

Loyola University of Chicago Health Sciences Campus

Policy and Procedure on Consenting Limited English Proficient Research Participants

Definitions:

Limited English Proficient Individual: An individual with limited English language skills that are reasonably expected to impact the informed consent process for research participation.

Limited English Proficient Research Population: A research population with at least 5% of limited English proficient individuals from a single non-english native language.

Translated Research Document: Any research document that has been translated by a certified translator and has a proof of certification.

Loyola University Health System wishes to facilitate opportunities for research participation for limited English proficient participants.

Consent Forms:

When investigators wish to enroll participants from a limited English proficient research population, the investigators must submit a translated research consent form for the native language of each limited English proficient population to the IRB with the original submission or as an amendment.

In the event that a non-English speaker is eligible for a study for which there is no translated consent document, investigators may enroll the potential subject using a "short form" consent that has been translated into the subject's native language (appendix 1). The IRB has approved a short form research consent document that has been translated into several languages. The English version of the short form research consent document as well as several translated short form consent documents are located on the IRB web page . For other languages, the investigator is responsible for obtaining a certified translation prior to conducting research in limited English proficient individuals. Translation of research documents may be facilitated by contacting the Department of Interpreter Services at extension 62300.

The consent process for limited English proficient participants must involve an interpreter who converts the spoken explanation given by the research investigator or staff member into the research participants preferred language. Researchers are strongly encouraged to use the Loyola provided access to interpretive services. Information regarding available interpretive services is located @ http://www.luhs.org/internal/clin_res/documents/interpreter.pdf. The interpreter must witness the full written English informed research consent document as well as the translated research short form consent to document that s/he interpreted the information provided during the informed research consent process. The research participant must sign the short form consent document. A copy of both the long and short form research consent must be given to the limited English proficient research participant.

Other Translated Research Documents:

All other translated study materials, such as questionnaires, surveys or any recruitment materials (flyers, radio advertisements, etc.) should also be provided to the IRB. The IRB must approve these translated documents before non-English speaking subjects can be enrolled into the study.

LOYOLA UNIVERSITY MEDICAL CENTER
MAYWOOD, ILLINOIS
CONSENT TO PARTICIPATE IN RESEARCH

Short Form Written Consent Document for Subjects That Do Not Speak English

Participant's Name: _____

Medical Record Number: _____

Protocol IRB#: _____

You are being asked to participate in a research study.

Before you agree, your doctor must tell you about the purposes, procedures, and length of the research; any procedures which are experimental; any potential risks, discomforts, and benefits of the research; any potential benefit from other types of procedures or treatments; and how information will be kept confidential.

Where applicable, the investigator must also tell you about any available compensation or medical treatment if injury occurs; the potential for risks; circumstances when the investigator may stop your participation; any added costs to you; what happens if you decide to stop participating; when you will be told about new findings which may affect your willingness to participate; and how many people will be in the study.

If you agree to participate, you must be given a signed copy of this document and a written summary of the research which is written in English.

You may contact _____ at _____ any time you have questions about the research.

You may contact _____ at _____ if you have questions about your rights as a research subject or what to do if you are injured.

Your participation in this research is voluntary, and you will not be penalized or lose benefits if you refuse to participate or decide to stop.

Signing this document means that the research study and the above information has been described to you orally, and that you voluntarily agree to participate.

Signature of participant

date

Signature of witness

date