

Phoebe Putney Health System, Inc.

POLICY TITLE: NON-ENGLISH SPEAKING SUBJECTS AND/OR LEGALLY AUTHORIZED REPRESENTATIVES

ENTITY: PPMH

Approved by: IRB CHAIR

Effective Date: 12-21-2016

Review Period: 3 Years

Review Date: 09-25-2019

Contact Information: IRB COORDINATOR

Scope: The IRB Non-English Speaking Subjects and/or Legally Authorized Representatives policy applies to all research involving human subjects, including behavioral, biomedical, and social sciences.

Purpose: To define the standards and parameters at Phoebe Putney Memorial Hospital (PPMH) for the involvement of non-English speaking subjects in research. Specifically, to outline the requirements for obtaining informed consent and other required study documentation of non-English speaking subjects.

Definitions:

Non-English Speaking Subjects: An individual unable to verbally comprehend the spoken English language or read and comprehend documents written in English.

Policy:

1. Non-English speaking subjects will not be excluded from research that may have potential benefits. Investigators will plan for populations that are likely to be recruited into the study and translations will be incorporated into the study design to allow for appropriate recruitment and enrollment. Justifications for exclusion of non-English speakers must be included in the IRB application.

Subjects who do not speak English must have all written documents written in their native language to include an IRB approved consent documented translated into the subject language by a certified translator (certification documentation is required). The subject must be given a copy of the translated ICD. An interpreter in the subject's native language must assist with the discussion. Please note: ad hoc translation may not replace the written document.

2. All Investigators are required to obtain a translated written consent document in a language understandable to the subject or the subject's legally authorized representative (LAR) if non-English speaking subjects will be participating in the study.

- a. The IRB must receive the translated version of the informed consent as a condition of approval.
 - b. To avoid duplicate translations, the investigator may obtain the translated document(s) after the IRB has conditionally approved the English version(s).
 - c. Expedited review of the translated version(s) may be acceptable if the protocol, English version of the consent, and all other pertinent materials have been conditionally approved by the convened IRB.
 - d. The IRB can rely on one certified translation. Two-way translations (i.e., back to English) are not required, however the IRB can require two-way translations if they feel it to be necessary.
 - e. Unless the investigator or his/her designee is fluent in the prospective subject's language, an interpreter will be necessary to facilitate the conversation. The interpreter should not be a member of the subject's immediate family or a close friend. If possible, interpreters should be provided copies of the relevant consent document before the consent conversation with the subject or subject's LAR. The interpreter may sign the consent document as the witness and, if so, should note "interpreter" under the signature line.
3. Any recruitment material (including advertisements and websites) that has been translated must also be provided to the IRB. In addition, investigators should translate all study materials that will be distributed to non-English speaking subjects, such as surveys or questionnaires, and submit these to the IRB when the translated consent is submitted.
 4. All translated documents must be approved by the IRB before non-English speaking subjects can be enrolled in the study.

Procedure:

1. The investigator must specify whether enrollment of non-English speaking subjects is expected on the initial study application.
2. In order to avoid duplicate translations, the investigator must obtain a translated consent form and any recruitment and/or study materials after the IRB has conditionally approved the English version of these documents.
3. The translated documents must be accompanied by a certification from the translator.
4. If the fully convened IRB has approved all other aspects of the study with the exception of the translated versions of the consent and recruitment or study materials (as applicable), the IRB Chair, relying on the certification of a qualified translator may expedite review of the translated documents.

References:

- 45 CFR 46.116, 46.117
- 21 CFR 50.20, 50.27

REVISION HISTORY

Revision Number	Description of Changes	Approvals	Date
N/A	Initial release of Policy for PPHS Policy Management System (Compliance 360 Program). This policy replaces all previous versions.	IRB Committee	12-21-2016
N/A	Reviewed with No Changes	IRB Committee	09-25-2019