.

If HIPAA is relevant to the research and an English version of the HIPAA authorization will be used instead of a translated version, the study should submit *HRP-257 - FORM - HIPAA Supplement* to request an "Alteration of HIPAA" to waive the HIPAA signature. The HIPAA form should be verbally interpreted.

Documents Used in the Short Form Consent Process

The documents needed for the short form consent process include:

a. An IRB-approved written summary of what is to be discussed with the research participant or LAR. The IRB-approved English language informed consent document (the "long form") may serve as the written summary.

b. An IRB-approved short form written consent document stating that the elements of informed consent have been presented orally to the participant or the participant's LAR. The short form is written in the language of the research participant or the participant's LAR.

Conducting the Short Form Consent Process

a. To conduct the short form consent process, at minimum the following individuals must be present:

   - Person obtaining consent
   - Participant (or the participant's LAR)
   - Witness

   In addition, an interpreter is needed if the person obtaining consent does not speak the participant's language (see Use of Interpreters). The interpreter may serve as the witness.

b. The person obtaining consent, with the assistance of an interpreter if needed, verbally provides the participant the elements of informed consent required by regulations at 45 CFR 46.116 and/or 21 CFR 50.25 and any additional pertinent information included in the IRB-approved English version of the long form.

c. A witness to the oral presentation, proficient in English and in the research participant's language (or the LAR's language, if applicable), must be present throughout the entire consent process (either physically or through video conference). The witness must be an impartial witness. When the person obtaining consent is assisted by an interpreter, the interpreter may serve as the witness. Alternatively, both an interpreter and a witness may be present during the consent discussion.

d. If the participant agrees to participate in the research, the following signatures are required:

- The research participant (or LAR) signs the short form.
- The witness signs the short form and the written summary.
- The person obtaining the consent signs the written summary.[2]

The rule of thumb is each person signs the form(s) they can read. **The participant should not sign a consent document written in a language they do not understand.**
Additional signature/documentation procedures may be followed as appropriate:

- If the English long form is used for the written summary, and it does not provide space for a witness signature, a witness attestation form may be used.
- If the long form/written summary contains consent choices for optional research, such as checkboxes or initial lines, the person obtaining consent should mark the choice made by the participant and initial and date the selection. Study staff should note in the research file what choice the participant made and how it was documented.
- If HIPAA was verbally interpreted, the researcher documents in the research record (and in the patient medical record per policies of the institution where consent is taking place) that a verbal HIPAA authorization was obtained.
- 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 the facility maintaining the medical record.

e. Copies of the short form and the written summary are given to the research participant or LAR.

f. Fred Hutch IRB recommends investigators consider translating the full English consent form (long form) into the participant's language.

SUPPORTING DOCUMENTS

IRB Policy 1.3 IRB Committee Structure (019)

IRB Policy 2.5 Modification to Ongoing Activities (025)

IRB Policy 2.11 Informed Consent (017)

HRP-001 - SOP - Glossary of Terms and Acronyms

HRP-252 - FORM - Modification Supplement

HRP-257 - FORM - HIPAA Supplement

HRP-280 - FORM - Translation Certification

HRP-374 - WORKSHEET - Short-Form Consent

REFERENCES

21 CFR 50.20

21 CFR 50.25

21 CFR 50.27

45 CFR 46.116

45 CFR 46.117

OHRP Guidance: Informed Consent of Subjects Who Do Not Speak English, November 9, 1995 (http://www.hhs.gov/ohrp/policy/ic-non-e.html)

FDA Information Sheets: Frequently Asked Questions: Informed Consent Process

FDA Information Sheets: A Guide to Informed Consent: Guidance for Institutional Review Boards and Clinical Investigators

[2] HHS: 45 CFR 46.117(b)(2); FDA: 21 CFR 50.27(b)(2)