The Weill Cornell Medical College Institutional Review Board follows Office of Human Research Protection Guidelines for consenting Non-English Speaking Subject as outlined below:

- **Expected enrollment of non-English speaking subjects**: For those studies where the recruitment efforts will target a certain population such that the PI expects a significant proportion of subjects will be non-English speaking, the IRB shall require a translated consent document to be prepared. In order to ensure that the translation is accurate, an affidavit of accuracy from the translation service or a back translation of the translated consent form to English by a third party (i.e., an individual not an investigator on the protocol). When non-English speaking subjects enroll, they must be given a copy of the translated consent document. Subjects and witnesses must sign the translated document.

- **Unexpected enrollment of a non-English speaking subject**: If a non-English speaking subject is unexpectedly eligible for protocol enrollment, there may not be an existing IRB-approved written translation of the consent document. Investigators should carefully consider the ethical and legal ramifications of enrolling subjects when a language barrier exists. If the subject does not clearly understand the information presented at the signing of the consent document or in subsequent discussions, his/her consent may not be informed, and therefore, not effective.

If a PI decides to enroll a subject into a protocol for which there is not an existing IRB-approved informed consent document in the prospective subject's language, the procedure for obtaining oral consent of a non-English speaker may be used. This procedure is outlined below. The PI must receive IRB approval to allow the procedures for oral informed consent.

A short form consent document in both English and the subject’s language should be reviewed and approved by the IRB. A certificate of accuracy or a back-translation of the short form by a third party should be included with the submission. Expedited review of these versions is acceptable if the protocol and the full English language informed consent document, have already been approved by the convened IRB.

When this procedure is used with subjects who do not speak English, (i) the oral presentation and the short form written document should be in a language understandable to the subject; (ii) the IRB-approved English language informed consent document may serve as the summary; and (iii) the witness should be fluent in both English and the language of the subject.
At the time of consent, (i) the short form document should be signed by the subject (or the subject's legally authorized representative); (ii) the summary (i.e., the English language informed consent document) should be signed by the person obtaining consent as authorized under the protocol; and (iii) the short form document and the summary should be signed by the witness. When the person obtaining consent is assisted by a translator, the translator may serve as the witness.

**Use of interpreters in the consent process:** Unless the PI or a co-investigator on the IRB approved protocol is fluent in the prospective subject’s language, an interpreter will be necessary to facilitate the conversation during the consent process and communication throughout the study. Preferably someone who is independent of the subject (i.e., not a family member) shall assist in presenting information and obtaining consent. Whenever possible, interpreters should be provided copies of the relevant consent documents well before the consent conversation with the subject (24 to 48 hours if possible). The interpreter may sign the consent document as the witness and should note “Interpreter” under the signature line. The PI or a member of the research team must document this process in the progress notes of the subject's research record, including the name of the interpreter.

A short form English consent and several translated versions of the short form consent are available on the WCMC intranet courtesy of Hematology/Oncology (Provide Website when Available).