

Announcements

- Erin Larson graduates, gets married, and leaves us!
- 5/25 4 pm BWH- ***"The Significance of the Belmont Report and the Need to Revise It."***
- 5/26 3:30 pm Slone Epidemiology Center- Norm Fost

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

- (3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as
 - children (Subpart D)
 - prisoners (Subpart C)
 - pregnant women (Subpart B)
 - [handicapped- FDA only]
 - mentally disabled persons
 - economically or educationally disadvantaged persons.

Belmont Principle: Justice

- Treat people fairly
- Fair sharing of burdens and benefits of research
- Need to distinguish procedural justice from distributive justice



Emanuel et al. JAMA 2000

Requirement	Explanation	Justifying Ethical Values	Expertise for Evaluation
Social or scientific value	Evaluation of a treatment, intervention, or theory that will improve health and well-being or increase knowledge	Scarce resources and nonexploitation	Scientific knowledge; citizen's understanding of social priorities
Scientific validity	Use of accepted scientific principles and methods, including statistical techniques, to produce reliable and valid data	Scarce resources and nonexploitation	Scientific and statistical knowledge; knowledge of condition and population to assess feasibility
Fair subject selection	Selection of subjects so that stigmatized and vulnerable individuals are not targeted for risky research and the rich and socially powerful not favored for potentially beneficial research	Justice	Scientific knowledge; ethical and legal knowledge
Favorable risk-benefit ratio	Minimization of risks; enhancement of potential benefits; risks to the subject are proportionate to the benefits to the subject and society	Nonmaleficence, beneficence, and nonexploitation	Scientific knowledge; citizen's understanding of social values
Independent review	Review of the design of the research trial, its proposed subject population, and risk-benefit ratio by individuals unaffiliated with the research	Public accountability; minimizing influence of potential conflicts of interest	Intellectual, financial, and otherwise independent researchers; scientific and ethical knowledge
Informed consent	Provision of information to subjects about purpose of the research, its procedures, potential risks, benefits, and alternatives, so that the individual understands this information and can make a voluntary decision whether to enroll and continue to participate	Respect for subject autonomy	Scientific knowledge; ethical and legal knowledge
Respect for potential and enrolled subjects	Respect for subjects by (1) permitting withdrawal from the research; (2) protecting privacy through confidentiality; (3) informing subjects of newly discovered risks or benefits; (4) informing subjects of results of clinical research; (5) maintaining welfare of subjects	Respect for subject autonomy and welfare	Scientific knowledge; ethical and legal knowledge; knowledge of particular subject population

*Ethical requirements are listed in chronological order from conception of research to its formulation and implementation.

2. Is the research problem/hypothesis adequately stated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Are the specific aims of the research and how these will contribute to scientific/medical knowledge adequately described?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments:

SECTION E: PROTOCOL RISKS/SUBJECTS

	YES	NO	N/A
1. Is this research more than minimal risk? Risk: The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk." Minimal Risk: A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [45 CFR 46.102(i)]. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Is the subject population appropriate for the research?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. If only English-speaking subjects are to be recruited, has an adequate justification been provided?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Is the scientific rationale provided for excluding women of child-bearing potential?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Are there any vulnerable populations (children, mentally handicapped individuals, fetuses, pregnant women and prisoners)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

- Principle of justice gives rise to moral requirements that there be fair procedures and outcomes in the selection of research subjects

- ...it seems unfair that populations dependent on public health care constitute a pool of preferred research subjects if more advantaged populations are likely to be the recipients of the benefits.

- Whenever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.

INSPIR- where to look

- Section E- Demographics
 - Gender
 - Exclusion of women of child-bearing age or potential?
 - Age categories
 - (upper age range?
 - exclusion/inclusion of children?
 - Race/ethnicities
 - Language
 - Exclusion of non-English speaking people? Adequately justified?
 - *Vulnerable populations*
- Section F- Procedures
 - Inclusion/Exclusion criteria
- Section J – Consent Process

Unanswered Questions

- Exclusion of non-English speakers
- Use of consent short form
 - Availability of interpreters, not only for consent process, but also for entire study participation
- When to include children
- Consent for vulnerable subjects

Consent Short Form

- 45 CFR 46.117 (b) (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.

Consent Short Form

- OHRP guidance
<http://www.hhs.gov/ohrp/humansubjects/guidance/ic-non-e.htm>

Consent Short Form

Before you agree, the investigator must tell you about

- the purposes, procedures, and duration of the research;
- any procedures which are experimental;
- any reasonably foreseeable risks discomforts, and benefits of the research;
- any potentially beneficial alternative procedures or treatments;
- how confidentiality will be maintained
- any available compensation or medical treatment if injury occurs;
- the possibility of unforeseeable risks;
- circumstances when the investigator may halt your participation;
- any added costs to you;
- what happens if you decide to stop participating;
- when you will be told about new findings which may affect your willingness to participate; and
- how many people will be in the study.

Consent Short Form

When this procedure is used with subjects who do not speak English,

- the oral presentation and the short form written document should be in a language understandable to the subject;
- the IRB-approved English language informed consent document may serve as the summary; and
- the witness should be fluent in both English and the language of the subject.

Unanswered Questions

- Exclusion of non-English speakers
- Use of consent short form
- When to include children, others who can't consent for themselves
- Consent for vulnerable subjects

Subtle considerations when defining “Vulnerable”:

- Language
- Culture
- Current Events or Incidents
- Age (elderly)
- Age (adolescents)
- Transient Cognitive Impairment
- Chemical Use
- Health Status
- Students
- Employees