

**COLUMBIA UNIVERSITY
INSTITUTIONAL REVIEW BOARD POLICY**

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 Columbia faculty, employees, and students. 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.

II. EFFECTIVE DATE: December 4, 2006, Revised November 19, 2009

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.

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”). The IRB will use its discretion in determining whether the credentials of the translator are acceptable, 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 a letter 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, although all may not be appropriate for all types of research:

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, for minimal risk studies.

For research that is greater than minimal risk, the translated document must be back-translated into English by another individual who is also bilingual and fluent in both

languages; for Spanish translations, item 5 below may be utilized in lieu of the back translation.

If the research is a minor increment over minimal risk, the IRB may waive the requirement of the back translation into English.

3. An external sponsor such as NIH, NSF, or private industry.
4. For Spanish translations, the University's Hispanic Translation Center (the "HTC"); the HTC stamp serves as an acceptable certification.
5. For Spanish translations, any translator so long as the translation is reviewed and certified by the HTC.

Flow Chart A attached to this Policy outlines the acceptable translators for minimal risk and greater than minimal risk studies.

The CU IRB will also accept translations generated by or under the auspices of a commercial or central IRB upon which the CU IRB relies, via an IRB Authorization Agreement. In such cases, documentation of translation by the commercial IRB may serve as certification.

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, must be submitted to the IRB in RASCAL, or if eligible through the IRB administrative approval procedure outside of RASCAL. It must be approved by the IRB prior to it being used to enroll any Expected Non-English Speaking Subjects who speak that particular language.

C. ORAL TRANSLATIONS AND SHORT FORM CONSENT DOCUMENTS

For studies where Non-English Speaking Subjects are not expected, but are encountered, investigators may rely on oral translations of the consent document. The following procedures must be followed in studies using oral translations:

1. 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 posted on the IRB website for immediate 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 on the IRB website, a translated Short Form Consent Document, together with the certification of translation, must be submitted to the IRB through RASCAL as a protocol modification and approved by the IRB prior to it being used to enroll Non-English Speaking Subjects who speak that particular language.

2. 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 Long Form Consent Document may serve as the Written Summary.

3. In addition to the individual authorized to obtain consent, there must be a witness present during the oral translation who is fluent in both English and the language of the Non-English Speaking Subject. If the individual authorized to obtain consent is not fluent in English and the language of the Non-English Speaking subject, a translator (more appropriately referred to as an interpreter) who is fluent in both languages is also required. The role of the witness is to attest to the accuracy of the translation and the apparent understanding of the subject.

4. The Short Form Consent Document must be signed by the Non-English Speaking Subject and the witness. The Written Summary must be signed by the witness and the individual authorized to obtain consent. The name of the person who served as the interpreter/translator should be noted in the research record as part of the documentation of the consent process.

5. 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.

6. If oral consent in any one language has been obtained from a significant number of subjects enrolled in a study, and enrollment is ongoing, the Principal Investigator is expected to submit a protocol modification through RASCAL 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. A significant number is 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.

Flow Chart B 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 legally 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, a translator will be necessary to facilitate the conversation during the consent process and communication throughout the course of the study. Translators should be fluent in English as well as in the language of the Non-English Speaking Subject.

E. RECRUITMENT OF SUBJECTS

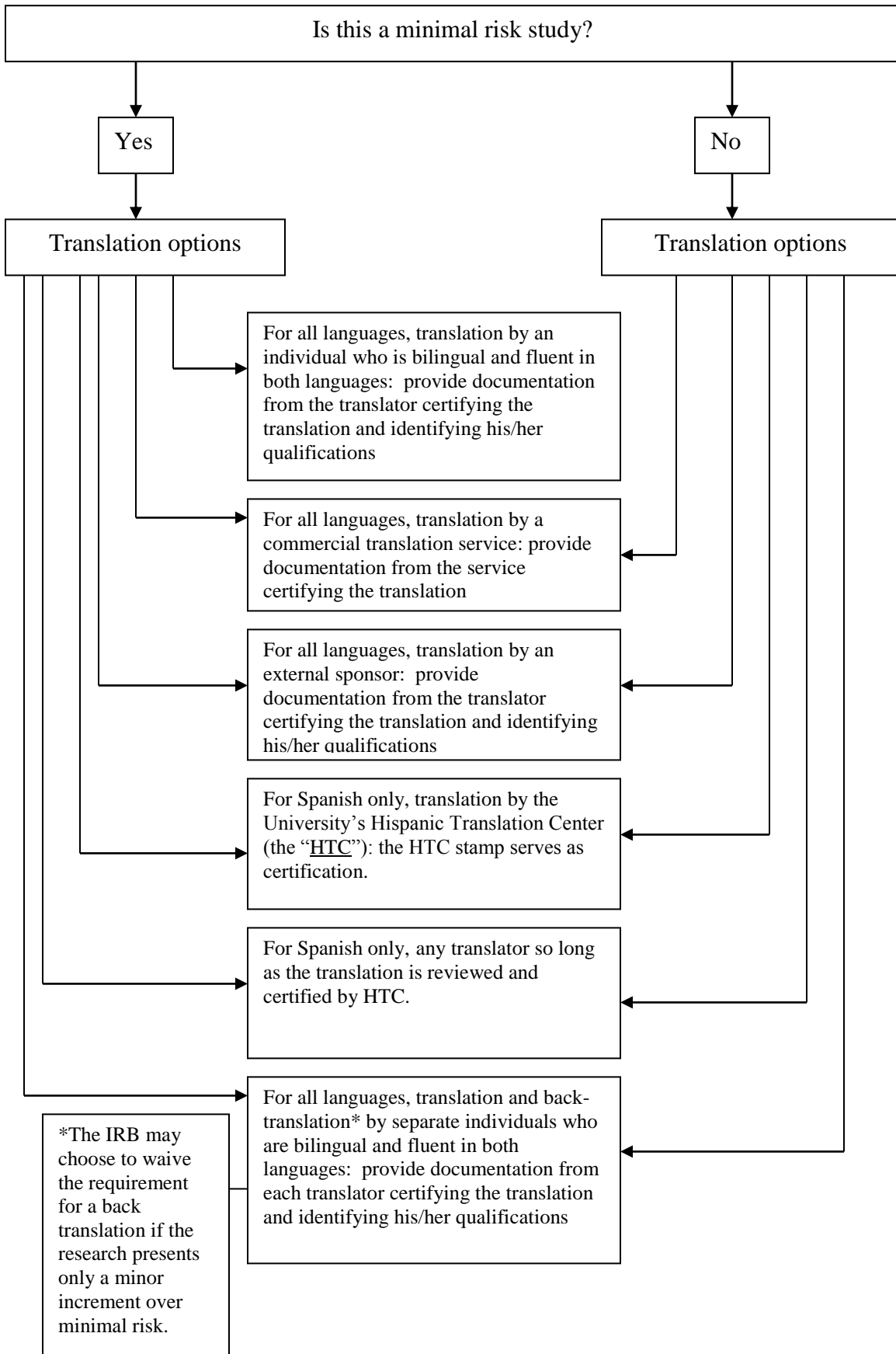
Based on the demographics of the geographic area surrounding parts of the University, and the experience of researchers at Columbia, it is expected that some of the adults eligible for enrollment in research studies at the University will not be fluent in English. To ensure that the principle of justice 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.

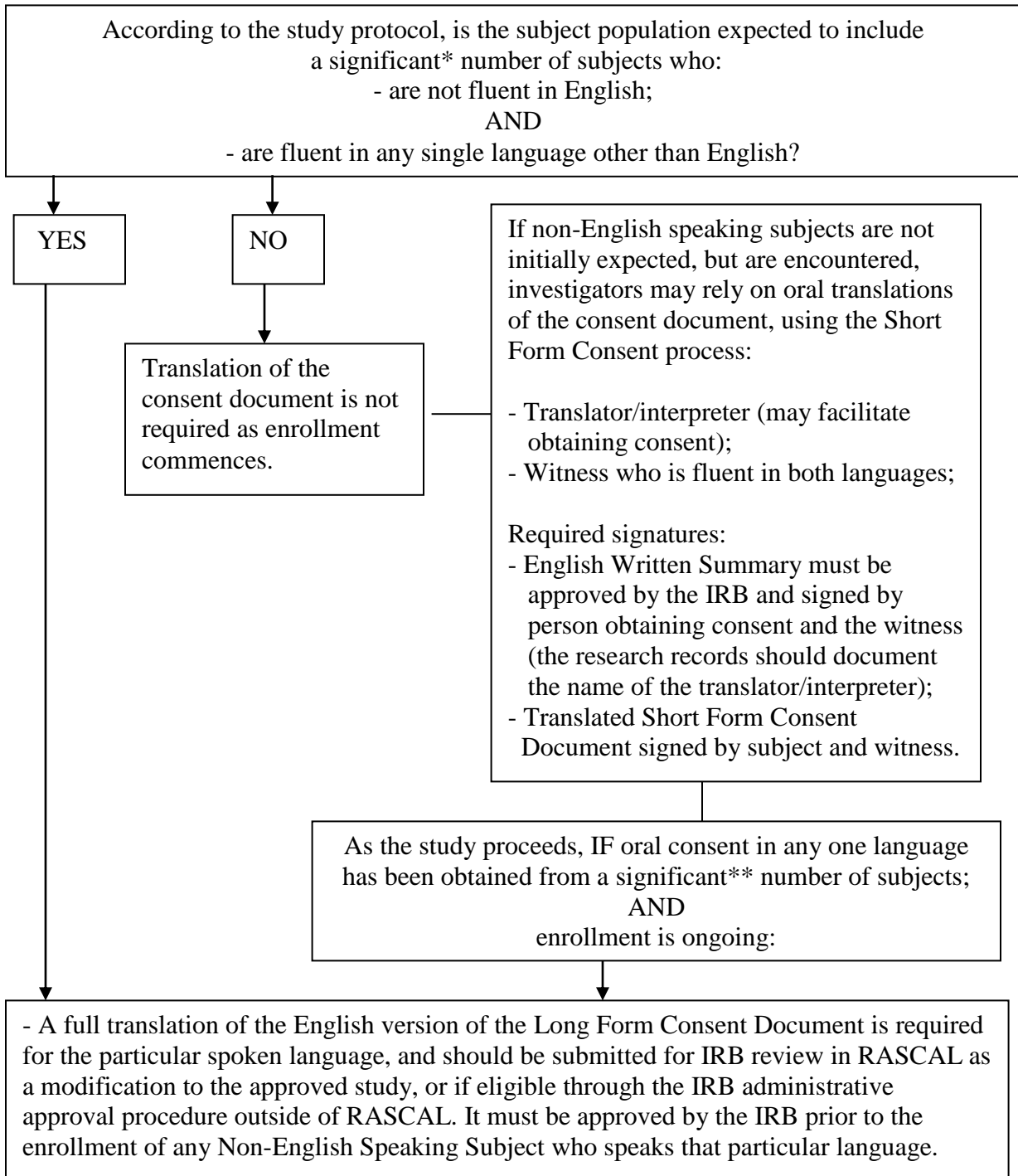
F. OTHER CONSIDERATIONS

If an investigator prefers to have any study instruments translated, the translations must be certified by an Acceptable Translator and approved by the IRB. Study instruments may be in English and translated orally by a translator or member of the research team who is fluent in the language spoken by the Non-English Speaking Subject.

Flow Chart A: Acceptable Translators and Certifications



Flow Chart B: Requirements for Translated Consent Document



* 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.