

SHORT FORM CONSENT PROCESS INSTRUCTIONS FOR USE

The IRB may approve an oral consent process (see 45 CFR 46.117(b)(2), and 21 CFR 50.27(b)(2), for FDA regulated research). This process requires that the IRB review and approve:

- A written summary of what the PI (or person authorized to obtain consent) will say to the subject/participant or his/her legally authorized representative. An IRB-approved informed consent document (long form) may serve as the summary. The summary must be signed by the person obtaining consent and a witness (or qualified interpreter) to the oral presentation, and
- A short form stating that the required elements of consent were presented orally to the subject/participant by the PI (or his designate). -This short form must be signed by the subject/participant and a witness who observed the presentation of information.

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Requirements for Use of the Short Form

- There must be a witness to the oral presentation.
- The written summary must be signed by the 1) witness and 2) person obtaining consent. A signature block for each individual should be included at the end of the summary.
- The short form must be signed by the 1) witness and 2) participant or the participant's legally authorized representative.
- If the research is subject/participant to FDA regulation, the participant or the participant's legally authorized representative must date the short form.
- The participant or the participant's legally authorized representative must be provided a copy of the 1) short form and 2) written summary.

Short Form Used for Participants Who Do Not Speak English

Informed consent information should be presented "in a language understandable to the subject/participant", and in most situations, that informed consent be documented in writing (45 CFR §46.116 and §46.117). Participants who do not speak English should be presented with a consent document written in a language understandable to them. The IRB strongly encourages the use of this procedure whenever possible. Alternatively, the regulations permit oral presentation of informed consent information in conjunction with a short form written consent document (stating that the elements of consent have been presented orally) in the participant's native or preferred language and a written summary of what is presented orally.

In October 2022, the University of Utah IRB adopted a policy which allows investigators to use an IRB-approved, must review both the English version of the short form once the short form process is approved without attaching the documents to the IRB application or having that document stamped with an approval stamp and the translated version. Translated versions of the short form, certified by the Research Translation Office of Research Participant Advocacy, are also made available for use in multiple languages. Investigators may use these short forms after the IRB approves a short form consent process procedure for their research protocol. An IRB-approved English language informed consent document may serve as the summary.

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.

Requirements for Use of the Short Form with Participants Who do not Speak English

- ~~A qualified interpreter must be used for the consent process.~~
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- The oral presentation and the short form must be in a language understandable to the subject participant.
- The witness (or qualified interpreter) must~~should~~ be fluent in both the language of the participant and the language of the consent process (i.e., English).
- ~~The short form document and the written summary should be signed by the witness (or qualified interpreter).~~ **When the person obtaining consent is assisted by an qualified interpreter, the qualified interpreter may serve as the witness.**
- The written summary (or consent form in English) must be signed by the 1) witness (or qualified interpreter) and 2) person obtaining consent. A signature block for each individual should be included at the end of the summary. A model signature block is available on the IRB website.
- The short form document must be signed by the 1) witness (or qualified interpreter) and 2) participant or the participant's legally authorized representative.
- If the research is subject to FDA regulation, the participant or the participant's legally authorized representative must also date the short form.
- The participant or the participant's legally authorized representative must ~~be provided~~ receive a copy of the signed 1) short form and 2) written summary upon completion of the informed consent process.

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Obtaining IRB Approval

- IRB approval is required prior to using the short form consent process. If you want to add the use of a short form in a currently approved protocol, you must submit an amendment to the application.
- Describe the use of the short form process in the application on the Consent Process page.
- ~~Attach a 1) written summary (which may be the full consent form in English) with the witness (or qualified interpreter) signature block, 2) short form, and 3) if applicable, the English translation of the short form to the application.~~
- ~~These documents should be attached to the~~ Documents and Attachments page in the Consent Documents section.
- Once the IRB has approved the short form consent process for documentation of consent, use of the University of Utah IRB approved short form in any of the languages posted on the IRB website is permitted.
 - If an investigator wishes to use their own translation of the short form, it must be reviewed and approved by the IRB prior to use.

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