

SPARROW HEALTH SYSTEM
INSTITUTIONAL RESEARCH REVIEW COMMITTEE

POLICY: OBTAINING INFORMED CONSENT

PURPOSE:

The purpose of obtaining informed consent is for investigators to provide the prospective subject or his or her legally authorized representative sufficient opportunity to consider whether to participate, and to minimize the possibility of coercion and undue influence. The information contained in the informed consent form must be written in language that is understandable to the subject or their representative. The consent process, whether oral or written, may not involve the use of exculpatory language through which the subject or representative is made to waive or appear to waive any of the subject's legal rights or releases or appears to release the investigator, the sponsor, institution, or agents from liability for negligence. (45 CFR § 46.116)

In most cases the federal regulations require that informed consent be documented (45 CFR § 46.117; 21 CFR § 50.27), but they also provide for some important exceptions. Documentation usually involves the use of a written consent form containing all the information to be disclosed and signed by the subject or the subject's legally authorized representative. It should be reiterated, however, that these documents are not substitutes for discussion. The person who signs the informed consent form must be given a copy as a reference and reminder of the information conveyed.

DEFINITION OF DOCUMENTATION OF INFORMED CONSENT:

- A. Except as provided in paragraph (C) of this section, informed consent shall be documented by the use of a written consent form approved by the IRRC and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.
- B. Except as provided in paragraph (C) of this section, the consent form may be either of the following:
 - (1) A written consent document that embodies the elements of informed consent required by 45 CFR § 46.116 (*see Policy: Elements of Information for Consent*). This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or
 - (2) A short form written consent document stating that the elements of informed consent required by § 46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRRC shall approve a written summary of what is to be said to the subject or the

representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

- C. The IRRC may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:
- (1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
 - (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases which the documentation requirement is waived, the IRRC may require the investigator to provide subjects with a written statement regarding the research.

PROCEDURE:

The principal investigator is responsible for obtaining informed consent from subjects entered into an approved research protocol at Sparrow Health System. He or she may delegate this responsibility to a qualified individual who has been properly trained, is knowledgeable about the research, and is able to respond appropriately to questions from patients, family members and healthcare workers. The principal investigator is ultimately responsible for assuring that "informed consent" has been obtained when this is delegated to another individual.

Furthermore, the principal investigator is responsible for ensuring that no human subject will be involved in the research prior to obtaining the signed consent. A copy of the signed informed consent form must be given to the subject. All copies of the consent form(s) and/or addendums to consent must contain the Sparrow Health System Institutional Research Review Committee's approval stamp with expiration date on the signature page. When enrolling new subjects, only the most recently approved consent form is to be used.

The IRRC may require the investigator to have subjects re-consent when there have been major revisions to the protocol or additional risk factors identified that would relate to the subject's willingness to continue participation in the project. The re-consenting process entails either having the subject sign an IRRC-approved revised informed consent form, if the study remains open to accrual, or an addendum to the consent form when a study is no longer enrolling subjects and the consent form is not in use.

SCOPE:

These policies and procedures apply to all research submitted to the IRRC.

RESPONSIBILITY:

The IRRC is responsible for initial review and approval of the informed consent form, or process, prior to the investigator's obtaining informed consent.

The IRRC staff is responsible for affixing the appropriate approval stamp, including approval expiration date, to the consent form document and issuing the original stamped consent to the investigator along with the IRRC approval letter for the investigator's subsequent use. The IRRC staff is also responsible for maintaining a copy of the current approved consent form in the administrative protocol file.

APPLICABLE REGULATIONS AND GUIDELINES:

45 CFR § 46.103(b)4

45 CFR § 46.116(b)5

45 CFR § 46.117

21 CFR § 50.25

21 CFR § 50.27

Amdur, Robert, and Elizabeth Bankert: Institutional Review Board, *Management and Function*, Chptr 6, pp 231-288, 2002, Jones and Bartlett Publishing.

IRB Guidebook: Chapter II, *Regulations and Policies*, Department of Health and Human Services, Office of Human Research Protection, 2004.

PROCESS OVERVIEW:

Investigators are expected to obtain the appropriate informed consent prior to enrolling a subject in an approved protocol.