



Institutional Review Board

University of Missouri-Columbia

Standard Operating Procedure

Non-English Speaking – Study Requirements

Non-English Speaking – Study Requirements

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1.0 Purpose

To aid in assuring knowledge and compliance of all persons involved in any aspect of human subjects research by documenting the processes for the review and implementation of studies that include participants who primarily speak a language other than English. This is to ensure that non-English speaking subjects are properly consented per 45 CFR 46.116 and 21 CFR 50.20.

2.0 Scope

The SOP applies to all human subject research falling under the purview of the University of Missouri Institutional Review Board.

3.0 Policy/Procedure

The governing principles of human subject research 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 to ensure that:

1. Study participation is voluntary, as indicated by free and truly informed consent; and
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; 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.

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.

Translated documents shall be prepared after IRB review and approval of the English version. The translated documents shall be submitted via an Amendment Form for IRB review.

Consent Methods:

There are 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** is allowed [21 CFR 50.27(b)(2) and 45 CFR 46.117(b)(2)]. For biomedical research, routine use of this method is strongly discouraged by the University and federal regulators.

Preferred Method for Obtaining Informed Consent from Non-English Speaking Subjects

1. The IRB supports the policy set forth by the Office of Human Research Protection (OHRP) and strongly encourages investigators to provide a written consent document in a language understandable to the subject.
2. If the investigator anticipates a substantial portion of eligible subjects to be non-English-speaking people, translated consent forms in the common languages should be prepared in advance.

Alternative Short Form Method for 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. IRB policy is consistent with the Office of Human Research Protection (OHRP) and the Food and Drug Administration (FDA). Routine use of the "short form" for obtaining informed consent is strongly discouraged.

- Only those study team members who are approved by the IRB to obtain informed consent from research participants may obtain short form consent.

Procedures for the Alternative Short Form Consent Method

1. The investigator can request a short form consent process. The short form consent process cannot be used for vulnerable subject populations (children, pregnant women and prisoners), Phase I studies or placebo controlled studies.
2. If IRB approved, the investigator consents non-English speaking subjects using the translated short form and approved English consent document. Note: the translated short form is generic, not study specific.
3. The subject will read the short form consent in his/her chosen language.
4. An interpreter, in the presence of the Lead Researcher or qualified Co-Researcher (approved by the IRB), 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 potential participant and the researcher.
5. A witness will be present during the oral presentation of the English version of the IRB-approved consent document. The witness must be an adult, fluent in both languages, who is not a member of the study team (i.e., is not listed in the protocol narrative). 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.

Translated Consent Materials:

The following documents should be translated before enrolling non-English speaking subjects on a study:

- The IRB-approved English informed consent/assent document(s)
- HIPAA documents (when applicable).

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- Any other approved document(s) as applicable (e.g. survey, recruitment material).

Certified Translation for Greater than Minimal Risk Studies: 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 translation of consent documents ensures that the tone, meaning and content of the translated documents remain consistent with the IRB-approved English version.

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. A letter from the translator describing their qualifications must be provided with the translation documents.

Submission Requirements:

- The study application and protocol must describe the consent process for non-English-speaking subjects.
- The application and protocol may also describe the consent process for unanticipated non-English speakers for whom translated consent forms have not been prepared. By including a description of the alternative short form consent method in the IRB application, the investigator is prepared to conduct informed consent discussions with individuals who may qualify and potentially benefit from being in the study, but whose encounter was not originally anticipated.
- For non-English speakers, the investigator should address the means for providing continued, qualified interpretive services.

Related SOPs

Informed Consent- Types & Elements

Informed Consent- Process & Issues

Consenting Subjects Who Do Not Read, Speak or Understand English Guidance

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