Short Form Consent Document and Process

Institutional Review Board and Human Subjects Office

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 and document their agreement to participate.

Applicability - This guidance is applicable to all University of Iowa research, regardless of IRB of record.

Template Documents - 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 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.

Additional Languages - If a UI researcher translates the English version of the Short Form into other languages, they should email a copy of the document and translator credentials to the Human Subjects Office. Prior IRB approval is not required for use of a new translation of the Short Form.

Planned Enrollment of Non-English Speaking Subjects - If the research team expects to encounter and recruit non-English speaking subjects, they should state that in the HawkIRB application (Section VI.16) and translate the Informed Consent Document into those languages in advance. The IRB must approve all documents that are translated into another language.

Additional Subjects - 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.

Optional Agreements - If the Informed Consent Document contains checkboxes and space for subject initials or signature to indicate agreement for optional aspects of the study, the subject should NOT mark those aggrements on the English consent document that they cannot read. The research team can consider the response 'No,' or reconsent subjects with an IRB-approved, translated consent document. Contact the Human Subjects Office for additional guidance about use of the Short Form for a study with optional agreements in the Informed Consent Document.

IRB Policy for Short Form Consent Process - See the UI IRB Standard Operating Procedures and Researcher Guide, Section II, Part 11.B.iii.a.

Translators and Witnesses

To obtain consent using the Short Form Document, the research team needs someone to verbally translate the informed consent to the prospective participant and someone to witness the consent process.

Translator - If the study involves complex procedures, the translator must understand and be able to translate the technical information in the consent document. The translator may be a member of the research team.

Witness - The witness to the consent process must:

- Be over 18 years of age.
- Be fluent in both English and the subject's language.
- Not a member of the research team.
- Be able to physically or electronically sign the Short form and the English Informed Consent Document.

The translator may serve as the witness, but they must be able to sign the Short Form Document and the IRB-approved English version of the Informed Consent Document with a pen or via an authenticated electronic signature. If the translator is unable to sign documents, the research team has three options:

1) Find another witness,
2) Submit a HawkIRB Modification form to enroll non-English speaking subjects (with a fully translated consent document and other study materials), or
3) Refrain from enrolling the individual using the Short Form document and process.

By signing these documents, the witness attests 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

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

1. **Short Form** - The research team member locates the Short Form Consent Document translated into a language the subject understands on the Human Subjects Office website.
2. **Subject and Study Information** - The research team member completes the open fields in the translated Short Form Document, indicating (using the English version, if necessary):
    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. **Verbal Translation** - The translator verbally presents the IRB-approved English version of the consent document to the potential subject. The translator will translate any questions from the potential subjects to the research team member conducting the consent process and translate the responses.
4. **Subject Signature** - The potential subject or their Legally Authorized Representative (LAR) reads the Short Form Document. If they choose to participate in the study, the subject or LAR signs and dates 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. **Team Member Signature** - The research team member signs and dates the IRB-approved English version of the Informed Consent Document as the "Person Who Obtained Consent."
6. **Witness Signature** - The witness signs and dates both the Short Form and the IRB-approved, English-language Informed Consent Document with a wet signature (pen) or authenticated electronic signature.

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. **Translator Signature** - 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. If the translator is unable to sign the document, the research team should include a separate attestation document indicating that the translation was completed. If the translator serves as the witness, they must be able to sign the Short Form and the IRB-approved, English-language Informed Consent Document with a wet signature (pen) or authenticated electronic signature.
8. **Provide Copies** - 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. **Consent Document Storage** - 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 study data.

Additional Steps for Study Participation Longer Than 60 Days

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 must 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 subject participation will last more than 60 days, the Principal Investigator must provide the subject with a translated version of the complete IRB-approved Informed Consent Document within 30 days of enrollment. This translated version must be approved by the IRB and have a valid IRB approval stamp. See instructions below for submitting a HawkIRB Modification form with the fully translated Informed Consent Document. After IRB approval, the research team must provide the translated consent document to the subject. Subject signature is not required on the translated document

HawkIRB Modification Form for Translated Documents

To obtain IRB approval for the translated consent document with no plans to enroll additional subjects who speak that language:

1. Generate a Modification form.
2. Use the Edit function to obtain a copy of the IRB-approved consent document to give to the translator.
3. Section XIII (Other Mod and/or Comments) – Explain the purpose of the modification.
4. Attach the translated version of the Informed Consent Document in the Consent Document Attachment Category (same format as the original template from HawkIRB with the IRB approval stamp placeholder).
5. Attach documents related to the credentials of the translator in the Miscellaneous Attachment category.

Notes:

- The consent document must always be saved in the same format as the original template from HawkIRB (either.docx or .rtf) so the IRB approval stamp populates correctly.

- If the Informed Consent Document needs to be edited, the research team should do that first so the IRB-approved changes can be incorporated into the translation.

To enroll additional subjects using the translated Informed Consent Document:

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