

Justice and Equitable Subject Selection

Enrolling Subjects with
Limited English Proficiency (LEP)

LEP Subjects

Limited English Proficiency (LEP)

- Limited English Proficiency (LEP) individuals are individuals who are not fluent in the English language

The Belmont Report

Justice Principle:

"Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly."

- The benefits and burdens of research should be equally distributed among populations

Criteria for IRB Approval

Equitable Selection of Subjects:

“Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.”

- Who is the target population?
- Are LEP subjects being unnecessarily excluded?

Inclusion of LEP Subjects

LEP subjects should be given an opportunity to fully and safely participate in research, particularly research that may have the potential for direct benefit

- Researchers should take into consideration the purposes and setting of the research when determining their plan for enrolling LEP subjects
- If LEP subjects are included, the informed consent form and all study information must be provided in a language that is understandable to subjects

Exclusion of LEP Subjects

- LEP subjects may be excluded only if appropriate rationale is provided
- Greatest effort should be made to include LEP subjects in research that offers the possibility of direct benefit
 - Appropriate rationale includes safety concerns
 - Concerns about the validity of the translation of the instruments being used may also be appropriate

Informed Consent

Consent document must be in a language understandable to the subject

- There should be an opportunity for subjects to ask & receive answers to questions
- Subjects should clearly understand involvement in research
- Two Options
 - Translated Consent
 - Short Form Consent

Translated Consent

- If targeted population may have 5% or more LEP subjects, study team should plan to translate consent and other study documents prospectively
- Study team may also consider hiring study personnel fluent in the language of largest LEP population

Translated Consent

- Translated consent forms & other study documents are created and submitted for prospective IRB review
 - Documents in English must be submitted
 - IRB recommends researchers submit materials in English first
 - Once English documents are approved, the study team can then submit translated documents via an amendment

Short Form Consent

- If the likelihood of encountering LEP individuals is small (less than 5%), the short form consent process may be used
- Short form only covers the *initial* consent, not the process for continued communication

Short Form Consent

- Short Form Consent - a brief translated document that covers the required elements of consent
 - NOTE: the Short Form must be used in conjunction with the full English consent form
 - IRB provides [Short Form Consents in 9 Languages](#)
 - May be used without prior IRB approval
 - If a new form is created, IRB must approve prior to use

Short Form Consent

Requirements for use of Short Form:

- 1) Qualified interpreter (for greater than minimal risk research) or person who speaks both English and the participant's language fluently
- 2) Witness who speaks both English and the participant's language must be present at the oral presentation of consent form
- 3) Complete process may be found on [VCU's website](#)

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.
- 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.
- The subject must be given a copy of the short form document translated into their language to read and review.

Short Form Consent Process

- 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 and the LEP's language. The witness cannot be the member of the study team conducting the short form consent process.

Who Signs Which Forms?

- 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.
- The short form document must be signed by the subject and the witness to the consent process.

What Must Be Submitted to the IRB?

- The use of the short form process in an IRB-approved study does not require separate 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.

RAMS-IRB Documentation

- RAMS-IRB should specify the plan to either enroll or exclude LEP subjects
 - Type of consent for LEP subject
 - How risks of participation are balanced with possible benefits
 - Plan for interaction and continued communication (submitted via amendment after a subject is enrolled with the Short Form)

RAMS-IRB: Participant Groups

6. * Check all participant groups that are likely to be involved in this study. If it is possible that a regulated vulnerable population (children, pregnant women, prisoners) COULD BE involved in the study, be sure to check them: ?

- Healthy Volunteers
- Children
- Emancipated Minors
- Pregnant Women
- Fetuses, Neonates, Fetal Material or In-Vitro Fertilization
- Prisoners
- Decisionally Impaired Adults
- When cancer is integral to the research - cancer Patients, Family Members, Healthcare Providers or Prevention
- VCU Health System Patients
- Non-VCU Patients
- VCU/VCUHS Students or Trainees
- VCU/VCUHS Employees
- Individuals with Limited English Proficiency
- Active Military Personnel
- When researching in a K-12 environment - populations Within School Districts or Other Learning Environments

- If you plan to enroll LEP subjects either via the Short Form process or with a fully translated consent, please check “Individuals with Limited English Proficiency” as a participant group in Q6
- If you plan to exclude/target LEP subjects specifically, please provide the rationale in Q7


7. If you are either targeting, or excluding, a particular segment of the population / community, provide a description of the group/organization/community and provide a rationale: ?

RAMS-IRB: Limited English Proficiency

Limited English Proficiency

1. * Describe how Non-English speaking or limited English proficiency participants will be able to communicate with the study staff at enrollment and throughout the study:

2. * Describe any additional risks or harms to the individual because of their limited English proficiency and how these will be minimized:

3. If an interpreter or translator will be involved in the study, upload documentation verifying qualifications: 

Document Name	Document Version	Date Modified	Uploaded By	Type	Approved
There are no items to display					

- Provide study specific information for Q1 and Q2
- If you are using VCUHS Language Services specify this in Q1
- If you plan to use a interpreter or translator specific to your study, upload verification of their qualifications in Q3

RAMS-IRB: Consent Groups

Consent Groups

1. * List all consent groups:

<input type="button" value="Add"/>			
	Group	Types	Waivers
<input type="button" value="Update"/>	LEP Subjects	Short Form Consent (limited applicability)	No Waivers Requested
<input type="button" value="Update"/>	English Speaking Subjects	Written/Signed Consent by Participant	No Waivers Requested

2. Upload any consent / assent documents:

<input type="button" value="Add"/>				
Document Name	Document Version	Date Modified	Uploaded By	Type Approved
There are no items to display				

- If you plan to enroll LEP subjects using the Short Form consent, please add them as a Consent Group and choose “Short Form Consent”
- If you plan to enroll LEP subjects with a fully translated consent, add them as a Consent Group and choose “Written/Signed Consent by Participant”

IRB's Review of Plan for LEP Subjects

- Pre-screening includes a screen for LEP subject exclusion
 - If LEP subjects are excluded an appropriate rationale must be included
- Consideration and discussion of plan for LEP inclusion/exclusion occurs for each initial protocol submission

Resources

- [*VCU WPP XI-5 “Enrolling Research Subjects with Limited English Proficiency \(LEP\)”*](#)
- [*VCU Short Forms*](#)
- [*Belmont Report: Justice Principle*](#)
- [*Criteria for IRB Approval*](#)
- [*LEP Enrollment Guidance Document*](#)