

# ***DENISON UNIVERSITY INSTITUTIONAL REVIEW BOARD*** **GUIDELINES AND POLICIES FOR** **HUMAN PARTICIPANTS RESEARCH**

(Revised, March, 2011)

## **1. Definitions**

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

*Human participant* means a living person about whom a researcher (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 participant or the participant's environment that are performed for research purposes. *Interaction* includes communication or interpersonal contact between researcher and participant.

*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 participant is or may readily be ascertained by the investigator associated with the information).

## **2. Policies and Procedures**

Denison University is responsible for assuring that research activities conducted under its auspices do not violate the rights and welfare of human participants. Its Guidelines for Human Participants 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).

i. Researcher reads Guidelines and Policies for Human Participants Research, considers the ethical implications of the proposed research, and completes the Human Participants Research Approval Form, available on the Denison website:  
[http://www.denison.edu/offices/provost/human\\_participants\\_review.html](http://www.denison.edu/offices/provost/human_participants_review.html)

Two examples of completed forms may be found online on the above website.

In order to avoid duplication of efforts, the researcher may submit a completed *departmental review form* instead.

ii. The Associate Provost, acting in consultation with, or on behalf of, the Institutional Review Board, 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*).

Note: A formal departmental review board consisting of at least three members may determine that research falls into the expedited or exempt category *and approve the research without further institutional approval*.

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

iv. In case of a full review (See # 4 below: Levels of Scrutiny), 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 researcher. The researcher may then reapply for approval, providing either a modified set of procedures or a more complete justification for procedures that were questioned. Researchers may *normally* expect to receive a decision from the IRB within ten class days.

v. IRB approval for research studies that continue over time is *three* years. Should the researcher make any alterations to the study within that three year period, a proposal that includes a full description of any modifications to the original research should be submitted through the human participants review process.

vi. Instructors of courses in which students carry out a research project as a part of their learning in the course must submit a human participants research approval form for each project. Once approved, the status of the research will last for a period of *three* years when no changes are made to the research design. Should the researcher make any alterations to the research project within that three year period, a proposal that includes a full description of any modifications to the original research should be submitted through the human participants review process.

vii. Researchers using biological, or psycho-active substances (e.g. caffeine, medications) in their research must include a standard dosage index in their proposals that is relevant to the kind of research being conducted. In addition, the researcher should cite a source that refers to the established guidelines for using such biological, or psycho-active substances in the research.

### **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, and summer scholar research).

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

Depending on the risk to participants, research may fall into one of the following three categories, for which review procedures differ. Student researchers must consult with their faculty research supervisor to determine the level of scrutiny and then proceed with

the review process.

**a. Full Review—**

Full review is required for all research involving more than minimal risk to participants. It usually requires signed consent from the participant or (in the case of children, developmentally delayed persons, etc.) that person's legal guardian. Examples are research on sensitive aspects of the participant'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 participant in legal jeopardy or might damage the participant's reputation. Full review also includes such procedures as analysis of external secretions (e.g. saliva) and collection of blood samples by venipuncture.

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

**b. Expedited Research –**

Research that involves minimal risk to participants 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 in consultation with any member of the Denison IRB. In the alternative, a departmental review board consisting of at least three members may determine that research falls into the expedited or exempt category and *approve the research project without further institutional approval*. However, research that clearly or potentially falls into the full review category must be reviewed by the Denison Institutional Review board.

**c. Exempted Research—**

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

Some research is exempt from review. A Faculty member must consult with a member of Denison's Institutional Review Board to make this determination with respect to student research they are supervising. Faculty members *can not approve their own research*. In such cases, faculty members should consult with the chair of their respective

departments or with another faculty member in their department to make the decision about whether the faculty member's research falls into the exempted category. Research that is exempt from review includes the following: research on accepted educational practices conducted in established educational settings, e.g., research on effectiveness of instructional practices; research involving educational tests if participants 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.

## 5. Basic Principles

*The Following principles apply to all of the above categories of research.*

a. Informed Consent -- Participants' involvement must be *voluntary and informed*. Before participation, participants 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 participant or to the participant'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 deception is necessary to the integrity of the study, the researcher must provide strong justification that specifies:

- Why deception is necessary
- Why the deception is not likely to cause harm to participants
- How consequences of the deception will be managed by the researcher (e.g. debriefing process, steps that can be taken by the human participants if they experience distress associated with the research or have questions or concerns relating to the research. These steps could include counseling hotlines or the provision of contact information for the researcher or research supervisor.)

b. Protection from Harm -- Stress to participants shall be minimized as much as possible. Signed consent must be obtained if the participant 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 researcher must provide strong justification. Anonymity refers to research in which the identity of the participants is not known to the researcher. Confidentiality ensures that, when the identity of participants is known to the researcher, information about the identity of the participant and information provided by the participant cannot be attributed back to the participant. If neither anonymity nor

confidentiality is to be provided or assured, this must be explained to respondents in the informed consent process.

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

e. Debriefing -- The exact nature and purpose of the study must be explained to participants after completing the study, and participants have a right of access to a report of the results of the study. Please note that the particular relationships between researcher(s) and participants and the context of the research may govern the form of debriefing. The researcher should provide the following content to participants: 1) the purpose of the investigation, 2) the research methods, 3) the general area of research (e.g., health psychology, organizational sociology), 4) person (s) to whom the participants can turn if they have questions about the research. For students, please include the name and contact information of the Denison supervising faculty member.

For an example of a Debriefing Statement—See the Denison IRB Human Participants Approval Form online at:

[http://www.denison.edu/offices/provost/human\\_participants\\_form.html](http://www.denison.edu/offices/provost/human_participants_form.html)

## **6. IRB 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 or part of the immediate family of a person who is affiliated with the institution. Gender diversity among committee membership is desired.

## **7. Human Participants Informed Consent Document**

(For an example of an Informed Consent Document/see- the Denison IRB Human Participants Approval Form

[http://www.denison.edu/offices/provost/human\\_participants\\_review.html](http://www.denison.edu/offices/provost/human_participants_review.html))