The Christ Hospital IRB
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STANDARD OPERATING PROCEDURE

Consent Translations and Interpreting Requirements for Non-English Speaking Participants

1.0 POLICY

It is the policy of TCH IRB that researchers obtain the legally effective informed consent of the research participants or their legally authorized representative (if they are not able to consent for themselves). As a consequence, all information provided to potential participants should be in a language that is understandable to those individuals.

Federal regulations (45 CFR 46.116 and 21 CFR 50.20) require that researchers obtain the legally effective informed consent of the research participants or their legally authorized representative (if they are not able to consent for themselves). As a consequence, all information provided to potential participants should be in a language that is understandable to those individuals. TCH IRB allows two means by which this can be accomplished: (1) Written translation of IRB-approved documents or (2) use of a Short Form and request for an exception.

The Principal Investigator must anticipate the need for written translations in considering the likely proportions of non-English-speaking people who may be encountered as eligible participants for a proposed study. For instances of consenting an occasional and unexpected non-English-speaking participants in a study for which no consent form in the prospective participant's language has been IRB-approved, the investigator must notify the IRB of the exception and utilize the IRB-approved short form consent in the prospective participant's language and an interpreter to translate the consent form in the participant's language.

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 prospective participant. 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.

2.0 PROCEDURE

2.1 Written Translation of IRB-Approved Documents

When the study design explicitly targets the enrollment of non-English-speaking participants, investigators are required to provide a written translation of relevant study documents in a language understandable to those persons. Translations are to be prepared by a skilled professional after initial IRB review and approval of the English version. The translated documents require IRB review and approval. Documents required to be translated include, but are not limited to:

- Written informed consent documents
- Verbal consent scripts
- Assent forms
- Information sheets
- Recruitment materials
- Surveys/questionnaires/interview guides
- Instructional materials
- Any other documents as requested at the discretion of the IRB

2.1.1 Requesting the Use of a Translated Informed Consent Document

The following are the steps which need to be taken:

1) Make a formal request with the IRB.
    a) For new protocol submissions:
        a) Select *Non-English Speaking* under *Vulnerable Populations* to indicate that you will enroll non-English speakers when creating a new protocol. This will populate the "Non-English Speaking Participants" section in the IRB Application.
        b) Submit English-language consent documents only. Also submit English-language versions of any recruitment materials or other study materials that will need to be translated.
        c) After IRB approval of the research, the PI, or designee, must obtain accurate written translations of the approved English-language documents, as appropriate, with Certificates of Translations and submits them as an Amendment for review and approval prior to enrolling participants using the translated language consent form(s).
    b) For approved research:
        a) the PI, or designee, must obtain accurate written translations of the approved English-language documents, as appropriate, with Certificates of Translations and submits them as an Amendment for review and approval prior to enrolling participants using the translated language consent form(s).
2) Provide an interpreter who:
    a) is not a family member of the prospective participant
    b) is not a member of the study team
    c) reads, speaks, and writes the native language of the prospective participant and English
    d) can be physically or remotely present for the consent process

    Note: Bilingual clinical staff who are not a member of the research team are permitted to act as an interpreter
3) Provide a Witness to the oral presentation who:
    a) reads, speaks, and writes the native language of the prospective participant and English
    b) is not a member of the research team
    c) can be physically or remotely present for the oral presentation of the study-specific details

d) is willing to sign and date both the Translated consent form the IRB-approved English-language version of the consent form

Note: The Interpreter is permitted to act as the Witness

2.1.2 Translated Consent Process, Signatures, and Documentation

1) The prospective participant reads the IRB-approved translated language consent form(s).
2) The interpreter presents the oral version of the translated language consent form(s).
3) A study team member, who is approved to obtain consent, must be present for this presentation and follows along with the IRB-approved English consent form.
4) The interpreter facilitates discussion by posing the prospective participant's questions and answers provided by study team members, to ensure participant understanding.
5) When all of the prospective participant's questions and concerns have been addressed, the prospective participant signs and dates the translated language consent form(s).
6) The witness signs and dates the translated language consent form(s) and the IRB-approved English-language consent form(s).
7) The study team member approved to obtain consent signs and dates the IRB-approved English consent form.
8) The participant must receive signed copies of both consent forms.
9) The study team member retains the signed/dated copies of both consent forms for study records.
10) The study team member documents in the research record the names of all individuals who were present for the consent process.

2.2 Use of a Short Form as an Exception

The use of a Short Form consent and request for an exception is acceptable in instances when the approved study does not specifically plan to target the enrollment of non-English-speaking participants; however, unexpectedly, a non-English speaking participants meets enrollment criteria and wishes to participate.

2.2.1 Requesting the Use of a Short Form and Request for an Exception

The following are the steps which need to be taken prior to obtaining consent:

1) Obtain a Short Form from the IRB Office
2) Submit a request for an exception for IRB approval
3) Await notification that the IRB has approved the request for an exception
4) Provide an interpreter who:
   - is not a family member of the prospective participant;
   - is not a member of the study team;
   - reads, speaks, and writes the native language of the prospective participant and English; and
   - can be physically or remotely present for the consent process.

Note: Bilingual clinical staff who are not a member of the research team are permitted to act as an interpreter

5) Provide a Witness to the oral presentation who:
   - reads, speaks, and writes the native language of the prospective participant and English;
   - is not a member of the research team;
   - can be physically or remotely present for the oral presentation of the study-specific details;
   - is willing to sign and date the Short Form consent; and
   - is willing to sign and date the IRB-approved English-language version of the consent form.

   Note: The Interpreter is permitted to act as the Witness
6) Provide the IRB-approved English language consent form to be orally communicated to the prospective participant by the Interpreter.

2.2.2 Short Form Consent Process, Signatures, and Documentation

1) The prospective participant reads the Short Form consent in their native language.
2) The interpreter presents the oral version of the IRB-approved English-language consent form.
3) A study team member, who is approved to obtain consent, must be present for this presentation.
4) If the interpreter is not also acting as the Witness, the Witness must be physically or remotely present during this presentation as well.
5) The interpreter facilitates dialog between the prospective participant's and study team member(s) to ensure the prospective participant's understanding.
6) When all of the prospective participant's questions and concerns have been addressed, the prospective participant signs and dates the Short Form consent document.
7) The witness signs and dates the Short Form consent and the IRB-approved English consent form.
8) The Study team member approved to obtain consent signs and dates the IRB-approved English consent form.
9) The participant must receive signed copies of both consent forms.
10) The study team member retains the signed/dated copies of both consent forms for study records.
11) The study team member documents in the research record the names of all individuals who were present for the consent process.

REFERENCES:

45 CFR 46.116
21 CFR 50.20
TCH Policy# 4.20.198 Language Access and Interpreter Services