



UNIVERSITY OF NORTH FLORIDA

Policy Number	Subject	Effective Date	Revised Date
	Research Involving Human Subjects	01/18/02	
Responsible Division/Unit: Academic Affairs/Research and Sponsored Programs			

I. OBJECTIVE & PURPOSE

To ensure the University of North Florida is in compliance with federal guidelines by assuring that human beings exposed to research procedures are adequately protected.

II. STATEMENT OF POLICY

All covered research, training, and demonstration projects involving human subjects must undergo thorough scrutiny by the University of North Florida's Institutional Review Board for the Protection of Human Subjects (IRB) prior to commencement of the project. The IRB is an administrative body established to protect the rights and welfare of human subjects recruited to participate in research activities conducted under the auspices of the University of North Florida. The IRB has full authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction and to conduct continuing reviews of the research activities at intervals appropriate to the degree of risk, but not less than once a year.

Authority:

Code of Federal Regulations, Title 45 (45 CFR 46) Protection of Human Subjects, Revised June 18, 1991 and Title 34 (34 CFR 97) Protection of Human Subjects

The Belmont Report, "Ethical Principles and Guidelines for the Protection of Human Subjects of Research." The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979

National Research Act, Public law 93-348, July 12, 1997

Definition:

Research is "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." It includes activities which meet this definition, whether or not conducted under a program considered "research" for other purposes. [34 CFR 97.102(d)] If an activity follows a deliberate plan whose purpose is to develop or contribute to generalizable knowledge, such as an exploratory study or the collection of data to test a hypothesis, it is research.

A human subject is “a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or obtains identifiable private information.” [34 CFR 97.102(f)(1) and (2)]

“Subject at Risk” means any individual who may be exposed to the possibility of injury; including physical, psychological, or social injury as a consequence of participation as a subject in any research, development or related activity which departs from the application of those established and accepted methods necessary to meet his needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service.

“Special Classes of Subjects” means those groups that require special consideration to assure their protection when they serve as human subjects, including; pregnant women and fetuses, prisoners and wards of the state or courts, mentally disabled, and educationally and economically disadvantaged persons. Special consideration is also required for research involving human in vitro fertilization. Research on any of these “Special Classes” will require approval of special protective measures with the IRB.

III. STATEMENT OF PROCEDURES

Each research, training, and demonstration project involving human subjects will be considered on an individual basis through an application process managed by the Office of Research and Sponsored Programs (ORSP). The Chair or one or more IRB members designated by the Chair will determine whether the research project is exempt or nonexempt from regulations. Those projects considered nonexempt may be processed through either expedited review or full board review. In those cases where subjects are “at risk,” full membership review by the IRB is required for approval. Human subjects may participate in a nonexempt project only after they are covered by an approved process of informed consent. A legally effective informed consent form will be prepared and provided to the Chair of the IRB on an annual basis.

The Institutional Review Board for the Protection of Human Subjects will be comprised of faculty and staff members or persons who because of particular skills are asked to serve on the Committee. Nomination for membership on the committee may be submitted through the IRB Chair to the Vice President for Academic Affairs or they may be submitted by deans of colleges. Members will be appointed by the Vice President for one, two, or three year terms.

The Chair of IRB shall be elected by the committee’s membership. The Chair (a voting member) will call the committee together, preside, and keep records of all actions of the committee. The Chair or delegated member is authorized by the Vice President to act on behalf of UNF for exempted projects and expedited review. In cases requiring full IRB review, actions will be made by majority vote of the members when at least a quorum (one more than one-half of the membership) is present.

This Committee has no fixed number of persons; however, there will not be less than five (5) members, at least one of whom shall not be affiliated with UNF. The membership shall be of varying backgrounds to promote complete and adequate review of projects. There will be at least one member of the IRB whose primary concerns are in scientific

areas and one member whose primary concerns are in nonscientific areas. Other membership may be of formal or ad hoc nature to ensure compliance with pertinent regulations when dealing with special types of research situations. The Director of the Office of Research and Sponsored Programs or his/her designee, shall serve as an ex-officio, non-voting member of the committee.

The Committee will normally meet on a monthly basis, but at least twice each semester to review protocols and for training purposes. The Chair and committee members are to be available to consult with faculty, department chairs, and deans as needs arise to answer questions or explain procedures.

The IRB will publish and maintain a "Procedure Guide for Research Involving Human Subjects" which will provide all necessary information and guidance to prospective researchers when preparing to submit a project for review to the IRB. The Guide will also include the appropriate format to be used by the researcher for submitting the project for formal review. The ORSP will make this Guide available to prospective researchers in both hard copy and automated formats.

The ORSP shall be the office of record for all files generated by the IRB. The Chair of the IRB is charged with the responsibility of seeing that the official record is complete at all times during research projects, and at their termination. The ORSP will provide necessary staff support