VI.COMMUNITY STANDARDS AND POLICIES: B. GUIDELINES FOR HUMAN PARTICIPANTS RESEARCH

The complete statement of Denison's Guidelines for Human Participants Research, Procedures, Approval and Consent forms is available at the Provost's Institutional Review Board (IRB) site (https://my.denison.edu/node/158/) on MyDenison. Applications for IRB approval should be submitted online using the Human Participants Research Approval Form (https://my.denison.edu/node/1826/) (hereafter "Approval Form"). For more information contact the Chair of the IRB, Eric Winters.

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 participants. The Denison University IRB is guided by the ethical principles set forth in the *Belmont Report: Respect for Persons, Beneficence and Justice*. We strive to create a culture of respect for, and awareness of, the rights and welfare of human research participants while facilitating compliance by our researchers with applicable guidelines and regulations. University IRB Guidelines for Human Participants Research are designed to conform to the Department of Health and Human Services (HHS) Code of Federal Regulations, revised as of January 2009 (Federal Register 45 CFR 46 (https://www.ecfr.gov/cgi-bin/retrieveECFR/?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML)), including the Revised Common Rule (2018).

The following activities are covered if they involve research that uses human subjects: All faculty research, all administrative research, and all student research (e.g., independent studies, senior research, student-designed research for courses). In addition, some classroom studies or projects have features that IRB principles apply to and thus will require IRB review.

Denison University IRB has a Federalwise Assurance (FWA) that enables prospective researchers (PIs) at Denison to secure Federal grant funds provided by agencies overseen by the HHS, where approval for research involving human subjects is required.

Well in advance of a study or project, instructors should discuss their plans with a member of the University IRB. Instructors and prospective researchers (faculty, staff, students) cannot approve their own research. All current IRB Members are listed on at the IRB MyDenison site (https://my.denison.edu/node/160/). See also federal regulations on protection of human subjects (https://www.ecfr.gov/cgi-bin/retrieveECFR/?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1107).

For student research (senior research, summer research, directed/independent study, course-related research, research projects conducted during off-campus study), students are expected to carefully consult with their faculty advisor about their research plan and if the faculty advisor deems it helpful, the student will consult with a member of the IRB to determine whether a project requires IRB review. For study abroad / away students, follow these procedures for IRB approval (https://my.denison.edu/node/2243/).

Students need to gain IRB approval for research/creative endeavors conducted off campus, if the organization that supervises their work does not have a process in place for granting human participants approval. In order for students to use research conducted off campus for academic work at Denison, the student will need to have such approval through an established process at the Off Campus site, or through Denison University's IRB.

2. Basic Principles

Ethical principles applicable to research with human subjects are based on the Belmont Report and are described in the Denison University IRB Guidelines, available at the IRB MyDenison site (https://my.denison.edu/node/158/), along with detailed information and resources regarding IRB processes. Those principles that apply to a researcher's research plan must be addressed fully in responses to items in the Approval Form.

a. Informed Consent: Informed consent refers to a process in any research or creative work plan with human subjects. Participants' participation 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 and benefits involved. They must be told that they may refuse to participate in the study and may discontinue participation at any time. In cases of verbal consent, a witness must be present, and a written copy of the oral summary must be approved by the IRB and given to the participants or to a 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); and child assent is needed for minors. Details about informed consent are in the Approval Form, and examples are on the IRB website.

b. Deception: Deception is a basic violation of informed consent and must be avoided whenever possible, even in the most seemingly minor forms. If a mild/benign form/degree of deception is necessary to the integrity of the study, strong justification must be made that specifies why deception is necessary, is not likely to cause harm to participants, and how consequences of the deception will be managed.

c. Protection from Risks: Stress and distress 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. Potential risks include physical, psychological, emotional, legal, financial, stigma, employment, and other risks. Equitable distribution of risk(s) is also important when potential risks are possible.

d. Anonymity / Confidentiality: Participants in research must be anonymous or any private/sensitive information about them must be kept confidential by the researchers. This is an extremely critical assurance researchers must plan for and make. The advent of new technologies (e.g., online surveys, electronic recording) has caused the IRB to review new aspects of data gathering that impact degrees of confidentiality more thoroughly than in the past. If anonymity or confidentiality cannot be maintained, the investigator must provide strong justification in the description of their research plan.

e. Benefits v. Risks: Risks to participants must be outweighed by the sum of the benefit(s) to participants and the importance of the knowledge to be gained.

f. Debriefing: For many research methods, the exact nature and purpose of the study must be explained to participants, either prior to, during, or after completing the study. Participants have a right of access to a report of the results of the research/project.

3. IRB Procedures

a. All researchers must complete the CITI Program Modules online course for ethical principles and procedures in research, and submit the resulting certificate to the University IRB prior to making a research submission

b. Prospective researchers should complete and submit the Human Participants Research Approval Form, along with any other necessary supporting documents (e.g., forms for informed consent, debriefing, and/or instruments). See instructions on the Approval Form (https://my.denison.edu/node/1826/).

c. All researchers must comply with the Best Practices for Electronic Data Security for Human Subject Research (BPEDS-HSR) document (adopted August 30, 2018).

d. For prospective student researchers, submission of the Approval Form (https://my.denison.edu/node/1826/) prompts an Advisor sign-off procedure in which, via automated email process, the student's faculty advisor is contacted to ensure the student has (i) worked closely with their advisor on the submission and (ii) that the faculty advisor approves of the full description of the research plan that the student has submitted. We wish to avoid students submitting IRB materials without obtaining faculty guidance or approval.

e. The Chair of the University IRB, acting in consultation with, or on behalf of, the IRB will review the Approval Form responses and determine whether the research falls in the exempt, expedited, or Full-Board Review category. Procedures appropriate to that category will be followed. Review categories are described in the IRB Guidelines (see Levels of Scrutiny).

f. Expected time frames for IRB Review are approximate and are described in the IRB Guidelines. Review duration will depend on level of scrutiny, length of submission queue, the extent to which submissions are complete and comprehensible, and researcher promptness in responding to IRB inquiries. With no queue, exempt and expedited reviews may take as little as 2-3 business days to complete. Full Reviews require an average of 40 days and could require several more weeks than that. These are rough estimates. Ensuring the welfare of people who volunteer for research involves processes and decisions that cannot be rushed by course demands, student urgency, limitations to prospective researcher's planning, or other outside circumstances.