Icahn School of Medicine at Mount Sinai

Institutional Review Board
Program for the Protection of Human Subjects

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ENROLLMENT OF NON-ENGLISH SPEAKING SUBJECTS IN RESEARCH

I. SCOPE OF POLICY:

This Policy sets forth the IRB requirements for recruitment and informed consent of human subjects who are not fluent in English ("Non-English Speaking Subjects") in all research studies conducted by Icahn School of Medicine or The Mount Sinai Hospital investigators at The Mount Sinai Hospital, Queens Hospital Center or Elmhurst Hospital Center. This Policy is intended to ensure that Non-English Speaking Subjects are (a) included in research studies with accommodations for their lack of fluency in English and (b) adequately provided with the information necessary to exercise informed consent.

EFFECTIVE DATE: DECEMBER 5, 2013

II. BACKGROUND:

The Belmont Report identifies "justice" and "respect for persons" as two fundamental ethical principles that must underlie the conduct of all human subjects research. The principle of justice requires that the burdens and benefits of research are equitably distributed. The principle of respect for persons requires that "adequate standards for informed consent are satisfied" so that subjects are provided with sufficient meaningful information to decide whether they want to enroll in a research study.

The Program for the Protection of Human Subjects (PPHS) strives to ensure that policies relevant to the conduct of human subjects research are consistent with institutional policies that affect patient-subjects. It is the belief of the PPHS that hospital standards regarding patient rights should be the same standards applied to subjects of research.

A patient is entitled to hear medical and research-related information in his/her preferred language, and the person conveying that information has to be a trained medical interpreter. At Mount Sinai, an employee who is bilingual and is performing daily work responsibilities can do so in the target language (for example, a Spanish speaking nurse/doctor caring for a Spanish speaking patient), but if that nurse/doctor is called upon to interpret for someone else (this is not considered part of daily work responsibilities), the nurse/doctor must be a trained medical interpreter.

III. POLICY:

A. ACCEPTABLE TRANSLATORS AND CERTIFICATIONS

All translations of documents referred to in this Policy must be certified by a qualified translator who is acceptable to the IRB (an "Acceptable Translator") based on the nature and level of risk involved in the research study.

For each translation described in items 1-3 below, the IRB must receive an attestation or other written documentation certifying that the translation is consistent in content, style, and level of readability with the IRB-approved document and, for non-commercial translators, an explanation of the translator's qualifications. The letter or other documentation should reference the IRB approval and expiration dates of the study, as well as a document identifier (i.e., consent form number, document title) that is unique to each IRB-approved item that is being translated.

Acceptable translators include the following:

1. A commercial entity that provides translations as a service to the public.
2. An individual who is bilingual and fluent in both English and the language of the Non-English Speaking Subject.
3. An external sponsor such as NIH, NSF, or private industry.

For studies utilizing a central or commercial IRB, under an Inter-Institutional Agreement (IIA), the consent documents approved by that IRB, in any language, are considered valid and accepted under the terms of the agreement.

B. LONG FORM CONSENT DOCUMENTS

When the subject population of any research study is expected to include a significant number of subjects who are not fluent in English but are fluent in any single language other than English ("Expected Non-English Speaking Subjects"), the IRB requires a full translation of the English version of the study's approved consent document (a "Long Form Consent Document") with a certification as described in Section III.A. above.

In such situations, once the IRB has approved a Long Form Consent Document in English, the investigator must obtain a certified translation in accordance with Section III.A. above. The translated Long Form Consent Document, together with the certification of translation and copy of the stamped English version consent used for the translation, must be submitted to the PPHS office for review and approval as a modification to the protocol. The version date on the translated version should match the version date of the approved English version consent. DO NOT TRANSLATE APPROVAL DATES in the footer of the consent document. The translated consent document must be approved by the IRB prior to use. If the Protocol Template does not indicate that non-English Speakers will be enrolled, the Protocol Template must also be modified to include enrollment of this subject population.

For studies utilizing an external IRB, follow the policies and procedures of that IRB for obtaining review and approval of the translated consent document. The translated consent documents must be approved by the external IRB prior to use. For studies utilizing an external IRB, do not submit translated consent documents to the PPHS.

C. ORAL TRANSLATIONS AND SHORT FORM CONSENT DOCUMENTS

For studies where Non-English Speaking Subjects (or Non-English Speaking parents of a potential child subject/agents of an incapacitated adult) of a particular language group are

not expected in a significant number, but are encountered upon rare occasion, investigators may rely on oral translations of the consent document. Hospital Policy and Procedures must be followed. Research conducted at The Mount Sinai Hospital must follow Institutional Policy or hospital practice as delineated by the Language Assistance Program at Mount Sinai. Research conducted at Elmhurst or Queens Hospital Centers must follow the HHC Administrative Policy and Procedure.

In addition to the above referenced Policy and Procedures, the following procedures must be followed in research studies using oral translations:

1. The Protocol Template must include provisions for enrolling non-English Speakers (in general) under the Short Form Consent Policy. If this information is not included in the Protocol Template, submit a modification to the protocol to include this subject population and ensure that the sections on the consent process and documentation describe the process to be followed accurately/appropriately.

2. The researcher must contact the PPHS office once a potential subject who does not speak English or Spanish has been identified to request the specific Short Form Consent Document to be used. The PPHS office will confirm if that language is available in the Short Form Consent library and make the Short Form Consent Document available to the researcher for this one use.

3. The English version of a short form consent document (the "Short Form Consent Document") must be translated into a language understandable to the Non-English Speaking Subject. The Short Form Consent Document is a one page form that identifies the principal investigator and title of the research study, and summarizes the elements of informed consent, but does not describe any specific research study. Several pre-approved translations of Short Form Consent Documents as well as an English sample are available from the PPHS office for use in the event that an investigator unexpectedly encounters a Non-English Speaking subject. If there is no translation of a Short Form Consent Document in a particular language available for use, the Short Form Consent Document must be translated and added to the PPHS Library in order to be available for use. The PPHS will provide a copy of the English Short Form Document to the requestor for the purpose of obtaining a translation. The translated Short Form Consent must be submitted to the PPHS along with the attestation of accuracy and summary of qualifications of the translator.

4. Given the large number of Spanish speaking persons in the areas served by the Institution, a Short Form Consent Document in Spanish is not available and will not be approved. It is the IRB's expectation that a Spanish translation of the Long Form Consent Document will be utilized with this subject population.

5. A written summary in English of the information provided in the Long Form Consent Document (a "Written Summary") must be approved by the IRB and provided to each Non-English Speaking Subject. The IRB-approved English Long Form Consent Document may serve as the written summary.

6. The interpreter must meet institutional standards and be approved as an interpreter through the Hospital policy. At Mount Sinai Hospital, if Pacific Interpreters will not be used, the hospital must assure the appropriateness of any interpreter used in the hospital setting. Family members or friends of the subject, research coordinators, etc. are not permitted to serve as the interpreter under this policy.

The current Mount Sinai Hospital standards for a trained Medical Interpreter are noted below[1]:

Minimum qualifications:

- Associates degree from an accredited institution, preferably a Bachelors (with a concentration in Translation/Interpreter studies)
- Fluent in both English and target language
- 2 years minimum interpreting experience in a medical setting
- Completion of 40 hour (minimum) certificate program in either: CultureSmart, Bridging the Gap, Hostos Community College/LaGuardia Community College or certified program from IMIA (International Medical Interpreters Association)

Elmhurst Hospital Center must comply with Elmhurst Hospital Policy (HHC Administrative Policy and Procedure ADM 30), and Queens Hospital Center must be comply with Queens Hospital Policy:

- Face-to-Face Interpreter Services: By calling 1500, option 1, from any EHC phone during daytime hours, (Monday-Friday 8 AM~7 PM and Saturday 10 AM ~3 PM), an EHC foreign language or American Sign Language (ASL) interpreter can be dispatched to your location. Interpreter dispatch is managed by Volunteer Services. If no face-to-face interpreter is available, you will be asked to use a telephonic interpreter (or video, in the case of ASL). EHC interpreters have demonstrated both bilingual fluency and an ability to interpret by passing an assessment tool and received training that includes: Medical Interpreter Ethics, Medical and Anatomical Terminology, Mechanics of Effective Interpreting Skills, discussions on the role of the medical interpreter and relevant cultural and diversity issues. Interpreters who have passed these qualifications can be easily recognized through their special photo I.D. card specifying the language-pair in which they are qualified.
- Telephonic Interpreter Services: Interpreters in over 140 languages can be reached by telephone 24 hours a day, 365 days a year, by calling 1500, option 2, from any EHC phone.
- If the language you require is not available through 1500, call the dispatcher (1500, option 1) in the daytime or, if in the evening or during weekends, call the AOD or the EHC Operator to arrange an interpreter through an approved vendor. Advance notification is helpful in providing an interpreter for languages not frequently requested.

NOTE: Interpreter services must be provided free of charge to persons with limited English proficiency. This policy does not imply that such services are available for free to researchers and there may be charges that apply.

7. In addition to the individual authorized to obtain consent, there must be an impartial witness present during the oral translation. The role of the witness is to attest to the consenting process and the apparent understanding of the subject. If the interpreter is onsite, he/she will serve as the witness, as long as the interpreter is not

[1] As delineated by the Language Assistance Program, The Mount Sinai Hospital, November 2013.

the person authorized to obtain consent. If the interpreter is available by phone, the witness must be a third party in the room (not the person authorized to obtain consent).The person authorized to obtain consent may not serve as the witness. The impartial witness may be a family member or friend. If a family member of friend of the potential subject is not available, the impartial witness may be a staff member who is not on the study team. The impartial witness may not be a person involved in the design, conduct, or reporting of the research study.

The Short Form Consent Document must be signed by the Non-English Speaking subject and the witness. The written summary (the IRB approved English Long Consent Document) must be signed by the witness and the individual authorized to obtain consent. As part of the documentation of the consent process, note the name or interpreter ID of the person who served as the interpreter in the research record.

8. A copy of the Written Summary and the Short Form Consent Document must be given to the Non-English Speaking Subject. The original Written Summary and Short Form Consent Document should be kept in the subject's research record.

9. If oral consent in any one language has been obtained from a significant number of subjects enrolled in a study (generally defined as five percent of the enrolled subjects), and enrollment is ongoing, the Principal Investigator is expected to submit a protocol modification to provide specific information (i.e., the number of subjects enrolled and their native language) to the IRB. A translated Long Form Consent Document with a certificate of translation must also be submitted and approved by the IRB prior to any additional Non-English Speaking subjects who speak that particular language being enrolled in the study.

Flow Chart attached to this Policy outlines the requirements for translated consent, when a long or short consent form is acceptable, and who needs to sign each form.

D. EFFECTIVE COMMUNICATION THROUGHOUT THE STUDY

In order for consent to be effective, the subject must be provided with all relevant research-related information and must clearly understand such information. When Non-English Speaking subjects are being asked to participate in a study, investigators must ensure that there is adequate communication between the research team and such subjects.

Unless the principal investigator or a member of the research team is fluent in the prospective Non-English Speaking subject's language, an interpreter will be necessary to facilitate the conversation during the consent process and communication throughout the course of the study. Interpreters must be fluent in English as well as in the language of the Non-English Speaking subject. The interpreter must meet Institutional standards and must be approved by the appropriate designee of the President of the Hospital.

E. RECRUITMENT OF SUBJECTS

Based on the demographics of the geographic area surrounding parts of the Institution, and the experience of researchers at Mount Sinai, it is expected that some of the adults eligible for enrollment in research studies will not be fluent in English. To ensure that the principle of justice enunciated in the Belmont Report is adhered to, the IRB may require

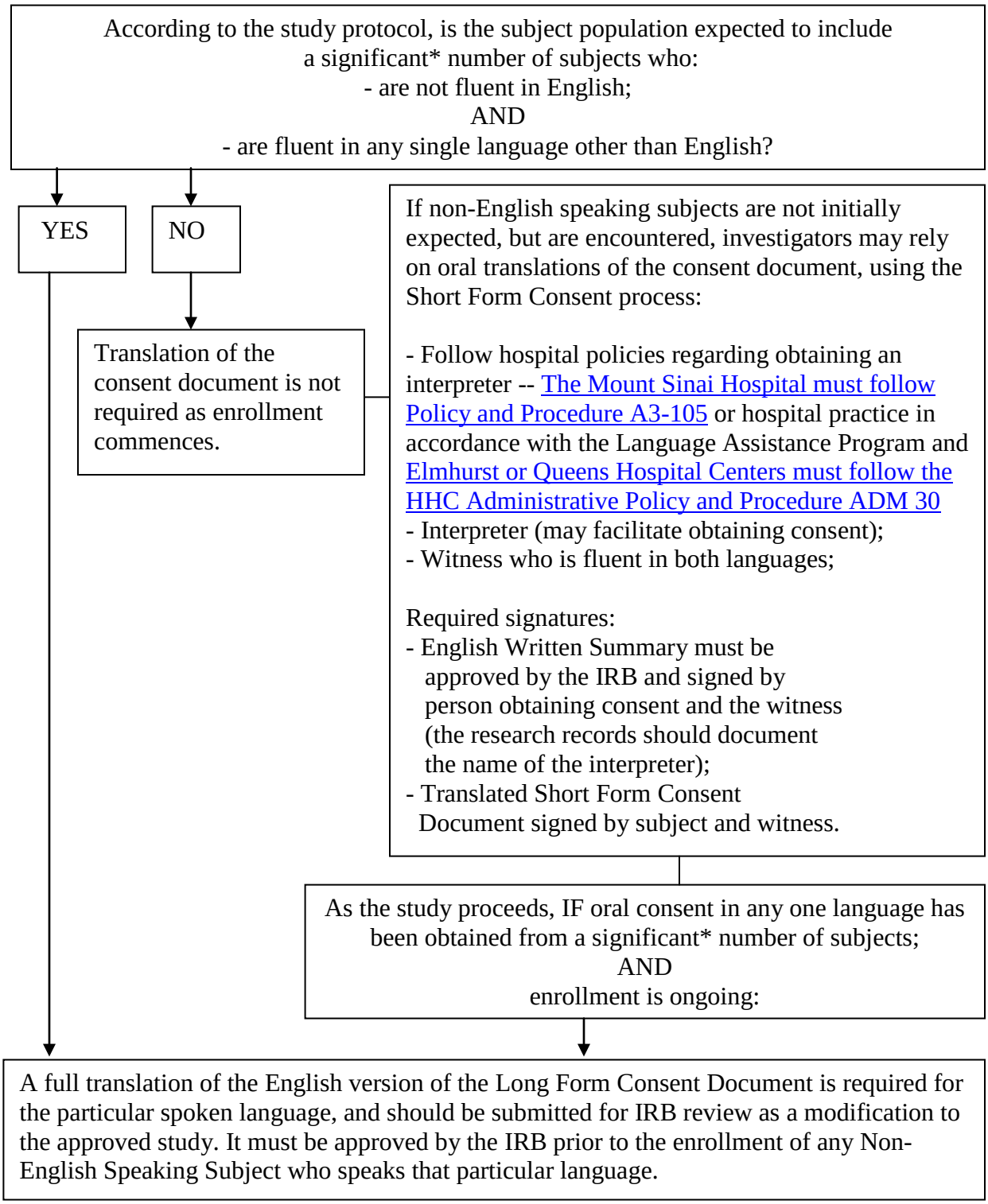
efforts to recruit individuals who are not fluent in English in research studies that offer the potential for therapeutic benefit.

Recruitment materials such as flyers must be translated in order to accommodate Expected Non-English Speaking Subjects (i.e., a significant number of subjects who are not fluent in English). All translations of recruitment materials must be certified by an Acceptable Translator and approved by the IRB prior to their use.

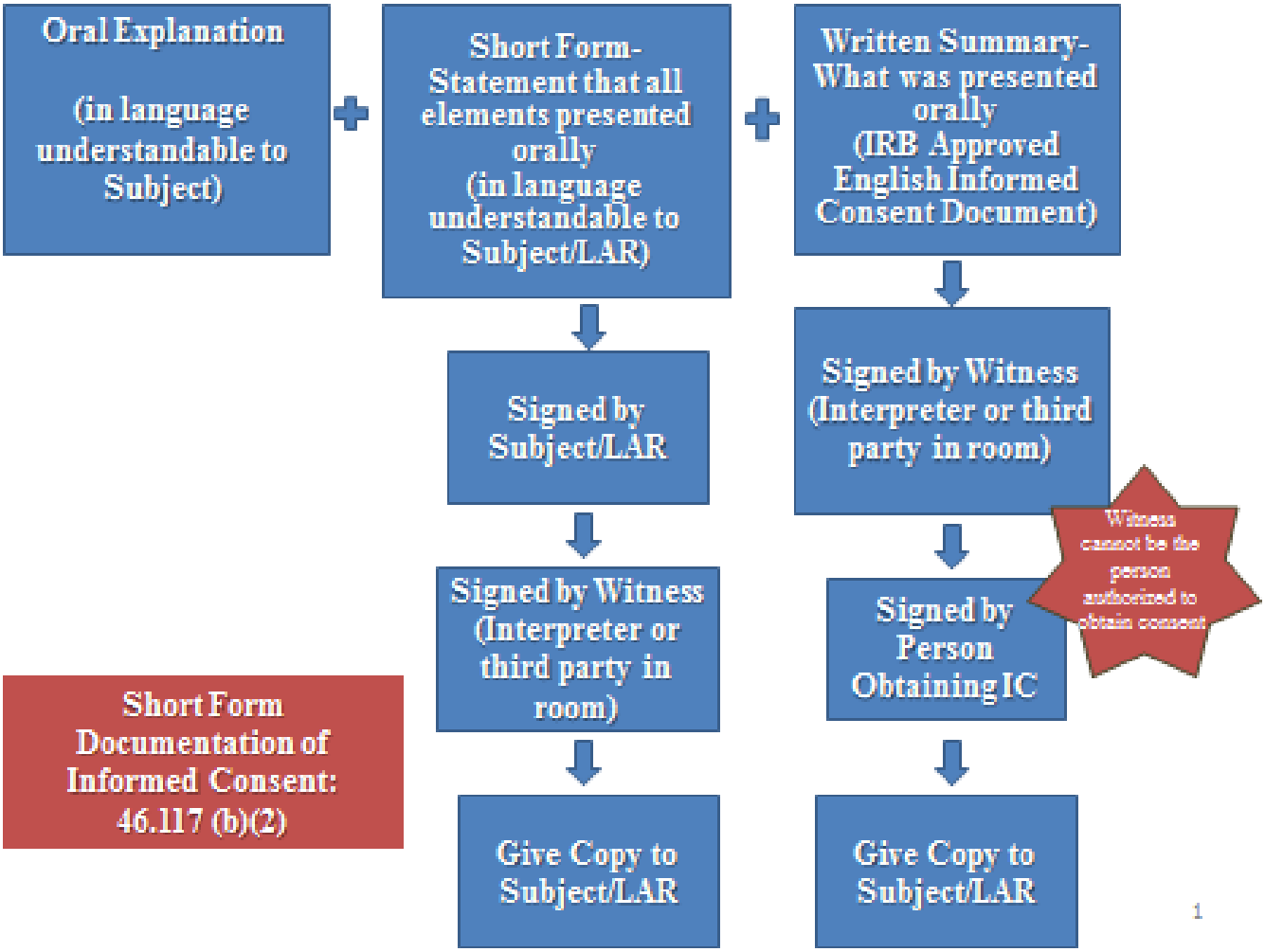
F. OTHER CONSIDERATIONS

If an investigator has study instruments that must be translated, the translations must be certified by an Acceptable Translator and approved by the IRB. Study instruments that are not viewed or completed by the subject (are completed by study personnel through interaction with the subject) may be in English and translated orally by an interpreter or member of the research team who is fluent in the language spoken by the Non-English Speaking Subject once consent has been obtained in accordance with the policy noted above.

Flow Chart: Requirements for Translated Consent Document and Use of Short Form Consent



* Generally defined as five percent of the enrolled subjects. For studies with a total anticipated sample size of less than 40, the IRB will generally allow a maximum of two subjects to be enrolled using the short form process.


Oral Explanation
(in language understandable to Subject)
Short Form- Statement that all elements presented orally (in language understandable to Subject/LAR)
Written Summary- What was presented orally (IRB Approved English Informed Consent Document)
Signed by Subject/LAR
Signed by Witness (Interpreter or third party in room)
Signed by Witness (Interpreter or third party in room)
Witness cannot be the person authorized to obtain consent
Signed by Person Obtaining IC
Short Form Documentation of Informed Consent: 46.117 (b)(2)
Give Copy to Subject/LAR
Give Copy to Subject/LAR
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