# Understanding what you need to enroll a Non-English Speaking Subject in your study

Requirements for planned and unexpected participation of non-English speaking individuals in a study vary as per the [NYU Grossman School of Medicine Policies and Procedures for Human Subjects Research Protection](https://med.nyu.edu/research/office-science-research/clinical-research/resources-researchers-study-teams/institutional-review-board-operations/irb-policies-structure-accreditation).

If a study subject does not clearly understand the information presented at the signing of the consent document or in subsequent discussions due to the language barrier, his/her consent may not be informed, and therefore, not effective. This document is intended to provide guidance on which documents must be signed and who should sign documents in order to receive informed consent from non-English speaking subjects.

To view more detailed guidance on obtaining and documenting informed consent of Non-English Speaking Subjects, please view additional guidance here ([studies approved prior to January 21, 2019](https://med.nyu.edu/research/office-science-research/clinical-research/sites/default/files/research-study-development-templates/guidance-consent-advertisments.docx) | [studies approved after January 21, 2019](https://med.nyu.edu/research/office-science-research/clinical-research/sites/default/files/research-study-development-templates/guidance-consent-of-non-english-speaking-newcrc.docx)). To view English and untranslated short forms, visit the [IRB Operations guidance document webpage](https://med.nyu.edu/research/office-science-research/clinical-research/resources-researchers-study-teams/institutional-review-board-operations/research-protocol-development-guidance-tools#consent-templates-short-forms). **What documents do I need?**

|  |  |  |
| --- | --- | --- |
|  | Unexpected participation of a non-English speaking subject | Planned participation of non-English speaking subjects |
| Translated short form (available on IRB Operations webpage) | **x** |  |
| IRB-approved long form English consent document (as accepted practice, the long form English IRB-Approved consent document can be used as the “written summary” that is indicated as a requirement in the short form) | **x** |  |
| IRB-approved translated long form consent document |  | **x** |
| Witness/interpreter present | **x** | **x** |

 **Who signs which documents?**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Subject | Witness (if required) | Researcher |
| Unexpected participation of a non-English speaking subject | * Translated short form
 | * Translated short form
* English long form consent document
 | * English long form consent document
 |
| Planned participation of non-English speaking subjects | * Translated long form consent document
 | * Translated long form consent document
 | * Translated long form consent document
 |

 **Interpreter/witness services**If the person obtaining consent is not fluent in the prospective subject’s language, an interpreter will be necessary to assist with the informed consent discussion. Whenever possible, study teams should use a certified medical interpreter to assist in the consent discussion. In cases where the person obtaining consent is fluent in the subject’s language, they may conduct the informed consent process with use of either the short form process or long form process for documentation of consent.

Researchers should consider the study’s level of complexity and its level of risk (as determined by the IRB) when deciding whether a non-certified interpreter will be used to facilitate the consent discussion. For example, a non-certified interpreter who is bilingual in both English and the subject’s language may be adequate for a study determined by the IRB to be minimal risk that measures subjects’ movements and heart rate, but involves no other intervention.

As of October 2019, [Just Interpretation LLC](http://justinterpretation.com/) accommodates researchers who are in need or interpreters that will also act as a witness. Depending on the nature of the research study, researchers can opt to have one interpreter signing the required documents as interpreter and witness, or you can opt to have two interpreters where one interprets and the other signs off as the witness through their services. Researchers placing requests should send the date, time, language, location and contact to request@justinterpretation.com. Requests should be placed 24 to 48 hours prior to the consent process. Please note there is a 3 business hour cancellation policy should there be any changes. Requestors should also provide a standing PO number for invoicing.

|  |  |
| --- | --- |
| **Unexpected participation of non-English speaking subject (short form consent process):** | **Planned participation of non-English speaking subject (translated full/long form consent):** |
| If the person obtaining consent is not fluent in the prospective subject’s language, an interpreter must be used to help deliver the information in the IRB-approved consent form and/or script and facilitate the consent discussion. The interpreter should be someone who is independent of the subject (i.e., not a family member).  | If the person obtaining consent is not fluent in the prospective subject’s language, an interpreter independent of the subject should be used to facilitate the consent discussion.  |
| Whenever possible, interpreters should be provided copies of the short form written consent and the IRB-approved consent script before the consent discussion with the subject; ideally, 24 to 48 hours prior.  | A witness who is conversant in both English and the subject’s language must also sign the consent form to attest to the adequacy of the consent process.The interpreter may serve as the witness. |
| If an interpreter is used with the short form method, a witness must sign the short form document to attest to the adequacy of the consent process. The interpreter may also serve as the witness.  | If the person obtaining consent fluently speaks the prospective subject’s language, they may conduct the consent process using the translated full consent form and sign the required documents as both the researcher and the interpreter. A witness to the consent process will not be required in this case.  |
| If the interpreter also serves as the witness, she/he may sign the short form consent document and script or the full translated consent form as the witness and should note “Interpreter” under the signature line. The person obtaining consent must document that the “short form” process was used in the progress notes of the subject's medical record, including the name of the interpreter.  |  |
| If the person obtaining consent is fluent in the subject’s language, they may deliver the information, but a separate witness fluent in English and the subject’s language must observe the consent process and attest to the adequacy of the consent process. |  |

 **NOTE:** *If the consent process is being conducted remotely (see the IRB’s* [*guidance on e-consent*](https://med.nyu.edu/research/office-science-research/clinical-research/sites/default/files/irb-template-library-guidance-on-econsenting.pdf)*) and an interpreter is used, the interpreter may provide their interpreter license number as their signature on the short-form or long form consent document, regardless of whether the short form or long form consent process is used. The study team must document that the interpreter serving as witness has acknowledged and agreed to provide this license number in place of a signature through a note to file in the study record.*