

Announcements

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

- (4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116. [part 50]

Issues to Consider

- Who approaches potential subject?
Training and oversight?
- When is subject approached? Is there a better time?
- Therapeutic misconception?
- Coercion vs voluntary?
- Time to consider participation?
- Understanding of alternatives?

[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

Reviewer Sheet- Section J

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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			