

## Guidance: Involvement of Non-English Speaking Subjects in Research

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The inability to understand spoken English or read and comprehend documents written in English prevents a subject from actively taking part in the consent process and from making an informed decision about participation. Investigators need to be aware of the difficulties inherent in providing accurate and effective consent to non-English speaking individuals and ensure appropriate safeguards are in place to protect the rights and welfare of these individuals.

### I. Involvement of Non-English Speaking Subjects in Research

The principle of Justice as embodied in the Belmont report (The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979) calls for "... *fair procedures and outcomes in the selection of research subjects.*" The UIC IRBs implement this principle for non-English speaking subjects by requiring UIC investigators:

- To provide an ethical and scientific justification for excluding subjects who can not understand or read English, but otherwise are eligible to participate, from a research proposal.
- To include non-English speaking subjects in research, particularly when the research offers the subject the potential for direct benefit, unless the UIC IRB reviews and approves the investigator's justification for exclusion.

### II. Obtaining and Documenting Informed Consent

The federal regulations (45 CFR 46.116 and 21 CFR 50.20) require that informed consent information be presented to a research subject "...*in language that is understandable to the subject (or authorized representative)*" and, except in infrequent situations, be documented in writing. Subjects who are not English-speaking should be provided with a translation of the consent document in a language understandable to them. The federal regulations (45 CFR 46.117 and 21 CFR 50.27) permit two methods by which this requirement can be fulfilled: (1) a written consent document translated into a language understandable to the subject (or their legally authorized representative), (e.g., foreign language translation of the IRB approved English informed consent form) or (2) a "short form" written consent document stating that the elements of consent have been presented orally to the subject (or their legally authorized representative). The IRB determines which procedure is appropriate for documenting informed consent on a protocol specific basis.

The process of obtaining and documenting informed consent of subjects who do not speak English at the UIC is also impacted by Illinois state law. Statute 110 ILCS 305/20 of the University of Illinois Act states that, *“If a person is to participate as a subject in a research experiment conducted at the College of Medicine but does not understand the English language, then the informed consent document for the research experiment must be written in a language that the person does understand. If the person cannot read or has difficulty reading, the document must be read to the person in that same language.”* As a result of this statute, only the first method (i.e., a written translation of the consent form) is acceptable for research conducted at the College of Medicine. At other locations on the UIC campus, such as the other Colleges, UIC Hospital, or UIC Outpatient Care Clinic, either a complete written translation of the English consent document or a short form and oral translation may be acceptable.

### **Method 1: Written Translation of IRB-Approved English Informed Consent**

- The UIC IRB requires a written translation of the full English consent document into a language understandable by potential subjects when:
  - The research targets a specific population that is non-English speaking;
  - A significant proportion of subjects are anticipated to be non-English speaking; or
  - The research is to be conducted at the College of Medicine.
- Translations of the informed consent documents must be reviewed and approved by the IRB.
- It is recommended to first obtain approval for the English version of the consent document, and then submit translations of the consent in other languages as an amendment.
- A back-translation of the consent document(s) to check for accuracy should be carried out. Whenever possible, the back translation should be performed by another qualified individual (Note: Depending on the scope, complexity and risk-benefit of the research, the IRB may require an independent back-translation).
- The subject, if agreeing to participate, and member of research team obtaining consent must sign and date the IRB-approved foreign language version of the consent document. If a translator is present, they also should sign the consent.
- If the member of the research team obtaining consent is not fluent in the subject’s language, a translator fluent in English and the subject’s language should be available to address the subject’s questions and assess their comprehension.
- The consent process, including the language used and presence of translators or witnesses, should be appropriately documented in the research record (i.e., source document) and, if applicable, medical record.
- The following items should be submitted for IRB review and approval of the foreign language translation of the full consent document:
  - IRB-approved English language informed consent document;
  - Consent document translated into the desired language;
  - Endorsement from translator that a back translation of the consent into English was performed and was found to be accurate;

- Documentation of the translator's qualifications (i.e., expertise in the foreign language, such as certified translator, native speaker or other evidence of fluency, and an appropriate scientific or medical background); and
- Plan to ensure an adequate consent process and how communication will be facilitated during the research.

### **Method 2: Short Form Consent Process**

- The UIC IRB may approve the use of an oral presentation along with a "short form" consent document in a language understandable to the subject when:
  - The research does not target a non-English speaking population, and
  - Only a small proportion of subjects are anticipated to be non-English speaking.
- The short form is a document written in language understandable to the subject stating that the elements of informed consent, which are outlined on the form in general terms, have been presented orally and understood by the subject (or their legally authorized representative).
- Templates for the short form in English and several foreign languages are provided on the OPRS form website for investigators to download and use. The translator assisting with the consent process should fill in the protocol specific information where indicated by the blank lines on the form.
- UIC IRB approval of the foreign language short form consent document and process is required, even when using the OPRS downloadable templates. To avoid delay in subject enrollment or incurrance of a protocol violation, investigators are urged to anticipate the presentation and language requirements of potential non-English speaking subjects.
- Requirements for obtaining informed consent when using a short form consent document:
  - A summary of the informed consent information for the research embodying the basic and additional elements of disclosure is presented orally in a language understandable to the subject (or their authorized representative). Typically, the IRB-approved English consent form is used for this purpose (this is the IRB recommended approach).
  - The subject is provided a copy of the short form written in the language the subject is fluent in to review.
  - A translator fluent in the subject's language and English must read the consent summary (i.e., IRB approved English consent form) to the subject (or their authorized representative) in their language. The translator should also be available to address the subject's questions and assess their comprehension. The translator may be a member of the research team.
  - A witness to the oral presentation fluent in the subject's language and English is required to attest to the adequacy of the consent process and to the subject's voluntary consent. The translator may also serve this role, if they are not a member of the research team.

- Requirements for documenting the consent process when using the short form:
  - The subject (or their authorized representative) must sign and date the short form written in the appropriate language, if agreeing to participate.
  - The witness must sign and date the foreign language short form and a written copy of the orally presented consent information (i.e., typically the IRB approved English consent form).
  - The research team member obtaining consent must sign and date a written copy of the orally presented consent information.
  - A copy of the signed short form in the subject's language and the orally presented consent information must be given to the subject (or their authorized representative).
  - The consent process, including the language used and presence of translators or witnesses, should be appropriately documented in the source document and, if applicable, medical record.
- The following items should be submitted for IRB review and approval of the short form consent process:
  - Justification for the short form process;
  - English and foreign language versions of the short form (if the short form is NOT from the UIC OPRS website, the source of the form and credentials of the translator should be described);
  - Written summary (in English) of the consent information to be presented orally (the IRB-approved English language consent is recommended to be used for this purpose); and
  - Plan to ensure an adequate consent process and how communication will be facilitated during the research.

### **III. Additional Considerations in the Informed Consent Process and Research Procedures**

Informed consent is a process that requires investigators to continuously re-assess the subject's understanding of the nature of the research, its risks and benefits. Adequate communication between the research staff and subject must occur throughout the research to ensure the safety and welfare of the subject and the integrity of the research data. The IRB submission should discuss the recruitment, consent and continuing participation of non-English speaking subjects in the research. In addition to the consent documents, the investigator must submit for IRB review and approval any recruitment materials that have been translated. Also, the investigator is expected to translate and submit to the IRB any study materials to be provided to non-English speaking subjects, such as surveys and questionnaires. The investigator should describe how communication with non-English speaking subjects will be facilitated throughout the course of the study.