



COLLEGE of CENTRAL FLORIDA
ADMINISTRATIVE PROCEDURE

Title: Research Review Board

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Implementing Procedure For Policy # N/A

Date Approved: 12/05/06

Division: General

Purpose

A Research Review Board 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 purpose of the RRB 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.

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 the Research Review Board (RRB) to provide oversight for all research conducted by faculty and staff of CF or by others under contract with CF to do so. CF bears full responsibility for the performance of all research involving human subjects 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.

The RRB has been established in accordance with Federal Regulations (45 CFR 46 and 21 CFR 56). This document sets forth policies and procedures for C's RRB under which the College, the RRB and Faculty Investigators (researchers) will comply with federal regulations for the protection of human subjects.

All research involving human subjects must be reviewed and approved by the RRB prior to conducting research. The involvement of human subjects in research will not be permitted until the RRB 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. Date 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 Research Review Board (RRB) 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 RRB in assuring that the rights and welfare of subjects are protected, including: 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).

Policy

It shall be the policy of CF that no research is 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 101I(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, 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. CF 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 RRB 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 RRB review may not be required (this determination however may only be made by the RRB). 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.

RRB Membership

- a) **Number of Members** The CF RRB 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 RRB 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** RRB 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 RRB 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 RRB members for renewable three-year terms.
- e) **RRB 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 RRB as needed; Advises and counsels

investigators; Screens potential RRB 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 RRB’s protection of human subjects in compliance with federal regulations; Keeps the RRB 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 RRB Members RRB members do not receive direct monetary compensation for participation on the Board.
- g) Conflict of Interest No CF RRB 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 RRB 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 RRB Member may have either a financial conflict of interest, non-financial conflict of interest, or both.

RRB Operations

Meeting Time, Place and Location RRB meetings are held annually. Additional meetings may be called by the Chair to complete unfinished business or resolve emergencies, or at the Chair’s discretion.

Vice President,

Date

Approved by President

Date