Background

This guidance is to explain how researchers should obtain and document informed consent for subjects who:

1. Are non-English speakers and require an interpreter and translated consent materials;
2. Understand English but cannot read due to blindness or illiteracy, or;
3. Understand English but cannot talk or write due to incapacitation.

Lehigh University faculty, staff, and students conduct research involving diverse populations that include many different cultures and languages. Investigators who enroll research subjects must consider the likelihood of encountering eligible subjects with limited English proficiency. The governing principles of human subjects research: **respect for persons, beneficence, and justice**, require that researchers not exclude subjects based solely on their inability to read, speak, or understand English. Investigators need either to communicate directly with subjects, or to provide a reliable alternative that:

1. Study participation is voluntary, as indicated by free and truly informed consent (**respect for persons**);
2. Study schedules, procedures, and risks are accurately communicated, and subjects have ongoing opportunities to express concerns and ask questions, in order to minimize risks to subjects (**beneficence**), and;
3. There are fair procedures and outcomes in the selection of research subjects so that risks and benefits of research are shared in society (**justice**).

Federal regulations (45 CFR 46.116 and 21 CFR 50.20) state that informed consent “shall be in language understandable to the subject or the representative” and describe how informed consent is to be documented (45 CFR 46.117 and 21 CFR 50.27).

In order to apply the federal requirements as outlined in the regulations, this guidance outlines the following two methods for obtaining and documenting informed consent for research subjects who do not read, speak, or understand English:

1. The **preferred** method is to provide consent forms written in the subject’s language.
2. For the occasional and unanticipated non-English speaking subject, an alternative “short form” method may be allowed [21 CFR 50.27(b)(2) and 45 CFR 46.117(b)(2)]. Routine use of this method is strongly discouraged by the University and by federal regulations.

Important Note:

- The IRB Application must describe the consent process for non-English speaking subjects.
- The IRB application may also describe the consent process for unanticipated non-English speakers for whom translated consent forms have not been prepared.
- **Informed consent is an ongoing process throughout a study.** For non-English speakers, the investigator should address the means for providing continued, qualified interpretive services. Likewise, for those who understand English but cannot read, talk, or write, the investigator should be prepared to provide the necessary support to ensure the subject’s ongoing comprehension of new information that may become available during the study.

Ethical and Legal Considerations

As part of each consent discussion, investigators have an ethical and legal obligation to assess the subject's understanding of the consent information to ensure that the consent is truly "informed". When the investigator and subject do not share a language, the investigator must depend on the accuracy of the translated consent documents and the working relationship with the interpreter. The investigator's familiarity with the subject's culture ("cultural competency") or lack of familiarity affects the communication.

Clinical Investigations and Biomedical Studies

The medical and technical information discussed during the initial consent discussion, as well as ongoing, study-related information, can be very complex and should be communicated to non-English speaking subjects **through an interpreter with training in and understanding of medical terminology**. In addition, an individual with a professional commitment to maintain strict confidentiality should handle the private medical issues discussed with subjects.

Working Effectively with Medical Interpreters: The field of medical interpretation is evolving and although protocols are being developed, standardized practices do not exist. Investigators may want to discuss some or all of the following topics with the interpreter before participating in an interpreter-medicated consent discussion.

1. Will the medical interpreter serve as patient/subject advocate as well as interpreting the consent material?
2. If the English version of the consent form is orally interpreted for the alternative "short form" method, how will the interpreter incorporate cultural considerations into the consent information?
3. How transparent will the interpreted conversation be? With three people communicating (subject, investigator, and interpreter), will everything that is said by each person be translated?
4. How will the investigator and interpreter determine whether the subject truly understands the consent information?
5. Informed consent is an ongoing process. How will the investigator ensure that the subject will understand ongoing study-related communication? If the subject has questions about continuing in the study, how will that be communicated to the researchers?

Anticipating the Need for Written Translations

As part of the IRB application process, investigators should estimate the likely proportions of non-English speaking people who may be encountered subjects for a proposed study. The English version consent and study materials submitted to the IRB should be written at the 8th grade level or lower. Translations are prepared IRB review and approval of the English version.

Translation Requirements:

Greater than minimal risk studies: a certified translation of the consent/assent form(s) and recruitment material(s) is required for studies that pose greater than minimal risk to subjects (see the LU IRB Guidance "Assessing Risk Using Magnitude of Harm" for more information), unless the IRB has granted a waiver of documentation of informed consent.

A certified translation is one that has been formally verified by a licensed translator or translation company for use in official purposes. Certified translators attest that the target-language text is an accurate and complete translation of the source-language text. Certified translations of consent documents ensure that the tone, meaning, and content of the translated documents remain consistent

with the IRB-approved English version. When a translation is certified, both it and the original are accompanied by a signed statement from the translator attesting to the completeness and accuracy of the translation. For a certified translation, a copy of the certification from the translator or translation service should be attached to the translation of any informed consent documents and recruitment materials. Certified translation may also be documented using the Lehigh University IRB Translation Documentation Form.

Minimal risk studies: Studies that are eligible for expedited review also require translation of the consent/assent forms; however, certified translation is not required. The IRB will accept documents translated by an individual fluent (i.e. can speak, read, and write) in a given language. The qualifications of the individual performing the translation will be assessed by the IRB. The qualifications of a translator may be documented and submitted for IRB review using the Lehigh University IRB Translation Documentation Form.

Differences between an interpretation and a translation: For purposes of research informed consent, an interpretation is a verbal exchange between two parties and the person serving as an interpreter is fluent (can speak, read, and write) in English and the language of the subject. A translation is the process of translating a written document (e.g. consent form) from one language into another, assuring the language of the translated document has the same meaning as the written document in the first language.

Cost of Translation: The cost of translating written consents is the investigator's responsibility. These costs may be quite high, particularly for large studies where multiple translations are needed and/or studies with relatively complex consent information that may require additional time by a skilled professional. Investigators should include the costs of written translations as well as medical interpreter services on grants and contracts. Industry sponsors are often willing to pay the costs of translating consent forms.

The Informed Consent Discussion with Non-English Speaking Subjects

As with all consent discussions, sufficient time should be allowed to explaining each section of the consent and for the subject to ask questions. Working with an interpreter to explain complex topics such as randomization, placebo control, dosing schedules, and invasive/noninvasive procedures may require additional time and/or subsequent discussions.

IMPORTANT NOTE: It is the investigator's responsibility to judge the subject's comprehension of the consent information including the understanding that participation is voluntary and that the subject has the right to withdraw at any time during the study. If the investigator doubts the subject's consent comprehension, he/she should not enroll the subject in the study. **The subject's autonomy must not be jeopardized due to a language barrier.**

Preferred Method of Obtaining Informed Consent from Non-English Speaking Subjects:

The LU IRB supports the policy set forth by the federal Office of Human Research Protection (OHRP) and strongly encourages investigators to provide a written consent document in the language understood by the subject.

If the investigator anticipates that a substantial portion of eligible subjects to be non-English speakers, translated consent forms in the common languages should be prepared in advance.

See the flowchart that summarizes the consent discussion using the preferred method.

Alternative Short Form Method of Obtaining Informed Consent from Non-English Speaking Subjects:

The alternative "short form" method for obtaining informed consent should only be used for the **occasional and unexpected enrollment** of a non-English speaking subject in a study for which no consent form in the subject's language has been prepared. Only those study team members who are approved by the IRB to obtain informed consent from research participants may obtain short form consent. A template for short form informed consent is available on the LU IRB website.

Procedures for the Alternative Short Form Consent Method:

1. The investigator requests use of the short form consent process in their IRB application. In general, the short from method should not be used for Phase 1 clinical trials, research that includes vulnerable subject populations (children, pregnant women, prisoners, adults otherwise unable to consent) and for true placebo controlled studies.
2. If the IRB approves the use of the short form consent process, the investigator consents non-English speaking subjects using the translated short form and approved English consent document. Note that the short form consent form is generic, not study-specific.
3. The subject will read the short form consent in his or her language.
4. An interpreter, in the presence of the PI or a qualified member of the research team will orally translate the English version of the IRB-approved consent document and will facilitate the question and answer phase of the informed consent process between the subject and the researcher.
5. A witness will be present during the oral presentation of the English version of the IRB-approved consent document. Note that the witness must be an adult, fluent in both languages, who is not a member of the study team. The interpreter may serve as the witness.
6. The following signatures will be obtained on the short form consent and the English version of the IRB-approved consent. The subject will sign and date the short form consent, and the witness and researcher will sign and date both the short form consent and the English informed consent document.
7. A copy of the English informed consent document and the short form consent will be given to the participant.
8. Once the subject has consented and eligibility is confirmed, the English version of the IRB-approved consent form must be translated into the subject's language by a professional or certified translator and provided to the subject within one month from the subject's initial consent.

See the flowchart that summarizes the consent discussion using the alternative short form consent method.

The Informed Consent Discussion with Legally Blind Subjects

If you are enrolling subjects who cannot read the consent materials due to blindness, or the subject's legally authorized representative is legally blind:

- It is recommended that an impartial witness observe the consent process.
- The LU IRB approved consent form should be presented orally.

- Sufficient time should be allowed for questions to be asked and answered, both by the subject and by the persons obtaining consent to ensure the subject comprehends the consent information.
- Consider using an audio recording of the consent discussion as part of the documentation of informed consent.

To document the consent process, the LU IRB recommendations are consistent with guidance endorsed by the FDA and set forth by the International Conference on Harmonisation (ICH E-6 4.8.9). If the subject (or subject's legally authorized representative) verbally agrees to participate in the study:

- If capable of doing so, the subject signs and personally dates the consent form.
- The witness signs and personally dates the consent form. By doing so, the witness attests that the consent information was accurately explained and that the subject apparently understood the information, and informed consent was given freely.
- The person obtaining consent signs and dates the consent form.
- Signed copies are given to the subject.

The Informed Consent Discussion with Illiterate Subjects

If you are enrolling subjects who cannot read the consent materials due to illiteracy:

1. It is recommended that an impartial witness observe the consent process.
2. Consent materials should be presented orally.
3. Sufficient time should be allowed for questions to be asked and answered, both by the subject, and by the person obtaining consent to ensure the subject comprehends the consent information.
4. Consider using a video/audio recording of the consent discussion as part of the documentation of informed consent.

To document the consent process, the LU IRB recommendations are consistent with guidance endorsed by the FDA and set forth by the International Conference on Harmonisation (ICH E-6 4.8.9). If the subject verbally agrees to participate in the study:

1. If capable of doing so, the subject signs, or marks an X to signify consent.
2. The witness signs and personally dates the consent form. By doing so, the witness attests that the consent information was accurately explained and that the subject apparently understood the information, and informed consent was given freely.
3. The person obtaining consent signs and dates the consent form.
4. Signed copies are given to the subject.

The Informed Consent Discussion with English-Speaking Subjects Who Cannot Talk or Write

To enroll subjects who understand English but who are unable to talk or write due to physical limitations, investigators must assess the subject's ability to understand the consent materials and to indicate their wish to participate or not. Obtaining and documenting consent for these subjects should be consistent with the FDA's A Guide to Informed Consent Information Sheet. The subject may be enrolled in the study if the person:

1. "…retains to ability to understand the concepts of the study and evaluate the risks and benefits of being in the study when it is explained verbally (still competent), and

2. 2 is able to indicate approval or disapproval to study entry…"

Informed consent should be obtained and documented as follows:

1. An impartial witness should be present during the entire consent discussion.
2. The IRB-approved consent form should be presented orally and clearly explained by the person obtaining consent.
3. Sufficient time should be allowed for questions to be asked if the subject is capable of doing so. The person obtaining consent should ask questions to ensure the subject comprehends the consent information.
4. If the subject indicates agreement to participate in the study, informed consent should be documented as follows:
    - The consent form should be annotated by hand to describe the method for communication with the prospective subject and the specific means by which the prospective subject communicated agreement to participate in the study.
    - Consider using a video tape recording to further document the consent discussion.
    - The witness signs and personally dates the consent form. By doing so, the witness attests that the consent information was accurately explained and that the subject apparently understood and informed consent was given freely.
    - The person obtaining consent signs and dates the form.