Fred Hutch Cancer Center

Institutional Review Board

Policy/Procedure

Title:	Use of Interpreter Services and Translated Documents
Version:	1.00
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Responsible Office:	Institutional Review Office (IRO)
Responsible Official / Approved By:	Meghan Scott, IRO Director

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 with appropriate protections in place, including interpretation and translation services to facilitate the proper communication of information to participants. All documents translated from English to another language must receive Institutional Review Board (IRB) review and approval before use, to ensure that the rights and welfare of research participants are adequately protected.

When there is insufficient time and opportunity to obtain an appropriate translation of the English language consent form before enrollment, as is often the case in the clinic, the investigator may request prospective IRB approval to use a short form consent process with non-English speaking participants.

This policy refers to “non-English speakers” and should be understood to include individuals who either do not speak English or those with another language preference who are unable to understand English at a level of proficiency that would allow them to participate in meaningful informed consent.

The same principles and processes apply when a non-English speaker is acting as the patient’s legally authorized representative (LAR) for informed consent.

DEFINITIONS

See *HRP-001 - 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 (PI) responsibility to ensure that non-English speakers are presented with the same opportunity to participate research as individuals who are fluent in English. Any plan to exclude non-English speakers from the research must be justified and approved by the IRB. This policy is supported not only by Fred Hutch’s

core values and commitments to diversity and health equity, but also by published regulatory guidance and Washington state law.[1]

Common allowable justifications for excluding non-English speakers from participation in a specific research study 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;
- Validated assessment tools, surveys, questionnaires or psychological tests that are only available and validated in English;
- Enrollment required in situations where interpreters 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.

The lack of funds to translate study materials does **not** generally constitute an allowable or sufficient reason to exclude non-English speakers.

When non-English speakers will be enrolled in the research, it is critical to ensure sufficient understanding to support informed consent. If the participant does not understand the information presented, the participant's consent will not truly be informed and may not be legally effective. The informed consent information must be presented (written or oral) in a language understandable to the participant.[2] Translation (of written materials) and interpretive services (for oral communication) must be used to facilitate the proper communication of information to such participants. The Fred Hutch IRB must review and approve any translated documents prior to their use in the research. The Fred Hutch IRB must also prospectively 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 Interpreter Services

a. Whenever a researcher interacts with a potential or current participant and does not speak the individual's preferred language, an interpreter must be used to ensure study information is properly communicated.

b. The interpreter must be sufficiently fluent in both languages to effectively facilitate communication between the 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.

c. For research consent discussions conducted in person, it is preferred that the interpreter be physically present with the participant and the person obtaining consent. However, there may be circumstances when the interpreter is unable to be physically present, and instead assists with the consent discussion remotely (i.e., phone, video conference, etc.).

d. If the short form consent process is used (see section Short Form Consent Process), federal regulations require an impartial **witness** to the research consent discussion if the individual

[1] FDA Guidance on Informed Consent (August 2023); OHRP Guidance on Informed Consent of Subjects Who Do Not Speak English (1995); WA state RCW 69.78.040
[2] HHS: 45 CFR 46.116; FDA: 21 CFR 50.20

conducting the consent discussion does not speak the language of the potential participant. In general, the interpreter may serve as the witness to the short from process; however:

i. if the interpreter assists with the consent discussion remotely, the interpreter may generally only serve as the required witness if a video conference is used, so they can adequately observe the consent discussion.

ii. if the interpreter is serving as the required witness, they must also be willing and able to sign the consent in the witness signature block.

e. If the interpreter is *not* serving as the witness (such as if either i. or ii. above cannot be met), the investigator needs to find another individual to serve as the required witness. The witness may be a family member or friend, but note that the witness must be conversant in both English and the participant's language.[3]

2. Use of Translated Documents

When a study **targets** a non-English speaking population, the materials a participant would see or hear during recruitment and during the study need to be translated, reviewed, and approved by the IRB. Materials may include, but are not limited to consent documents; recruitment ads, flyers, or broadcasts; study tools such as drug diaries, questionnaires, etc.; participant letters; or other participant-directed communications.

When a study is not targeting non-English speakers, but the PI **unexpectedly** encounters a potential non-English speaking participant and there is not sufficient time to translate the English consent, the short form consent process may used during the consent conference (see next section for details on the process). Once the short form process is used to consent someone, the consent must then be translated into that individual's preferred language.

If the PI proposes to enroll non-English speakers but *not* to translate participant-facing study documents other than the consent, the PI must provide sufficient justification, such as:

- A written questionnaire will be administered orally using an interpreter in clinic (only appropriate for questionnaires that are not validated).
- A questionnaire will not be administered for non-English speaking participants (only appropriate if the data collection is not critical data to meet the primary research aims).
- The non-English speaking participant has an English-speaking caregiver who can complete a diary for the participant.

Methods of Translation

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

- Forward translation: The document is translated into the target language.
- Back translation (optional, may be required by some sponsors): 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.

Artificial Intelligence (AI)-supported translation methods may be used to reduce cost but the initial AI-supported translation must be followed by human validation such as editing, post-editing and proofreading, and quality control steps.

The Fred Hutch Interviewing, Translation and Interpretation Services (ITIS), part of the Shared Resources Collaborative Data Services (CDS) group, is available to translate into Spanish and to coordinate translation requests for other languages with existing vendors.

[3] AAHRPP element II.3.F

Translation Certificates

A translation certificate (also known as a certificate of accuracy) must be provided to the IRB along with the translated documents. If a translation certificate from a translation vendor is unavailable, the person providing the translation services may complete *HRP-280 - FORM - Translation Certificate*.

Fred Hutch IRB encourages, but does not require, the use of professionally certified translators. If the translator is not professionally certified, a written summary of their qualifications must be included.

Process for IRB Submissions of Translated Materials

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, considering the cost and time necessary for translation services, the IRB recommends that the translated documents be submitted (via Modification) only *after* the English version of the documents have been reviewed and approved by the IRB, because the IRB may request changes to English documents for accuracy, clarity, or to aid in understandability.

For ongoing studies: Translated documents are submitted:

- When a translated version of IRB-approved English documents is ready for review, or
- After the English version of the document(s) underwent revisions and a re-translation of the documents is necessary.

For a Modification that includes **only** translated documents (no other changes are being made), submit it in Hutch IRB with a completed *HRP-287 - FORM - Translated Materials Modification Supplement*. Also attach the translated document(s) and the translation certificate in Hutch IRB. See *IRB Policy 2.5 Modification to Ongoing Activities* (025) for general procedural instructions for modifications.

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

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.

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

3. Short Form Consent Process

Overview

When a researcher **unexpectedly** encounters a potential participant who is a non-English speaker and there is not sufficient time to translate the English consent (as is often the case in the clinic), the short form consent process may used during the consent conference, provided the IRB has approved the use of the short form consent process for the study. A translated short form consent document captures that the elements of informed consent required by 45 CFR 46.116 (or 21 CFR 50.25) were presented orally to the research participant.

After the use of the short form consent process, if the participant enrolls, research procedures may begin immediately. However, the investigator also needs to start the process to obtain a translation of the full English consent form. Once obtained, the translation is submitted for IRB review as soon as possible and within 30 calendar days after the participant consented using the short form process. After the IRB approves the translated consent form, it must be provided to the enrolled participant as soon as possible and within two weeks (14 calendar days). It may be provided to the participant via MyChart, email, mail, or at the next clinic visit. A re-consent discussion is not required.

The IRB may grant rare exceptions to the requirement to translate the full consent form into the participant's language after short form usage, for example if the study only involves a single interaction with the participant. The investigator must present rationale for the IRB's consideration of an exception. The IRB is likely to deny requests if the study involves ongoing data collection from the medical record or if you are storing identifiable specimens in a repository, because participants

should have written information in their language about this on-going research activity and how to revoke their participation.

If HIPAA is relevant to the research and an English version of a 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 by the non-English speaker. The HIPAA form should be orally interpreted. Document in the study record that the HIPAA process was completed orally.

NOTE: If the non-English speaker is physically unable to read, or has no or low literacy in their preferred language, the short form process is not appropriate. Instead, an oral presentation of the consent materials as used for any non-reader should be used. An interpreter may serve as the witness to an oral consent discussion, as long as the interpreter is not a member of the research staff. Refer to *IRB Policy 2.11 Informed Consent* (017) for more information about the witness requirements when consenting individuals who cannot read.

Short Form Process Details

a. IRB approvals necessary for use of short form consent process:

Before using the short form consent process with a potential participant, researchers must first ensure that the IRB has approved all of the following:

- Enrollment of non-English speakers in the study.
- Use of the short form consent process for unexpected enrollment of this population.
- If HIPAA applies to the study: A waiver of the HIPAA signature, unless there is an existing translated HIPAA form in the target language.

b. Documents used in the short form consent process:

The documents needed for the short form consent process include:

- An IRB-approved English consent form.
- An IRB-approved, translated "short form" written consent document.
    - The short form states that the elements of informed consent are being presented orally to the participant. The short form is written in the preferred language of the participant.
    - The Fred Hutch IRB has pre-approved the short form, including an English version and certified translated versions in over 50 languages. It is available for download from the IRB Translated Short Forms webpage.
    - If a researcher requests the short form in a language or dialect other than one of the existing translations, the English short form needs to be translated into the new language or dialect and receive IRB approval prior to use. IRO staff coordinates obtaining a new translated version of the short form, following *HRP-374 - WORKSHEET - Short Form Consent* to process any new translation request of the short form.
- If HIPAA applies: The English HIPAA authorization or a translated HIPAA authorization.

c. Conducting the short form consent process:

To conduct the short form consent process, the following individuals must be present throughout the entire consent discussion:

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

In addition, an interpreter is needed if the person obtaining consent does not speak the participant's preferred language (see section on Use of Interpreters). The interpreter may serve as the witness if present in person or available via video conference and willing and able to sign as the witness.

The person obtaining consent, with the assistance of an interpreter if needed, orally 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 consent form.

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. If the participant agrees to take part in the research, the following signatures are required:

- The participant signs the translated short form, and if applicable/available, a translated HIPAA authorization.
- The witness signs both the translated short form and the English consent form.
- The person conducting the consent discussion signs the English consent form.[4]

Additional signature/documentation procedures may be followed as appropriate:

- If the English consent form does not provide a signature block for a witness signature, a separate witness attestation form may be used.
- If the English consent form 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 on the English consent form. Study staff should note in the research file what choice the participant made and how it was documented.
- If an English HIPAA authorization was used and 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 non-English speaking participant may be documented in the medical record and as required by the facility maintaining the medical record.

Copies of the translated short form and the English consent form are given to the research participant.

d. After the short form consent process is used:

Only if the non-English speaker enrolls into the study, the investigator should then:

i. Obtain a full translation of the English consent form in the participant's preferred language (unless the IRB has approved an exception to this requirement, see Overview section above).

ii. Submit the translated consent form for IRB approval **within 30 days** after use of the short form consent process.

iii. After IRB approval, the translated form should be provided to the participant as soon as possible and **within two weeks**. It may be provided to the participant via MyChart, email, mail, or at the next clinic visit. A re-consent discussion is not required.

Any other written study materials for participants should be translated as well, to support the individual's participation (unless the IRB has approved an exception to this requirement).

The IRB asks about any use of the short form process at the time of continuing review.

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)

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

HRP-001 - Glossary of Terms and Acronyms

HRP-257 - FORM - HIPAA Supplement

HRP-280 - FORM - Translation Certificate

HRP-287 - FORM - Translated Materials Modification Supplement

HRP-374 - WORKSHEET - Short Form Consent

ADM602 Informed Consent: Use of Interpreters in the Informed Consent and Assent Process for Research Protocol (clinic policy)

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

Washington state RCW 69.78.040

AAHRPP Element II.3.F

VERSION HISTORY

Version	Effective Date
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