Frederick Community College

Institutional Review Board Policy and Procedures

BOT Approved:	10/18/2017
Revised:	6/26/2018
Revised:	7/1/2019
Reviewed:	7/1/2020
Revised:	7/1/2021

Table of Contents

Institutional Review Board Policy and Procedures

I. Philosophy and Scope

Frederick Community College ("FCC" or the "College") supports research in higher education and the free exchange of ideas. The purpose of the Institutional Review Board (IRB) is to protect the rights and welfare of human subjects for all research that is conducted at the College. This Policy and Procedures is aligned with federal regulations related to research that can be found in [34 CFR 97-98].

The IRB reviews and approves all internal and external research requests that are not conducted as part of official College business. This Policy and Procedures does not apply to research conducted as part of class instruction, unless the research entails more than minimal risk to human subjects.

II. Definitions for the Purpose of this Policy and Procedures

A. **"Assent"** refers to a child's affirmative agreement to participate in research.

B. **"Children"** refers to persons under the age of 18.

C. **"College community"** refers to trustees, students, and all employees of the College as well as any independent contractors or other third parties to the extent articulated under contractual agreements.

D. **"Guardian"** refers to an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

E. **"Human Subject"** refers to a living individual about whom an investigator (whether professional or student) conducting research obtains:

1. Data through intervention or interaction with the individual; or
2. Identifiable information including personally identifiable information (see the College Protection of Personally Identifiable Information Policy and Procedures)

F. **"Informed Consent"** refers to the assurance that prospective participants understand the nature of the research, and are sufficiently knowledgeable to decide voluntarily whether or not to participate. Investigators may seek consent only under circumstances that provide the prospective subject or their representative sufficient opportunity to consider whether or not to participate, and that minimize the possibility of coercion or undue influence. The information must be written in language that is understandable to the subject or representative. The consent process may not involve the use of language through which the subject or representative is made to waive or appear to waive any of the subject's legal rights, or releases, or appears to release the investigator, sponsor, institution, or agents from liability for negligence.

G. **"Minimal Risk"** refers to the probability that the magnitude of harm or discomfort anticipated in the research is not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

H. **"Parent"** refers to a child's biological, step, or adoptive parent.

I. **"Vulnerable Populations"** refers to human subjects who are likely to be vulnerable to coercion or undue influence and require special treatment with respect to safeguards of their well-being. Populations of students and/or employees may be vulnerable as determined by the IRB. Other examples of vulnerable populations include children, cognitively impaired persons, incarcerated or formerly incarcerated persons, and educationally disadvantaged individuals.

J. **"Workdays"** refers to Monday through Friday and does not include weekends, holidays, scheduled breaks, or other days the College is closed.

III. Responsible Senior Leader and Responsible Office

Special Assistant to the President for Institutional Effectiveness

Office of Planning, Assessment, and Institutional Research

IV. Entities Affected by this Policy and Procedures

The College community

V. Procedures

A. Chair

The Chair of the IRB is appointed by the Special Assistant to the President for Institutional Effectiveness (SA).

The duties of the Chair are to:

1. Nominate new members to serve on the IRB to be approved by the SA in consultation with the nominee's supervisor;
2. Serve as the liaison to internal and external stakeholders;
3. Establish meeting agendas;
4. Maintain meeting minutes or documentation;
5. Communicate with applicants and IRB members;
6. Ensure that IRB member expectations are followed;
7. Ensure that procedures are followed;
8. Seek assistance for research projects on vulnerable populations from expert staff; and
9. Review IRB procedures annually and update as necessary.

B. Members

The IRB is comprised of five (5) voting members who are College employees and must include:

1. The Registrar, as a voting ex-officio member;

2. Four additional members with an earned doctorate and experience evaluating research; and
3. A culturally diverse representation of the College community.
4. Members of the IRB are expected to:
    a. Serve a three-year term, with the possibility of renewal, based on the recommendation of the Chair and the approval of the SA;
    b. Attend all scheduled meetings or participate in the research approval process;
    c. Maintain the confidentiality of all proceedings;
    d. Keep abreast of trends in research in higher education;
    e. Complete periodic training as determined by the IRB;
    f. Disclose potential conflicts of interest and recuse themselves when appropriate;
    g. Maintain extensive knowledge of FERPA (Family Educational Rights Privacy Act of 1974); and
    h. Review applications during the academic year (August – May).

C. Role of the IRB

The IRB must ensure that:

1. The minimal risks to human subjects are reasonable in relation to anticipated benefits;
2. Informed consent is sought from each prospective human subject or the human subject's legally authorized representative;
3. Informed consent is documented;
4. Data collection is monitored to ensure the safety of the human subjects;
5. Human subjects' privacy is protected and confidentiality of data is maintained;
6. Research procedures are not to be used where identification of the human subjects and/or their responses would reasonably place them at greater than minimal risk;
7. Without exception, the confidentiality of human subjects, including any personally identifiable information, is maintained throughout the research and thereafter. The IRB must review the protection of participants at all points during or following the research to assure those appropriate steps are taken to protect the rights and welfare of humans participating as subjects in the research. At any point (before, during, and after the research process, publication, or presentation of findings), if the IRB has concerns about the possibility the research may reveal the identity of any participants, the IRB must withdraw approval, temporarily, or permanently. ;
8. Investigators avoid coercion and ensure that participation in the research is voluntary and confidentiality is preserved;

9. The rights and welfare of human subjects from vulnerable populations are protected by additional safeguards; and
10. Special caution is exercised by investigators when conducting research on the following vulnerable populations.
    a. Children: Investigators must obtain assent from each child considered for inclusion in a research project, as appropriate. Investigators must also obtain parent/guardian permission for conducting the research, along with documented informed consent. The IRB may require additional safeguards, if warranted, to protect the rights and welfare of the children involved in the project.
    b. Employees: If an FCC employee's supervisor is an investigator on the research project being considered, the SA must approve the employee's participation in the project in consultation with the employee's Senior Leader.

D. Application and Approval Process

1. Investigators interested in doing research at FCC must fill out the Institutional Review Board Application for Use of Human Participants, which includes a template to document the informed consent of all human subjects involved in the research project, and follow the directions on the form to submit to the IRB for review.
2. The full IRB reviews each application and makes a majority decision to either "approve" or "disapprove" applications. If one IRB member is absent from a meeting, and a quorum of four IRB members is met, any decision to "approve" an application must include three 'yes' votes.
3. Decisions of the IRB will be e-mailed to the applicants by the Chair within twenty (20) workdays. If additional information is required by the IRB, the Chair will notify the applicant of the information needed. Once the requested information has been received, the application will be shared by the Chair with all the IRB members to review and make the final decision within ten (10) workdays.
4. Research must be completed within one year after receiving the approval, or a formal request for an extension must be submitted.
5. Any changes in approved research methodology or timelines must be submitted to the IRB for reconsideration.
6. The IRB will revoke the investigator's research privilege at FCC if the investigator violates or deviates from the approved application.
7. If the IRB application is approved and the study includes FCC specific data that is not publicly available or not currently available, the IRB will follow the Public Information Requests Policy and Procedures. In this case, the IRB Chair consults with the Public Information Officer about the cost of data preparation and notifies the applicant about the fees associated with the preparation of the data request.

VI. Related Policy and Procedures

Public Information Requests

Protection of Personally Identifiable Information