

## OBTAINING AND DOCUMENTING INFORMED CONSENT FROM SUBJECTS WITH LIMITED ENGLISH PROFICIENCY

The purpose of this guidance is to outline the proper procedures for enrolling subjects with limited English proficiency (LEP).

Department of Health and Human Services and U.S. Food and Drug Administration regulations at 45CFR46.116, §46.117 and 21CFR50.20, respectively, require that investigators present prospective subjects with an informed consent document that is written in a language that they understand. This requirement applies to readability (grade-level) and language.

### Documenting informed consent from LEP subjects

Human subject investigators have two options for obtaining and documenting informed consent from a LEP subject.

- 1) The investigator may present the prospective subject with a copy of the informed consent document that has previously been translated into a language that the subject understands. This translated document must be currently approved and bear the Institutional Review Board (IRB) approval stamp. If the investigator does not speak the subject's language, an interpreter must facilitate the informed consent discussion. Subject, investigator and witness (interpreter) sign the translated consent form.

This method is required by the IRB when the study targets a population in which there is a high or certain likelihood of encountering non-English speakers (e.g., migrant farm workers or recent immigrants or a study performed in a demographic area that has a large proportion of non-English speakers)

- 2) Alternatively, oral presentation by an interpreter of the informed consent information is permitted under 45CFR46.117(b)(2) when used in conjunction with a translated, abbreviated written consent document and a written summary of what is presented orally. In most cases, it will be easiest to use the IRB-approved English language consent form as the written summary.

The OHSU Research Integrity Office (ORIO) currently provides abbreviated consent documents written in Spanish, Russian, Chinese, Vietnamese, and Korean on its IRB Forms website (<http://www.ohsu.edu/research/rda/forms.shtml#hsf>). These documents are called "short forms" in the OHRP guidance (see link below). If you intend to use a translated short form, download it from the website and add study specific information to the boxes. Submit it to the ORIO via PRAF (or eIRB Modification Request) for approval. Once you receive a stamped copy, you may use it to seek consent from subjects. If the investigator does not speak the subject's language, an interpreter must facilitate the informed consent discussion. An interpreter must read the written summary (standard consent form) in the appropriate language. The interpreter should also facilitate any of the subject's questions to the investigator. The subject signs the short form, the investigator signs the summary, and the interpreter signs both the short form and the summary.

If an investigator wishes to use this method to enroll a subject in a language for which the ORIO has not posted a translated short form, the investigator must obtain a written translation and submit it for IRB approval. The ORIO does not pay for this service.

This method may be used to seek consent from the occasional non-English speaker.

### Obtaining Written Translations

OHSU has established an agreement with a company called viaLanguage for OHSU departments to procure translation services directly from this vendor. The OHSU Translation & Interpreter Services (503.494.8720) is no longer able to translate study-related documents. Purchase orders must be obtained prior to requesting services from viaLanguage. Requests for translation should be submitted directly to the viaLanguage website at [www.health.viaLanguage.com](http://www.health.viaLanguage.com). Standard turnaround time and quotation on all projects will be sent to and approved by the requesting OHSU department prior to viaLanguage processing the request. Invoices will be sent and paid by

the requesting OHSU department. To set up an account please contact OHSU Account Manger, Jessica Gusick, by phone at 503-243-2007 x32 or by email at [Jessica@viaLanguage.com](mailto:Jessica@viaLanguage.com) . The ORIO does not pay for this service.

It is not necessary to obtain a back-translation to verify accuracy. The translated form must be submitted to the IRB for review and approval prior to use. If viaLanguage is not used, this submission must include a memo certifying the qualifications of the translator.

### **Use of Interpreters**

Investigator, interpreter and subject must be physically present during the informed consent discussion. It is not sufficient to have the interpreter on the telephone or speaker-phone. The exception to this requirement is in the event that OHSU Translation & Interpreter Services does not have a staff member who is fluent in the required language and can not secure an on-site interpreter from one of OHSU's language vendors. In this case, an appropriate interpreter may facilitate the discussion via telephone. Other exceptions include using interpreters to perform phone screens, scheduling visits, and telephonic consent where approved by the IRB.

The cost of an interpreter's services will be billed to the study. Neither the OHSU Interpreter & Translations Services nor the OHSU Research Integrity Office pay for this service.

OHSU's Administrative Policy 1.08, states that OHSU staff should not ask, suggest or encourage that a subject's friends or family members interpret for a subject except in urgent situations.

The subject who chooses to use his/her own interpreter must sign a waiver releasing OHSU from Liability for any adverse consequences that may result from interpretation not provided by an approved OHSU qualified interpreter

The August 11, 2003 Office for Civil Rights Policy Guidance (<http://www.os.dhhs.gov/ocr/lep/summaryguidance.html>) states:

Some LEP persons may feel more comfortable when a trusted family member or friend acts as an interpreter. When an LEP person attempts to access the services of a recipient of federal financial assistance, who upon application of the four factors is required to provide an interpreter, the recipient should make the LEP person aware that he or she has the option of having the recipient provide an interpreter for him/her without charge, or of using his/her own interpreter. Recipients should also consider special circumstances that may affect whether a family member or friend should serve as an interpreter, such as whether the situation is an emergency, and whether there are concerns over competency, confidentiality, privacy, or conflict of interest. Recipients cannot require LEP persons to use family members or friends as interpreters.

The ORIO adopts these standards for human subject research.

### **Interpreter/Translator Qualification**

A "Qualified Interpreter or Translator" is a healthcare interpreter who meets the qualification requirements as set by the OHSU Translation & Interpreter Services Department.

Under certain circumstances, the ORIO will accept interpreter services or translations performed by other interpreters. In these cases, a description of the interpreter/translator's qualifications must be provided to ORIO in writing.

Title VI of the Civil Rights Act of 1964 prohibits recipients of federal financial assistance from discriminating based on national origin by, among other things, failing to provide meaningful access to individuals who are limited English proficient (LEP).

The ORIO (503.494.7887) will answer any questions regarding this guidance.

For additional guidance on readability see the ORIO consent form readability policy at <http://www.ohsu.edu/research/rda/irb/docs/policies/readtips.pdf>

For additional guidance please see the Office for Human Research Protections website at <http://www.hhs.gov/ohrp/humansubjects/guidance/ic-non-e.htm>.