

Short Forms



Summary

In studies for which it is expected that subjects will include a significant number of persons who do not speak English, PI's will be expected to translate the informed consent documents into that subjects' language(s). However, when non-English speaking subjects are not expected but are eligible to enroll in research, short forms may be used.

Guidance

Short forms can be used when-

- The Participant/Legal Guardian does not speak/understand English.
- An approved translated consent form in the participants language has not been previously approved by the IRB and/or there is not adequate time to prepare a translated consent to be approved by the IRB.
- Short forms are located on CHOA.org- <https://www.choa.org/research/institutional-review-board/forms>

Process of obtaining consent using a short form-

- There must be an interpreter. Children's interpreters may act as both the interpreter and "Witness" (as required by the regulations). The witness must be fluent in both English and the language being used. CHOA does not allow family members or minors to act as interpreters*.
- Interpreter will use the English language consent form to present the study in the participant/Legal Guardian's primary language.
- The Person Obtaining Consent will assist the Interpreter in the explanation of the study.
- The Participant/Legal Guardian will be provided the short form in their language, which is available on the CHOA IRB website.

*Exceptions may be made on availability of interpreters; however, it is best practice to notify the IRB for approval **prior to** using anyone other than a CHOA interpreter for non-English speaking consent.

Signatures required for short form consent-

- The Interpreter signs the English Consent Form as the Interpreter and the Short Form as the Witness.
- The Person Obtaining Consent (study staff) signs and dates the English Consent Form.
- The Participant/Legal Guardian signs and dates the short form only.

- The Participant/Legal Guardian is given a copy of the signed short form and English Consent Form.
- Study staff keep originals for study file.

Other Considerations-

- If you are using a CHOA approved short form, then there is no need to submit the specific short form documents to the IRB. If you are creating a new short form document, then it must be submitted to the IRB along with a certification of translation prior to use. The translation should be based on the English version of the short form document.
- The short form documents should not be altered except to do the following (in English):
 - Protocol title
 - PI name and contact phone number
 - Emergency contact person and phone number
- If the study has ongoing interventions or interactions and the subject was initially consented using the short form process, the investigators and IRB may assess the feasibility of translating the full English consent into the participant's language, when possible.
- Optional Consent Items for Short Form: If the English consent has optional consent items (e.g., extra blood for research, permission for central imaging review), the Interpreter must document on the last page of the short form to indicate the subject made specific choices on the English consent. The Qualified Interpreter should indicate the subject's choice (e.g., checks/circles Yes or No) and include the Qualified Interpreter's initials for each choice on the English consent.

Questions

Contact the IRB at irb@choa.org

