

SHORT FORM – 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 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 to the oral presentation, and
- A **short form** stating that the required elements of consent were presented orally to the subject by the PI (or his designate). This short form must be signed by the subject and a witness who observed the presentation of information.

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) participant or the participant's legally authorized representative.
- The **short form** must be signed by the 1) witness and 2) person obtaining consent.
- If the research is subject 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 witness 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", and in most situations, that informed consent be documented in writing. 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) and a written summary of what is presented orally. The IRB must review both the English version of the short form and the translated version. An IRB-approved English language informed consent document may serve as the summary.

Requirements for use of the short form with participants who do not speak English

- The oral presentation and the short form must be in a language understandable to the subject.
- The witness should be fluent in both the language of the participant and the language of the consent (i.e. English).
- The short form document and the written summary should be signed by the witness. When the person obtaining consent is assisted by an interpreter, the interpreter may serve as the witness.
- The **written summary** must be signed by the 1) witness and 2) participant or the participant's legally authorized representative.
- The **short form** must be signed by the 1) witness and 2) person obtaining consent.

- If the research is subject 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 witness must be provided a copy of the 1) short form and 2) written summary.

Obtaining IRB approval

- IRB approval is required prior to using the short form consent. If you want to use a short form in a currently approved protocol, you must submit an amendment application.
- Describe the use of the short form process in the application under Consent Process.
- Attach a 1) written summary and 2) short form in the application. These documents should be attached to the Documents and Attachments page under Consent Documents.