DATE OF INITIAL ADOPTION AND EFFECTIVE DATE: 03-30-05/11/2005

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 two Institutional Review Boards (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 Organization 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 one of the UCF Institutional Review Board's, or its a designated reviewing authority, prior to any research engagement with human participants. The UCF IRB office is the designated authority to determine whether research constitutes human subjects research. 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).

The UCF IRB 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 appropriate reason by the organizational official. The IRB 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 IRB.

Noncompliance with this policy may result in suspension of human subjects research and disciplinary action up to and including termination.

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 study application and a human subjects research protocol submitted for review and approval through the Office of Research’s iRIS on-line system electronic IRB portal. Applications should be submitted through the portal a minimum of six weeks for domestic research or four months for international research prior to the anticipated study start date, including recruitment activities. Human research protocols submitted to the IRB must be pre-approved by the appropriate university department or unit. Protocols from student investigators conducting human research must also be pre-approved by a faculty advisor. Human research protocols submitted to the iRIS on-line system must be pre-approved by the appropriate university department or unit. The

When the application is received by the UCF Institutional Review Board IRB office the pre-review process begins and the IRB may ask for clarifications to existing documents or for additional documents will be. When there is enough detail to determine the final review process, the study moves to IRB review where a designated reviewer may make a determination of not human subject research or of an exemption category, conduct an expedited review, or refer the study for a convened board review. During the post-review process, the IRB notifies the Principal Investigator-investigators of all UCF Institutional Review Board IRB final protocol decisions and any ensuing stipulations additional clarifications 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 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
https://www.va.gov/vhapublications/publications.cfm?pub=2
Electronic IRB Portal

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.


INITIATING AUTHORITY

Vice President for Research & Dean, College of Graduate Studies and Commercialization


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