Issuing Department: Human Subjects Protection Program
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 | Legally Authorized Representative

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.

To allow the use of the short form of consent documentation, the IRB shall determine:

- The short form consent document states that the basic and appropriate additional elements of disclosure have been presented orally to the subject or the subject's legally authorized representative, including required disclosures when the research involves private identifiable information or identifiable biospecimens.
- A written summary embodies the basic and required additional elements of disclosure.

The IRB must receive the foreign language version(s) 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 oral presentation will be required if a short form written consent has been approved for oral presentation to the subject.

Procedure

The person obtaining consent from the subject or the subject's legally authorized representative (LAR) 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/LAR stating that the elements of informed consent have been presented orally, and
- for federally supported research a statement that the key information required by 45 CFR 46.116(a)(5)(i) was presented first to the subject, before other information, if any, was provided.
- an IRB approved written summary of what is presented orally to the subject/LAR (an approved informed consent form may serve as the written summary).

A witness who is fluent in English and the language of the subject/LAR must be present throughout the oral presentation.

At the time of consent:

- the subject /LAR 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/LAR 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
21 CFR 50

Document Attributes

Date Effective: 11/20/23

Replaced Version: 3/16/23

Reviewed and Approved By:

Richard H. Simon *11/01/23*

Richard H. Simon, MD **Date**
Director, Human Subjects Protection Program