# 5.7 Obtaining Informed Consent from Non-English Speaking Persons, or Persons with Additional Needs or Vulnerabilities

Last Revised: 11/12/2024

## 1.0 Purpose

The purpose of this policy is to describe the Organization's requirements for the process and documentation of informed consent for non-English speaking persons, or persons with additional needs or vulnerabilities participating in human subject research. For general considerations of informed consent see HRPP policy 5.1 (Obtaining Informed Consent from Research Subjects).

## 2.0 Policy

It is the policy of the Organization that:

- 2.1. Non-English speaking persons, or persons with additional needs or vulnerabilities will be offered accommodations and additional protections regarding the process and documentation of informed consent.

## 3.0. Specific Protections and Requirements for Non-English Speaking Subjects

- 3.1. Expected Enrollment of Non-English Speaking Subjects
  For research where it is reasonable to expect that a significant number of non-English speaking persons will participate, the IRB may require that a translated CF be prepared and used.
  - 3.1.1. Consent forms must be prepared by a qualified translator, as defined in the addendum A to this policy.
  - 3.1.2. A Qualified Interpreter, as defined in addendum B to this policy, must be identified.

    - 3.1.3. Interpreters should be provided with a copy of the IRB-approved ICF. Whenever possible, the ICF(s) should be provided in advance of initiating the consent process with the subject.
    - 3.1.4. Upon conclusion of the consent process the subject must sign and date the non-English version of the ICF.
    - 3.1.5. The person obtaining consent must sign and date the English version of the ICF.
    - 3.1.6. The process of consent must be documented in the medical or individual study subject record (if applicable). This documentation should include the names of the individuals involved in the process of consent, including the name or other identifying information (such as employee number) of the interpreter.
- 3.2. Unexpected Enrollment of a Non-English Speaking Subject
  If a non-English speaking prospective subject is unexpectedly eligible to enroll in research and there is no IRB-approved translated ICF, the following requirements apply:
    - 3.2.1. If the research offers no prospect of direct therapeutic benefit the person can only be enrolled a) after the IRB has reviewed and approved a translated ICF, and b) an interpreter who is fluent in both languages is used during the process of consent. The PI or other study personnel may serve as the interpreter.
    - 3.2.2. If the research offers the prospect of direct therapeutic benefit, the person can be enrolled using the IRB-approved short form as per the requirements of HRPP policy 5.5 (Use of the Short Form Consent Document).

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## 4.0. Specific Protections and Requirements for Visually Impaired or Blind Subjects

- 4.1. For research where it is reasonable to expect that a significant number of blind or low vision subjects will participate, the investigator must describe a plan to assure that materials are available to assist the prospective subject in the process of consent. This may include large font (electronic or paper) consent forms, audio version of consent form, Braille consent form, or other technology as appropriate.
- 4.2. If Braille CF is utilized, the IRB may require a transcription into print text or review of the document by a qualified person who reads Braille in order to ensure that a Braille ICF is accurate.
- 4.3. If an unexpected blind or visually impaired subject is encountered, the IRB Executive Chair or designee may authorize use of any of the above methods or technologies as appropriate.
- 4.4. If possible, the subject should sign or make an X to signify consent. A witness unaffiliated with the research team must observe the consent process, and witness the signature or mark. The witness must sign the consent form attesting that the information in the consent document and any other written information was accurately conveyed.

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## 5.0. Specific Protections and Requirements for Hearing Impaired or Deaf Subjects

- 5.1. For research where it is reasonable to expect that a significant number of hearing impaired or deaf subjects will participate, the investigator must describe a plan to assure that the process of consent can be conducted in an appropriate manner. This may include use of an American Sign Language (ASL) interpreter, or appropriate assistive technologies.
- 5.2. If an unexpected deaf or hearing impaired subject is encountered, the IRB Executive Chair or designee may authorize use of any of the above methods or technologies as appropriate.

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## 6.0. Specific Protections and Requirements for Illiterate or Low Literacy Subjects

- 6.1. For research where it is reasonable to expect that a significant number of illiterate or low literacy subjects will participate, the investigator must describe a plan to assure that the process of consent can be conducted in an appropriate manner. This may include reading the CF to the subject, use of a pre-recorded audio version of consent form, use of other technology as appropriate, or use of a Short Form (per HRPP policy 5.5 Use of the Short Form Consent Document).
- 6.2. If an unexpected illiterate subject is encountered, the IRB Executive Chair or designee may authorize use of any of the above methods or technologies as appropriate.
- 6.3. If possible, the subject should sign to signify consent. If the subject is unable to sign, they may make an X to signify consent. A witness unaffiliated with the research team must observe the consent process, and witness the mark. The witness must sign the consent form attesting that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject and that consent was freely given.

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Addendum A: Minimal Requirements for Translation of Informed Consent Documents

Translation of Consent forms into a language other than English must be performed by qualified persons, with adequate competence in English and the language of the translation, and preferably with knowledge of research methodology.

A. For research conducted solely within the Organization acceptable translation by a “qualified” translator includes, in order of preference:

1. Translation provider by a translator certified by The American Translators Association (https://www.atanet.org/)
2. Translation provided by a translator certified by any other non-profit organization, or Federal, State or Municipal government agency
3. Translation provided by a professional translation service that will certify the accuracy of the translation
4. Translation by a person deemed “competent to translate” and accompanied by a certification statement that the document translation is complete and accurate (see https://www.atanet.org/client-assistance/what-is-a-certified-translation/). A person deemed “competent to translate” includes (a) foreign language instructors employed by an

accredited university or college; or (b) graduate students in foreign language currently in training at an accredited university or college; or (c) a bilingual person able to write in two languages with equal fluency (including members of the research team). For research involving greater than minimal risk (per 45 CFR 46.102(j)), translation by someone other than a certified translator (categories 1 and 2) or a professional service (category 3) must be accompanied by a back-translation by a different person or group, preferably of categories 1, 2 or 3. B. For Multi-institution research where the Organization is a participating site, translation must be accompanied by documentation that the translation was performed by a “qualified” individual, as defined above.

Addendum B: Minimal Requirements for Interpretation

Interpretation must be performed by qualified persons, who are fluent in both English and the language of the subject, and preferably with knowledge of research methodology.

Qualified interpreters include, in order of preference:

1. A person holding certification by the National Board of Certification for Medical Interpreters, the Certification Commission for Healthcare Interpreters, or any similar credentialling body, or certified by any other non-profit organization, or Federal, State or Municipal government agency.
2. A person employed by, or contracted by, the Organization to provide interpretation services in a clinical context. This includes commercial interpretation services (such as CyraCom).
3. UNMC, Nebraska Medicine, CH&MC, BMC, UNO or study site staff who are fluent in both English and the language of the subject.
4. Study personnel who are fluent in both English and the language of the subject.
5. Other persons, including (a) foreign language instructors employed by an accredited university or college; or (b) graduate students in foreign language currently in training at an accredited university or college; or (c) a bilingual person; specifically, a person using or able to speak in two languages with equal fluency.

If a prospective subject wishes to designate his/her own interpreter, a Qualified Interpreter must also be present to ensure the quality and accuracy of the interpretation. A minor cannot be used as an interpreter.

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DOCUMENT HISTORY:

? Written: 11/2/2022

? Revised: 1/27/2023 - updated hyperlinks for HRPP references 5.1, 5.3, and 5.5.

? Revised: 3/7/2023 – deleted requirement for signature of interpreter when obtaining informed consent using a translated ICF (section 3.1.1.4); revised Addendum A to explicitly state use of a profession translation service is acceptable.

? Revised: 2/7/2024 – add use of Short form to section 4.4.1.

? Revised: 11/12/2024 – allowed for recording or employee number of interpreter (rather than name) (section 3.1.6); revised numbering.

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