



7-IRB-0

HUMAN RESEARCH PROTECTION PROGRAM PLAN

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

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Responsible Executive: Vice President for Research Gary K. Ostrander

Approving Official: Gary K. Ostrander Vice President for Research

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I. INTRODUCTION

Scope

~~Throughout this document "Institution" refers to Florida State University.~~

Purpose

~~The Florida State University (FSU) Institution is committed to protecting the rights and welfare of subjects in Human-human Researchresearch. The purpose of this plan is to describe this Institution'sthe FSU Human Research Protection Program (HRPP) plan ("Plan-olicy") to comply with ethical and legal requirements for the conduct and oversight of Human-human Rresearch and the terms of the FSU Federalwide Assurance. This Institution's Human Research Protection Program is a comprehensive system to ensure the protection of the rights and welfare of subjects in Human Research. The Human Research Protection Program is based on all individuals in this Institution along~~

~~with key individuals and committees fulfilling their roles and responsibilities described in this plan.~~

Definitions

Agent

~~An agent for the purposes of Human Research 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. individual who is an employee is considered an agent of this Institution for purposes of engagement in Human Research when that individual is on duty in any capacity as an employee of this Institution.~~

~~An individual who is not an employee is considered an agent of this Institution for purposes of engagement in Human Research when that individual has been specifically authorized, via the Volunteer Appointment process or a signed agreement through College of Medicine, to conduct Human Research on behalf of this Institution. Any student (non-employee) led protocol is required to have faculty advisor signature or acknowledgement.~~

~~Legal counsel has the ultimate authority to determine whether someone is acting as an agent of this Institution.~~

Clinical Trial

A research study in which one or more human ~~human subjects~~ 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, ~~this Institution~~ FSU is considered engaged in Human ~~human~~ Research research when ~~this Institution's~~ FSU employees or agents for the purposes of the Human ~~r~~ Research obtain: (1) data about human ~~the~~ subjects of the research through intervention or interaction with them; (2) identifiable private information about the human ~~s~~ subjects of the research; or (3) the informed consent of human subjects for the research. ~~This Institution~~ FSU follows the Federal Policy for the Protection of



Human Research Subjects¹ and related federal guidance OHRP guidance on “Engagement of Institutions in Research”⁴ to apply this definition and exceptions to this definition.

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 ~~either:~~

- ~~• Is “Research” and that as defined by DHHS and involves “Human Subjects” as these terms are defined below and by DHHS (“DHHS Human Research”) under applicable federal law; or~~
- ~~• Is “Research” as defined by FDA and involves “Human Subjects” as defined by FDA (“FDA Human Research”). 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 DHHS~~

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

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 the signatory federal agencies under their own agency-specific regulations, including for example Title 45 of the U.S. Code of Federal Regulations, Part 46, Subpart A. ~~Which signatory federal agencies’ regulations may be accessed here:~~ <https://www.govinfo.gov/>.

A living individual about whom an investigator (whether professional or student) conducting research (1) obtains information or biospecimens through ~~Intervention~~ intervention or ~~Interaction~~ 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** ~~means~~ 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** ~~means~~ includes communication or interpersonal contact between investigator and subject.
- **Private Information** ~~means~~ 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 ~~which~~ 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).
- **Identifiable Private Information** ~~means~~ 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** ~~means~~ is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

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

~~Human Subject as Defined by FDA~~

An individual who is or becomes a ~~subject~~ 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. ~~A human subject includes an individual on whose specimen (identified or unidentified) a medical device is used.~~

Investigator:

~~Any The person~~ individual who is involved in conducting ~~who conducts~~ responsible for the conduct of the ~~Human~~ Research ~~research~~ at one or more sites. If the ~~Human~~ human ~~Research~~ research is conducted by a team of individuals ~~at a trial site~~, the investigator who is the responsible leader of the team ~~and~~ may be referred to as



~~called~~ the principal investigator. The term investigator is synonymous with researcher.

Research: ~~as Defined by DHHS~~

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.²²

Research as Defined by FDA

~~Any experiment that involves a test article and one or more human subjects, and that meets any one of the following:~~

- ~~• Must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act meaning any use of a drug other than the use of an approved drug in the course of medical practice;~~
- ~~• Must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act meaning any activity that evaluates the safety or effectiveness of a device;~~
~~OR~~
- ~~• Any activity the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.~~

II. POLICY ~~(Including any Forms and Attachments)~~

~~¹ <http://www.hhs.gov/ohrp/policy/engage08.html>~~

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.”

~~² For research conducted within the Bureau of Prisons: Implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research.~~

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. The mission of this Institution's Human Research protection program plan is to protect the rights and welfare of subjects involved in Human Research that is overseen by this Institution.~~

Ethical Requirements

In the oversight of all Human Research, ~~this Institution FSU (including its investigators, research staff, students involved with the conduct of Human Research, the Institution's institutional review boards (IRBs), IRB members and chairs, IRB staff, the Institutional Official/Organizational Official (IO/OO), and employees)~~ 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:"~~

- Respect for Persons
- Beneficence
- Justice

Legal Requirements

~~This Institution FSU commits to apply adhering to The Belmont Report its ethical standards principles and their applications to all Human-human Research-research regardless of funding.~~

-Legal Requirements

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



All ~~Human-human Research-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-one of the institutionally designated IRBs.~~ ~~Activities that do not meet the definition of Human Research do not require review and approval by one of the Institution's IRBs and do not need to be submitted to one of the Institution's IRBs unless there is a question regarding whether the activity is Human Research.~~

When ~~this Institution~~FSU is engaged in ~~DHHS H~~human ~~Research-research~~ that is conducted, funded, or otherwise subject to regulations by a federal department or agency ~~who is a signatory of the Common Rule, the Institution~~FSU commits to ~~applying and apply following~~ the ~~applicable human research regulations and policies of that that federal department or agency-relevant to the protection of Human Subjects.~~

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

Any questions about whether an activity meets the regulatory definitions of ~~Human-human Research-research~~ should be referred to the ~~IRB Office~~OHSP ~~who which~~ will provide a determination.

Other Requirements

~~Applicable p~~When reviewing research that involves community based research, the IRB ~~obtains consultation or training.~~

All ~~p~~olicies and procedures ~~are applied identically~~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 ~~all~~ necessary approvals are met
- Coordination and communication with local IRBs

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

~~This Institution~~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.”).

~~When Human Research is conducted or funded by the Department of Justice (DOJ), this Institution commits to apply 28 CFR §22. When Human Research is conducted with the federal Bureau of Prisons (DOJ), the Institution commits to comply with 28 CFR §512.~~

~~When Human Research is conducted or funded by the Department of Defense (DOD), this Institution commits to apply the Department of Defense (DOD) Directive 3216.02, which includes the requirement to apply 45 CFR §46 Subparts B, C, and D⁴. This Institution will comply with the terms of the DFARS clause or comparable language used in the agreement with the Department of Defense (DOD) Component supporting the research involving human subjects.~~

~~When Human Research is conducted or funded by the Department of Education (ED), this Institution commits to applying 34 CFR §97 Subpart D (equivalent to 45 CFR §46 Subpart D), 34 CFR §98.3, 34 CFR §98.4, 34 CFR §356.3, and 34 CFR §99.~~

~~When Human Research is conducted or funded by the Department of Energy (DOE), this Institution commits to applying the Department of Energy (DOE) O 443.1B and to use “DOE Institutional Review Board Template for Reviewing Human Subjects~~

~~Research Protocol that Utilize Personally Identifiable Information (PII).”~~

~~When Human Research is conducted or funded by, or when the results of research are intended to be submitted to or held for inspection by the Environmental Protection Agency (EPA), this Institution commits to applying 40 CFR §26, which includes the requirement to apply 45 CFR §46 Subparts B and D.~~

⁴Quick applicability table for DHHS Subparts:

	DHHS	DOD	ED	EPA	VA
Subpart B	X	X		X	
Subpart C	X	X			X
Subpart D	X	X	X	X	X



~~When Human Research is subject to the European Union General Data Protection Regulations (GDPR), this Institution coordinates with legal counsel to ensure that the research activities conform to broader institutional policies related to GDPR, where applicable, as well as legal counsel's interpretation of study specific GDPR requirements.~~

Sponsored Human Research

For both sponsored and non-sponsored ~~Human human Research 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 categories of Human human subjects Research conducted at FSU or by an FSU agent. overseen include:~~

- ~~• All forms of human research~~
- ~~• International research~~
- ~~• FDA regulated research~~
- ~~• Research conducted or funded by the Department of Defense (DOD)~~
- ~~• Research conducted or funded by the Department of Justice (DOJ)~~
- ~~• Research conducted or funded by the Department of Education (ED)~~
- ~~• Research conducted or funded by the Department of Energy (DOE)~~
- ~~• Research conducted, funded, or subject to oversight by the Environmental Protection Agency (EPA)~~
- ~~• Federally funded research~~
- ~~• Research involving fetuses.~~
- ~~• Research involving *in vitro* fertilization.~~
- ~~• Research involving devices that require an abbreviated IDE.~~
- ~~• Investigator held abbreviated IDE.~~
- ~~• Investigator held IND or IDE.~~
- ~~• Research involving devices that require an IDE issued by FDA.~~
- ~~• Research involving drugs that require an IND.~~
- ~~• Research involving pregnant women as subjects.~~

- ~~• Research that plans to or is likely to involve prisoners as subjects.~~
- ~~• Research involving children as subjects.~~
- ~~• Research involving children, pregnant women, fetuses, or neonates that is not otherwise approvable without approval of an agency secretary or director.~~
- ~~• Emergency use of a test article in a life-threatening situation.~~
- ~~• Activities involving humanitarian use devices.~~
- ~~• Research using the short form of consent documentation.~~
- ~~• Research that includes processing or holding personal data of subjects residing in the European Union.~~

The categories of Human Research not overseen include:

- ~~• Research conducted or funded by the Veteran Administration (VA)~~
- ~~• Research involving non-viable neonates.~~
- ~~• Research involving neonates of uncertain viability.~~
- ~~• Research involving a waiver of consent for planned emergency research.~~

~~Classified Research (Classified research is secret research to which access is restricted by law to a particular hierarchical class of people. A security clearance is required to review classified research.)~~

Human Research Protection Program Policies and Procedures

~~PPolicies and procedures for the FSU Human Research Protection Program are maintained by OHSP and are available at the OHSP web on the following Web site: at <https://www.research.fsu.edu/research-offices/ohsp/policies-and-procedures/><https://www.research.fsu.edu/research-offices/humansubjects/policies-and-procedures/>.~~

Human Research Protection Program Components

Institutional Official/~~Organizational Official (IO/OO)~~

~~Gary Ostrander, 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/~~FO~~ has the authority to take the following actions or delegate these authorities to a designee:

- ~~Create~~ Establish and maintain the Human Research Protection Program, including staffing, -budget and other resourcing.
- ~~Allocate resources within the Human Research Protection Program budget.~~
- Appoint and remove IRB members and IRB chairs.
- ~~Hire and fire research review staff.~~
- Approve of ~~Determine what~~ IRBs upon which the Institution will rely for review of research upon.
- ~~Approve and rescind authorization agreements for IRBs.~~
- Place limitations or conditions on an investigator's or research staff's privilege to conduct ~~Human-human Research~~ research.
- ~~Create~~ Establish policies and procedures related to the Human Research Protection Program that are binding on the Institution.
- Suspend or terminate research approved by ~~one of the Institution's~~ the IRBs.
- Disapprove research approved by ~~one of the Institution's~~ the IRBs.

The IO/~~OO~~ has the responsibility to:

- Oversee the review and conduct of ~~Human-human Research~~ research under the jurisdiction of the Human Research Protection Program.
- Periodically review this ~~plan~~ HRPP to assess whether it is providing the desired results and recommend and approve amendments as needed.
- Establish policies and procedures designed to ~~increase the likelihood~~ ensure that ~~h~~ Human-uman Research research will be conducted in accordance with applicable ethical and ~~and~~ legal requirements .
- ~~Institute~~ Implement ~~regular, effective,~~ educational and training programs for all individuals involved in human research and ~~with~~ 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 ~~one of the IRBs designated by the Institution.~~

- Ensure that the IRB Chair ~~(s)~~ 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.
 - ~~Follow up on findings of serious or continuing non-compliance of IRB staff and IRB members.~~
 - ~~Implement an auditing program to monitor compliance and improve compliance in identified problem areas.~~
- Investigate and remediate identified systemic problem areas ~~, and where necessary removal of individuals from involvement~~ in the Human Research ~~Protection program~~Program.
- Ensure that the Human Research Protection Program has sufficient IRB members, OHSP resourcesstaff, facilities, equipment, development opportunities and other resources ~~, including IRBs~~ appropriate for the volume and types of Human human Research research ~~to be reviewed, to ensure that human research so that~~ reviews are accomplished in a thorough ~~, and~~ 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.

~~•~~
~~Department of Energy (DOE) Institutional Official~~

~~The DOE Institutional Official is responsible for:~~

- ~~Ensuring the Central DOE Review Board and the Central DOE Institutional Review Board Classified comply with applicable requirements.~~
- ~~Approving classified research conducted with DOE funding at its sites/laboratories and by its employees and contractors after IRB approval and prior to initiation.~~

~~Department of Energy (DOE) Human Protections Program Manager~~

~~The DOE Human Protections Program Manager is responsible for:~~

- ~~The classified research program in consultation with the National Nuclear Security Administration Human Subject Protection Program Manager.~~
- ~~Conducting biennial performance reviews of all IRBs that review classified research involving human participants to assess compliance, in consultation with the National Nuclear Security Administration human participant protection program manager.~~
- ~~Reviewing and approving local plans to correct noncompliance or mitigate adverse events and unanticipated problems involving risks to participants or others.~~
- ~~Reviewing and approving statements of work for classified Human Terrain Mapping projects submitted by DOE's non-National Nuclear Security Administration sites or projects.~~
- ~~Making recommendations to the Secretary after concurrence from the Institutional Official, on a project by project basis, regarding exemptions from the requirements for classified research.~~

~~• Concur on human participant provisions for classified research in interagency agreements, in consultation with the National Nuclear Security Administration, as appropriate.~~

~~• Maintaining an unclassified list of classified projects.~~

~~All members of the Institution~~

~~All individuals within the Institution have the responsibility to:~~

~~Be aware of the definition of Human Research.~~

~~Consult the IRB when there is uncertainty about whether an activity is Human Research.~~

~~• Not conduct Human Research or allow Human Research to be conducted without review and approval by an IRB designated by the IO/OO.~~

~~• Report allegations of undue influence regarding the oversight of the Human Research Protection Program or concerns about the Human Research Protection Program to the IO/OO.~~

~~• Report allegations or finding of non-compliance with the requirements of the Human Research Protection Program to the IRB.~~

~~Individuals who are responsible for business development are prohibited from carrying out day to day operations of the review process.~~

IRBs

~~Information about the FSU IRB, including the roster of IRB members, The list of IRBs designated by the IO/OO to be the IRBs relied upon by the Human Research Protection Program and the scope of review of these IRBs is listed in the IRB rosters is available from OSHP the IRB Office.~~

This Institution may when permitted or required by applicable federal regulation rely upon an IRBs 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.~~
- ~~• This Institution's investigator is a collaborator on Human Research that is primarily conducted at another institution or organization and the investigator's role does not include interaction or intervention with subjects.~~



- ~~• The Institution is engaged in the Human Research solely because it is receiving federal funds. (Employees and agents of the institution do not interact or intervene with subjects, gather or possess private identifiable information about subjects, nor obtain the consent of subjects.)~~ 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 ~~Authorization Agreement~~ or similar documented arrangement ~~and an active Institutional Profile~~, as well as a local review for compliance with local institutional policies ~~of the Institution~~. When Human human Research research carried out at this institution or by ~~its FSU employees or other~~ agents is considered for review ~~ed~~ by an IRB at another institution or organization, this HRPP-Institution will follow established institutional policies and procedures that specify which studies are eligible for reliance and, how reliance is determined. The OHSP, ~~and~~ will provide information to researchers about reliance criteria and the process for arranging and documenting seeking IRB reliance.

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

- Approve, require modifications to secure approval, and disapprove all Human human Research research overseen and conducted by ~~the this~~ Institution. All Human Research research must be approved by one of the IRBs designated under an IRB authorization agreement ~~by the IO/OO~~. Officials of this Institution may not approve Human human Research research that has not been approved by ~~one of the Institution's IRBs~~ an IRB.
- Suspend or terminate approval of Human human Research 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 human Research research.
- ~~• Determine whether an activity is 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 human Research research to be approved.
- ~~Serve as the Privacy Board, as applicable, to f~~ Fulfill the requirements of the HIPAA Privacy Rule for use or disclosure of non-FSU protected health information for research purposes.

This ~~institution~~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~~Institution provides IRB review for other institutions, this ~~HRPP~~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~~ 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, ~~the IRB chair~~, and the ~~the~~Institutional Official/OO.

Legal Counsel

Legal Counsel has the responsibility to:



- Provide advice upon request to the ~~†~~Institutional Official/OO, IRB, OHSP and other individuals involved with the Human Research Protection Program.
~~Determine whether someone is acting as an agent of the Institution.~~
- Determine who meets the definition of “legally authorized representative” and “children” when Human-human Research-research is conducted in jurisdictions not covered by policies and procedures.
- Resolve conflicts among applicable laws.

Deans/Department Chairs

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

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

Grants and Contracts OfficeThe Office of Sponsored Research Administration and the FSU Research Foundation

The Office of Sponsored Research Administration or the FSU Research Foundation, as applicable, Grants and Contracts Office 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

~~All new employees are to review this plan as part of initial orientation. The human resources department is to conduct refresher training on current employees as needed to maintain awareness of this policy.~~

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

Investigators and research staff must complete ~~the~~ 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 ~~Office wants~~ your questions, information, and feedback.

Contact ~~and location~~ information for the IRB and OHSP ~~office is provided below is:~~

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>.

~~Office of Human Subjects~~
~~2010 Levy Avenue, Building B~~
~~Suite 276~~
~~Tallahassee, FL 32310 850 644 7900~~
humansubjects@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, -of the~~ Office ~~for of~~ 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 ~~the~~ Institutional Official or designee.

To make such reports, contact the ~~the~~ Institutional Official at:

Office of the Gary K. Ostrander

Vice President for Research

~~Office #3019~~

3012 Westcott North

Tallahassee, Florida 32306

Email: research@magnetgary@f.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 federal and state statutes, regulations and institutional requirements will ~~may~~ conduct periorandom, 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. ~~Random audits may also be conducted.~~

Disciplinary Actions

The Institutional Official may place limitations or conditions on an investigator's or research staff's privilege to conduct ~~Human-human~~ Research-research whenever in the opinion of the ~~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 ~~Chief~~ and reviewed and amended as the Vice President deems necessary with advice from the Institutional Official.

~~Executive Officer.~~ This plan is intended to be flexible and readily adaptable to changes in regulatory requirements. The ~~IO/OO~~ Institutional Official has the responsibility to review this plan to assess whether it is providing the desired results. ~~At the request of the IO/OO, the Chief Executive Officer~~ The Vice President for Research has the authority to amend ~~or to delegate the amendment of~~ this plan as deemed necessary.

/s/ ~~Gary K. Ostrander~~

[Proof of approval retained in file]