

Consenting Non-English Speaking Subjects Using a Short Form

Guidelines for the Use of the Short Form

For the occasional and unanticipated recruitment of **non-English speaking subjects**, the **short form consent** can be used in conjunction with the *IRB-approved English version of the (longer) Informed Consent Form*, which will be orally translated into the target language by a translator.

Although the *short form* is characterized to be a more “condensed” version of the full (longer) written informed consent version, the *short form* must contain the same core/basic elements and possibly additional elements found in the IRB-approved English version. Examples of these core/basic elements are the following but not limited to:

- Purpose of Research,
- Research Procedures,
- Risk/Benefit,
- Contact Information (IRB and PI)

When TO USE a Short Form:

As mentioned above, OPHS-IRB recommends that a Short Form **only** be used when recruitment of non-English speaking subjects was **NOT** originally **foreseen** during the initial planning of the research protocol. The following are circumstances in which a *Short Form* can be used:



- The subject or subject’s representative does not understand or speak English.
- The subject or subject’s representative speaks a language not originally anticipated in the study protocol.
- A translated consent form (i.e. in language understandable to subject) has not been approved by the IRB. **Note** that the Short Form has to be reviewed and approved by the IRB before implementation; therefore, non-English speaking subjects cannot be consented prior to IRB review and approval.
- There is not sufficient time for the preparation of a properly translated written informed consent and IRB review of such document.

How to Request IRB Review and Approval of a Short Form:

If investigators find that the above circumstances are applicable, a Short Form in the target language **must** be submitted for **IRB review and approval**.

Before submitting the Short Form for IRB review...

- Visit the [OPHS website](#) and download the [Short Form Template](#). Currently, UNTHSC-IRB has an IRB-approved Short Form Template in **Spanish**.
- Insert the appropriate information into blank spaces which have been designated in red font. This information is pertinent to the specific protocol for which it will be used for (i.e. protocol title and appropriate contact information).

The image shows a screenshot of a web browser displaying the 'SHORT FORM TO CONSENT TO PARTICIPATE IN A RESEARCH PROJECT' from the University of North Texas Health Science Center at Fort Worth. The form is in Spanish and contains 11 numbered sections, each with a checkbox. Red text is used to indicate where to insert protocol-specific information. Arrows from the text on the left point to these red sections. The form includes sections for: 1. Purpose of the research study, 2. Duration of the study, 3. Risks and benefits, 4. Confidentiality, 5. Compensation, 6. Medical treatment, 7. Circumstances for stopping participation, 8. Contact information for the principal investigator, and 9. Contact information for the Institutional Review Board (IRB). The form is titled 'UNTHSC-IRB (revised September 2009)' and is labeled 'Page 1'.

Submitting the Short Form for IRB review...

- For a protocol which has been **IRB-approved**, a *signed* memo can be submitted requesting the implementation of a Short Form. In the memo, include an explanation as to why a Short Form is needed and justification for using this method instead of translating the English version of the IRB-approved Informed Consent into the target language.
- If a protocol has NOT yet received IRB approval and this Short Form is part of the proposed protocol design, please consult first with OPHS staff to discuss whether or not this is a viable option. This should be done **before** the protocol including the Short Form is submitted for IRB review and approval. Note that where possible, the IRB recommends that a full fledged (longer) version of the Informed Consent be translated into the target language instead of using a Short Form. Having a “longer” version of the consent form provides subjects with a hard copy of all the information pertinent to the study (instead of an outline). Additionally, providing a translated document deters from having to completely rely on an oral account (i.e. interpretation).

Process for Consenting Subjects with a Short Form

- An interpreter must orally translate the IRB-approved English version of the Informed Consent into language understandable to the subject. The interpreter must be **fluent** in both English and the target language (e.g. Spanish). OPHS recommends that the investigator or research team meet with the interpreter to discuss the research study and review the informed consent **prior** to consent meeting.

- A copy of the *short form* must be given to the subject to read after the oral explanation/translation of the study is given. Subjects can then verify that all points outlined in the short form were covered by the person obtaining consent. Note that the *short form* must also be in language understandable to the subject (i.e. in the target language).



- Only the *short form* is to be signed and dated by the subject or the subject's representative.
- A witness who is both fluent in English and the target language is required to sign the *short form* and the English version of the Informed Consent Form; thereby, attesting to the validity of the translation. A witness can also act as the translator.
- The IRB-approved English version of the Informed Consent must be signed by the person authorized by the IRB to obtain subject consent. Note that the person obtaining consent can also act as the translator. A separate person acting as a witness still needs to be present to verify the interpretation (oral translation) of the consent process. Basically, besides the subject, at least two different people need to be involved in the process of consenting: one the consenter, and another as a witness.
- Finally, a copy of the signed *short form* and IRB approved Informed Consent (English version) must be given to the subject or the subject's representative.
- Investigators should also plan for future study meetings or visits on providing interpretation (oral translation) services for non-English speaking subjects.

When NOT to use a Short Form:

In almost all cases, the “long” (full) consent document should be used. OPHS-IRB recommends that studies involving a study population or location in which subjects are non-English speaking, or where the study design for subject enrollment provides sufficient time to translate the informed consent and receive IRB approval for it, a *short form* should NOT be used. In these cases, use a properly translated regular long (complete) IRB–approved consent document.



If you have any questions about the information presented here or about the use of a Short Form, please contact the *Office for the Protection of Human Subjects* at 817-735-0409.