The Christ Hospital IRB
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STANDARD OPERATING PROCEDURE

Consent Translations and Interpreting Requirements for Non-English Speaking Participants

POLICY:

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

Federal regulations (45 CFR46.116 and 21 CFR50.20) require that researchers obtain the legally effective informed consent of the research subjects or their legally authorized representative (if they are not able to consent for themselves). As a consequence, all information provided to potential subjects 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 subjects for a proposed study. For instances of consenting an occasional and unexpected non-English-speaking subject in a study for which no consent form in the subject'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 subject's language and an interpreter to translate the consent form in the subject'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 subject. 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.

PROCEDURE:

Written Translation of IRB-Approved Documents

When the study design explicitly targets the enrollment of non-English-speaking subjects, investigators are required to provide a written translation of relevant study documents in a language understandable to those subjects. 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

Use of a Short Form and Request for 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 subjects; however, unexpectedly, a non-English speaking subject meets enrollment criteria and wishes to participate. The following are the steps which need to be taken-

1) Prior to obtaining consent
   a) Obtain a Short Form from the IRB Office
   b) Locate an interpreter who-
      i) is not a family member of the participant
      ii) is not a member of the study team
      iii) reads, speaks, and writes the native language of the participant and English
      iv) can be physically 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
   c) Find a Witness to the oral presentation who:
      i) reads, speaks, and writes the native language of the participant and English
      ii) is not a member of the research team
      iii) can be physically present for the oral presentation of the study-specific details
      iv) is willing to sign and date the Short Form consent
      v) is willing to sign and date the IRB-approved English version of the consent form

      Note: The Interpreter is permitted to act as the Witness
   d) Provide the IRB-approved English language consent form to be orally communicated to the subject by the Interpreter
   e) Submit a request for an exception for IRB approval
   f) Await notification that the IRB has approved the request for an exception
2) Consent Process, Signatures, and Documentation
   a) Participant reads the Short Form consent in their native language
   b) Interpreter presents the oral version of the IRB-approved English consent form
   c) A study team member, who is approved to obtain consent, must be present for this presentation.
   d) If the Interpreter is not also acting as the Witness, the Witness must be present during this presentation as well
   e) The Interpreter facilitates participants asking questions and study team members providing answers, to ensure participant understanding
   f) When all of the Participant's questions and concerns have been addressed, the Participant signs and dates the Short Form consent document
   g) The Witness signs and dates the Short Form consent and the IRB-approved English consent form
   h) The Study team member approved to obtain consent signs and dates the IRB-approved English consent form

i) The subject must receive signed copies of both consent forms.
j) The Study team member retains the signed/dated copies of both consent forms for study records
k) 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

REVISION HISTORY:

Date Revised	Reason For Change	Revised By