Virginia Commonwealth University IRB Guidance Document

***Enrolling Limited English Proficiency (LEP) Subjects in Research***

**Purpose**

The purpose of this guidance document is to outline the procedures for enrolling subjects with Limited English Proficiency (LEP). Further required information and details are outlined in the VCU IRB’s Written Policies and Procedures and the VCU Health System’s Policies and Procedures.

**Background**

Limited English Proficiency (LEP) individuals include any person who is not fluent in English.

The Justice Principle outlined in the Belmont Report requires that the benefits and burdens of research be equally distributed among subjects. Additionally,thecriteria for IRB approval [45 CFR 46.111, 21 CFR 56.111] specify that the selection of subjects must be equitable, and also require that the consent form and other study documents be presented to subjects in a language that is understandable to them. Therefore, both ethical and regulatory requirements indicate that LEP individuals should be included in research when possible.

***When should LEP subjects be included in research?***

Researchers should consider the populations likely to be included in their study, and determine the demographics of the target population as well as the local demographics of the area where the research is taking place. If the target population is likely to include LEP individuals, researchers should make efforts to include them in the research, either by utilizing the short form consent process, or by prospectively translating study documents. LEP individuals should not be specifically excluded from research if an LEP individual has the potential for direct benefit from the study, such as in a treatment or intervention study.

Involving LEP individuals in research requires that all aspects of a study be conducted in a way that ensures the ability to fully and safely participate. Although the informed consent process must take place in a language the subject understands, all other study activities, such as follow-up visits, must also be conducted in a language that is understandable to the subject.

If a research protocol specifically excludes LEP subjects, an adequate justification for exclusion must be provided, such as safety concerns or concerns regarding the validity of translated instruments.

***When should the consent form and study materials be translated prospectively?***

If the targeted population is anticipated to include 5% or more of LEP subjects, investigators should include translated consent forms and documents with their protocol, as well as a plan for continued communication with the LEP subjects.

The consent form must be submitted to the VCU IRB either with the initial submission or as an amendment submission. An English language document should also be submitted with the translated document. It is strongly recommended that documents be submitted in English first, and once the English language documents are approved by the IRB, translated documents can be submitted via an amendment.

***When should the short form consent process be used?***

The short form process is intended for situations where the likelihood of encountering eligible LEP individuals is small (i.e., <5% of the patient population typically served). However, in order to provide equitable access to research, there may be the need to enroll subjects who are not fluent in English.

The short form process involves the combination of a short form consent (a translated document indicating that the elements of consent have been verbally discussed with the subject) and the English language, IRB approved consent form. Pre-translated short form consents are available in several languages on the IRB website (see resources below).

***How does the short form consent process work? Who signs which forms when using the short form consent process?***

Consent is obtained from subjects by using the short form in the language understandable to the LEP subject in combination with the full English version of the consent form.

1. The IRB approved English version of the consent form must be orally translated to the LEP subject in a language understandable to him/her by a qualified interpreter.
2. The subject must be given a copy of the short form document translated into their language to read and review.
3. The entire consent process must include a witness to the oral conversation and presentation of the consent form. (NOTE: The witness may be the interpreter or a family member of the LEP subject who speaks English. The witness cannot be the member of the study team conducting the short form consent process.)
4. The IRB-approved English version of the consent form must be signed by the individual authorized in the approved protocol to obtain consent (PI, research nurse etc.) and the witness.
5. The short form document must be signed by the subject and the witness to the consent process.
6. Copies of the signed IRB approved English version of the consent form and translated version of the short form must be given to the subject. Original copies of both documents should be maintained appropriately by the study team.

***What must be submitted to the IRB if the short form is used?***

The use of the short form process in an IRB-approved study does not require prospective IRB approval. For studies with more than one study visit, an amendment should be submitted with the plan for continued communication with the LEP subject at subsequent study visits, as well as translated versions of any additional study documents.

**NOTE:** If a VCUHS patient has been enrolled in a treatment or intervention protocol, the study team can submit additional study documents to Language Services for translation so that subsequent study visits may be conducted in the subject’s language.

***What type of translator or interpreter should be used to conduct consent and continuing study activities with LEP subjects?***

The short form consent process requires the assistance of a qualified interpreter or an individual who speaks the subject’s language and English fluently. When possible, a trained interpreter should be used. When the LEP research subject is also a VCUHS patient, an interpreter from VCUHS Language Services may be requested without charge to the investigator.

During the informed consent process of a clinical study, the use of a qualified medical interpreter is encouraged. In some cases, the medical and technical information discussed during the initial consent discussion can be complex.

For studies that are greater than minimal risk, the individual involved in the informed consent process cannot be a family member or in the social circle of the subject.

Once a subject is enrolled in the study, subsequent study visits may be conducted with the assistance of the Cyracom phones, the MARTI video interpretation service, or with the assistance of a family member or friend of the subject who is fluent in English and the subject’s language.

***Who is responsible for the costs of translation and interpretation services?***

Intervention or treatment protocols conducted with VCUHS patients may utilize translation and interpreter services through VCUHS Languages Services at no charge.

Translation and interpreter services for studies not involving VCUHS patients are the responsibility of the investigator or sponsor. These costs should be factored into the study budget. Please see below for local translation and interpretation resources.

***How do I obtain translation and interpretation services at VCUHS?***

The Office of Communication and Language Services at VCUHS will provide translation and interpretation services for **treatment** and **intervention** research protocols being conducted at VCUHS when the subject is also a patient of the health system.

Researchers can request translation or interpretation services via the VCUHS intranet site. Additionally, researchers may use the CyraCom interpreter system (“blue phones”) or the MARTI video interpretation system.

Detailed instructions outlining the process for utilizing Language Services can be found on VCUHS’s intranet at <http://portal.vcuhs.mcvh-vcu.edu/mcvh/home/LanguageServices/SitePages/Home.aspx>

***How do I obtain translation and interpretation services if I am not conducting research at VCUHS?***

If researchers are not conducting treatment or intervention research at VCUHS, they (or the study sponsor) are responsible for obtaining and paying for translation and interpretation services. Below are links to translation and interpretation resources in the Richmond, VA area.

**NOTE:** The VCU IRB does not endorse or require the use of these specific translation and interpretation services. They are listed as a resource only.

[Commonwealth Catholic Charities (Local Interpretation Services)](http://cccofva.org/services/resettlement-services/interpreter-services-program/)

[CyraCom Language Solutions (Interpretation and Translation Services)](http://www.cyracom.com/)

**Resources:**

[VCU IRB WPP XI-5, “Enrolling Research Subjects with Limited English Proficiency (LEP)”](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.111)

[VCU Short Forms](http://www.research.vcu.edu/forms/#irb_forms)

[VCUHS Patient Centered Communication Policy](file:///\\orf1.rams.adp.vcu.edu\vpresearch\ORSP\IRB%20Shared\Associate%20Director\AAHRPP%202015\Contingency%20Report\Documents%20for%20Report\%5bhttp:\vcuhspolicy.mcvh-vcu.edu\Policies\zav_PC.AD.004.htm)

[VCUHS Language Services Intranet](http://portal.vcuhs.mcvh-vcu.edu/mcvh/home/LanguageServices/SitePages/Home.aspx)

[Belmont Report-Justice Principle](http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html#xjust)

[Criteria for IRB Approval [45 CFR 46.111]](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.111)

[OHRP Policy on Obtaining and Documenting Informed Consent of Subjects Who Do Not Speak English](http://www.hhs.gov/ohrp/policy/ic-non-e.html)