

Institutional Review Board & Human Subjects Office

Short Form Consent Document and Process 3/18/2019

Introduction

UI researchers may use the Short Form Consent Document and Process when the research team unexpectedly identifies a potential subject who does not speak English. The Short Form Consent Process allows the team to verbally translate the IRB-approved Informed Consent Document into the language the subject understands.

The IRB provides a [template Short Form in English and has Short Forms translated into several different languages](#). The Short Form is a brief document that summarizes the information the investigator must tell the participant before consent and indicates that the process was conducted in a language the subject or their Legally Authorized Representative (LAR) understands. This document does not contain study-specific information. If a UI researcher translates the English version of the Short Form into other languages, they should email a copy to the [Human Subjects Office](#). Prior IRB approval is not required for use of a new translation of the Short Form.

If the research team expects to encounter and recruit non-English speaking subjects, they should translate the informed consent document to those languages in advance. The IRB must approve all documents that are translated into another language. The Short Form Consent Process may be used to enroll up to five subjects in a study. To enroll any additional subjects, the team must use an IRB-approved, translated version of the full Informed Consent Document.

For information about the Short Form Consent Document Policy, see the [IRB Standard Operating Procedures & Researcher Guide](#) (Section II, Part 11.B.iii.a).

Translators and Witnesses

To consent using the Short Form Document, the research team will need someone to verbally translate the informed consent to the prospective participant, and someone to serve as the witness to the consent process. If the study involves complex procedures, research team members should ensure the translator understands and can translate the technical information in the consent document. To serve as a witness to the consent process, someone will need to be over 18 years of age, fluent in both English and the subject's language, and not be a member of the research team. The translator can serve as the witness. The witness signs both the Short Form and the

IRB-approved English version of the informed consent document. By signing the Short Form, the witness attests to the fact that

- they observed the consent process
- the information was presented in a language understandable to the subject
- the subject had the opportunity to ask questions

Short Form Consent Process

Researchers should carefully review these guidelines for using a Short Form before enrolling a non-English speaking subject.

1. The research team member provides the potential subject with the Short Form Consent Document translated into a language the subject understands.
2. The research team member completes the open fields in the Short Form Document, indicating:
 - a. the subject's full name
 - b. the study IRB ID#
 - c. the Principal Investigator's name and phone number
 - d. the applicable language fields in the translator and witness signature sections on page 2
3. The translator translates and verbally presents the information in the IRB-approved English version of the consent document to the potential subject. Instruct the translator to translate any questions the individual may have for the investigator and provide the potential subject with the investigator's responses.
4. The potential subject reads the Short Form Document. If the potential subject chooses to participate in the study, they sign and date the "Participant" signature section on page 2. This signature indicates that the consent form was presented orally in a language understandable to them and that they consent to participate in the study.
5. The research team member signs and dates the IRB-approved English version of the Informed Consent Document as the "Person Who Obtained Consent."
6. The witness signs and dates both the Short Form and the English-language Informed Consent Document. The English version of the consent document does not have a

separate signature section for the witness, so they sign below the “Person Who Obtained Consent” line.

7. The translator signs the Short Form to affirm that they are fluent in both languages, that they orally presented the information in the English version of the consent document, and answered any questions.
8. Provide the subject with a copy of the Short Form and a copy of the English version of the consent document. The research staff must write a note (either on the consent document or a separate Note to File in the research records) documenting the use of the Short Form Consent Document and Process.
9. Store the original, signed forms in the research records. Per IRB policy, the best practice is to store the signed ICDs (including Short Forms) separate from the subject data.

Short Form Consent in a Multi-Visit or Long-term Study

Informed consent is an ongoing process. Therefore, the research team must be able to communicate with the subject for the duration of the study. The best practice is to have a person of the subject’s choosing, who is fluent in both languages, accompany the subject to subsequent visits. Alternately, the research team may arrange for a translator to be available at subsequent visits to ensure that subject has an opportunity to ask questions, understands the responses and receives relevant study information.

If the study requires multiple visits or the subject’s participation will last more than 60 days, the Principal Investigator must provide the subject with a translated version of the complete IRB-approved ICD within 30 days of enrollment. The PI must submit a HawkIRB Modification form with the translated Informed Consent Document. The IRB must approve translated versions of all study documents.

HawkIRB Modification Form for Translated Documents

1. From the Project Summary page, generate a HawkIRB Modification Form
2. Section VI.16 – Select “Yes”
3. Section VI.17 – List the languages of non-English speaking subjects that the PI expects to enroll
4. Section VI.17.a – Provide the translator’s name, qualifications and role (e.g. document translation, verbal interpretation, attending future study visits etc.)
5. Review Section VII.D and make any updates necessary to describe the recruitment and consent process
6. Section VII.D.29 and/or VII.D.30 – Provide a detailed description of the consent process for non-English speaking subjects.

7. Attach the translated version of the Informed Consent Document in the Consent Document Attachment Category. The document must be in rich text format, with the IRB approval stamp placeholder.
8. Attach any documents related to the credentials of the translator in the Miscellaneous Attachment category.
9. If the Informed Consent Document needs to be edited, please do that so the IRB can review it before attaching the translation.

Short Form Documents

The IRB provides an [English version of the Short Form Consent Document and has Short Forms available in several languages](#). Prior IRB approval is not required for translation into another language. However, if a UI researcher translates the Short Form into another language, please email it to the [Human Subjects Office](#).