University Compliance, Ethics, and Risk Office

UNIVERSITY OF CENTRAL FLORIDA

University of Central Florida
Draft Policy Submission Cover Memo Form

Policy No. and Title: 4.202 Human Research Protections

Initiating Authority: VP for Research and Innovation

Initiating Authority Approval Date: 4/17/2026

Date of Submission for Review: 4/17/2026

Submitted by: Renea Carver

Department: Institutional Review Board

☐ New Policy ☑ Existing Policy (5-year Review) ☐ Existing Policy (Out of Cycle Review)

Summary of Revisions: (For a new policy, please provide a summary of the policy. For an existing policy, please provide a summary of the revisions made to the policy.)

The revised draft substantially clarifies institutional authority, roles, and regulatory alignment within UCF's Human Research Protection Program (HRPP). The policy more explicitly affirms the independence and authority of the IRBs, including the ability to approve, modify, suspend, or terminate research, and clarifies circumstances under which chairs and the Organizational Official may act to protect participant safety. Regulatory coverage is expanded and modernized to clearly incorporate the 2018 Revised Common Rule, FDA regulations, HIPAA, FDAAA 801, NIH clinical trial registration and results reporting requirements, and Good Clinical Practice standards. The policy strengthens language confirming that UCF IRB (or designated IRB Office reviewers) is the sole authority for determining human subjects research status, exemptions, and engagement determinations. The revision adds detailed requirements related to single IRB (sIRB) compliance and reliance agreements for multi-site research, including investigator responsibility for eligibility determination and associated costs. Expectations for pre-approval by academic units, documentation of such approvals, and student research oversight are more fully defined. Investigator responsibilities are expanded and clarified, particularly regarding training, funding and conflict-of-interest reporting, safety reporting, continuing review, study closure, and records retention, with explicit acknowledgment of Florida public records and retention laws. Finally, the revised draft strengthens the quality assurance and compliance framework, formally describing routine Quality Improvement Assessments, For-Cause Investigations, potential corrective actions, and consequences of noncompliance, reinforcing UCF's commitment to ongoing oversight and research integrity.

Stakeholders included in the Review Process: (Provide a list of departments involved in the review/revision process.)

College of Medicine
College of Health Professions

Stakeholder feedback must also be requested from the Faculty Senate and the College Policy Liaisons. By checking the boxes below, you are confirming that feedback from these groups was requested, received, and considered in the draft policy.

☒ College Policy Liaisons ☒ Faculty Senate

Regulatory Requirements (if applicable)**:** (Provide information on regulatory requirements pertaining to the policy, including specific statute or regulation number.)

Title 21 Code of Federal Regulations (CFR) Food and Drug
Title 45 CFR 46 Protection of Human Subjects

Presenters: (Provide the name(s), position title(s), and email address(s) for all individuals who will be presenting the policy to the university's Policies and Procedures Committee.)

Renea Carver, Associate Director Human Research Protection Program, rcarver@ucf.edu

Draft - Human Research Protections

Policy Number	4-202.~~2~~3
Responsible Authority	~~Vice President for~~Associate Director, Human Research Protection Program ~~Research & Dean, College of Graduate Studies~~and Innovation
Initiating Authority	Vice President for Research ~~& Dean, College of Graduate Studies~~and Innovation
Effective Date	
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 conducted under the auspices of the University of Central Florida (UCF), regardless of ~~the~~ funding source or location.

UCF will determine whether the institution or its personnel are "engaged in research" consistent with applicable federal guidance.

Investigators may not independently determine that research qualifies as exempt or not human subjects research. Such determinations must be made by the UCF IRB Office.

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, and privacy of all human participants in ~~human~~ research conducted under its auspices. T~~he purpose of t~~his document ~~is to~~ describe~~s~~ UCF's ethical and regulatory requirements for the conduct and oversight of human subjects research and affirms the authority and independence of UCF's IRBs.

The HRPP includes the Organizational Official (OO), IRB(s), HRPP/IRB Office, investigators and research staff, compliance offices, and ancillary committees.

The IRBs report administratively to the OO but function independently in their review and decision-making authority. The IRBs operate free from undue influence and have authority to approve, require modifications to secure approval, defer, disapprove, suspend, or terminate research.

Human subjects research at UCF is governed by 45 CFR 46 (the Common Rule, including the 2018 Revised Common Rule), 21 CFR Parts 50 and 56 (FDA regulations), the ethical principles set forth in the Belmont Report, the Declaration of Helsinki, and Good Clinical Practice (GCP) standards. Where applicable, research must also comply with the Health Insurance Portability and Accountability Act (HIPAA) (45 CFR Parts 160 and 164), as well as FDAAA 801 and NIH Clinical Trial Registration and Results Reporting requirements.

The UCF IRB office is the designated authority to determine whether research constitutes human subjects research. The IRB office may issue a written agreement to specific units or departments within UCF delegating the authority to issue Not Human Subject Research determinations.

Prior to initiating any research activities involving human participants, including advertisement and recruitment, all human subjects research, regardless of funding, must be reviewed and approved by UCF IRB, or by a designated reviewer from the UCF IRB office authorized to conduct expedited review consistent with 45 CFR 46.110.

~~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)~~collaborating in human subjects research in collaboration with university investigators must have an assurance (e.g., Federalwide Assurance or FWA) or other acceptable ~~means of~~ compliance mechanism approved by the Office for Human Research Protections (OHRP) within the US Public Health Service (e.g., Individual Investigator Agreement). For multi-site research subject to federal requirements, including NIH-funded multi-site studies, UCF will comply with applicable Single IRB (sIRB) policies and reliance agreements.

Protocol approvals may be suspended or terminated by the organizational official or by a vote of the convened IRB.~~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 temporarily suspend an approved protocol when participants safety or rights may be at risk ~~of~~

~~adverse effects on their rights or welfare before further action is considered by the convened IRB.~~pending full board review.

Approved protocols are subject to routine post-approval monitoring.

Noncompliance with this policy may be classified as minor, serious, or continuing an may result in corrective action, suspension of human subjects research activities, additional training, restriction of investigator privileges, ~~and~~ or other disciplinary ~~action up to and including termination.~~consistent with HRPP procedures.

DEFINITIONS

Clinical Investigation *(FDA definition):* A research study that involves a test article (drug, biologic, or device) and one or more human subjects as defined by FDA regulations. This includes studies that are subject to prior submission to the FDA or those that are not, but whose results are intended for submission to the FDA as part of an application for a research or marketing permit.

Clinical Trial *(HHS definition):* A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effect of the intervention on biomedical or behavioral health-related outcomes

Human Subject~~.~~ (*HHS Definition*) A living individual about whom an investigator (whether professional or student) conducting research ~~obtains~~ 1) obtains ~~data~~ information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information of biospecimens, or 2) obtains, uses, studies, analyzes, or generates identifiable private information or biospecimens. ~~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.~~

For the purpose of this definition:

Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes

I**nteraction** includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Human Subject (~~*under U.S. Food and Drug A*~~ ~~*dministration*~~*definition*). A~~ research means an~~ individual who is or becomes a participant in research, either as a recipient of the test article or control. A~~Human~~ subject~~s can~~may be either a healthy individual or a patient.~~ 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.~~ Subjects can include de-identified human tissues or medical images when used in FDA device studies.

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.

Human Research Protection Program UCF's system of interdependent elements that implement policies, procedures and practices to protect human subjects involved in research. This program includes the Vice President for Research and Innovation, the Institutional Review Boards (IRB), Sponsored Programs, Compliance, Legal Counsel, Deans/Department Chairs, and Investigators and Research Staff. The IRB Office coordinates HRPP activities.

Organizational Official (also known as the Institutional Official)~~.~~ is t~~T~~he ~~associate v~~Vice ~~president~~ President for ~~research~~Research and Innovation. 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. The organizational official may designate other person or persons from the HRPP to perform some duties, such as signing reliance agreements.

Principal Investigator. For the purposes of IRB activities and this document, ~~the~~ a Principal Investigator (PI) is the primary individual responsible for the design, conduct, and reporting of research involving human subjects. The PI on UCF IRB applications must be qualified by education, training, or experience in the area in which the research is being conducted. The PI must have sufficient authority and accountability to oversee all aspects of the research. Note

that PI eligibility for IRB submissions is different than for sponsored projects. For UCF IRB review purposes, a PI may fall into one of the following categories:~~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.~~

- **A faculty member** paid by UCF with an academic appointment (clinical professor, assistant professor, associate professor, professor, assistant scientist, associate scientist, senior scientist, or instructor).
- **A staff member, postdoctoral scholar, visiting scholar, or medical resident**, with written permission from the individual's supervisor indicating that the person has a legitimate need to conduct the research protocol on behalf of the university.
- **A graduate or medical student** under the supervision of a Faculty Advisor (FA) who is a faculty member paid by UCF with an academic appointment. The FA must have the appropriate background and experience to oversee the student research. The FA is accountable for the conduct of the research and must be listed as a study team member on the IRB electronic application. The FA must document initial review of the student's application materials via a comment or ancillary review on the application.

~~**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~~REQUIREMENTS

The UCF HRPP outlines it's policies and procedures in the Human Research Protection Plan (HRP-101) and Investigator Manual (HRP-103) and the IRB toolkit. UCF PIs proposing human subjects research activities are required to submit an electronic application through the IRB electronic research administration portal.

1. Application Requirements

IRB Electronic Research Administration Portal
All applications for human subject research approvals or determinations must be submitted to the IRB Office through the current IRB electronic portal. This includes all requests for Not Human Subjects Research determinations, exemption determinations, expedited or full board approvals, and studies reviewed by an external IRB.

UCF Templates
All applications must use documents created from current UCF IRB templates unless the research is (a) industry-sponsored or (b) reviewed under an approved external IRB process.

Pre-Approval by Academic Units
Human research protocols must receive pre-approval from the appropriate department or academic unit prior to IRB submission.

- Student-initiated research must be pre-approved by a faculty advisor.
- Pre-approval must be documented through a study comment in the online IRB application, entered by the unit head or faculty advisor.

2. External IRB Requirements

The UCF IRB may enter into Institutional Authorization Agreements (IAAs) that allow reliance on an external IRB in limited circumstances. Investigators must contact the IRB office to determine eligibility for an IAA prior to **initiating** any research activities under an external IRB's oversight.

Investigators are responsible for any costs associated with external IRB review.

3. Investigator Requirements

Investigator Manual and Guidance Documents
The UCF IRB Investigator Manual HRP-103 and Guidance Documents are housed in the IRB electronic portal. PIs are responsible for applying policies, procedures and best practices outlined in those electronic resources.

Funding and Conflict of Interest (COI) Disclosure
PIs are responsible for:

- Providing and updating accurate funding information in IRB submissions; and
- Collecting and reporting conflict-of-interest information for all study team members as required.

Training Requirements
Investigators and key study personnel must complete all required training, as described in the Investigator Manual (HRP-103), prior to submitting an IRB application.

Safety and Compliance Reporting
Investigators must promptly report unanticipated problems involving risks to subjects or others, serious adverse events, and protocol deviations to the IRB Office through the Report of New Information function in the IRB electronic portal.

Continuing Review and Study Closure

Continuing review is required at least annually for:

- Expedited review studies initiated prior to 2018

- All non-exempt studies that are subject to regulations of the FDA and some other federal agencies
- More than minimal risk studies and others designated for continuing review by the convened board.
- When specifically required by the IRB

In accordance with the 2018 Revised Common Rule, continuing review is not required for minimal risk research unless specifically required by the IRB.

Requests for continuing review must be submitted to the IRB through the IRB electronic portal in time for IRB staff review to be completed before the posted renewal deadlines. Studies requiring annual review by the convened board must be submitted and ready for board review prior to the deadline for posting the board agenda, which is at least 10 days prior to the meeting date.

Study Closure: PIs must submit study closure reports through the IRB electronic portal once all research activities are completed.

ClinicalTrials.gov Registration & Results Reporting

Responsible parties must register Applicable Clinical Trials and submit results per FDAAA 801 and NIH policy , including informed consent posting requirements where applicable.

Records Retention

PIs are responsible to maintain IRB records per 45 CFR 46.115 (federal retention requirement, at least 3 years after completion of the research). Additional retention is required for FDA regulated research under 21 CFR 56.115 (FDA requirement, typically 2 years after marketing approval or study discontinuation) or the Health Insurance Portability and Accountability Act (HIPAA) 45 CFR 164 .530(j) (6-year documentation retention requirement) where applicable.

Florida also has applicable state public records and retention requirements, particularly for public universities like UCF.

UCF, as a Florida public institution, is subject to:

• Florida Public Records Law (Chapter 119, Florida Statutes)

• Florida Administrative Code Rule 1B-24 (General Records Schedules)

• State of Florida General Records Schedule GS1-SL (State and Local Government Agencies)

• UCF Records Management Policy 2-003 (institutional implementation)

These may impose longer retention requirements than federal regulations in certain categories.

Quality Assurance and Non-Compliance

The HRPP maintains a quality improvement and post-approval monitoring program to ensure that human subjects research conducted at UCF remains compliant with applicable federal, state, and institutional requirements.

Quality Improvement Assessments:

To promote ongoing compliance and research integrity, five (5) active research protocols are selected each month for a Quality Improvement Assessment conducted by an HRPP compliance specialist. Selection may be random or risk-based, and any open protocol is eligible for review.

Principal investigators of studies selected for review will receive notification from an HRPP compliance specialist (HRPPQIA@ucf.edu) regarding the assessment and any required documentation or follow-up actions.

For Cause investigations:

In addition to the routine Quality Improvement Assessments, the IRB or other authorized entities within the HRPP may initiate a For-Cause Investigation

when warranted.

Circumstances that may prompt such an investigation include, but are not limited to:

• Evidence or allegations of serious or continuing noncompliance;

• Suspicion of research misconduct or fraud;

• Failure to adhere to IRB-approved protocols;

• New information suggesting that research participants may be exposed to increased risk or harm.

Findings from Quality Improvement Assessments or For-Cause Investigations may result in required corrective actions, modification of research procedures, suspension of research activities, restriction of investigator privileges, or other actions consistent with HRPP policies and applicable regulations.

4. Faculty Advisor/Faculty Mentor Requirements

Graduate and Medical student PIs must have a faculty advisor. Undergraduate research must be conducted under a faculty PI who also serves as the student's mentor.

The faculty advisors or mentors are responsible for:

- Meeting regularly with the student investigator to monitor study progress and provide appropriate oversight;
- Being personally available to supervise the student investigator and assist in resolving issues that arise during the conduct of the research;
- Ensuring that the research is conducted only by qualified personnel and in accordance with the IRB-approved protocol and applicable regulations;
- Ensuring that the student investigator promptly reports any unanticipated problems involving risks to participants or others, as well as any serious adverse events (whether anticipated or unanticipated), to the IRB in accordance with applicable IRB policies and procedures;

- Assuming responsibility for the accurate documentation, investigation, and follow-up of all study-related adverse events and unanticipated problems involving risks to participants;
- Ensuring that the student investigator provides the IRB with any requested information in a timely manner;
- Ensuring that the student investigator submits a study closure report to the IRB upon completion of the research activities;
- Ensuring that, if the research will continue after the student investigator graduates or otherwise leaves UCF, a modification is submitted to the IRB to transfer responsibility to another qualified investigator.

~~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

UCF Human Research Protection Program Plan

UCF IRB Investigator Manual

UCF IRB Policies and Procedures

UCF IRB Guidance Documents

UCF IRB Federal-Wide Assurance and IRB Registration

Title 21 Code of Federal Regulations (CFR) Food and Drug

Title 45 CFR 46 Protection of Human Subjects

https://clinicaltrials.gov/policy/fdaaa-801-final-rule

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 and TEMPLATES

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

History: 4-202 4/11/2005, 4-202.1 12/8/2011; 4-202.2 3/05/2020