Office of the Vice President for Research at the university of georgia ®

Back to Basics – Approval Criteria

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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

Minimized Risks

(1) Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

Minimizing Risk with Sound Research Design

- Qualified Investigators
- Scientific Value
- Scientific Validity
  - Design
  - Analysis
  - Sample Size
  - Correct Control Group
- Eligibility Criteria (Inclusion/Exclusion Criteria)

Documentation

Where do I find this stuff in the submission?

Research Design Page

- What is the study question?
- How are investigators seeking to answer the study question?
- Is this study design likely to answer this study question?

Cont…

Continued

Human Research Participants Page

- Target Population
- Sample Size
- Eligibility Criteria

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.

Review Criteria

Reasonable Risk/Benefit Ratio

2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research.

The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

Documentation

Where do I find this stuff in the submission?

Risks and Benefits page

- What are the risks?
- Are risks mitigated by sound research design and/or proper inclusion/exclusion criteria?
- Are there any benefits to subjects? Society?

Consent form

- Are participants fully informed of potential risks?

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Review Criteria

Equitable Subject Selection

(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.

Documentation

Where do I find this stuff in the submission?

- Research participants page
  - Demographics
  - Age ranges
- Vulnerable Populations page
  - Race/ethnicities
  - Language – Exclusion of non-English speaking people? Adequately justified?
- Research Design page
- Recruitment process and Consent process

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Research Criteria
Informed Consent Process

(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.

(we can cover ALL of the requirements of 46.116 next month ☺)

Documentation

Where do I find this stuff in the submission?

Recruitment Process and Consent Process page

- Who approaches the potential subjects?
- When is the subject approached?
- Coercion vs voluntary?
- Time to consider participation?
- Understanding of alternatives?
- Literacy of subject?

Review Criteria
Informed Consent Documentation

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

Review Criteria
Data Monitoring for Safety

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

Review Criteria
Confidentiality/Privacy Maintained

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

Documentation

Where do I find this stuff in the Submission?

- Privacy and Confidentiality page
- Consent Form

Review Criteria
Vulnerable Populations Protected

Additional protections for subjects likely to be vulnerable to coercion or undue influence:

- Children
- Prisoners
- Pregnant Women
- Mentally Disabled Persons
- Economically or Educationally disadvantaged persons

Summary

These are the criteria on which we base all approvals. If we do not have the information in the submission needed to make these determinations, then we cannot approve. These are also areas where we should, as an IRB, attempt to limit our determinations. Lets not fall in to the tempting areas that lead to mission creep, our job is already challenging enough as it is.