

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

<http://research.uic.edu/human-subjects-irbs/>

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Approved by: Human Protections Administrator and  
Director of OPRS

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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, and communication throughout the study, 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](#) 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 cannot 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**

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 key information and 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. As a result of the following statute, only Method 1 is acceptable at the College of Medicine. [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.”*

### **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 is 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 prospectively reviewed and approved by the IRB.
  - IRB approval of the English version of the consent document should be obtained first with translations of the consent in other languages and certification of translation and/or documentation of qualifications of translator submitted via an amendment.
- 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 the member of the research team obtaining consent is not fluent in the subject's language, an interpreter fluent in English and the subject's language should be available to address the subject's questions and assess their comprehension.
  - Family members cannot be the interpreter for the consent process.
- The consent process, including the language used and who provided the interpretation (i.e., research personnel, interpreter from service), should be appropriately documented in the research record and, if applicable, medical record.

### **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 (or their legally authorized representative) when:
  - The research does not target a non-English speaking population,
  - A non-English speaking subject is unexpectedly encountered, and
  - Only a small proportion of subjects are non-English speaking. (Note: If repeated use of a short form suggests that a significant proportion of non-English-speaking subjects is being enrolled, the UIC IRB may require the

submission of a written translation of the full English consent document via an amendment.)

- OPRS has provided the translation of numerous short forms on their [website](#).
  - An English short form is also available for reference, but should not be used with subjects when the main study consent form is in English. The English short form does not need to be included in any materials submitted to OPRS.
- If a short form is required in a language not provided by OPRS, the investigator is responsible for obtaining a translation of the short form (including the cost of the translation).
  - An amendment submission that includes documentation of a certified translation and/or documentation of the interpreter's qualifications (i.e., expertise in the foreign language, native speaker or other evidence of fluency, and an appropriate scientific or medical background) must be submitted and approved before the short form may be used.
- Requirements for obtaining informed consent when using a short form consent document:
  - The informed consent document for the research states that the elements of consent have been presented orally in a language understandable to the subject or their Legally Authorized Representative (LAR).
  - A written summary of what is to be said to the subject or the LAR that embodies the key information and basic and additional elements of consent and any elements of disclosure. The IRB-approved English consent form is typically used for this purpose (this is the IRB recommended approach).
  - An interpreter fluent in the subject's language and English must read the consent summary (i.e., IRB-approved English consent form) to the subject (or LAR) in their language. The interpreter should also be available to address the subject's questions and assess their comprehension.
    - The interpreter may be a member of the research team, but cannot be a family member.
  - An impartial witness must be present for the entire consent discussion and must be fluent in English and the subject's language.
  - The subject (or LAR) must sign and date the short form written in the appropriate language, if agreeing to participate.
  - The impartial witness must sign and date the foreign language short form and a written copy of the orally presented consent information.
  - The research team member obtaining consent must sign and date a written copy of the orally presented consent information (i.e., IRB-approved English consent form).
  - The subject (or LAR) will receive a copy of the signed short form and summary (i.e., IRB-approved English consent form).
  - The consent process, including the language used and presence of interpreter (i.e., research personnel, hospital interpreter) and witnesses, should be appropriately documented in the research record and, if applicable, medical record.

### III. Responsibilities after using a Short Form consent process:



- Within 10 business days of enrolling a subject using a short form:
  - Submit a [Protocol Exception](#) form to the IRB to report the use of a short form;
  - Include a blank copy of the short form utilized for the consent process.
- Provide the following to the IRB via an Amendment submission in a timely manner:
  - Certified translation of all documents the participant will be required to complete (e.g., surveys, questionnaires, etc.);
  - The plan for ensuring ongoing communication with the participant is in a language understandable to the participant.

#### REVISION LOG:

Version (#, date)	Replaces (#, date)	Summary of changes
2.8, 03/01/17	2.7, 04/07/12	Editorial changes (hyperlinks, header, spelling errors). Removal of the requirement to provide a back translation of the consent.
2.9, 01/21/19	2.8, 03/01/17	Clarification regarding witness signature; Editorial revisions.
3.0, 10/01/19	2.9, 01/21/19	Removal of requirement of OPRS provided short forms to be prospectively approved by IRB.