

**PARTNERS HUMAN RESEARCH COMMITTEE
REQUIREMENTS FOR INFORMED CONSENT
45 CFR 46.116 and 21 CFR 50.25**

General Requirements for Informed Consent:

- No investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.
- Consent will be obtained only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.
- The information given to the subject or the representative will be in language understandable to the subject or the representative.
- No informed consent, whether oral or written, may include any exculpatory language through which the subject or the 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, the institution or its agents from liability for negligence.

THE FOLLOWING INFORMATION ABOUT THE STUDY MUST BE PROVIDED TO RESEARCH SUBJECTS WHEN OBTAINING INFORMED CONSENT:

Basic Elements of Informed Consent [45 CFR 46.116(a) and 21 CFR 50.25(a)]

- (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- (2) A description of any reasonably foreseeable risks or discomforts to the subject;
- (3) A description of any benefits to the subject or to others which may reasonably be expected from the research;
- (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained [**a general statement is included in the standard language**];
- (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained [**a general statement is included in the standard language**];
- (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; [**a general statement is included in the standard language**] and
- (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled [**a general statement is included in the standard language**].

Additional elements of informed consent [45 CFR 46.116(b) and 21 CFR 50.25(b)]

When appropriate, the following information must be provided to each subject:

- (1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
- (2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- (3) Any additional costs to the subject that may result from participation in the research;
- (4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- (5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject [**a general statement is included in the standard language**]; and
- (6) The approximate number of subjects involved in the study.

DOCUMENTATION OF INFORMED CONSENT [COMMON RULE 45 CFR 46.117]

- (a) Informed consent shall be documented by use of a written consent form approved by the IRB 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 46.116 and 50.25. 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 and 50.25 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 IRB 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. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.
- (c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subject 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 in which the document requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

In cases where the documentation requirement is waived under paragraph (c)(1) of this section, the IRB may require the investigator to provide subjects with a written statement regarding the research.

DOCUMENTATION OF INFORMED CONSENT [FDA REGULATIONS 21 CFR 56.109 & 21 CFR 50.27]

- (c) An IRB shall require written documentation in accordance with 50.27 of this chapter, except as follows:
 - (1) The IRB may, for some or all subjects, waive the requirement that the subject, or the subject's legally authorized representative, sign a written consent form if it finds 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 the research context; or
 - (2) The IRB may, for some or all subjects, find that the requirements in 50.24 of this chapter for an exception from informed consent for emergency research are met.
- (d) In cases where the documentation requirement is waived under paragraph (c)(1) of this section, the IRB may require the investigator to provide subjects with a written statement regarding the research.

WAIVER OR ALTERATION OF SOME OR ALL OF THE ELEMENTS OF INFORMED CONSENT [45 CFR 46.116(c)(d)] Note: These regulations do not apply to FDA regulated research.

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

- (c)(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) Public benefit of service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and
- (2) The research could not practicably be carried out without the waiver or alteration.
- (d)(1) The research involves no more than minimal risk to the subjects;
- (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- (3) The research could not practicably be carried out without the waiver or alteration; and
- (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.