Franklin & Marshall College

Guidelines and Procedures for Use of Humans in Research

I. Background: Overall Goals and Basic Principles

The "Common Rule"

Adapted from the National Science Foundation Policy Office

- **Basic principles of … the Common Rule**
  "The fundamental principle of human subjects protection is that people should not (in most cases) be involved in research without their *informed consent*, and that subjects should not incur increased risk of harm from their research involvement, beyond the normal risks inherent in everyday life (include risks of embarrassment or discomfort as well as physical or emotional injury.)
  The regulations are designed mainly to pertain to biomedical research, based on the philosophical principles contained in a key document, The Belmont Report: "Ethical Principles and Guidelines for the Protection of Human Subjects of Research"

- **What are the overall goals of … the Common Rule?**
  "The policy is designed to ensure minimal standards for the ethical treatment of research subjects. The major goal is to limit harms to participants in research. That means that no one should suffer harm just because they became involved as subjects or respondents in a research project. Institutions engaged in research should foster a culture of ethical research."

- **"Ethical research rests on three principles:**
  1. RESPECT for persons, meaning the researcher gives adequate and comprehensive information about the research and any risks likely to occur, understandable to the participant, and allows them to voluntarily decide whether to participate.
  2. BENEFICENCE, meaning the research is designed to maximize benefits and minimize risks to subjects and society.
  3. JUSTICE, meaning that the research is fair to individual subjects and does not exploit or ignore one group (e.g., the poor) to benefit another group (e.g., the wealthy).

"Research produces benefits valued by society. … oversight seeks to ensure that any potential harm of the research is balanced by its potential benefits."

- **What exemptions of the Common Rule are most appropriate?**
  1. Research in educational settings involving educational practices.
  2. Research involving educational tests (cognitive, diagnostic, aptitude, achievement), surveys, interviews, or observations of public behavior, unless subjects are identified and disclosure of responses would involve more than reasonable risk.
  3. Consumer studies, including taste and food quality studies.

II. The Review Process at Franklin & Marshall

***General Points about the Process*:**

1. Guidelines, not statutes
    a. General rules do not specify all contingencies
    b. Process of review is "highly democratic" (more like a jury than a judge)
    c. Applied across wide-ranging disciplinary traditions and practices

2. The mechanisms of review are multilayered
    a. Institutional Review Board (IRB): Required for externally funded research (NSF, NIH, NIMH), includes members from outside the institution
    b. Internal College Review: Applies primarily to faculty research programs and to all research that involves off-campus participants
    c. Departmental Review: Applies primarily to on-campus student research and instructional laboratories

Objective:

Provide guidelines to be used in reviewing research proposals involving the use of human subjects.

- These guidelines should be explicit and comprehensive enough that routine reviews can be conducted by departments in a manner that is responsible, fair, timely, and consistent with institutional and national standards.
- Also, there should be a clear process whereby questionable cases can be referred by departments to the Institutional Review Board (IRB) for expeditious consideration.
- Guidelines selected from the last section of the Belmont Report.

Informed Consent:

- Will subjects be provided with adequate information about the study to allow informed consent: e.g., research purposes, procedures, risks and benefits?
- Will the presentation of this information be appropriate for the subjects' abilities of comprehension?
- Will subjects be given an opportunity to ask questions about the research?
- Will subjects be informed that their participation is voluntary?
- Will subjects be given opportunities to withdraw from the research?
- Will the study be free of coercion (e.g., from the researchers' authority or influence over the participants, or from excessive rewards for participation)?
- Will subjects be assured of confidentiality?
- Will the subjects (or their guardians) be required to sign a form indicating their informed consent?

Risks and Benefits:

- Has the investigator adequately assessed the risks to subjects and benefits to society as justification for this research?
- Have the risks to subjects been minimized?
- Are there unjustified risks to the College or to students who are conducting the research?

Cell Size Consideration:

- Given the demographic information that the survey solicits, it is possible that individuals might be identifiable if there are only a small number of individuals within a given "cell," e.g., Native American and female. There should be some protocol like "no results on groups containing fewer than "n" individuals will be reported." The size (n) of such groups is usually about 6. This is to ensure the anonymity of the participants' responses. Please add this to your protocol and send the revised version to the Associate Dean overseeing Human Subject Studies.

Process for Departmental Review and Referral:

- Routine instructional laboratories will generally be managed by departments.
- New laboratory exercises and original student research projects will be examined most carefully at the departmental level and referred to the IRB if there is a *shadow* of concern.
- In the case of original student research that involves use of human participants, the department will assure that all students have read and followed relevant guidelines for use of humans in research.
- Each department will submit an annual report to the IRB listing the experiments reviewed and outcomes of their reviews. These will be kept on file in the Provost's Office.
- Faculty research will continue to undergo IRB review.
- The Associate Dean responsible for research will provide expedited review and approval when appropriate.

For More Information:

- National Science Foundation Policy Office
  http://www.nsf.gov/bfa/dias/policy/human.jsp
- The Belmont Report: "Ethical Principles and Guidelines for the Protection of Human Subjects of Research."