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Research: Illiterate and Non-English-Speaking Subjects- AD.0197

PURPOSE

The purpose of this policy is to describe the procedures for conducting the informed consent process for participation in Research and Clinical Trials when a potential subject cannot read English or is a non-English speaking individual. Our policies guide our practices and ensure that we place people at the heart of all we do to deliver the best outcomes and safest care.

APPLICABILITY

This policy applies to Lakeland Regional Health's **Workforce** and **Research Personnel** engaged in research.

POLICY

I. **General**

A. The informed consent process must be conducted in accordance with Lakeland Regional Health's Research: Informed Consent, Assent, Re-Consenting, Parental Permission, Remote Consent and Remote Assent Process- CL.0218.

B. Department of Health and Human Services (DHHS) regulations require that informed consent information be presented in "language understandable to the subject" and that, in most instances, informed consent be documented in writing, unless appropriate waiver criteria are met (45 CFR § 46.116-117 and 21 CFR § 50.27).

1. For waivers of informed consent or documentation of informed consent, see Lakeland Regional Health's Waiver of Informed Consent Policy (link policy).

C. The preferred method is to provide consent forms written in the subject's language.

For biomedical research, the Experimental Subject's Bill of Rights must also be provided in the language in which the subject is fluent.

D. For the occasional and unanticipated non-English-speaking subject, an alternative "short form" method is allowed (21 CFR § 50.27(b)(2); 45 CFR § 46.117(b)(2)). For biomedical research, the Experimental Subject's Bill of Rights must still be provided in the language in which the subject is fluent.

E. If a potential subject is non-English-speaking, the consent form must be translated into the subjects' language. In the **translation**, particular attention must be paid to meanings and cultural nuances surrounding words and phrases, as they may have different meanings or connotations in the potential subjects' own language. If the translation is not accurate, the subject could be misinformed and this would undermine the ability of the subject to give truly informed consent.

F. The IRB must receive all foreign language versions of the consent document. Expedited review of these versions is acceptable if the protocol, the full English language informed consent document, and the English version of the short form document (if applicable) have already been approved by the convened IRB.

PROCEDURE

I. Persons Illiterate in English

An individual who understands, but does not read, English may have the consent form read to him/her and he/she may "make his/her mark." The signature of an impartial witness to the consent process and that of the person conducting the consent interview and the investigator are required. The witness can be a family member or a staff member not involved with the study.

II. Persons Who Do Not Understand or Speak English

A. If an individual meets the inclusion/exclusion criteria for the study, but does not speak English, he/she cannot be denied participation on the study, but must be offered the opportunity to read and understand a consent form translated into his/her native language.

1. In situations where time does not permit a full translation to be prepared, the provisions for the short form consent process are permitted (Research: Informed Consent, Assent, Re-Consenting, Parental Permission, Remote Consent and Remote Assent Process- CL.0218), but the short form consent documents must be approved by the IRB prior to being used.
2. If the short form process is used, the research summary and short form consent must be translated into the subject's native language and a translator must be present for the consent interview. The translator may serve as a witness for the short form consent process.
3. A translation of the full consent form should be provided to the subject as soon as possible and the subject should be reconsented with it.

B. When an investigator is specifically targeting particular non-English speaking populations for enrollment in a study, appropriately translated consent forms must

be approved by the IRB prior to enrolling members of those populations.

III. Translation of the Consent Form

A. For translation of the consent form, the investigator may use either: 1) a professional translator who can provide interpretation services; or 2) an individual with special expertise in the particular language required.

B. Companies providing translation services will provide certification that the translation is an accurate representation of the original English consent form. For individual translators, the investigator must provide the IRB with the name and qualifications of the translator as well as a statement form the translator that the translation is accurate and contains the appropriate cultural nuances.

C. For any study that plans to enroll a non-English-speaking subject, the IRB reserves the right to evaluate the translator's credentials and, if deemed necessary, require translation of the consent form by another party.

IV. Presence of a Translator

A. A translator should be present during the consent interview for a non-English speaker. The translator must be someone who can accurately translate between spoken English and the subject's native language and who understands the cultural nuances of the language. The translator may be a member of the subject's family or someone else who can adequately fulfill the duty, including a member of the study team. A translator should also be available during the full course of the non-English speaker's participation in the study, so that the subject can always communicate reliably with the **PI** and research team. The PI should assume responsibility for assuring that appropriate arrangements with the translator or translation services can be made before the non-English speaker is enrolled.

B. If the IRB, Research Department, PI or member of the study team requires an in-person translator, LRH policy, Providing Services to Patients with Communication/ Language Barriers- CL.0194 will be followed. The IRB is allowed to use a translator as a consultant, as needed.

DEFINITIONS

Interpretation: For purposes of research informed consent, an interpretation is a verbal exchange between two parties and the person serving as interpreter is fluent (can speak, read and write) in English and the language of the subject.

Principal investigator (PI): The individual ultimately responsible for the conduct of human subjects research, including oversight of investigators serving on a research team.

Research Personnel: All individuals designing or directing research, serving as a principal or co-investigator, enrolling research subjects (including obtaining subjects' informed consent or screening potential subjects), or making decisions related to eligibility to participate in research, analyzing or reporting research data, analyzing or reporting adverse events, or submitting manuscripts concerning the research publication.

Translation: A translation is the process of translating a written document (e.g., consent form) from one

language into another, assuring the language of the translated document has the same meaning as the written document in the first language.

Workforce: All LRH employees, volunteers, trainees/students, contractors, and medical staff.

REFERENCES

I. eCFR :: 21 CFR § 50.20 -- General requirements for informed consent.
II. eCFR :: 21 CFR § 50.27 -- Documentation of informed consent.
III. eCFR :: 45 CFR § 46.116 -- General requirements for informed consent.
IV. eCFR :: 45 CFR § 46.117 -- Documentation of informed consent.
V. Informed Consent of Subjects Who Do Not Speak English (1995) | HHS.gov
VI. Consent and Non-English or Disabled Subjects - UCI Office of Research

Approval Signatures

Step Description	Approver	Date
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