# Witness and Interpreter Consent Process Documentation Instruction

# Background

This document addresses the need for the services of an impartial witness or interpreter when vulnerability exists due to communication barriers between investigators and subjects. Additional consent plans may be required to safeguard respect for persons’ autonomy when prospective participants are vulnerable to coercion or undue influence. The presence of an interpreter and the translation of consent & other research documents may be needed to ensure comprehensibility. The presence of a witness who can impartially assess the adequacy of the consent process may be needed when individuals are unable to read, to see, or are represented by a surrogate because they lack decisional capacity. The IRB evaluates human research applications to determine whether these additional protections apply to the proposed research.

**Impartial Witness**

An impartial witness must observe the consent discussion to attest that the information in the consent form and any other information provided—including documents provided in Braille, when applicable--was accurately explained to, and apparently understood by, the subject or their representative (i.e., a parent, their legal guardian, or a surrogate representing an adult lacking decisional capacity) under the following circumstances:

* Subject or representative cannot read or write due to illiteracy or low literacy;
* Subject or representative cannot see due to blindness or visual impairment;
* Subject or representative cannot hear due to deafness or hearing impairment;
* Subject/representative does not speak/read English well;
* Adult subject represented by a surrogate due to lack of decisional capacity; or
* IRB determines that an impartial witness is needed to assure respect for persons autonomy.

The impartial witness may not be the person obtaining consent.

**NOTE EXCEPTIONS**:

* If the research must comply with FDA or is conducted, supported or otherwise subject to regulation by any Federal Department or agency, such as DoD, DoE, DoJ, Dept. Of Education, or EPA, additional requirements may exist about who may serve as an impartial witness. For example, when enrolling subjects/representatives who cannot read or write, FDA states that an ‘impartial third party—a person not involved in the research—*should* serve as the witness.
* Check with state law where the research will occur to determine whether there are other circumstances when an impartial witness is required, as well as additional restrictions on who may serve as an ‘impartial’ witness. For example, in NJ, State law requires that when enrolling adults who are represented by a surrogate, the impartial witness cannot be the subject, his/her guardian or surrogate, or a person involved in the design, conduct, or reporting of the research.

# Add the following signature section after the ‘Investigator or Person Obtaining Consent’ signature section to document the presence of a witness during the consent discussion when conducting the consent conversation in English, Braille and/or American Sign Language, and when using the long form of consent to enroll subjects/representatives who speak a language other than English:

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| --- |
| **Witness to Consent Process**  I have observed the consent process which included a description of the purposes and procedures of this Study and an opportunity for questions and answers about this Study. I attest that I am not a person involved in the design, conduct or reporting of the research study [add if the subject is an adult represented by a surrogate: or the subject, his/her guardian or authorized representative], and that the requirements for informed consent to the research have been satisfied.  Name of Witness (Print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_ |

When using the short form method of consent to enroll subjects/representatives who speak a language other than English, the witness must sign both the long form English consent and the short form consent. Copy the signature block above and paste it below the Section: Investigator/Person Obtaining Consent of the long form consent that will be used to orally present the details of the study; then follow the directions for documenting the presence of the witness on the short form as illustrated on HRP-507 Template Short Form of Consent at <https://go.rutgers.edu/HSPP-Toolkit>.

# Interpreter

# A qualified interpreter, fluent in both English and the language understood by the subject/representative—or fluent in American Sign Language (ASL), when applicable, must orally present the entire English language IRB-approved consent form. The interpreter must also ask if the subject/representative has any questions and then be available to answer their questions. A qualified interpreter may be a certified interpreter, native speaker, or someone who possesses dual language fluency by education or training and is able to orally communicate complex ideas and procedures, as applicable, about the research. However, when communicating in ASL, the individual must be a certified interpreter fluent in ASL. Family members may not serve as interpreters for the consent process except in emergency, life- threatening situations. Skill and impartiality are key qualities of an interpreter.

# The qualified interpreter may be a member of the research team. However, when the research plans to have the interpreter serve a dual role as the interpreter and as the impartial witness, the interpreter may not be the person obtaining consent. [See above section Impartial Witness, above, for additional restrictions, as applicable to the research.]

# NOTE: The IRB or the research site where the consent process will take place may require that the interpreter be certified by a national organization or employed by the site or through a contracted interpreting agency. Add the following signature section after the ‘Witness to Consent Process’ signature section of the long form of consent to document the presence of an interpreter during the consent discussion:

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Interpreter**  The person, who has signed above, ***[Full name]****,* ***[choose: does not read or speak English well OR is fluent in American Sign Language]****.* **I *[choose: read English well and am fluent in******[Language] OR am fluent in American Sign Language]****,* a language the subject or his/her representative understands well. I understand the content of this consent document and confirm that, to the best of my knowledge and belief, I have accurately interpreted the entire content of this document. The subject or representative has had an opportunity to ask questions about the research and this consent document, and these questions have been answered.   |  |  | | --- | --- | | *[Full Name in Print]* | *[Qualified Interpreter (if present) Signature]* | | Qualified Interpreter (if present) Full Name | Signature | |  | [Date Signed] | |  | Date | |  | | | *[Qualified Interpreter Full Name]* | *[Company Name]* | | Qualified Interpreter  (If Service Provided By Telephone/Electronic Media) | Interpretation Company Name (if applicable) | | *[Qualified Interpreter ID Number]* |  | | ID# |  | |  |  | | Time | Date | |

For additional information about the consent process, consent documentation and/or enrolling special consent populations, see Toolkit HRP:090 Consent Process and Toolkit HRP:091 Written Documentation of Consent at <https://go.rutgers.edu/HSPP-Toolkit>.

For additional information about enrolling individuals who speak a language other than English, go to HSPP Guidance Non-English-Speaking Subjects at <https://go.rutgers.edu/HSPP-Guidance>. For documenting translator services, Translator Qualifications and Assurances Instruction and Certificate of Translation Form at <https://go.rutgers.edu/HSPP-Toolkit>.