Issuing Department: Human Subjects Protection Office
Policy Number: 2011-008.4
Policy Title: Informed Consent – Short Form

Purpose

The purpose of this policy is to identify when the short form consent process may be used.

Definitions

See 2011-007.0 for definitions of the following:

Informed Consent Form | Informed Consent Process

Policy

At times investigators may unexpectedly encounter a potential subject who does not speak/understand English. In such a situation, or other situations deemed appropriate by the Institutional Review Board (IRB), it may be acceptable to use the short form consent process. This process also applies to FDA regulated studies.

The IRB must receive all foreign language versions of the short form informed consent form For studies initially reviewed by the full board, expedited review of the translated document is acceptable only if the English language version of the informed consent document has already been approved.

The IRB makes the final determination as to whether to require a complete written informed consent form or to accept an oral presentation of consent with the summary documents.

Per Federal regulation, a witness to the process will be required if a short form written consent has been approved for oral presentation to the subject.

Procedure

The person obtaining consent conducts an oral presentation of the informed consent information in conjunction with providing

- an IRB approved short form consent document written in a language understandable to the subject stating that the elements of informed consent have been presented orally, and
- an IRB approved written summary of what is presented orally (an approved informed consent form may serve as the written summary).

A witness who is fluent in English and the language of the subject must be present throughout the process.

At the time of consent:

- the subject or the subject's legally authorized representative signs and dates the short form
- the witness shall sign and date both the short form and a copy of the summary,
- the person obtaining consent shall sign and date a copy of the summary.
- the person obtaining consent provides the subject with copies of the short form document and the summary.

Related Policies

2011-008.1 – Informed Consent - Process
2011-008.5 – Informed Consent – Providing and Obtaining

Basis

45 CFR 46.117 (2)
21 CFR 50.27(b)(2)

Document Attributes

Date Created: 7/8/2011

Replaced Version: Section in HSPO manual dated 11/14/2008

Reviewed and Approved By: **Signed RS** **Date:** **7/21/11**

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