TITLE: Obtaining Informed Consent of Non-English Speakers		
POLICY #: CON-101	**Page:** 1 of 8	**Effective Date:** 3/2/2020

1. POLICY STATEMENT:

All informed consent information (initial or updates for new information) must be presented in a language that is understandable to the subject (or legally authorized representative).

2. BACKGROUND:

Federal regulations require that informed consent information be presented "in a language that is understandable to the subject." Discussions with subjects about their participation in research should be conducted by an individual who is fluent in both English and the language of the subject.

There are currently two accepted procedures for obtaining consent from a non-English speaking subject (or legally authorized representative).

3. RESPONSIBLE PERSONNEL:

3.1. Principal Investigator (PI)
3.2. Subinvestigator
3.3. Research Nurse
3.4. Study Coordinator

4. DEFINITIONS:

4.1. **Interpreter:** An individual who is fluent in both English and the language of the subject (or legally authorized representative) who interprets the discussion between the investigator/research team and the subject (or legally authorized representative). The preferred individual would be affiliated with the institutional interpreter services department or a commercial interpretation service; however, a staff member who is documented as a qualified interpreter under institutional policy may serve in this role.

4.2. **Legally Authorized Representative:** An individual qualified by state law who may make medical decisions on behalf of another individual.

4.3. **Obtaining Informed Consent**: The act of presenting information to persons enabling them to decide voluntarily whether or not to participate in research. If a subject decides to enter into the research, this will result in the subject signing an

Informed Consent Document, where required by an Institutional Review Board (IRB).

4.4. **Short Form**: A modified consent form written in a language understandable to the subject (or legally authorized representative) that sets out the basic requirements for informed consent.

Witness: An individual that is fluent in both English and the language of the subject (or legally authorized representative) that attests that the oral presentation of the long form English consent document was conducted. The witness may be the interpreter. The witness cannot be a member of the research team and ideally should not be a family member.

4.5. **Written Summary**: A document accompanying a short form that provides an account of what is presented orally during the consent interview. An IRB-approved English language consent document may serve as a written summary.

5. POLICY:

5.1. Option 1: Translation of Entire Consent Form

5.1.1. This is the preferred method of obtaining informed consent from non-English speakers and should be followed whenever possible.

5.1.2. If a PI prospectively plans on recruiting non-English speakers, he or she must arrange to have the entire informed consent document translated into a language understandable to the subject (or legally authorized representative) and notify the core site.

5.1.3. The core site will submit the fully translated informed consent document for IRB approval prior to use (typically submitted as an amendment after IRB approval of the English informed consent document). A statement from the translator certifying that the translation is accurate must be included in the submission.

5.1.3.1. The full translated informed consent document will be posted on OncPro.

5.1.3.2. Any subsequent amendments to the full English informed consent document must also be made to the fully translated informed consent

document(s).

5.1.4. The PI or person authorized to obtain informed consent will provide an oral explanation of the research to the subject (or legally authorized representative) with the assistance of an interpreter. A witness is not required.

5.1.5. The fully translated version of the informed consent document will be signed by the subject (or legally authorized representative). Interpreter signature is not required when using the fully translated version of the consent form.

5.1.6. The person obtaining informed consent will sign the English language consent document.

5.1.6.1. If a member of the research team is fluent in the participant's (or legally authorized representative's) language and qualified as an interpreter under institutional policy, this individual may act as the interpreter. However, in this case, a separate witness is required.

5.1.7. The subject (or legal authorized representative) will receive a signed and dated copy of all documents.

5.2. **Option 2: Short Form Consent Document**

5.2.1. If obtaining an IRB-approved "fully" translated informed consent document is not feasible, the use of a Short Form and Addendum written in a language understandable to the subject (or legally authorized representative) that sets out the basic requirements for informed consent documents is allowed.

5.2.1.1. The PI or person authorized to obtain informed consent will use an appropriate, pre-approved Short Form from the IRB of record. Studies under the DFCI IRB will use the Short Form and Addendum available on the Office for Human Research Studies (OHRS) website.

5.2.1.2. If a Short Form is not available in a language understandable to the subject (or legally authorized representative), the PI must arrange to have a Short Form created and approved by the IRB of record, if allowed. If the study is under the DFCI IRB, the PI will have a Short

Form and Addendum in that language created using the OHRS Short Form and Addendum English template available on the OHRS website. For studies under the DFCI IRB, the core site must submit the created Short Form and Addendum for IRB approval prior to use, with a statement from the translator certifying that the translation is accurate included in the submission.

5.2.2. An interpreter and a witness are required during each informed consent process (i.e., initial and when informing subjects of updated information). The interpreter may also act as the witness. If the interpreter is not willing or able to serve as the witness, then a separate witness must participate and sign the documents.

5.2.2.1. The witness must participate for the entire consent process and be willing to attest that "an oral presentation" of the long form English consent document was conducted.

5.2.2.2. The role of the interpreter is to interpret the discussion between the person obtaining informed consent and the subject (or legally authorized representative). The interpreter is not expected to do a sight translation of the long IRB approved English consent document.

5.2.2.3. Neither the witness nor the interpreter is asked to confirm the subject's or legally authorized representative's understanding.

5.2.2.4. If a member of the research team is fluent in the participant's (or legally authorized representative's) language and qualified as an interpreter under institutional policy, this individual may act as the interpreter. However, in this case, a separate witness is required. The separate witness must be conversant in both the language of the participant and the language of the Short Form.

5.2.3. With the use of an interpreter, the person obtaining informed consent will explain the research in detail using an IRB approved written summary (i.e., the IRB-approved English language consent document). The person obtaining consent will also answer, to the best of his/her ability, any questions asked by the potential subject through the interpreter.

5.2.4. The subject (or legal authorized representative) will sign the Short Form, and Addendum in the language he or she understands, to indicate his or her

willingness to participate in the research. If assent is required, the minor participant also signs the short form.

5.2.5. The witness will sign the Short Form and Addendum, indicating the oral presentation was conducted, **and** will also sign the IRB-approved written summary (i.e., the IRB-approved English language consent document).

5.2.5.1. When using a remote interpreter (i.e., the interpreter is not present to sign the documents), the person obtaining informed consent will confirm whether the interpreter is also acting as the witness. If so, the person obtaining informed consent will ask the subject, through the interpreter, to verbally confirm understanding of the information and inquire whether there are any additional questions. The person obtaining consent then documents the following additional information:

- The name and the ID# of the remote Interpreter on the witness signature lines of both the short form and the witness signature line on the long English consent.
- The reason why a remote interpreter was used (i.e., the reason on site interpretation was not available).
- The language used and the date and time the discussion took place
- That the subject was asked about understanding research information and whether there were any other questions.

5.2.6. The person obtaining informed consent will sign the IRB-approved written summary (i.e. the IRB-approved English language consent document).

5.2.7. The subject (or legal authorized representative) will receive a signed and dated copy of all consent documents.

5.2.8. The consenting process will be documented according to CON-100.

5.3. **Special Requirements for Optional Studies:**

5.3.1. If the written informed consent document contains optional studies (embedded in the informed consent document), the subject (or legally authorized representative) is assumed to not have consented to these unless there is a method of capturing the subject's agreement (or that of the legally authorized representative) in a language understandable to the subject (or legally authorized representative).

5.3.2. If using Option 1 above, the optional studies will have been translated as part of the long informed consent document and IRB approved. The subject (or legally authorized representative) can consent to participate directly on the full informed consent document.

5.3.3. If using Option 2, the use of an Addendum to the Short Form in a language understandable to the subject (or legally authorized representative) must be employed to document consent to the optional studies. If an Addendum is not used, it is assumed that the subject (or legally authorized representative) did not consent to the optional studies.

5.3.3.1. If a translated Addendum is not available, the subject (or legally authorized representative) cannot be invited to participate in the optional studies because proper consent cannot be obtained and documented.

5.3.3.2. If a translated addendum becomes available later, it is acceptable to approach the subject (or legally authorized representative) and offer the optional studies if still appropriate.

5.4. **Updated Information Based on New Significant Findings**

5.4.1. The subject (or legally authorized representative) will be informed in a timely manner when new information becomes available that may be relevant to the subject's willingness (or that of the legally authorized representative) to continue participation in the research. The IRB will make the final determination regarding what information, how and when the subject (or legally authorized representative) will be informed. Unless otherwise stated by the IRB, the subject (or legally authorized representative) will be updated with the information at the next study visit.

5.4.2. There are three (3) acceptable methods for informing a subject (or legally authorized representative) of updated information: a written informed consent document (a.k.a "re-consent"); a letter or addendum (i.e. written correspondence); or by verbal communication. The IRB will require that one of these methods or a combination of these methods be used to update the subject (or legally authorized representative). The PI and all research team members will follow the method(s) approved by the IRB.

5.4.2.1. If a revised IRB approved informed consent document must be signed (a.k.a "re-consent"), the PI or person authorized to obtain informed consent must use either Option 1 or Option 2 above to inform the subject (or legally authorized representative) of the updated information.

5.4.2.2. If a letter or addendum (i.e. written correspondence) must be utilized to inform the subject (or legally authorized representative) of the updated information, the PI must arrange to have a fully translated document available in a language understandable to the subject (or legally authorized representative) and the core site will submit the document to the IRB for approval prior to use. A statement from the translator certifying that the translation is accurate must be included with the submission.

5.4.2.3. If the information must be communicated verbally, an interpreter must be used to inform the subject (or legally authorized representative) of the updated information.

5.4.3. Research personnel (i.e. who may obtain informed consent) and documentation requirements for informing the subject (or legally authorized representative) are the same as the initial consenting process. If any updated information is presented to the subject (or legally authorized representative) that may affect participation and is not documented in an informed consent document or through a letter or addendum, the verbal consent of the subject (or legally authorized representative) to continue participation must be documented.

6. APPLICABLE REGULATIONS & GUIDELINES:

21 CFR 50 – Protection of Human Research Subjects
21 CFR 54 – Financial Disclosure by Clinical Investigators
21 CFR 56 – Institutional Review Boards
21 CFR 312 - Investigational New Drugs – Drugs for Human Use
21 CFR 812 – Investigational Device Exemptions
45 CFR 46 – Protection of Human Subjects
FDA Industry Guidelines and Information Sheets
FDA Compliance Policy Guidance Programs: 7348.809, 7348.810, and 7348.811

7. RELATED REFERENCES:

International Conference on Harmonisation – E6
OHRS Information Sheet: Instructions for Obtaining and Documenting Informed Consent of Non-English-Speaking Participants
OHRS Information Sheet: Legally Authorized Representatives

8. RELATED FORMS & TOOLS:

OHRS Short Form Consent Document
OHRS Short Form Addendum Document
Oncology Protocol System (OncPro)