University Hospitals Clinical Research Center

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Consenting Non-English Speakers Tip Sheet

21 CFR 50.20: Participants who do not speak English must be given an informed consent document written in a language understandable to them.

An investigator who intends to include non-English speaking individuals must provide sufficient detail in the research protocol regarding the plan for obtaining informed consent and HIPAA Authorization during the conduct of the study. Translated informed consent documents and oral presentation must be submitted for review and approval by the IRB.

> **NOTE**: It is important to clarify if the participant can read and what language is preferred. Also, if the participant speaks a dialect for a specific region in a country, the translator must be able to translate to that dialect.

When informed consent is obtained from non-English speaking participants using a translated informed consent form, all of the following apply:

- A translator must be fluent in English and the preferred language of the participant. The translator will sign the witness line.
  - A family member or friend is **not** a witness nor can be the sole translator.
  - A remote translator **cannot** be a translator as they cannot sign the informed consent document.
  - A member of the study team **can** be a translator, however, be aware of any potential bias.
- The participant or the participant's legally authorized representative will sign the participant line.
- The person obtaining consent signs the informed consent document, if the person obtaining consent *does not* speak the participant's language, then the translator signs this line.

If there are time constraints, a "short form" may be approved for use by the IRB. A short form is a brief document in the participant's language that affirms all elements of informed consent were reviewed with them in a language understandable to them. During the process, the English IRB approved document is also present to use during the discussion.

- Short form can only be used once per language per protocol, because the ICF must then be translated and reviewed with the participant as well as be available for future participants
- 13 different language short forms are available through the UH IRB.

Signatures required:

- Participant or Legally Authorized Representative (ONLY on the short form)
- The translator (signs short form AND English IRB approved informed consent document on the witness line)
- Person consenting/study team member (ONLY English IRB approved informed consent document)
- Document an Informed Consent Note to File:
  - The language used on the short form
  - The informed consent process and that the English content of the informed consent was presented in the participants preferred language
  - Who was involved with the discussion
  - The subject will re-consent with the translated consent

Reminder: A person only signs documents that are in the language they understand.

Reference: Investigator Manual for IRB Submissions