

Announcements

- Mary – new staff

Criteria For Approval

45 CFR 46.111

25 CFR 56.111

- Minimized risks
- Reasonable risk/benefit ratio
- Equitable subject selection
- Informed consent process
- **Informed consent documentation**
- Data monitored for safety
- Confidentiality/privacy maintained
- Vulnerable populations protected

Review Criteria

45 CFR 46.111

21 CFR 56.111

- (5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117. [§50.27]

Documentation of Informed Consent

45 CFR 46.117

21 CFR 50.27

(a) Except as provided in paragraph (c) of this section [*FDA: 21.CFR 56.109(c)*], informed consent shall be documented by the use of a written consent form approved by the IRB and signed [*FDA: and dated*] by the subject or the subject's legally authorized representative [*FDA: at the time of consent*]. A copy shall be given to the person signing the form.

Documentation of Informed Consent

45 CFR 46.117

21 CFR 50.27

(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 [§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 [§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, 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.

Waiver of Documentation of Consent

46 CFR 46.117(c)

(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.

Waiver of Documentation of Consent

21 CFR 56.109(c)

(c) An IRB shall require documentation of informed consent 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.

Documentation of Informed Consent

21 CFR 50.27

(b) Except as provided in 56.109(c), informed consent form shall be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or subject's legally authorized representative at the time of consent. A copy shall be given to the person signing the 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.

[Ethical Principles and Guidelines for Research Involving Human Subjects](#)

[A. Boundaries Between Practice and Research](#)

[B. Basic Ethical Principles](#)

[1. Respect for Persons](#)

[2. Beneficence](#)

[3. Justice](#)

[C. Applications](#)

[1. Informed Consent](#)

[2. Assessment of Risk and Benefits](#)

[3. Selection of Subjects](#)

The Belmont Report

Ethical Principles & Guidelines for Research Involving Human Subjects

Scientific research has produced substantial social benefits. It has also posed some troubling ethical questions. Public attention was drawn to these questions by reported abuses of human subjects in biomedical experiments, especially during the Second World War. During the Nuremberg War Crime Trials, the Nuremberg code was drafted as a set of standards for judging physicians and scientists who had conducted biomedical experiments on concentration camp prisoners. This code became the prototype of many later codes⁽¹⁾ intended to assure that research involving human subjects would be carried out in an ethical manner.

The codes consist of rules, some general, others specific, that guide the investigators or the reviewers of research in their work. Such rules often are inadequate to cover complex situations; at times they come into conflict, and they are frequently difficult to interpret or apply. Broader ethical principles will provide a basis on which specific rules may be formulated, criticized and interpreted.

Three principles, or general prescriptive judgments, that are relevant to research involving human subjects are identified in this statement. Other principles may also be relevant. These three are comprehensive, however, and are stated at a level of generalization that should assist scientists, subjects, reviewers and interested

- [Basic Protections for Human Subjects](#)
- [Human Subject Research Decision Charts](#)

Individual Investigator Agreement **[NEW]**

- Individual Investigator Agreement [[HTML](#) | [PDF - 43.9KB](#)]

Informed Consent

- [Emergency Research Informed Consent Requirements](#)
- [Exculpatory Language in Informed Consent Documents](#)
- [Informed Consent Tips](#)
- [Informed Consent Checklist](#)
- [Informed Consent, Legally Effective and Prospectively Obtained](#)
- [Informed Consent, Non-English Speakers](#)

IRB (Institutional Review Board)

- [AIDS Research, Guidance for IRBs](#)
- [Designation of an Independent IRB](#)
- [Expedited Review-- 1998 Revised Categories](#)
- [Knowledge of Local Research Context](#)
- [Meetings Convened via Telephone Conference Call](#)
- [Multicenter Clinical Trials, Local IRB Review](#)
- [Multicenter Clinical Trials, Local IRB Review, DAIDS, NIAID](#)
- [Reliance on Another Institution's IRB](#)
- [Review of Applications for HHS Support](#)
- Written Institutional Review Board (IRB) Procedures [[PDF](#)] [[HTML](#)]

Multicenter Clinical Trials

Consent Documentation in INSPIR

- Section J3 = Waiver of Documentation
- Section J4 = Waiver of Informed Consent
- Section Q = Informed Consent forms

Reviewer Sheet- Section J

http://www.bumc.bu.edu/www/bumc/irb/images/IRBReview_NewApp.doc - Microsoft Internet Explorer

File Edit View Insert Format Tools Table Go To Favorites Help

Back Forward Stop Home Search Favorites Refresh Print Mail Stop

Address http://www.bumc.bu.edu/www/bumc/irb/images/IRBReview_NewApp.doc Go

1. Will the investigator(s) be recruiting subjects for the study?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Will recruitment procedures ensure voluntary participation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Are recruitment procedures non-coercive and consistent with all regulations, laws and institutional policy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Will the potential subject, or the subject's legally authorized representative, be approached for informed consent in an appropriate manner?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Will qualified study personnel be consenting the subject?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Will informed consent be appropriately documented?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. If requesting waiver of documentation of the Informed Consent process, does the study meet one of the two CFR criteria?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Is the consent form in lay language (i.e., 8 th grade level or below)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Is the informed consent form correctly formatted and include all basic elements per the BUMC Consent Form Checklist?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:			
SECTION K: CONFIDENTIALITY			
1 Will the investigator(s) collect sensitive information about the subject?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Are adequate provisions in place to protect privacy/confidentiality?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Will participation be documented in subject's institutional medical record (including a copy of the consent/assent form(s))?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Are issues related to the Privacy Policy adequately addressed in the			

Unknown Zone

Review Criteria

45 CFR 46.111

21 CFR 56.111

- (6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

Review Criteria

45 CFR 46.111

21 CFR 56.111

- (7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data

Review Criteria

45 CFR 46.111

21 CFR 56.111

- b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, [handicapped] mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

