



COLLEGE of
CENTRAL
FLORIDA

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ADMINISTRATIVE PROCEDURE

Title: Institutional Review Board

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Implementing Procedure For Policy # 3.15

Date Approved: 12/05/06
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Division: General

Purpose

The purpose of the Institutional Review Board (IRB) is to review all protocols for human research before the research is conducted to determine whether the research plan has adequately included the ethical dimensions of the project. An IRB is a committee mandated by the National Research Act, Public Law 93-348, to be established within each institution of higher education that conducts research involving human participants and receives Federal funding for research involving human participants.

The responsibility for compliance with federal, state and college regulations concerning activities involving human subjects and for assuring the protection of human subjects rests with the President of the College of Central Florida (CF). The President has delegated this authority to IRB. The IRB has been established in accordance with Federal Regulations (45 CFR 46 and 21 CFR 56). This document sets forth procedures for CF's IRB under which the College, the IRB and Faculty Investigators (researchers) will comply with federal regulations for the protection of human subjects.

CF bears full responsibility for the performance of all research involving human subjects of faculty, staff and students at the college and for the protection of the rights and welfare of human subjects, including complying with Federal, State or local laws as they may relate to such research and protections.

Anyone, internal or external to CF, interested in conducting research involving human subjects at the college will submit an application to be reviewed and approved by the IRB prior to conducting research. The involvement of human subjects in research will not be permitted until the IRB reviews and confirms that the research is exempt as defined below or complies with the required protocols.

The Federal Regulations define research as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to general knowledge and human subject as 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 private information

Intervention includes both physical procedures by which data are gathered 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 which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Principles

All of the College's human subject activities and all activities of the (IRB) are guided by the basic ethical principles that underlie the conduct of research involving human subjects set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, regardless of funding source. The three basic principles contained in The Belmont Report are central to the ethics of research involving human research and guiding the IRB in assuring that the rights and welfare of subjects are protected, include: respect for persons, beneficence, and justice.

- **Respect for persons** requires that potential subjects be given the opportunity to choose what will or will not happen to them and is the principle upon which obtaining informed consent and the consent process is based. Respect for persons also provides additional protections for potentially vulnerable subjects.
- **Beneficence** is exemplified in the expressions of "do no harm" and "maximize possible benefits and minimize possible harms", both on individual investigator and societal levels, as they extend both to particular research projects and to the research enterprise as a whole, respectively.
- **Justice** requires that there be fair procedures and outcomes in the selection of subjects, both individually (by offering potentially beneficial research to all who might benefit) and socially (based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened persons).

Procedure

Any one internal or external to CF interested in conducting research at the college will submit an application for IRB review with all required documentation as described in the application instructions. The IRB will conduct initial review of the application either through expedited or full review and make a determination.

Once the research protocol is reviewed and determined to be exempt or is reviewed by the IRB under expedited or full review, the Principal Investigator will receive an IRB Determination Form detailing the IRB's findings. If the research protocol is approved, the IRB Determination Form will include additional documents for review and completion by the investigators involved in the protocol.

Changes in research activity that has already been approved by the IRB may not be initiated without IRB approval. Principle investigators are responsible for reporting any changes to approved research using the IRB Addendum Request Form.

IRB approvals are given for a period of one year. For research that extends beyond one year, the principle investigator must apply for approval for continuation using the Continuing, Renew/Termination form.

In the event that a research participant chooses to withdraw from a study or has any concerns related to the study, the participant and/or the principle investigator must notify the IRB using the Participant Withdrawal/Complaint form. The IRB will review and take appropriate action as needed.

The IRB chair submits an annual report to the president on any actions of the IRB. The report will include the names of the principle investigator, title of research, brief description of the study, dates of the study and all actions of the IRB related to the study.

The IRB has the authority to approve, disapprove, request additional information, suspend or terminate any research.

At the conclusion of research the principle investigator must inform the IRB using the Project Close Out form and submit a copy of the research findings.

At CF no research will be conducted except for

- 1) research in which the only involvement of humans is in one or more of the categories exempted or waived under 45 CFR 46.101(b)(1-6) or 101(i) or
- 2) research that involves human subjects and is not exempt that has been approved in writing in advance by the Institutional Review Board of another institution of higher education. This applies to all research involving human subjects conducted by CF faculty, staff, and students, research conducted by individuals external to CF and in all other activities that, even in part, involve such research, regardless of sponsorship.

The Federal regulations (§46.101(b)) define categories of human subjects research that are exempt from further review and regulation. Research investigators who intend to involve human subjects in research activities do not have the authority to make an independent determination that research involving human subjects is exempt from the applicable regulations. The IRB Chair, designated member, or full membership are responsible for reviewing the preliminary determinations of exemption made by investigators and their supervisors and for making the final determination.

Research activities involving no more than minimal risk and in which the only involvement of human subjects will be in one or more of the following categories are exempt from 45 CFR 46:

1. **Normal Classroom Setting** Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on regular and special educational instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. **Standard Test Results** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
 - a. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
 - b. Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. **Subject Limited to Special Populations** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior not otherwise exempt under the above two categories if the human subjects are elected or appointed public officials or candidates for public office; or federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. **Pre-existing Public Data** Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
5. **Only involve Public Programs** Research and demonstration projects which are designed to study, evaluate, or otherwise examine public benefit or service programs; procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payments for benefits or services under those programs.
6. **Only involve Consumers Use of Wholesome Foods** Taste and food quality evaluation and consumer acceptance studies if wholesome foods without additives are consumed; or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA or approved by the EPA or the Food Safety and Inspection Service of the US Department of Agriculture.

Non-Human Subject Research Some types of research may be undertaken without definite plans to include human subjects (as defined in 45 CFR 46.102(f)). In the event that the research does not include human subjects, federal regulations do not apply and IRB review may not be required (this determination however may only be made by the IRB). Examples of non-human subject research may include:

- Data obtained from another source (not directly from the student or their records) that is either:
 1. Totally anonymous and unlinkable to the person who it was obtained from, or
 2. Is coded such that the researcher obtaining the data does not know who it belongs to, AND
 3. A confidentiality agreement assures the research cannot learn the identity of the person who the data was obtained from.
- Data obtained directly from individuals who are deceased prior to their involvement in the study.

IRB Membership

- a) Number of Members The CF IRB membership will be consistent with 45 CFR 46.107 and 21 CFR 56.107 and will have five members including at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. The IRB membership will 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.
- b) Qualifications of Membership IRB members are selected with varying backgrounds of expertise, experience, and diversity to promote complete and adequate review of research activities commonly conducted by the institution and to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.
- c) Diversity of Membership The IRB membership is monitored to assure diversity of its members, including representation by varying professions and ethnic backgrounds, both genders, individuals knowledgeable about community attitudes and subject populations, and individuals knowledgeable about and experienced working with vulnerable subjects.
- d) Appointment of Members The President appoints all IRB members for renewable three-year terms.
- e) IRB Chair The duties of the Chair, include, but are not limited to the following: Presides at all meetings of the IRB; Calls special meetings of the IRB as needed; Advises and counsels investigators; Screens potential IRB Board Members and presents acceptable nominees to the President's Office for review, selection and appointment; Makes decisions on emergency conditions as they relate to the IRB's protection of human subjects in compliance with federal regulations; Keeps the IRB informed of developing problems in the area of human research on any project that has been reviewed or is going to be reviewed.

- f) Compensation of IRB Members IRB members do not receive direct monetary compensation for participation on the Board.

- g) Conflict of Interest No CF IRB member may participate in the review of any protocol in which the member has a conflicting interest, other than to provide information to the Board and should leave the room for the final deliberation and vote on that study. A person recusing themselves for personal reasons can still be counted in the quorum and may remain in the room; otherwise, unless requested to remain in order to provide additional information, conflicted members are asked to leave the room before deliberations begin and until after the vote has been taken. The minutes will identify the conflicted member as not voting, and that member will not be counted toward quorum for that specific project.

An IRB Member has a conflict of interest when that individual also has a financial interest, or any other personal or professional relationship, which may make it difficult for the individual to exercise independent judgment in safeguarding the rights and welfare of human research subjects. An IRB Member may have either a financial conflict of interest, non-financial conflict of interest, or both.

IRB Operations

Meeting Time, Place and Location IRB meetings are held quarterly. Additional meetings may be called by the Chair to complete unfinished business or resolve emergencies, or at the Chair’s discretion. Meeting schedules will be announced on the IRB website.

Vice President,

Date

Approved by President

Date