

SUBJECT: Human Research Protections	Effective Date: 11-16-11	Policy Number: 4-202.1	
	Supersedes: 4-202	Page 1	Of 4
	Responsible Authority: Vice President for Research and Commercialization		

DATE OF INITIAL ADOPTION AND EFFECTIVE DATE: 03-30-05

APPLICABILITY/ACCOUNTABILITY:

This policy applies to all departments and units and all persons engaged in live human subject research regardless of the funding source.

PREAMBLE

UCF is committed to protecting the rights and welfare of participants in human research. The purpose of this document is to describe UCF's ethical and regulatory requirements for the conduct and oversight of human subjects research.

BACKGROUND INFORMATION

The University of Central Florida maintains one Institutional Review Board (IRB) that operates under a federal-wide assurance (FWA#00000351) approved by the Department of Health and Human Services, Office for Human Research Protections. The UCF IRB is registered by the federal government under IRB#00001138, IORG#0000781. The UCF Human Research Protection Program is accredited by the Association for the Accreditation of Human Research Protection Programs.

POLICY STATEMENT

All research conducted by the university's faculty members, staff members, and students that meets the federal definition of human subjects research must be reviewed and approved by the UCF Institutional Review Board, or its designated reviewing authority, prior to any research

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engagement with human participants. Entities and/or individuals outside of the university engaged (conducting or supporting) in human subjects research in collaboration with university investigators must have an assurance or other acceptable means of compliance approved by the Office for Human Research Protections (OHRP) within the US Public Health Service (e.g., Individual Investigator Agreement).

DEFINITIONS

Human Subject. A living individual about whom an investigator conducting research obtains 1) data through intervention or interaction with the individual or 2) identifiable private information. Human Subject under U.S. Food and Drug Administration research means an individual who is or becomes a participant in research. Human subjects can be given the “test article” (medical device or drug) or they can be given a placebo to serve as a “control” factor when measuring the intervention efficacy.

Human Subjects Research. A systematic investigation about living individuals where information is obtained through intervention or interaction including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge.

Organizational Official. The associate vice president for research and commercialization. The organizational official oversees the review and conduct of human research under the jurisdiction of the university’s human research protection program. The organizational official is legally authorized to obligate the university to the terms of the Department of Health and Human Services Office of Human Research Protections Federal Wide Assurance. The organizational official has the authority to suspend or terminate an approved Institutional Review Board protocol in accordance with the university’s human research protection program standard operating procedures.

Principal Investigator. For the purposes of Institutional Review Board activities and this document, the principal investigator is the faculty member, post-doctoral associate, graduate student, medical student, or other suitably trained individual responsible for the conduct of a particular research project. Any given project may have additional co- or sub-investigators. Undergraduate students may not act as the principal investigator; the faculty supervisor must serve as the principal investigator and the undergraduate student is listed as a co-investigator.

Protocol. A document that outlines the proposed research, including a research design that clearly states the objectives, background, methodology, and significance of the study.

PROCEDURES

All research, development, and other activities involving human participants, whether funded or not, require a human subjects protocol submitted for review and approval through the Office of Research & Commercialization's iRIS on-line system. Human research protocols submitted to the iRIS on-line system must be pre-approved by the appropriate university department or unit. The UCF Institutional Review Board office will notify investigators of all UCF Institutional Review Board final protocol decisions and any ensuing stipulation as required. The UCF Institutional Review Board will establish its own policies and procedures to receive and review human research protocols, approve those protocols, and monitor the human research activities defined in those protocols. Protocol approvals may be suspended or terminated for any reason by the organizational official. The Institutional Review Board chair may suspend an approved protocol when participants may be at risk of adverse effects on their rights or welfare before further action is considered by the convened Institutional Review Board.

RELATED INFORMATION

[21 Code of Federal Regulations \(CFR\), Part 50, Protection of Human Subjects](#)

[21 Code of Federal Regulations \(CFR\), Part 56, Institutional Review Boards](#)

[21 Code of Federal Regulations \(CFR\), Part 312, Investigational New Drug Application](#)

[21 Code of Federal Regulations \(CFR\), Part 314, Application for FDA Approval to Market a New Drug](#)

[21 Code of Federal Regulations \(CFR\), Part 600, Biological Products](#)

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

[Veterans Health Administration Handbook 1200.5](#)

RELATED DOCUMENTS

[University of Central Florida IRB Policies and Procedures](#)

[UCF Human Research Protection Program Plan](#)

[UCF IRB Investigator Manual](#)

[UCF IRB Federal-Wide Assurance and IRB Registration](#)

FORMS

[iRIS User Request Form](#)

[IRB Human Research Protocol template](#)


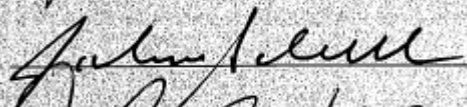
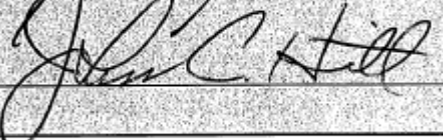
CONTACTS

For questions regarding the policies and procedures of the UCF HRPP, contact the UCF IRB office at 407-823-2901.

Visit the IRB Web page at: <http://www.research.ucf.edu/Compliance/irb.html>

INITIATING AUTHORITY

Vice President for Research and Commercialization

POLICY APPROVAL (For use by the Office of the President)	
Policy Number: 4-202.1	
Initiating Authority: <u></u>	Date: <u>12-6-11</u>
Policies and Procedures Review Committee Chair: <u></u>	Date: <u>12-5-11</u>
President or Designee: <u></u>	Date: <u>12/8/11</u>