HUMAN SUBJECTS IRB POLICY

Revised January 21, 2019 to be compliant with Revised Common Rule.

Davidson College Institutional Review Board (IRB) policy governing human subjects research:

Statement of Purpose and Authority

Davidson College (hereinafter "the College") affirms that human research subjects should be treated with dignity, respect, and with due regard for their welfare. To protect these values, the College established the Institutional Review Board (hereinafter "IRB"). The IRB reviews all research involving human subjects, conducted by the College's faculty, staff and students, for compliance with federal guidelines and ethical standards. The IRB has the authority to review and approve, require appropriate modifications to, or disapprove human subject research in accordance with 45 Code of Federal Regulations, Part 46 and Davidson College policy.

Definitions

"Human subject" means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) information or biospecimens through intervention or interaction with the individual, and uses, studies or analyzes the information or biospecimens; or 2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

"Research" means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities that qualify as "research" under this policy. The following activities are deemed not be research: Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research and historical scholarship), including the collection and use of information that focuses directly on the specific individuals about whom the information is collected.

“Intervention” includes both physical procedures by which information or biospecimens 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).

"Identifiable private information" is private information from which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

An "identifiable biospecimen" is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

"Limited review" is a review carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among the members of the IRB, and is confined to approving the storage and maintenance plan for the privacy and confidentiality of identifiable data under Exempt Category (2) and (3).

1.0 Statement of Principles

1.1 The Rights of Subjects

The college recognizes that the rights of research subjects include: the right to be informed regarding the nature of the research, including its methods and procedures, any aspect of the research that could reasonably influence a subject's willingness to participate, the nature of any expectable benefits for the research subject or for society, and its reasonably foreseeable risks (if any); the right to withdraw from participation in the research without penalty; and the right to have the subject's confidentiality respected. The college subscribes to the ethical principles of respect for persons, beneficence and justice outlined in The Belmont Report and therefore elects to apply federal regulations to all of its human subjects research regardless of source of support. Davidson maintains a Federalwide Assurance (FWA) for the protection of human subjects with the Office of Human Research Protection (OHRP).

1.2 The Responsibilities of Investigators

Faculty, staff and student investigators must be fully informed of all pertinent federal guidelines and ethical principles.

1.2.1 Investigators must provide to the IRB formal assurance of compliance with all applicable guidelines and standards by submitting certification of human subjects training and a complete application for approval of either a request for exemption or non-exempt research protocol.

1.2.2 Research projects shall not proceed until the investigator receives written notice of approval from the IRB.

1.2.3 Student-directed research must be formally sponsored by a faculty member of the College.

1.2.4 Faculty investigators shall not require students to participate in their own research projects, nor shall faculty investigators offer "extra credit" as an inducement for students to participate in their own research projects.

1.2.5 Investigators should promptly report to the IRB any unanticipated or undisclosed problems involving risks to subjects or others, or any serious or continuing noncompliance with the protocol or with the requirements or determinations by the IRB. For federally funded projects, the IRB Chairperson shall ensure prompt reporting, within 30 days, to the IRB, appropriate College officials, the Office of Human Research Protections of the U.S. Department of Health and Human Services, and any other appropriate entities of any unanticipated problems involving risk to subjects or others, or any serious or continuing noncompliance with 45 CFR, Part 46, or the requirements or determinations of the IRB or any suspension or termination of IRB approval.

2.0 Research Exempted from Further Review

Federal guidelines and the Davidson College IRB policy permit certain types of research to proceed without IRB oversight. The determination as to whether any particular research project qualifies as "exempted" must be made by at least one IRB member. Investigators do not have the discretion to make this determination. Investigators who believe their research projects should be classified as "exempted" must submit an Application for Exempt Research (DOC) to the IRB, and a Notification of Approval for

Exemption from Further Review signed by the IRB chair or vice chair must be received in response to the submission.

The following research activities shall normally be exempt from IRB review:

2.1 *Exemption #1 [45 CFR 46.104 (1)]:* Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special educational strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2.2 *Exemption #2 [45 CFR 46.104 (2) i, ii, iii]:* Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

2.3 *Exemption #3 [45 CFR 46.104 (3) i, ii, iii]:*

(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

A. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
B. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement or reputation, or
C. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

2.4 *Exemption #4 [45 CFR 46.104 (4) i, ii]:* Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects.

[Criteria (iii) and (iv) involve the use of identifiable health information which usually would not apply to research at Davidson College and therefore is not listed in this policy.]

Exempt Categories 5, 6, 7 and 8 are not applicable to the research conducted at Davidson College, and therefore are not listed in this policy.

3.0 Research Reviewed Elsewhere

In certain instances, an investigator from Davidson College may be involved in a collaborative research project involving human subjects which is to be conducted at another institution. If this project has already been approved by the IRB at the collaborating institution, Davidson's IRB Chair may waive review requirements by the Davidson College IRB if the collaborating institution's IRB is willing to enter into an Institutional Review Board Authorization Agreement (IAA) (DOC), which would allow Davidson's investigator to rely on the IRB oversight and OHRP Federalwide Assurance (FWA) at the collaborating institution. Likewise, Davidson College may provide IRB oversight to a collaborating institution by entering into an IAA as the institution providing IRB review.

4.0 Expedited Review

"Expedited review" does not mean a "fast" review. Under an expedited review procedure, review of certain types of research which meet the specified criteria may be carried out by the IRB Chair and by one or more experienced reviewers selected from members of the IRB (not Full Board) outside of the time of a convened IRB Committee meeting. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

Investigators submitting a protocol for expedited review must complete and submit a standard Application for Non-Exempt Research (DOC).

NOTE: Most human subjects research at the College meets the criteria for expedited review.

The following categories of research may be reviewed by the IRB through an expedited review procedure.

4.1 Research Categories that Meet Criteria for Expedited Review

NOTE: The Office for Human Research Protections (OHRP) provides 7 research categories meeting the criteria for Expedited Review. However, categories 1, 2, 3 and 4 are specific to clinical studies and/or medical procedures, which are generally not applicable at Davidson College, and therefore are not provided in the list below.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects (45 CFR 46.104). This listing refers only to research that is non-exempt.)
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects (45 CFR 46.104). This listing refers only to research that is non-exempt.)

4.2 Applicability for Expedited Review

A. Research activities present no more than minimal risk to human subjects.
B. Expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
C. Expedited review procedure may not be used for classified research involving human subjects.
D. Standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or Full Board--utilized by the IRB.

5.0 Criteria for IRB Approval of Research

5.1 In order to approve research covered by the Davidson College Human Subjects IRB Policy, the IRB shall determine that all of the following requirements are satisfied:

5.1.1 Risks to subjects are minimized by: (i) using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

5.1.2 Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

5.1.3 Selection of subjects is equitable. In making the assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, individuals with impaired decision-making capability, or economically or educationally disadvantaged persons.

5.1.4 Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

5.1.5 Informed consent will be appropriately documented in accordance with, and to the extent required by §46.117.

5.1.6 When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

5.1.7 When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

5.2 When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capability, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

6.0 IRB Composition

6.1 The Davidson College IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas.

6.2 Every nondiscriminatory effort will be made to ensure that the IRB does not consist entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

6.3 The IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

6.4 At least two student members shall be appointed annually by the Student Government Association (SGA).

6.5 The IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

6.6 An IRB member may not participate in the IRB's review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

6.7 The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

7.0 The Responsibilities of the IRB

7.1 *Training for the IRB Membership:* The Office for Human Research Protections (OHRP) requires that all members of the college's Human Subjects Institutional Review Board and any individual conducting and/or supervising federally-funded research involving human subjects complete a program of instruction on the responsible treatment of human subjects. Additional IRB reviewer resources are also available to IRB members and the larger research community. See more on reviewer resources.

7.2 *IRB Meeting Schedule:* The IRB schedules monthly meetings during the academic year (September through May). Additional meetings may be called at the discretion of the Chair.

7.3 *Conflict of Interest:* No IRB member shall participate in the IRB's review of a project in which the member has a conflicting interest. Except when requested by the IRB to be present to provide information, IRB members with conflicting interests must absent themselves from the meeting room when the IRB reviews research in which they have conflicting interests. Their absence shall be reported in IRB meeting minutes.

8.0 IRB Records

8.1 The IRB shall prepare and maintain adequate documentation of IRB activities, including the following:

8.1.1 Copies of all research protocols reviewed, along with any approved supplemental documents, including but not limited to sample consent documents, questionnaires, and recruitment materials.

8.1.2 Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

8.1.3 Records of continuing review activities (if required) and modifications.

8.1.4 Copies of all correspondence between the IRB and the investigators.

8.1.5 A list of IRB members in the same detail as described in §46.108(a)(2).

8.1.6 Written procedures for the IRB in the same detail as described in §46.108(a)(3) and (4).

8.2 The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. If applicable, all records shall be accessible for inspection and copying by authorized representatives of the OHRP or NIH at reasonable times and in a reasonable manner.