

MANUAL OF PROCEDURES

<u>Title:</u> Use of Human Subjects in Research Projects	<u>Number:</u>	<u>Page:</u>
---	----------------	--------------

<u>Based on Title and Policy Number:</u> N/A	<u>Date:</u>
---	--------------

Purpose

This policy regarding the use of human subjects in grant-funded research activities recognizes the institution's responsibility to comply with applicable Federal Regulations; protect the rights, well-being and personal privacy of individuals; assure a favorable climate for the conduct of academic-oriented inquiry; and, protect the interests of Florence-Darlington Technical College.

Procedures

1. Any principal investigator related to Florence-Darlington Technical College (as defined below) who engages in scholarly research involving human subjects, either on- or off-campus, must apply to the Institutional Review Board (IRB) for approval of the research. Such approval must be obtained before undertaking the research. Individuals who meet the definition of a "principal investigator" must apply for approval from Florence-Darlington Technical College's Institutional Review Board even if their research has been approved by another institution's or organization's Institutional Review Board.

Under this policy, the following individuals are considered to be principal investigators:

- Florence-Darlington Technical College faculty and staff,
- Florence-Darlington Technical College faculty who are on leave, and who are conducting grant-funded research involving human subjects either at Florence-Darlington Technical College, with grant funds administered by Florence-Darlington Technical College, or with Florence-Darlington Technical College Students.
- Researchers not affiliated with Florence-Darlington Technical College who are conducting primary research with human subjects on campus. These unaffiliated researchers include visitors to the campus and off-campus scholars engaged in human subjects research on campus. While at Florence-Darlington Technical College, these individuals may, through the courtesy of an on-campus liaison, conduct Board-approved research on human subjects. The liaison should provide the visitor with appropriate institutional forms including this Policy, and assure that the forms are sent to the Board before the research is undertaken.

2. No grant-funded research activity involving human subjects shall be undertaken unless an Institutional Review Board has reviewed and approved such activity. This review shall determine whether the activity/research design will adequately protect the rights and welfare of such subjects.

MANUAL OF PROCEDURES

3. Renewal petitions

Projects eligible for continued funding beyond the duration of the initial project award are subject to renewal application review. Projects for which scope of work or activities that involve human subjects change substantially during the project are also subject to renewal application review.

4. Minimum Risk Proposals - Expedited Review

Research activities which involve no more than minimal risk and in which the only involvement of human subjects as outlined below may be reviewed and approved the Institutional Review Board through its expedited review procedure. Under this procedure, the Institutional Review Board review may be carried out by the chairperson of the board, or, in the chairperson's absence, by a member of the board designated by the chairperson. In reviewing research under this procedure, the reviewer may not disapprove the research. A research activity can only be disapproved after review by the full Board.

The following activities shall be eligible for expedited review:

a. Minor changes in previously authorized research during the period for which approval is authorized.

b. Research involving survey or interview procedures where all of the following conditions occur:

- Responses are recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects.
- The subject's responses, if they become known outside of the research, would not place the subject at risk of civil or criminal liability or be damaging to the subject's financial standing or employability.
- The research does not deal with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol, and is not likely to cause the subject undue stress, fatigue, or any other psychological reactions.
- The research proposal makes adequate provision for obtaining the informed and voluntary participation of subjects.

If, in the reviewer's judgment, the proposal goes beyond the criteria for expedited review, it shall be subject to full board review and approval. The chair shall provide to the Institutional Review Board summaries of research proposals certified through expedited review procedures and copies of review disposition letters to investigators.

All other cases require a full board review.

Institutional Review Board

1. The purpose of the Institutional Review Board is to conduct initial and continuing reviews of projects that involve the use of human subjects in accordance with the policy.

2. Review board will be composed of five members: the Vice-President for Enrollment Management and Student Services, Vice-President for Academic Affairs, the Director of Institutional Research, two members of the faculty from different academic divisions of

MANUAL OF PROCEDURES

the college and one member of the greater Florence/Darlington/Marion County community not affiliated with the college appointed by the President of Florence-Darlington Technical College to serve one to three-year terms to insure that the review board is sufficiently qualified through the diversity, maturity, experience, and expertise of its members for its advice and counsel to safeguard the rights and welfare of human subjects. The Vice-President for Academic Affairs will serve as chair in even-numbered years and the Vice-President for Enrollment Management and Student Services will serve as chair in odd-numbered years. Either of the alternating Chairpersons may conduct an initial review at any time.

3. In the event that a conflict of interest arises with a member of the Institutional Review Board related to a project under review, the member will not participate in the review process for that project.

4. The review board will be guided by and operate in compliance with applicable sections of Title 45, CFR, Part 46, Protection of Human Subjects, June 23, 2005.

5. The Institutional Review Board will accept petitions for review from principal investigators at any time and will return decisions within twenty (20) working days. Decisions will be in writing. To be eligible for review, Petitions for Review will contain the following information:

- Name of Principal Investigator with e-mail address and telephone number with signature and date.
- Name of Co-Principal Investigators with e-mail addresses and telephone numbers.
- Administering division or department of project.
- Project duration.
- Project title.
- Funding Agency and Proposal ID number (if applicable).
- Statement addressing real or potential conflict of interest.
- Indication of whether or not the project may be exempt from full board review.
- Brief statement of how human subjects are to be involved in the project.
- Project summary.
- Copy of the grant proposal.

The following types of projects are exempt from Institutional Review Board review: data gathered for the purposes of fundraising; market research for the purposes of admissions recruiting; recruiting efforts for faculty or staff; and statistical data collected for the management of institutional affairs, including surveys of students, prospective students, and alumni. Please note that a project that does not clearly fall into one of these categories should be brought to the IRB Chair for a determination of whether it is exempt. **The determination as to whether a project is exempt from Board review cannot be made by the principal investigators themselves.**