Human Subject Protection Program
Investigator Guidance
June 3, 2020

Consenting Participants with Limited English Proficiency

Overview

- The purpose of this guidance is to explain how investigators should obtain and document informed consent for subjects who are have limited English proficiency and require an interpreter and translated consent materials.

- Because the Los Angeles County area is a diverse region of many cultures and languages, investigators who enroll research subjects in Los Angeles County must consider the likelihood of encountering eligible subjects with limited English proficiency. A look at the populations served by CHLA and satellite clinics will help investigators anticipate the languages spoken by potential subjects.

- The governing principles of human subject research (respect for persons, beneficence, and justice) require that investigators not exclude subjects based solely on their inability to read, speak or understand English. CHLA bilingual employees may communicate directly with subjects, or a CHLA qualified medical interpreter should be used to ensure that:

  - ❑ Study participation is voluntary, as indicated by free and truly informed consent.

  - ❑ Study schedules, procedures, and risks are accurately communicated, and subjects have ongoing opportunities to express concerns and ask questions.

  - ❑ There are fair procedures and outcomes in the selection of research subjects so that risks and benefits of research are shared in society.

- **IMPORTANT NOTE:** Investigators are responsible for understanding the CHLA policies for certified translation of written communication and who may serve as an interpreter. Refer to the Investigator Guidance document, CHLA Requirements for

Certified Translations and Use of Interpreters for Human Research and Clinical Trials, for more information.

Obtaining Consent and Assent from Participants with Limited English Proficiency

- The preferred consenting method is to provide consent and assent forms and other study materials written in the requested language of the participant and/or their parent(s)/guardian(s)/representative(s).

- Certified translations of consent and assent forms should be used whenever the study budget allows. Investigators should include the costs of written translations as well as CHLA interpreter services in grants and contracts. Industry sponsors are often willing to pay the costs of translating consent and assent forms.

- "Short form" consent is an alternative to using translated consent and assent forms. The short form consent form is a document translated into the requested language of the participant and/or their parent(s)/guardian(s)/representative(s) that contains a description of the required elements of informed consent as they pertain to the study, which will be presented orally to the participant and/or their parent(s)/guardian(s)/representative(s).

- As with all consent discussions, sufficient time should be allowed for explaining each section of the consent and for the participant and/or their parent(s)/guardian(s)/representative(s) to ask questions. Working with an interpreter to explain complex topics such as randomization, placebo control, dosing schedules and invasive/noninvasive procedures may require additional time and/or subsequent discussions.

- It is the investigator's responsibility to judge comprehension of the consent information including the understanding that participation is voluntary and that the participant and/or their parent(s)/guardian(s)/representative(s) have the right to withdraw at any time during the study. If the investigator doubts comprehension of the participant and/or their parent(s)/guardian(s)/representative(s), the investigator should not enroll the participant in the study.

- The short form consent process involves the following:

  - ❑ An oral presentation of English informed consent information in conjunction with a short form written consent document.
  - ❑ A witness to the oral presentation is required.
  - ❑ The witness must be fluent in both English and the language of the subject.

- ❑ The witness cannot be a member of the study team, or a family member of the participant.
- ❑ The participant and/or their parent(s)/guardian(s)/representative(s) must be given copies of the short form document and the English consent form.

- ➢ The CHLA short form document is available on the CHLA HSPP Web site in several languages.

Documenting Consent Using the Short Form Consent Method

Required Signatures on the Short Form Consent and the English Consent Document:

- ➢ The short form document must be signed by the participant and/or their parent(s)/guardian(s)/representative(s).

- ➢ The English consent document must be signed by the person obtaining consent as authorized under the protocol.

- ➢ The short form document and English consent document must be signed by the witness.

HIPAA Research Authorization

- ➢ If the IRB requires a written HIPAA research authorization, a HIPAA authorization short form may be used to document that HIPAA authorization has been obtained.

- ➢ The HIPAA short form must be provided in the language in which the participant and/or their parent(s)/guardian(s)/representative(s) is fluent. The CHLA HIPAA short form is available on the CHLA HSPP Web site in several languages.

California Experimental Subject Bill of Rights (ESBOR)

- ➢ If the IRB requires an ESBOR, it must be provided in the language in which the participant and/or their parent(s)/guardian(s)/representative(s) is fluent. The ESBOR form is available on the CHLA HSPP Web site several languages.