

PROCEDURES FOR HUMAN SUBJECTS RESEARCH DENISON UNIVERSITY

1. Statement of Policy / Activities Covered

Denison University is responsible for assuring that research activities conducted under its auspices do not violate the rights and welfare of human subjects. Its Guidelines for Human Subjects Research are designed to conform to the Department of Health and Human Services Code of Federal Regulations, revised as of October 1, 1992 (Federal Register, 10-1-92 edition, 119-129).

The following activities are covered: *all faculty research, all administrative research, and all student research (e.g., independent studies, senior research, and student-designed research for courses). Normal classroom studies are not among the activities covered.*

2. Basic Principles

These principles apply to all of the above categories of research.

a. Informed Consent -- Subjects' participation must be *voluntary and informed*. Before participation, subjects must receive an explanation of the purposes of the research, what they will be asked to do, and any potential risks involved. They must be told that they may refuse to participate in the study and may discontinue participation at any time.

In the case of *minors or another protected group*, signed permission should be obtained from a parent or legal guardian, after the parent or legal guardian has been informed (as indicated above).

Deception is basically a violation of informed consent and shall be avoided; if it is necessary to the integrity of the study, strong justification must be made (e.g., it is impossible to get the information in any other way).

b. Protection from Harm -- Stress to subjects shall be minimized as much as possible. Signed consent must be obtained if the subject is subjected to more than minimal risk or stress.

c. Anonymity and/or confidentiality must be observed when possible. If anonymity or confidentiality cannot be maintained, the investigator must provide strong justification.

d. Risks to subjects must be outweighed by the sum of the benefit to subjects and the importance of the knowledge to be gained.

e. Debriefing -- The exact nature and purpose of the study must be explained to subjects after completing the study; subjects have a right of access to a report of the results of the study.

3. Procedures

1. Investigator completes the Human Subjects Research Approval Form, available in the Office of the Associate Provost (Doane 205). (In order to avoid duplication of efforts, the investigator may submit a *departmental review form* instead.)

2. Kim Coplin, Associate Provost, acting in consultation with, or on behalf of, the Institutional Review Committee, will review the approval form and determine whether the research falls in the exempted, expedited, or full review category. Procedures appropriate to that category will be followed. (See *Faculty Handbook*).

3. In the case of exempted or expedited review, the investigator will receive notification as soon as possible; in the case of full review, normally within five class days of proposal submission.

Note: A departmental review board may determine that research falls in the exempt or expedited category and *approve the research project without further institutional approval*. Research that clearly or potentially falls into the full review category must be reviewed by the Denison Institutional Review board.