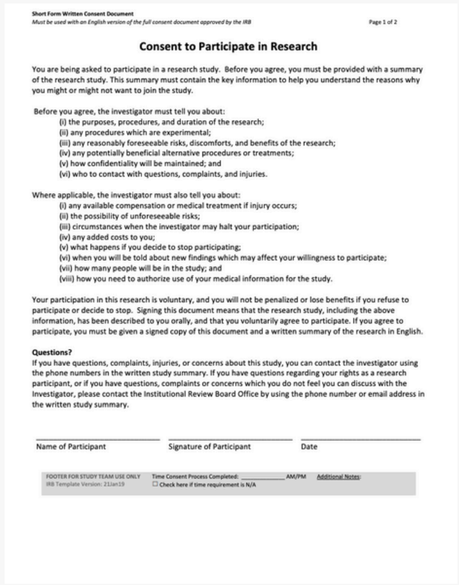
THE UNIVERSITY OF UTAH

INSTITUTIONAL REVIEW BOARD

SHORT FORM CONSENT PROCESS

WHAT IS A SHORT FORM?

A short form is a document that contains the required elements of informed consent and can be used to enroll non-English-speaking participants while in the process of conducting research.



Short Form Written Consent Document
Must be used with an English version of the full consent document approved by the IRB Page 1 of 2

Consent to Participate in Research

You are being asked to participate in a research study. Before you agree, you must be provided with a summary of the research study. This summary must contain the key information to help you understand the reasons why you might or might not want to join the study.

Before you agree, the investigator must tell you about:
(i) the purposes, procedures, and duration of the research;
(ii) any procedures which are experimental;
(iii) any reasonably foreseeable risks, discomforts, and benefits of the research;
(iv) any potentially beneficial alternative procedures or treatments;
(v) how confidentiality will be maintained; and
(vi) who to contact with questions, complaints, and injuries.

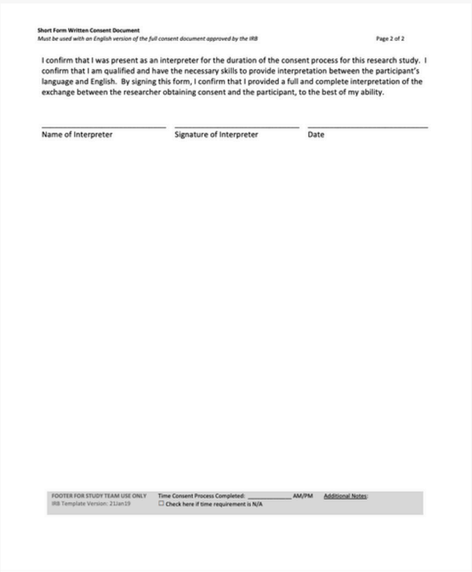
Where applicable, the investigator must also tell you about:
(i) any available compensation or medical treatment if injury occurs;
(ii) the possibility of unforeseeable risks;
(iii) circumstances when the investigator may halt your participation;
(iv) any added costs to you;
(v) what happens if you decide to stop participating;
(vi) when you will be told about new findings which may affect your willingness to participate;
(vii) how many people will be in the study; and
(viii) how you need to authorize use of your medical information for the study.

Your participation in this research is voluntary, and you will not be penalized or lose benefits if you refuse to participate or decide to stop. Signing this document means that the research study, including the above information, has been described to you orally, and that you voluntarily agree to participate. If you agree to participate, you must be given a signed copy of this document and a written summary of the research in English.

Questions?
If you have questions, complaints, injuries, or concerns about this study, you can contact the investigator using the phone numbers in the written study summary. If you have questions regarding your rights as a research participant, or if you have questions, complaints or concerns which you do not feel you can discuss with the Investigator, please contact the Institutional Review Board Office by using the phone number or email address in the written study summary.

Name of Participant | Signature of Participant | Date

FOOTER FOR STUDY TEAM USE ONLY
IRB Template Version: 21Jan19
Time Consent Process Completed: _____ AM/PM Additional Notes:
☐ Check here if time requirement is N/A



Short Form Written Consent Document
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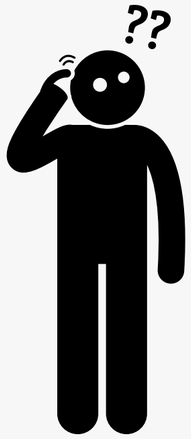
I confirm that I was present as an interpreter for the duration of the consent process for this research study. I confirm that I am qualified and have the necessary skills to provide interpretation between the participant's language and English. By signing this form, I confirm that I provided a full and complete interpretation of the exchange between the researcher obtaining consent and the participant, to the best of my ability.

Name of Interpreter | Signature of Interpreter | Date

FOOTER FOR STUDY TEAM USE ONLY
IRB Template Version: 21Jan19
Time Consent Process Completed: _____ AM/PM Additional Notes:
☐ Check here if time requirement is N/A

WHEN SHOULD YOU USE A SHORT FORM CONSENT PROCESS?

The use of the short-form consent process is appropriate when not *specifically* targeting or anticipating non-English speakers, and there is not enough time or resources available to translate the English version of the approved consent document into the spoken language of the potential participant.



DO SHORT FORMS REQUIRE IRB APPROVAL?

The short forms are all based on an English version of the document that has been pre-approved by the IRB for use with all IRB-approved research.

However, the **process** you will use to obtain consent from Limited English Proficiency (LEP) participants must be approved by the IRB on a per-study basis before including LEP individuals in your research.

If you **fully translate your documents**, you must submit the translated documents, along with a translation certification, to the IRB for approval prior to their use.

WHO IS INVOLVED IN THE SHORT FORM CONSENT PROCESS?

1. **Non-English Speaking Participant:** After carefully listening to the person obtaining consent and the qualified interpreter and having the ability to ask questions, they will sign the **Translated Short Form.**
2. **Person Obtaining Consent:** After conducting the consent process in English using the full consent document and answering questions, they will sign the **English Full Consent Document.**
3. **Qualified Interpreter:** After cogently repeating what the person obtaining consent says, they will sign the **Translated Short Form *and* the English Full Consent Document.**
4. **Witness:** The witness should be fluent in both English and the language of the participant. After observing the oral presentation, they will sign the **Translated Short Form *and* English Full Consent Document.**

HOW DOES THE SHORT FORM CONSENT PROCESS WORK?

Careful preparation and coordination are required to conduct a compliant consent process using a short form. You should be prepared to include:

1. Non-English Speaking Participant
2. Person Obtaining Consent
3. Qualified Interpreter
4. Witness

After completing the consent process, you should provide the participant with a copy of both signed documents. You should keep the original documents stored together, along with an explanation of how the consent process was conducted.

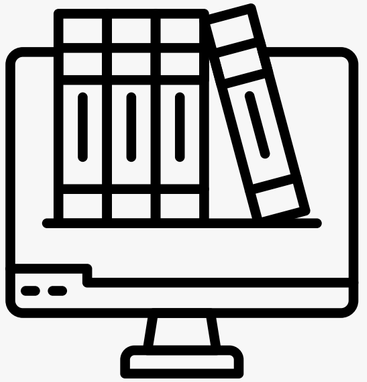
WHAT RESOURCES ARE AVAILABLE TO YOU?

The University of Utah, as well as the IRB, has several resources available to you.

On our website, you can find a **Translation Library** that houses the IRB short form consent document translated into multiple languages.

If you opt to use the short form to document consent, please review the **Short Form Consent Process Instructions for Use**. This guidance summarizes the requirements for using the short form.

Further, **The Office of Research Participant Advocacy (RPA)** has language services available to help you translate your consent documents and connect with interpreters.



HELPFUL LINKS

Please see the links below for more information regarding the Short Form Consent Process.

1. Translation Library
2. Short Form Consent Process Instructions For Use
3. Office of Research Participant Advocacy
4. Frequently Asked Questions

THANK YOU!

For more information, you can reach us at:

IRB@hsc.utah.edu

Tel: 801-581-3655