

# GUIDELINES FOR HUMAN SUBJECTS RESEARCH DENISON UNIVERSITY INSTITUTIONAL REVIEW BOARD (Spring, 1994)

## **1. Definitions**

*Research* means a systematic investigation designed to develop or contribute to generalized knowledge.

*Human subject* means a living person about whom an investigator (professional or student) conducting research obtains (a) data through intervention or interaction with the individual, or (b) identifiable private information.

*Intervention* includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. *Interaction* includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record). To count as "private," information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator associated with the information).

## **2. Policies**

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).

## **3. Activities Covered**

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

#### **4. Levels of Scrutiny**

Depending on the risk to subjects, research may fall into one of the following three categories, for which review procedures differ:

**a. *Exempted Research*** -- Research that is exempt from review includes the following: research on normal educational practices conducted in established educational settings, e.g., research on effectiveness of instructional practices; research involving educational tests if subjects cannot be identified; survey and interview research unless it falls into one of the categories requiring full review; and analysis of existing data such as documents or specimens.

*Research on members of protected groups (e.g., children, retarded persons, prisoners, etc.) never falls into the exempted category and is subject to expedited or full review, depending on what will be done with subjects.*

The decision that research falls into the exempted category is made by the faculty member or administrator conducting or supervising the research. Inquiries about questionable areas may be made to the associate provost.

**b. *Expedited Research*** -- Research that involves minimal risk to subjects receives expedited review. *Minimal risk* means that the risk of harm anticipated is not greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations. Examples include the following: recording of data from adults using physical sensors (e.g., electrocardiogram); voice recordings; survey research instruments or psychological tests that are part of standardized batteries, provided there is anonymity or confidentiality appropriate to the sensitivity of the data; program evaluation projects; and research involving standard protocols or non-invasive procedures that are generally accepted as posing no more than minimal risk.

Expedited research should be reviewed by the Institutional Review Board (IRB) member from that department (if one has been designated) or by the chairperson of the IRB.

**c. *Full Review*** -- Full review is required for all research involving more than minimal risk to subjects. It usually requires signed consent from the subject or (in the case of children, retarded persons, etc.) that person's legal guardian. Examples are research on sensitive aspects of the subject's own behavior, such as illegal conduct,

drug use, sexual behavior, or any other behaviors which, if they became known outside the research, would put the subject in legal jeopardy or might damage the subject's reputation. Full review also includes such procedures as analysis of external secretions such as saliva, and collection of blood samples by venipuncture.

*The signed consent form may be waived if the only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality or anonymity.*

## **5. 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 cases of *oral consent*, a witness must be present, and a written copy of the oral summary must be approved by the IRB and given to the subject or to the subject's legal guardian.

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

*Deception* is a basic 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.

## **6. Membership**

All members of the Institutional Review Board are appointed from the office of the provost. There will be one member from each of the following departments: Biology, Education, Psychology, and Sociology/Anthropology. There will be one member who is an administrator; his/her responsibility is to ensure conformity to institutional commitments and legal standards. One member will be a community representative. This person will not be otherwise affiliated with the institution nor part of the immediate family of a person who is affiliated with the institution. The committee will include members of both sexes.

## **7. Procedures**

In case of full review, a minimum of five members of the IRB must review the research. A majority of those voting must approve the research for it to pass. In cases in which the research is not approved, written feedback as to the reasons for disapproval must be given to the investigator. The investigator may then reapply for approval, providing either a modified set of procedures or a more complete justification for procedures that were questioned. Investigators may normally expect to receive a decision from the IRB in five class days.

## **8. Consent Form**

(see following page)

## DENISON UNIVERSITY CONSENT FORM

My signature on this form confirms that I voluntarily agree to participate in the following survey/research:

Title: \_\_\_\_\_

Experimenter: \_\_\_\_\_

Department: \_\_\_\_\_

My signature confirms the following:

1. My participation is voluntary. I understand that I may refuse to participate in this study, and that I may discontinue my participation at any point.
2. The overall purpose and uses of the study have been explained to me, along with any risks, and I have been informed that a fuller debriefing will be made available to me after the study is completed.
3. It has been made fully clear to me that this study is anonymous and/or confidential.

Signature \_\_\_\_\_

(Please note: in the case of minors, the signature of a parent or guardian is needed.)