Human Research Protections

Policy Number	4-202.2
Responsible Authority	Vice President for Research & Dean, College of Graduate Studies
Initiating Authority	Vice President for Research & Dean, College of Graduate Studies
Effective Date	3/05/2020
Date of Origin	4/11/2005

APPLICABILITY/ACCOUNTABILITY

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

BACKGROUND INFORMATION

The UCF Human Research Protection Program (HRPP) operates under a federal-wide assurance approved by the Department of Health and Human Services, Office for Human Research Protections. The UCF HRPP maintains two Institutional Review Boards (IRB) that are registered by the federal government. The UCF HRPP is accredited by the Association for the Accreditation of Human Research Protection Programs.

POLICY STATEMENT

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. 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 IRBs, or 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 office 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 chairs 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. The organizational official oversees the review and conduct of human research under the jurisdiction of the UCF HRPP. 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 UCF IRB protocol in accordance with the UCF HRPP standard operating procedures.

Principal Investigator. For the purposes of IRB 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 electronic IRB portal. Human research protocols submitted must be pre-approved by the appropriate university department or unit. Protocols from student investigators conducting human research must be pre-approved by a faculty advisor. the application is received by the UCF IRB office, the pre-review process begins, and

When the IRB office may ask for clarifications to existing documents or for additional documents. 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 subjects 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 office notifies the Principal Investigator of all UCF IRB final protocol decisions and any additional clarifications required.

RELATED INFORMATION or DOCUMENTS

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

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

IRB Human Research Protocol template

CONTACTS

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

Visit the IRB Web page

POLICY APPROVAL
(For use by the Office of the President)

Policy Number: 4-202.2

Initiating Authority: _____ Date: 3/5/20

University Policies and
Procedures Committee Chair: _____ Date: 2/27/20

President or Designee: _____ Date: 3/5/2020

History: 4-202 4/11/2005, 4-202.1 12/8/2011