

ST. LUKE'S UNIVERSITY HEALTH NETWORK

IRB POLICIES AND PROCEDURES MANUAL

600 Informed Consent (IC)

Policy IC 605: Illiterate, Non-English Speaking Subjects, and Subjects Physically Unable to Sign

1. PURPOSE

To delineate the policy and procedures for conducting the informed consent process when a potential subject cannot read English, is non-English speaking, or is physically unable to sign a consent form.

2. RESPONSIBILITY FOR EXECUTING THE POLICY

IRB Medical Director; IRB Associate Directors; IRB Administrative Support; IRB Chair; IRB Vice-Chair; IRB Members and Subcommittees; Investigators

3. POLICY STATEMENT

Department of Health and Human Subjects (DHHS) regulations require that informed consent information be presented in "language understandable to the subject" and, that, in most instances, informed consent be documented in writing unless appropriate waiver criteria are met (45 CFR §46.116 and §46.117). If a potential subject is non-English speaking, the consent form must be translated into the subjects' language. In the translation, particular attention must be paid to meanings and cultural nuances surrounding words and phrases as they may have different meanings or connotations in the potential subjects' own language. If the translation is not accurate, the subject could be misinformed and this would undermine the ability of the subject to give truly informed consent.

4. PROCEDURES

4.1: Persons Illiterate in English

An individual who understands, but does not read English may have the consent form read to him/her and s/he may "make his/her mark". The signature of an impartial witness to the consent process and that of the person conducting the consent interview are required [21 CFR §50.27(b)(2)]. ***Ideally, the witness should be a relative of the subject, but the witness cannot be study personnel.***

4.2: Individual Does Not Understand or Speak English

Having a translator present during the consent interview to do an ad hoc translation of the consent form is not permitted under federal regulations. If an individual meets the inclusion/exclusion criteria for the study, but does not speak English, s/he cannot be denied participation on the study, but must be offered the opportunity to read and understand a consent form translated into his/her native language. Federal regulations do not elaborate on who is qualified to translate the consent form into the required language. In situations where time does not permit a full translation to be prepared, the provisions for the short form consent process, as per 45 CFR 46.117(b)(2), are permitted.

However, the research summary and short form consent required by this regulation must be translated into the native language of the subject and a translator must be present at the consent interview. The translator may serve as the witness for the short form consent process. The short form documents must be approved by the IRB prior to being used.

The above procedure is allowable in circumstances where a non-native speaker who is not part of a targeted non-English speaking subject population presents as a potential research subject. When an investigator is specifically targeting particular non-English speaking populations for enrollment in a study, appropriately translated consent forms must be approved by the IRB prior to enrolling members of these populations.

4.3: Individuals Physically Unable to Sign a Consent Form

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If a subject is cognitively capable of consent, but is physically unable to sign the consent form (e.g. paralyzed), the subject's power of attorney or an impartial witness must be present for the entire consent interview. Ideally, the witness should be a relative of the subject and cannot be study personnel. After the subject has indicated the intention to consent, the subject's name and the current date may be written in the appropriate places on the consent form signature page.

If able, the subject will make his/her mark on the signature line. The witness will initial and date each page of the consent form and complete the witness section of the signature page.

4.4: Translation of the Consent Form

For translation of the consent form, the investigator must use a professional translator. Companies providing translation services will provide certification that the translation is an accurate representation of the original English consent form.

4.5: Presence of a Translator

A translator should be present during the consent interview for a non-English speaker. The translator must be someone who can accurately translate between spoken English and the subject's native language and who understands the cultural nuances of the language. The translator may be a member of the subject's family or someone else who can adequately fulfill the duty. A translator should also be available during the full course of the non-English speaker's participation in the study, so that the subject can always communicate reliably with the research team, which is a right of any research subject. The principal investigator should assume responsibility for assuring that appropriate arrangements with the translator or translation service can be made before the non-English speaker is enrolled.

4.6: Short Form Consent

All foreign language versions of short form consent documents must be approved by the IRB under the provisions of §46.117(b)(2). Review of the foreign language versions of the documents may be carried out by expedited review, but only if the protocol and full English language informed consent document have been given prior approval by a convened IRB.

Approved by:

Senior Vice President for
Medical and Academic Affairs

Date: _____

Medical Director, IRB

Date: _____