THE OHIO STATE UNIVERSITY

SHORT FORM INFORMED CONSENT

1. Overview

Federal regulations require that the informed consent process is conducted in "language understandable" to research participants, and, with certain exceptions, that informed consent is documented in writing by use of a written consent form approved by the IRB and signed and dated by the individual or the individual's legally authorized representative. In limited situations the regulations permit the informed consent process to be conducted orally, with a written "short form" consent document. This process may be used to obtain the informed consent of non-English speaking subjects or their legally authorized representatives as described in detail below.

2. Definitions

Short Form: A written document stating that the elements of informed consent required by regulation have been presented orally to the subject or the subject's legally authorized representative. The short form consent document must be written in a language understandable to the subject or the subject's legally authorized representative.

Summary Document: A written version of the full information presented to a subject or the subject's legally authorized representative during the informed consent process, used in conjunction with a short form consent document. For non-English speaking individuals, the IRB-approved English language consent form may serve as the summary when an appropriately translated document is not available.

3. Use of the Short Form Consent Document

The short form consent document may be used only in the following circumstances:

- The participant or legally authorized representative does not speak/understand English,
- The participant or legally authorized representative speaks only a language(s) that was not anticipated in the study population or location (i.e., "unexpectedly encountered"),
- An appropriately translated consent form in the participant's language has not been approved by the IRB, and
- There is not adequate time for preparation and IRB review and approval of a translated consent form.

When the study population or location includes people who speak a language other than English, or where the circumstances of subject enrollment provide sufficient time for preparation and IRB review of translated documents, the short form should not be used.

4. Informed Consent Process Using the Short Form

When informed consent is obtained using the short form, an oral translation of the approved English language consent form is presented. If needed, an interpreter should be available to assist with any questions from prospective participants during the consent process. Participants must also receive both:

- The written short form consent document translated into the appropriate language, and
- A copy of the IRB-approved English language consent form to serve as the written summary of the research.

A witness to the oral presentation of the informed consent information is required as described below.

A. Witness Requirements

An adult who is fluent in both English and the language understandable to the prospective participant must witness the entire consent process. The witness is required to verify the adequacy of the informed consent process and the participant's voluntary consent. An individual who assists as an interpreter may also serve as the witness. The individual obtaining consent may not serve as a witness to the process.

B. Interpreter Requirements

A qualified healthcare interpreter with specific training in medical interpretation should be used in research involving complex diagnostic or medical procedures. Family members may not serve as interpreters for the consent process except in emergency, life-threatening situations.

C. Signature Requirements

The subject or the subject's legally authorized representative and the witness must sign and date the short form consent document. The witness and the individual obtaining the informed consent of the participant must sign and date a copy of the summary document (i.e., IRB-approved English language consent form).

D. Copies

Copies of the signed and dated short form and the summary document (i.e., IRB-approved English language consent form) must be given to the subject or the subject's legally authorized representative.

5. Short Form Document Requirements

Translations of the short form consent document must receive IRB approval before use. The IRB-approved English language short form template and approved translations are available on the Office of Responsible Research Practices (ORRP) website. Investigators who require a short form consent document in a language not previously approved are advised to contact ORRP staff for assistance with translation costs. New translations of the

approved English language short form may receive expedited IRB review. As additional versions of the short form are approved, they will be made available for general use.

6. Follow-up Translation Requirements

The full IRB-approved English language consent form must be translated into a written document in the language of the subject or the subject's legally authorized representative. Translation into a language other than English must be performed by a qualified translator (e.g., native speaker in the language, professional translation services, etc.). The IRB may request verification by an independent expert in that language, as necessary. The translated document, as well as documentation of the qualifications of the translator, must be submitted to the IRB for final approval. This document must be provided to the participant or representative as a reference for the study within a reasonable time, usually no more than 90 days following use of the short form. The costs associated with translation of the full consent form will not be borne by ORRP.

Subsequent participants speaking the same language who enroll in the research must be presented with the translated written consent document. Routine oral presentation of informed consent information documented by use of the short form may not be substituted for fully translated written materials.

7. Applicable Regulations/Guidance

45 CFR 46.117(b)(2), 21 CFR 50.27(b)(2), OHRP Guidance "Obtaining and Documenting Informed Consent of Subjects Who Do Not Speak English" (11/09/95), FDA Information Sheets "A Guide to Informed Consent" (09/98), "Interpretation & Translation Services" The Ohio State University Policy and Procedure Manuals for University Hospitals and James Cancer Hospital and Solove Research Institute (# 03-05, revised 2012)

8. History

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