COOK COUNTY HEALTH
Research & Regulatory Affairs
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Consenting Non-English Speaking Study Participants

The informed consent document should be presented in a language understandable to the participant. Translating the entire document in the participant's language is the gold standard. If you anticipate that research recruitment will occur from a population with a substantial number of non-English speakers, full translations of consent forms are required. You can submit documents for translation via an amendment to your IRB approved study in IRBManager.

In unexpected situations, when a full translation of a consent document is not available, an interpreter can make an oral presentation of informed consent in conjunction with a short form written consent form and a written summary of what is presented orally. Since the short form is a standard document, it is not necessary to obtain a new translation of this form for each study. The study summary can be in English, and with the IRB's approval, may be the full English version of the consent form modified to include space for a witness signature and date. Standard short form consents in several languages are made available by the CCH Office of Research & Regulatory Affairs (https://cookcountyhealth.org/education-research/research/office-of-research-regulatory-affairs-irb/).

An interpreter should be used for the short form consent process. Interpreters are competent in being fluent in the English language and trained in the cultural knowledge and subject matter language as per CCH policy. A family member or friend of the participant should not be asked to interpret, unless the patient declines the use of free interpreter services and requests to use a family member or friend. Minor children (age < 18 years old) may never serve as interpreters. The study staff obtaining consent must be present during the oral presentation to answer questions. (For more information on the use of interpreters, see the Interpreter Services Policy #RI.001.05).

A third person must witness each oral presentation. The witness must be an individual who is fluent in both English and the necessary foreign language and will be physically present during the consent process to observe the process and sign consent forms. The witness may be the interpreter, a family member, another staff member, or another person. A member of the study staff who is also an interpreter may act as the interpreter and the person obtaining consent, but may not act additionally as the witness in this scenario.

Steps for using a short form consent for non-English speaking study participants:

1. An interpreter verbally delivers the information contained in the full consent document or study summary
2. The short form document is signed by the participant (or the participant's LAR)
3. The short form is signed by a witness (can be the interpreter, unless the interpreter is also the person obtaining consent)
4. The study summary or consent is signed by the person obtaining consent
5. The study summary or consent is signed by a witness (can be the interpreter, unless the interpreter is also the person obtaining consent)

The participant should receive a copy of both the signed short form and the signed study summary to keep for themselves. When either the short form or a full translated consent is used, copies of both the English version of the consent form and the signed translated or short form consent must be placed in the participant's research record.

If the interpreter is not physically present during the consent process, documentation of this process should be made on the IRB approved consent or medical record note. If the consent process includes optional research consent questions, regardless of the physical presence of the interpreter, this should be documented in the IRB approved consent or medical record note as well.

For NCI CIRB studies: Quality of life/Patient Reported Outcome research components should be presented to the patient in their native language if available.

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June 26, 2019
Date