

Responsible Executive: Vice President for Research
Approving Official: Vice President for Research
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I. INTRODUCTION

Purpose

Florida State University (FSU) is committed to protecting the rights and welfare of subjects in human research. The purpose of this plan is to describe the FSU Human Research Protection Program (HRPP) plan (“Policy”) to comply with ethical and legal requirements for the conduct and oversight of human research and the terms of the FSU Federalwide Assurance.

Definitions

Agent

An agent for the purposes of this Policy refers to an individual who: (1) acts on behalf of FSU; (2) exercises FSU authority or responsibility; or (3) performs FSU designated activities for human research purposes. An agent may include employees, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation.

Clinical Trial

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 effects of the interventions on biomedical or behavioral health-related outcomes.

Engaged in Human Research

In general, FSU is considered engaged in human research when FSU employees or agents for the purposes of the research obtain: (1) data about human subjects of the research through intervention or interaction with them; (2) identifiable private information about the human subjects of the research; or (3) the informed consent of human subjects for the research. FSU follows the Federal Policy for the Protection of Human Research Subjects¹ and related federal guidance to apply this definition.

¹ Also known as the federal “Common Rule” and accessible at <https://www.govinfo.gov/content/pkg/FR-2017-01-19/pdf/2017-01058.pdf>. The Common Rule is promulgated by signatory federal agencies under their own agency-specific regulations, including for example Title 45 of the U.S. Code of Federal

Federalwide Assurance (FWA):

An institution's written federal assurance of compliance approved by the U.S. Office for Human Research Protections (OHRP) under which the institution commits to compliance with applicable regulations for the protection of human subjects, and which is approved for federalwide use by other U.S. federal departments and agencies that have adopted the Federal Policy for the Protection of Human Subjects. The FSU FWA is approved by OHRP, FWA00000168.

Human Research:

Any activity that is "Research" and that involves "Human Subjects" as these terms are defined below and under applicable federal law. The term "human research" is synonymous with research involving human subjects.

Human Research Protection Program:

FSU's system of interdependent elements that implement policies, procedures and practices to protect human subjects involved in research. This includes the Office of the Vice President for Research (OVPR), the Institutional Review Board (IRB), the Office for Human Subjects Protection (OHSP), and FSU employees and agents who have responsibilities under this Policy for protecting the rights and welfare of subjects in human research in their research.

Human Subject:

As defined by Federal Policy for the Protection of Human Research Subjects:

A living individual about whom an investigator (whether professional or student) conducting research (1) obtains information or biospecimens through intervention or interaction with the individual, and uses studies, or analyzes the information or biospecimens, or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. For the purpose of this definition:

- **Intervention** includes both physical procedures by which information or biospecimens are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
- **Interaction** 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 (for example, a medical record).

Regulations, Part 46, Subpart A. Signatory federal agencies' regulations may be accessed here: <https://www.govinfo.gov/>.

- **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.
- **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.

As defined by U.S. Food and Drug Administration Regulations:

An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.

Investigator:

Any individual who is involved in conducting human research. If the human research is conducted by a team of individuals, the investigator who is the responsible leader of the team may be referred to as the principal investigator. The term investigator is synonymous with researcher.

Research:

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.²

II. POLICY

Mission

The Mission of FSU’s Human Research Protection Program is to protect the rights and welfare of human subjects research participants by adherence to ethical principles and compliance with applicable laws governing the protection of human subjects.

Ethical Requirements

In the oversight of all Human Research, FSU follows the ethical principles outlined in the April 18, 1979 report of The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research titled “Ethical Principles and Guidelines for the Protection of Human Subjects of Research,” also known as “The Belmont Report.”³ The Belmont Report was developed in response to federal law (Public Law 93-348) requiring the issuance of basic ethical principles, guidelines and administrative actions applicable to human research. The underlying principles for the protection of human subjects of research are:

² The term “research” is synonymous with the terms clinical research, clinical study, study and clinical investigation. See FDA regulations at 21 CFR 56, section 56.102(c), “Clinical investigation.”

³ The Belmont Report is accessible at <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>. [Public Law 93-348](https://www.congress.gov/bill/93rd-congress/house-bill/7724) is accessible at <https://www.congress.gov/bill/93rd-congress/house-bill/7724>.

- Respect for Persons
- Beneficence
- Justice

FSU commits to adhering to The Belmont Report ethical principles and their applications to all human research regardless of funding.

Legal Requirements

All human research at FSU must, before being undertaken, undergo advance review by OHSP and the IRB and receive approval or a regulatory determination as provided under applicable law and policy.

When FSU is engaged in human research that is conducted, funded, or otherwise subject to regulations by a federal department or agency, FSU commits to applying and following the applicable human research regulations and policies of that federal department or agency.

When FSU conducts Human Research that is subject to the U.S. Food and Drug Administration (FDA), FSU commits to applying and following the applicable FDA regulations and policies relevant to the protection of human subjects.

Any questions about whether an activity meets the regulatory definition of human research should be referred to the OHSP which will provide a determination.

Other Requirements

Applicable policies and procedures apply to all human research regardless of whether the research is conducted domestically or in another country, including:

- Confirming the qualifications of investigators for conducting the research
- Conducting initial review, continuing review, and review of modifications to previously approved research
- Post-approval monitoring
- Handling of complaints, non-compliance, and unanticipated problems involving risks to subjects or others
- Consent process and other language issues
- Ensuring necessary approvals are met
- Coordination and communication with local IRBs

For clinical trials, FSU commits to apply human research requirements in accordance with the “International Conference on Harmonisation – Good Clinical Practice E6” (ICH-GCP).

FSU prohibits payments to professionals in exchange for referrals of potential subjects (“finder’s fees”) and payments designed to accelerate recruitment that were tied to the rate or timing of enrollment (“bonus payments”).

Sponsored Human Research

For both sponsored and non-sponsored human research this Institution abides by its ethical principles, regulatory requirements and its policies and procedures.

Scope of Human Research Protection Program

The FSU HRPP applies to all research that may involve human subjects conducted at FSU or by an FSU agent.

Human Research Protection Program Policies and Procedures

Policies and procedures for the FSU Human Research Protection Program are maintained by OHSP and are available at the OHSP web at <https://www.research.fsu.edu/research-offices/ohsp/policies-and-procedures/>.

Human Research Protection Program Components

Institutional Official

The FSU Vice President for Research is designated as the Institutional Official (sometimes referred to as the “IO”) who is legally authorized to represent FSU regarding this Institution’s Federalwide Assurance (FWA).

The IO has the authority to take the following actions or delegate these authorities to a designee:

- Establish and maintain the Human Research Protection Program, including staffing, budget and other resourcing.
- Appoint and remove IRB members and IRB chairs.
- Approve of IRBs upon which the Institution will rely for review of research.
- Place limitations or conditions on an investigator’s or research staff’s privilege to conduct human research.
- Establish policies and procedures related to the Human Research Protection Program that are binding on the Institution.
- Suspend or terminate research approved by the IRB.
- Disapprove research approved by the IRB.

The IO has the responsibility to:

- Oversee the review and conduct of human research under the jurisdiction of the Human Research Protection Program.
- Periodically review this HRPP to assess whether it is providing the desired results and recommend and approve amendments as needed.
- Establish policies and procedures designed to ensure that human research will be conducted in accordance with applicable ethical and legal requirements.

- Implement educational and training programs for all individuals involved in human research and the Human Research Protection Program.
- Ensure that the human research review process is independent and free of coercion or undue influence and ensure that officials of the Institution cannot approve human research that has not been approved by the IRB.
- Ensure that the IRB Chair and members have direct access to the IO for appeal if they experience undue influence or if they have concerns about the function of the IRB.
- Implement a process to receive and act on complaints and allegations regarding the Human Research Protection Program.
- Follow-up on findings of serious or continuing non-compliance of researchers, IRB members and OHSP staff.
- Implement a post-approval compliance program to monitor compliance and improve compliance in human research and identified problem areas.
- Investigate and remediate identified systemic problem areas in the Human Research Protection Program.
- Ensure that the Human Research Protection Program has sufficient IRB members, OHSP staff, facilities, equipment, development opportunities and other resources appropriate for the volume and types of human research to ensure that human research reviews are accomplished in a thorough, timely and regulatory compliant manner.
- Review and sign federal assurances (FWA) and addenda.
- Fulfill IO educational requirements mandated by OHRP.

The IO delegates to the Director, Office for Human Subjects Protection, the above authorities and responsibilities, except for the following:

- Establish the Human Research Protection Program, including staffing, budget and other resourcing.
- Appoint and remove IRB members and IRB chairs.
- Disapprove research approved by the IRB.
- Ensure that the human research review process is independent and free of coercion or undue influence and ensure that officials of the Institution cannot approve human research that has not been approved by the IRB.
- Ensure that the IRB Chair and members have direct access to the Institutional Official for appeal if they experience undue influence or if they have concerns about the function of the IRB.
- Follow-up on findings of serious or continuing non-compliance of IRB members and OHSP staff.
- Fulfill IO educational requirements mandated by OHRP.

IRB

Information about the FSU IRB, including the roster of IRB members, is available from OSHP.

This Institution may when permitted or required by applicable federal regulation rely upon an IRB of another institution or organization provided one of the following is true:

- The human research is cooperative research, and either OHSP has approved of an IRB other than the FSU IRB to serve as the designated IRB or an IRB other than the FSU IRB has been accepted by a federal sponsor.
- The FSU IRB lacks the requisite experience and expertise to review human research.
- Other reliance is on a case-by-case basis deemed by OHSP as appropriate and acceptable.

Reliance on an external IRB requires an IRB authorization agreement or similar documented arrangement, as well as a local review for compliance with institutional policies. When human research carried out at this Institution or by FSU employees or other agents is considered for review by an IRB at another institution or organization, this Institution will follow established institutional policies and procedures that specify which studies are eligible for reliance and how reliance is determined. The OHSP will provide information to researchers about reliance criteria and the process for arranging and documenting IRB reliance.

The IRBs relied upon by this Institution have the authority to:

- Approve, require modifications to secure approval, and disapprove human research overseen and conducted by this Institution. Human research must be approved by one of the IRBs designated under an IRB authorization agreement. Officials of this Institution may not approve human research that has not been approved by an IRB.
- Suspend or terminate approval of human research not being conducted in accordance with an IRBs' requirements or that has been associated with unexpected serious harm to subjects.
- Observe, or have a third party observe, the consent process and the conduct of the human research.
- Evaluate financial interests of investigators and research staff and have the final authority to decide whether the financial interest and management plan, if any, allow the human research to be approved.
- Fulfill the requirements of the HIPAA Privacy Rule for use or disclosure of non-FSU protected health information for research purposes.

This Institution will comply with the determinations of the reviewing IRB, follow reporting and conflict of interest disclosure requirements as specified in the authorization agreement, conduct monitoring, identify an appropriate contact person, ensure researchers have

appropriate qualifications and provide local context information (and any updates) to the reviewing IRB.

When this Institution provides IRB review for other institutions, this Institution will follow established policies and procedures to ensure that the composition of the IRB is appropriate to review the research and will comply with applicable laws of the relying site. This includes ensuring the IRB is appropriately constituted, members are appropriately qualified, members will not participate in the review of research in which they have a conflict of interest, and that the IRB separates business functions from ethical review.

The IRB will review the research in accordance with established policies and procedures to determine that research is ethically justifiable, according to all applicable laws, including initial review, continuing review, review of modifications to previously approved research and unanticipated problems involving risks to subjects or others. The IRB will also have the ability to suspend or terminate IRB approval; as well as have the final authority to decide whether researcher or research staff conflict of interest and its management, if any, allows the research to be approved and request audits of research reviewed.

The IRB will notify the researcher (and organization) of its decisions, make relevant IRB policies and records available to the relying institution or organization and specify an IRB contact for communication.

IRB member and IRB staff have the responsibility to follow Human Research Protection Program policies and procedures that apply to IRB members and staff.

Investigators and Research Staff

Investigators and research staff have the responsibility to:

- Follow the Human Research Protection Program requirements described in the INVESTIGATOR MANUAL (HRP-103).
- Comply with all determinations and additional requirements of applicable law and policy, the decisions of the IRB, OHSP determinations, and the Institutional Office.

Legal Counsel

Legal Counsel has the responsibility to:

- Provide advice upon request to the Institutional Office, IRB, OHSP and other individuals involved with the Human Research Protection Program.
- Determine who meets the definition of “legally authorized representative” and “children” when human research is conducted in jurisdictions not covered by policies and procedures.
- Resolve conflicts among applicable laws.

Deans/Department Chairs

Deans, Department Chairs and Center/Institute Directors have the responsibility to:

- Oversee the review and conduct of human research in their department or school.
- Forward complaints and allegations regarding the Human Research Protection Program to the Institutional Official.
- Ensure that each human research study conducted in their department or school has adequate resources.

The Office of Sponsored Research Administration and the FSU Research Foundation

The Office of Sponsored Research Administration or the FSU Research Foundation, as applicable, has the responsibility to review contracts and funding agreements for compliance with Human Research Protection Program policies and procedures.

Office of Research Compliance Programs

The Office of Research Compliance Programs has the responsibility to report as well as require researchers to report researchers' conflicts of interests to OHSP for any human research.

Education and Training

The IRB Chair and Vice Chair, IRB members, OHSP staff, and others involved in the review of human research, including the Institutional Official, must complete applicable initial and continuing human subjects protection training.

Investigators and research staff must complete initial and continuing human subjects protection training and any required remedial human subjects protection training and education described in the INVESTIGATOR MANUAL (HRP-103) and/or as required by the IRB.

Questions and Additional Information for the IRB and OHSP

The IRB and OHSP welcome your questions, information, and feedback.

Contact information for the IRB and OHSP is provided below.

Office for Human Subjects Protection
Institutional Review Board
Florida State University Office of Research
2010 Levy Avenue, Building B Suite 276
Tallahassee, Florida 32306
850-644-7900
Email: humansubjects@fsu.edu

Related subordinate procedures as well as instructions, templates and other information or links to these materials are available at: <https://ohsp.fsu.edu>.

Reporting and Management of Concerns

Questions, concerns, complaints, allegations of undue influence, allegations or findings of non-compliance, or input regarding the Human Research Protection Program may be reported orally or in writing. Employees are permitted to report concerns on an anonymous basis. Concerns may be reported to the Director, Office for Human Subjects Protection.

The IRB has the responsibility to investigate allegations and findings of noncompliance and take corrective actions as needed, including reporting to relevant federal department or agencies any unanticipated problems involving risks to subjects or others; serious or continuing noncompliance with applicable law and policy or the requirements and determinations of the IRB; and suspension or termination of IRB approval. The Institutional Official has the responsibility to investigate all other reports and take corrective actions as needed.

Employees who report in good faith possible compliance issues shall not be subjected to retaliation or harassment as a result of the reporting. Concerns about possible retaliation should be immediately reported to the Institutional Official or designee.

To make such reports, contact the Institutional Official at:

Office of the Vice President for Research
3012 Westcott North
Tallahassee, Florida 32306
Email: research@magnet.fsu.edu
(850) 644-9694

Monitoring and Auditing

In order to monitor and ensure compliance, internal or external auditors who have expertise in applicable law and policy may conduct random, for cause and periodic audits. Audits will focus on areas of concern that have been identified by any entity, i.e., federal, state or institutional.

Disciplinary Actions

The Institutional Official may place limitations or conditions on an investigator's or research staff's privilege to conduct human research whenever in the opinion of the Institutional Official such actions are required to maintain the Human Research Protection Program.

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

Article IX, Section 7, Florida Constitution, BOG 1.001, Delegations by BOT to President and by President to VPs, various Federal law and Regulation, cited in text, 1001.22, F.S.

Title 42, United States Code, section 289.

82 Federal Register 7149-7274 (January 19, 2017), Federal Policy for the Protection of Human Subjects.

Approval Review and Revisions to the Policy Plan

This Human Research Protection Program Plan, to be promulgated as an FSU Policy, is to be approved by the FSU Vice President for Research and reviewed and amended as the Vice President deems necessary with advice from the Institutional Official

/s/ Laurel Fulkerson

Proof of approval retained in file]