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Policy Name: Human Subjects in Research

Policy Number: A-12

Functional Area(s) Responsible: Assessment, Planning and Continuous Improvement

Owner(s) of Policy: APCI, Institutional Research

Most Recent BOT Approval Date: Fall 2011

Most Recent Review Date: Spring 2023

Most Recent Review/Revision Type: none minor/non-substantive substantive/extensive

Policy Statement:

In compliance with federal law and institutional policy and in order to protect the well-being of participating subjects, all research activities involving human subjects or human material that are carried out at Finger Lakes Community College must follow specific guidelines and must be submitted to the College's Institutional Review Board (IRB) for prior approval.

Research activities conducted by the faculty, staff, and students of Finger Lakes Community College or by outside researchers gathering data at FLCC are subject to this policy.

Drawing from College policy and federal regulations guiding research with humans, the Institutional Review Board (IRB) may approve, modify, or disapprove protocols based upon consideration of human subject protections. Annual progress reports from investigators may be requested depending upon the category of research.

Criteria for Approval

For a research activity to be approved, the following criteria must be satisfied:

- The risks to subjects are minimized as much as possible.
- The risks to subjects are reasonable in relation to anticipated benefits.
- The informed consent process is adequate.
- The research plan makes provisions for the safety of the subjects during the data collection process.
- Provisions are in place to protect the privacy of subjects and maintain confidentiality of data.
- Appropriate safeguards are included within the study to protect the rights and welfare of Federally defined *vulnerable subjects* (pregnant women, fetuses, children, and prisoners).

These criteria ensure that the privacy and welfare of the research participants are adequately protected. Anyone engaged in research with human subjects **MUST** submit requests for review to the Institutional Review Board before beginning the research. Anticipate between two and four weeks for review.

The federal regulations are intended to provide the necessary information to determine:

- Whether a review is needed.
- What sort of review is appropriate.
- What procedures should be followed in submitting an application.

There are several categories of review; each submission is scanned to determine which category of review is appropriate for the research proposed, and then reviewed accordingly.

Reason(s) for Policy:

The Human Subjects Research policy safeguards the rights and welfare of all human subjects who participate in research projects conducted at Finger Lakes Community College.

Applicability of Policy:

All FLCC employees and students, and any outside researchers at FLCC should be familiar with this policy.

Definitions:

None

Related Documents:

- US Dept. of Health & Human Services Code of Federal Regulations, Title 45: Public Welfare, Part 46: Protection of Human Subjects
- The Belmont Report regarding ethical principles and guidelines for research involving human subjects that was published in 1979 by The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
- IRB Review Levels (Employee Intranet)

Procedures:

None

Forms/Online Processes:

FLCC's division of Assessment, Planning and Continuous Improvement (APCI) maintains survey forms to collect applications for each category of IRB review and should be contacted to be directed to the correct form.

Appendix:

None