

**NEW COLLEGE OF FLORIDA
REGULATIONS MANUAL**

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4-6305 Use of Human Subjects in Research

- (1) The following broad principles are the basis for the development of New College's regulations concerning review of research involving humans.
 - (a) The direct or potential benefits to the subject, and/or the importance of the knowledge gained, must outweigh the inherent risks to the individual.
 - (b) Participation in the project must be voluntary and informed consent must be obtained from all subjects, unless the Institutional Review Board waives the requirement.
 - (c) A subject has the right to withdraw from a research project at any time or may refuse to participate without loss of benefits to which the subject would be otherwise entitled.
 - (d) Safeguarding information about an individual that has been obtained in the course of an investigation is a primary obligation of the investigator.
 - (e) No distinctions in the approval and monitoring of projects will be drawn between funded and non-funded projects, sponsored and unsponsored projects, or on-campus or off-campus projects, except for requirements concerning reporting information to a funding agency.
- (2) Safeguarding the rights and welfare of human subjects in research is a general institutional policy delegated by the President through the Provost to the Institutional Review Board (IRB). Any research project involving human subjects that is conducted by College faculty, staff, or students, or that takes place on the New College property, is subject to review and approval by the IRB. In order to approve proposed research protocols, the IRB shall determine that all of the following requirements are satisfied:
 - (a) Risks to subjects are minimized by utilizing instruments or procedures that are consistent with sound research design. In addition, researchers do not unnecessarily expose subjects to risks, and whenever appropriate, use instruments or procedures already established for learning, diagnostic, or treatment purposes.
 - (b) Risks to subjects are reasonable in relation to the anticipated benefits, if any, to subjects, and the importance of knowledge that may be reasonably expected to result. In evaluating risks and benefits, the IRB shall consider only those risks and benefits that result from the research (as distinguished from risks and benefits of interventions subjects would receive even if not participating in the research).
 - (c) Selection of the subjects is equitable. In making this assessment, the IRB shall take into account the purposes of the research and the setting in which the research will be conducted.
 - (d) Voluntary informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR Part 46.
 - (e) Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR Part 46.

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- (f) Where appropriate, the research methodology includes adequate provisions for monitoring data collection and storage in an attempt to insure the subjects' safety. If any serious breach in the procedure or harmful event occurs with a subject it should be reported to the IRB as soon as possible.
 - (g) Where appropriate, adequate provisions are included to protect the privacy and confidentiality of subjects and data. Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as subjects with acute/chronic physical and/or psychological impairment, or subjects who are economically or educationally disadvantaged, appropriate safeguards must be included in the study in order to protect their rights and welfare.
- (3) The ethical conduct of research is a shared responsibility. It requires cooperation, collaboration, and trust among the institution principal investigators, research associates/assistants, participating subjects, and the IRB. A clear delineation of the responsibilities for each of these parties can help protect the participants who volunteer for research.
 - (4) New College of Florida (NCF) Office of Research Programs (ORPS) serves as the office of record for all NCF IRB activities, and, hereafter, may be referred to as the IRB Administration or IRB Office.
 - (5) NCF Institutional Responsibilities. It is the responsibility of NCF to assure Federal Agencies in writing that it will comply with regulations governing the protection of human subjects. As part of its written Assurance to the government, NCF must develop policies and procedures for conducting human subject research in a responsible and ethical fashion, including how research will be reviewed by the IRB, the reporting of unanticipated problems to the IRB and appropriate regulatory bodies, and other issues.
 - (6) The Provost serves as the Institutional Signatory Official for NCF's Assurance and is ultimately responsible for overseeing the protection of human subjects within NCF. The Institutional Signatory Official must also maintain open channels of communication between the IRB, research investigators and staff, and administration, and provide the IRB with sufficient meeting space and staff to support its substantial review and record keeping responsibilities.
 - (7) The Director of Research Programs and Services is designated as overall Human Protection Administrator (HPA) for NCF's IRB and is responsible for ensuring that it functions and operates within compliance with all Federal, State, and local laws and regulations that govern human subject protection.
 - (8) The HPA is responsible for immediate notification of the Chair of the IRB as well as the Provost regarding any injury, breach of trust, unanticipated problem involving risks to subjects or others, serious or continuing non-compliance with IRB requirements by research investigators, or suspension or termination of IRB approval. The Provost is responsible for notifying OHRP of such incidents in accordance with applicable Federal regulations.
 - (9) The Institutional Review Board (IRB). An IRB is an appropriately constituted group formally designated to review and monitor research involving human subjects. In accordance with the Common Rule, the IRB has responsibility for approving, determining modification (to secure approval), or disapproving research. The IRB has authority to suspend or terminate research for continued noncompliance with the Common Rule or its own findings, determinations, and initial and

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continuing review procedures. Note that protections for human subject involved in research are required by the Department of Health and Human Services (HHS) regulations. 45 CFR Part 46, Subpart A of the HHS regulations constitutes the Federal Policy (Common Rule) for the Protection of Human Subjects, which has been additionally adopted by 16 Executive Branch Departments and Agencies.

- (10) The Principal Investigator. As the individual responsible for the implementation of research, the principal investigator (whether faculty or student) bears direct responsibility for protecting every research subject. This responsibility starts with protocol design, which must minimize risks to subjects and maximize benefits. In addition, the principal investigator and all members of the research team must comply with the findings, determinations, and requirements of the IRB. The principal investigator must also be responsible for the adequacy of both the informed consent document and the informed consent process, regardless of which members of the research team actually obtain and document consent. Principal investigators must ensure:
- (a) Completion of adequate training, currently offered through the CITI training module, prior to undertaking human subject research;
 - (b) All human subject research conducted at NCF or as employees or agents of NCF has received prospective review and approval by the IRB;
 - (c) Approval and continuing review (if applicable) of the research has been secured in a timely fashion; and
 - (d) The research is conducted in compliance with all applicable Federal, State, local, and college regulatory requirements and with the findings, determinations, and requirements of the IRB.
- (11) No changes to approved research may be initiated without prior IRB approval, except where necessary to avoid potentially immediate hazards to subjects. Where the investigator believes that a proposed change is so trivial that IRB review is not required, the investigator should contact the IRB for confirmation before initiating the change. The principal investigator must notify subjects of all changes that would affect the subject's willingness to continue in the research project. No research may be continued beyond the IRB-designated approval period.
- (12) Principal investigators must notify the IRB promptly when they become aware of:
- (a) Any unanticipated problems or adverse events involving risks; and/or
 - (b) Any issue(s) of noncompliance with applicable regulatory requirements or determinations of the IRB. In addition to notifying the IRB, NCF guidelines require that information regarding any adverse event be reported to the research sponsor.
- (13) Other Members of the Research Team. Every member of the research team is responsible for protecting human subjects. Student researchers and all other research staff have a strict obligation to comply with all IRB determinations and procedures, adhere rigorously to all protocol requirements, inform investigators of all adverse subject reactions or unanticipated problems, oversee the adequacy of the informed consent process, and take whatever measures are necessary to protect the safety and welfare of subjects.

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- (14) Researchers at any level are responsible for notifying the IRB promptly of any serious or continuing noncompliance with applicable regulatory requirements or determinations of the designated IRB of which they become aware, whether or not they themselves are involved in the research.
- (15) Research Subjects may be viewed as having certain responsibilities as well. They can be expected to make every effort to comprehend the information researchers present to them so that they can make an informed decision about their participation in good faith. While participating, they should also make every reasonable effort to comply with protocol requirements and inform the investigators of unanticipated problems. Of course, subjects always have the right to withdraw from their participation in research at any time and for any reason without penalty or loss of benefits to which they would otherwise be entitled.

Authority: Article IX, Sec. 7, Fla. Constitution; 45 CFR Part 46; Fla. Board of Governors Regulation 1.001

History: Adopted 04-27-02, as Policy 0-305; Revised and renumbered 05-15-10; Revised 03-11-17 (technical amendment)