§46.116 General requirements for informed consent

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent 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 that is given to the subject or the representative shall 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.

§46.116(a) [Required Elements]

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

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;
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;
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; 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.

§46.116(b)
[Optional Elements]

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also 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; and
(6) The approximate number of subjects involved in the study.

§46.116(c)
[Applies to research on public benefit or service programs – not usually applicable to CUNY]

(c) 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:
(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 or 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.

§46.116(d)
[Waiver of requirement to obtain informed consent, and waiver or alteration of required elements of informed consent]
(d) 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 in this section, or *waive the requirements to obtain informed consent* provided the IRB finds and documents that:
   (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.

§46.116(e)

(e) The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

§46.116(f)

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

§46.117 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 IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

§46.117(b):

*Acceptable forms of informed consent: written documentation, or orally with short form documentation*

(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. 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 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, 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.

§46.117(c):
[Waiver of documentation (signature)]

(c) An IRB 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 in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.
Other Considerations

**OHRP GUIDANCE:**

**Documentation of Findings.** HHS regulations at 45 CFR 46.116(d) require that the IRB make and document four findings when approving a consent procedure which does not include, or which alters, some or all of the required elements of informed consent or when waiving the requirement to obtain informed consent. OHRP recommends that when approving such a waiver for research reviewed by the convened IRB, these findings be documented in the minutes of the IRB meeting, including *protocol-specific* information justifying each IRB finding.

Similarly, where HHS regulations require specific findings on the part of the IRB, such as:

(a) approving a procedure which waives the requirement for obtaining a signed consent form [see 45 CFR 46.117(c)];
(b) approving research involving pregnant women, human fetuses, or neonates (see 45 CFR 46.204-207);
(c) approving research involving prisoners (see 45 CFR 46.305-306); or
(d) approving research involving children (see 45 CFR 46.404-407), the IRB should document such findings.

OHRP recommends that for research approved by the convened IRB, all required findings be *fully documented in the minutes* of the IRB meeting, including *protocol-specific* information justifying each IRB finding.

For research reviewed under an expedited review procedure, these findings should be documented by the IRB Chairperson or other designated reviewer elsewhere in the IRB record.