Human Research Protection Program Plan

Date: May 1, 2020
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Scope

Throughout this document “Institution” refers to The University of South Florida Board of Trustees.

Purpose

This Institution is committed to protecting the rights and welfare of subjects in human subjects research. The purpose of this plan is to describe this Institution’s plan to comply with ethical and legal requirements for the conduct and oversight of human subjects research. This Institution’s Human Research Protection Program (HRPP) is a comprehensive system to ensure the protection of the rights and welfare of subjects in human subjects research. The HRPP 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 individual who is an employee is considered an agent of this Institution for purposes of engagement in human subjects research when that individual is on-duty in any capacity as an employee of this Institution. Persons who have been designated by the Institution’s Central Human Resources as a volunteer are, pursuant to Florida Statutes and USF HRPP Policy, acting as agents of the Institution so long as they act within the scope of their defined volunteer role. Investigators who are employed by the Physician's Group but are engaged in USF research are also considered to be operating as agents of the Institution. USF students, who are not employees of this Institution, may act as agents of the Institution when performing human subjects research overseen by the USF HRPP.

An individual who is not an employee is considered an agent of this Institution for purposes of engagement in human subjects research when that individual has been specifically authorized to conduct human subjects research on behalf of this Institution.

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

Engaged in Human Research

In general, this Institution is considered engaged in human subjects research when this Institution’s employees or agents for the purposes of the human subjects research obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about or identifiable biospecimens from the subjects of the research; or (3) the informed consent of human subjects for the research. This Institution follows OHRP’s guidance on “Engagement of Institutions in Research”\(^1\) to apply this definition and exceptions to this definition.

\(^1\) [http://www.hhs.gov/ohrp/policy/engage08.html](http://www.hhs.gov/ohrp/policy/engage08.html)
Human Subjects Research

Any activity that either:

- Is “Research” as defined by DHHS and involves “Human Subjects” as defined by DHHS (“DHHS Human Subjects Research”); or
- Is “Research” as defined by FDA and involves “Human Subjects” as defined by FDA (“FDA Human Subjects Research”).

Human Subject as Defined by DHHS

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 means both physical procedures by which information or biospecimens is gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.
- Interaction means communication or interpersonal contact between investigator and subject.
- Private Information means 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 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 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 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 as Defined by FDA

An individual who is or becomes a subject 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 whose specimen (identified or unidentified) is used on or in a medical device.

Investigator

The person responsible for the conduct of the human subjects research at one or more sites. If the human subjects research is conducted by a team of individuals at a trial site, the Investigator is the responsible leader of the team and may be called the Principal Investigator.
Research as Defined by DHHS

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.²

The following activities are not considered Research as Defined by DHHS:

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- Public health surveillance activities conducted by a public health authority, limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance.
  - Including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.
  - Including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products.
  - Including those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- Authorized operational activities (as determined by the relevant federal agency) in support of intelligence, homeland security, defense, or other national security missions.
- Secondary research involving non-identifiable newborn screening blood spots.

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;

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.
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.

**Mission**

The mission of this Institution’s HRPP is to protect the rights and welfare of subjects involved in human subjects research overseen by this Institution.

**Ethical Requirements**

In the oversight of all human subjects research, this Institution (including its investigators, research staff, students involved with the conduct of human subjects research, the Institution’s Institutional Review Boards (IRBs), IRB members and Chairs, IRB staff, the Institutional Official (IO), Organizational Official (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”:

- Respect for Persons;
- Beneficence; and
- Justice.

**Legal/Policy Requirements**

This Institution commits to apply its ethical standards to all human subjects research regardless of funding.

All human subjects research must undergo review by one of the institutionally designated IRBs. Activities that do not meet the definition of human subjects 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 subjects research.

When this Institution is engaged in DHHS human subjects research that is conducted, funded, or otherwise subject to regulations by a federal department or agency that is a signatory of the Common Rule, the Institution commits to apply the regulations of that agency relevant to the protection of human subjects. This Institution applies the 2018 Common Rule to research approved on or after January 21, 2019. Additionally research approved prior to January 21, 2019 may be eligible to transition to the 2018 Common Rule.

When this Institution is engaged in FDA-regulated human subjects research, this Institution commits to apply the FDA regulations relevant to the protection of human subjects.
Any questions about whether an activity meets the regulatory definitions of human subjects research should be referred to the IRB Office, which will provide a determination.

**Other Requirements**

When reviewing community based research, the IRB obtains consultation or training as necessary.

All policies and procedures are applied identically to all 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 Human Subjects or Others;
- Consent process and other language issues;
- Ensuring all necessary approvals are met; and
- Coordination and communication with local IRBs.

For clinical trials, this Institution applies the “International Council on Harmonisation – Good Clinical Practice E6-R2” (ICH-GCP) to the extent it is consistent with FDA and DHHS regulations.

This Institution 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”).

This Institution utilizes the IRB to review and approve the use of a Humanitarian Use Device (HUD) before it can be used at a facility for clinical care (with the exception of emergency use).

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

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

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3 Quick applicability table for DHHS Subparts:

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When human subjects 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 subjects research is conducted or funded by the Department of Energy (DOE), this Institution commits to applying DOE O 443.1C and to use “DOE Institutional Review Board Template for Reviewing Human Subjects Research Protocols that Use Personally Identifiable Information (PII).”

When human subjects 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 Subparts B and D.

When human subjects research is subject to Veterans Administration (VA) oversight, this Institution commits to apply VHA requirements, which include the requirement to apply 45 CFR §46 Subparts C and D, and all regulations pertaining to the participation of veterans as subjects, including requirements for indemnification in case of research-related injury pertaining to non-veteran subjects enrolled in Veterans Administration (VA) approved research. In cases where VA and the Institution’s policies conflict, the stricter policy will be applied.

When human subjects 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 subjects research, this Institution abides by its ethical principles, regulatory requirements, and its policies and procedures.

Scope of Human Research Protection Program
The categories of human subjects research overseen may include:

- Clinical trials
- 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.)
- Emergency use of a test article in a life threatening situation
- Federally funded research
- FDA-regulated research
- International Research
- Research conducted or funded by the Veteran Administration (VA)
- 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)
• Research involving fetuses
• Research involving in vitro fertilization
• Activities involving humanitarian use devices
• Research involving drugs that require an IND
• Research involving devices that require an abbreviated IDE
• Investigator held abbreviated IDE
• Investigator held IND or IDE
• Research involving pregnant women as subjects
• Research involving adults unable to consent
• Research involving neonates of uncertain viability
• Research involving children, pregnant women, fetuses, or neonates that is not otherwise approvable without approvable of an agency secretary or director
• Research involving devices that require an IDE issued by FDA
• Research that plans to or is likely to involve prisoners as subjects
• Research involving children as subjects
• Research that includes processing or holding personal data of subjects residing in the European Union

The categories of human subjects research not overseen include:
• Research involving non-viable neonates
• Research involving a waiver of consent for planned emergency research
• Research using the short form of consent documentation

**Human Research Protection Program Policies and Procedures**

Policies and procedures for the Human Research Protection Program are available on the following website: https://irb.research.usf.edu/IRB.

**Human Research Protection Program Components**

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

The Senior Vice President of Research, Innovation & Knowledge Enterprise is designated as the IO. The Director for Research Integrity and Compliance is designated as the OO. The IO has the authority to take the following actions or delegate these authorities to the OO or a designee:

• Create the HRPP budget.
• Allocate resources within the HRPP budget.
• Appoint and remove IRB members and IRB Chairs.
• Hire and fire dismiss HRPP research review staff.
• Determine what IRBs the Institution will rely upon.
• Approve and rescind authorization agreements for IRBs.
• Place limitations or conditions on an investigator’s or research staff’s privilege to conduct human subjects research.
• Create policies and procedures related to the HRPP that are binding on the Institution.
• Suspend or terminate research approved by one of the Institution’s IRBs.
• Disapprove research approved by one of the Institution’s IRBs.
• Establish a contingency plan for transferring oversight of one or more studies to another institution or IRB in the event the IRB is unable to continue oversight of the study (e.g. the IRB closes, suffers loss due to fire or a natural disaster).

The IO has the responsibility to take the following actions or delegate these responsibilities to the OO or a designee:

• Oversee the review and conduct of human subjects research under the jurisdiction of the HRPP.
• Periodically review this plan to assess whether it is providing the desired results and recommend amendments as needed.
• Establish policies and procedures designed to increase the likelihood that human subjects research will be conducted in accordance with ethical and legal requirements.
• Institute regular, effective, educational and training programs for all individuals involved with the HRPP.
• Ensure that the research review process is independent and free of coercion or undue influence, and ensure that officials of the Institution cannot approve research that has not been approved by one of the IRBs designated by the Institution.
• Ensure that the IRB Chair(s) and members have direct access to the IO if they experience undue influence or if they have concerns about the function of the IRB.
• Ensure there is a process to receive and act on complaints and allegations regarding the HRPP.
• Follow-up on findings of serious or continuing non-compliance of IRB staff and IRB members.
• Maintain an auditing program to monitor compliance and improve compliance in identified problem areas.
• Investigate and remediate identified systemic problem areas, and where necessary, remove individuals from involvement in the HRPP.
• Ensure that the HRPP has sufficient resources, including establishing/maintaining IRBs appropriate for the volume and types of human subjects research to be reviewed, so that reviews are accomplished in a thorough and timely manner.
• Review and sign federal wide assurances (FWA) and addenda.
• Fulfill 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 Safety 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.
- Concurs 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.

**Veterans Administration (VA) Facility Director**
The VA Facility Director is responsible for overseeing the creation and implementation of an HRPP for research involving human subjects or human biological specimens commensurate with the local VA facility, the resources of the facility, and the size and complexity of the research program at the facility.

VA Facility Director is responsible for:

- Ensuring that the institution’s HRPP functions effectively and that the institution provides the resources and support necessary to comply with all requirements applicable to research involving human subjects;
- Overseeing the R&D Committee, IRB, and other applicable subcommittees of the R&D Committee, facility research office, and all VA investigators and VA research staff who conduct human subjects research at that facility.
- Delegating authority in writing for respective roles and responsibilities for the HRPP. This delegation of authority must provide the organizational structure and ensure leadership for oversight activities for all human subjects research conducted at or by the facility.
- Ensuring provision of adequate resources to support the operations of the HRPP.
- Ensuring independence of the IRB.
• Appointing the facility’s IRB voting members in writing when the VA facility operates its own IRB.
• Appointing the Chair and, when applicable, Co-chair(s) or Vice Chair(s) for a term of up to 3 years when the VA facility operates its own IRB.
• Serving as the official representative of the institution to external agencies and oversight bodies, and providing all written communication with external departments, agencies, and oversight bodies.
• Ensuring that a procedure is in place to review and approve recruiting media, including documents, flyers, and advertisements for research that is not VA research prior to being posted or distributed in any form within or on the premises of a VA facility. Posting or distributing may include announcing, distributing, publishing, or advertising the study either electronically, by hard copy, or other means to anyone, including Veterans, clinicians, or other staff (see ORD guidance at http://www.research.va.gov/resources/policies/default.cfm).
• Ensuring that a documented procedure is in place for determining when a research activity approved by the IRB, prior to January 21, 2019, can transition to the 2018 Requirements, if applicable. The documented procedure must list what individuals or groups are designated to make the determinations. NOTE: Investigators may not make a determination that their studies can be transitioned to the 2018 Requirements.
• Ensuring appropriate documentation of required actions and responsibilities pertaining to review, approval, conduct and oversight of research conducted at that facility set forth in VHA Directive 1200.05.
• Ensuring that any IRB operated by the VA facility is established in accordance with the requirements of VHA Directive 1200.05 and registered through ORO with the HHS OHRP (see VHA Handbook 1058.03);
• Obtaining approval of the Chief Research and Development Officer (CRADO) if the VA facility wants to establish a new HRPP or change its IRB of record.
• Ensuring that detailed SOPs are developed and implemented to satisfy all requirements of VHA Handbook 1058.01, including requirements affecting the facility’s academic affiliates.
• Ensure appropriate auditing of local human subjects research studies to assess compliance with all applicable local, VA, and other Federal requirements including, but not limited to, ORO requirements.
  o Each VA-approved human subjects research study must be completely audited in accordance with VHA Handbook 1058.01.
  o Each study must be audited for compliance with the regulations and policies on informed consent in accordance with VHA Handbook 1058.01.
• Approve the request for permission to conduct international research at the local VA facility and ensure CRADO approval of international Cooperative Studies Program research is obtained prior to its initiation at the facility.
• For research involving pregnant women, human fetuses, and neonates as subjects, certifies that the medical facility has sufficient expertise in women’s health to conduct
the proposed research (see guidance at http://www.research.va.gov/resources/policies/default.cfm).

- For research involving children as subjects, approve participation in the proposed research (see guidance at: http://www.research.va.gov/resources/policies/default.cfm).
- Contract for the needed care for a research-related injury if VA facilities are not capable of furnishing economical care or are not capable of furnishing the care or services required.
- Contract for inpatient care in a non-VA medical facility if it must be provided to a non-Veteran research subject for a research-related injury.
- Provide reasonable reimbursement for emergency treatment in a non-VA facility for a research subject that needs treatment in a medical emergency for a research-related injury.
- Delegate authority in writing for respective roles and responsibilities for the HRPP. This delegation of authority must provide the institutional structure and ensure leadership for oversight activities for all human subjects research conducted at or by the facility.
- Obtain permission from the central research and development officer if the facility wants to establish a new IRB or change the IRB of record, and ensure any IRB is established according to VA requirements, and has approval from ORO.
- When the facility engages another entity’s IRB, ensure that responsibilities are detailed in a memorandum of understanding or authorizing agreement.
- Ensure that IRB members, Researchers, and Research Staff are appropriately knowledgeable to conduct research in accordance with ethical standards and all applicable regulations.
- Fulfill educational requirements mandated by VA Office of Research and Development and OHRP.
- Ensure that all persons working in research or performing any research activities have been officially appointed by Human Resources Management.
- Unless a waiver for a part-time research compliance officer is approved by the VA Under Secretary for Health, appoint at least one full-time research compliance officer to conduct annual research consent document audits and triennial regulatory audits, and to assist in VA assessments of regulatory compliance.
- Report any appointment, resignation, or change in status of this VA facility’s research compliance officer to Office of Research Oversight (ORO) and VHA Central Office, with a copy to the relevant Office of Research Oversight (ORO) research officer, within 10 business days after the appointment, resignation, or change takes effect.
- Report in writing to Office of Research Oversight (ORO) Research Officer in writing within 2 business days after being notified of any research-related citation or determination of noncompliance by any state or federal agency; or any situation that has generated media attention or Congressional interest.
- Provide follow-up reports detailing any additional findings and appropriate remedial actions to the relevant ORO office at intervals and in a manner specified by that office.
• Provide a copy of any ORO compliance reports regarding the research program to the associate chief of staff for research, Research and Development Committee, any relevant research review committee(s), and the research compliance officer in a timely fashion.
• Report the following research events to ORO Central Office, with a simultaneous copy to the appropriate ORO research officer:
  o IRB changes in number of IRBs and changes in membership rosters.
  o Substantive Memorandum of Understanding (MOU) changes must be reported to ORO Central Office within five business days.
• Ensure that individuals working under a contract with VA cannot serve as VA investigators, but may participate in research in other ways, such as collaborators or consultants.
• Provide a copy of any Office of Research Oversight (ORO) compliance reports regarding the research program to the associate chief of staff for research, Research and Development Committee, any relevant research review committees, and the research compliance officer in a timely fashion.

When the VA Facility uses an external IRB as an IRB of record for single or multi-site protocols this VA Facility Director is responsible to:

• Ensure that any IRB designated as an IRB of record for the facility is established in accordance with the requirements of the VHA Directive 1200.05 and registered through the ORO with the Office for Human Research Protections (OHRP).
• Establish and sign a memorandum of understanding (MOU) or Authorizing Agreement with other VA facilities or external organization(s) providing IRB services (see VHA Handbook 1058.03 and MOU Checklist: http://www.va.gov/ORO/orochecklists.asp); and
• Ensure that external IRBs of record used by the VA facility hold current IRB registrations with FDA/OHRP and provide updates to membership as required by VHA Handbook 1058.03

When this VA facility uses the VA Central IRB, the Facility Director delegates authority to one or more individuals from the local VA facility to:

• Provide comments or suggestions to VA Central IRB, in response to VA Central IRB’s initial review considerations.
• Respond to VA Central IRB’s approval of the study on behalf of the VA facility as to whether the VA facility chooses to participate or declines to participate in the study.
• Serve as liaison between the VA facility and both the local site researcher and VA Central IRB.

A VA facility’s own IRB, also known as an internal IRB, and the VA Central IRB, cannot serve as an IRB of Record for any non-VA entity except a Department of Defense (DoD) facility, Department of Energy laboratory, or a VA NPC.
A VA facility must request CRADO approval if the facility wants its internal IRB to serve as an IRB of Record for a non-VA entity listed above.

**Veterans Administration (VA) Research Compliance Officer (RCO)**

The Veterans Administration (VA) Research Compliance Officer (RCO) reports directly to the Veterans Administration (VA) Facility Director. Research Compliance Officer activities may not be determined or managed by the Research Service, research investigators, or any other research personnel. The IRB accept audits conducted by the Research Compliance Officer to fulfill the IRB’s auditing requirements.

The Research Compliance Officer has the responsibility to:

- Audit and review research projects relative to requirements for the protection of human subjects including:
  - Annual consent document audits.
  - Triennial regulatory audits on all research protocols.
- Consider auditing research projects more frequently in cases of:
  - Involvement of vulnerable populations
  - Level of risk
  - Phase I or Phase II studies
  - Involvement of FDA approved drugs for which there has been a new safety warning issued, or change in the labeling that indicates increased risks
  - Issues of noncompliance
  - Data confidentiality or security concerns.
- Within five business days of identifying apparently serious non-compliance or continuing non-compliance based on a consent document audit, regulatory audit, or other systematic audit of VA research, a Research Compliance Officer must report the apparent non-compliance directly (without intermediaries) to the Facility Director.
  - The report must be made in writing, with a simultaneous copy to the associate chief of staff for research, the Research and Development Committee, the IRB, and any other relevant research review committee.
  - An initial report of apparently serious or continuing non-compliance based on a Research Compliance Officer consent document audit, Research Compliance Officer regulatory audit, or other systematic Research Compliance Officer audit is required regardless of whether disposition of the matter has been resolved at the time of the report.

The Research Compliance Officer has the authority to:

- Serve as a nonvoting consultant, as needed, to the IRB.
  - The Research Compliance Officer may not serve as a voting or nonvoting member of the IRB.
- Attend meetings of the IRB when requested by the IRB.
Veterans Administration (VA) Privacy Officer and the Information Security Officer

The Privacy Officer and the Information Security Officer (ISO) are responsible for:

- Ensuring the proposed research complies with all applicable local, VA and other Federal requirements for privacy and confidentiality, and for information security, respectively, by identifying, addressing, and mitigating potential concerns about proposed research studies.
- Reviewing the proposed study protocol, study specific privacy and security information, and any other relevant materials submitted with the IRB application.
- Identifying deficiencies in the provisions for privacy and confidentiality or information security, respectively, of the proposed research, and making recommendations to the investigator and/or the IRB of options available to correct the deficiencies.
- Following up with the investigator and/or the IRB, in a timely manner, to ensure the proposed research is in compliance with relevant privacy and confidentiality and information security requirements, respectively, before the investigator initiates the study.
- A final review is required only after the IRB has approved the study to ensure no further changes impact the privacy and security requirements of this study. NOTE: If a study includes information covered under 38 U.S.C. 7332 that will be disclosed outside of VA, the study must include written assurance from the VA researcher, e.g. within the protocol, that the purpose of the data is to conduct scientific research and that no personnel involved in the study will identify, directly or indirectly, any individual patient or subject in any report of such research, e.g. manuscript or publication.

All members of the Institution

All individuals within the Institution have the responsibility to:

- Be familiar with the definition of human subjects research.
- Consult the IRB when there is uncertainty about whether an activity is human subjects research.
- Not conduct human subjects research or allow human subjects research to be conducted without prospective review by and approval from an IRB designated by the IO/GO.
- Report allegations of undue influence regarding the oversight of the HRPP or concerns about the HRPP to the IO/GO.
- Report issues affecting the rights, safety, or welfare of human subjects and compliance issues with HRPP requirements to the IRB.
- For Veterans Administration (VA) research, follow this Institution’s procedures to ensure reporting in writing to the IRB within 5 business days of becoming aware of unanticipated problems involving risks to subjects or others, apparently serious or continuing non-compliance, suspension of IRB approval, termination of IRB approval, and local (i.e. occurring in the reporting individual’s own VA facility) unanticipated serious adverse events in writing to the IRB within five business days of.
This requirement is in addition to other applicable reporting requirements (e.g. reporting to the sponsor under FDA requirements.) The unfounded classification of a serious adverse event as “anticipated” constitutes apparently serious non-compliance.

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

IRBs
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 Human Subjects or Others. The IRB will also have the ability to suspend or terminate IRB approval. The IRB has the final authority to decide whether researcher or research staff’s conflict of interest and its management, if any, allows the research to be approved and request audits of research reviewed. IRB members and IRB staff are responsible for following HRPP policies and procedures that apply to IRB members and staff.

Serving as the IRB of Record
When this Institution provides IRB review for other institutions, this HRPP 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 with which they have a conflict of interest, and that the IRB separates business functions from ethical review. Whether this Institution will provide review for another institution is determined by the IRB Office based on a number of factors, including but not limited to:

- Whether the use of a single IRB has been mandated by the study sponsor/supporting agency;
- The number of proposed studies involved in the collaboration;
- The anticipated level of risk associated with the proposed study;
- The location in which the majority of study procedures will take place; and
- The Principal Investigator’s standing with this Institution and their role in the overall research.

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

This Institution may rely upon IRBs of another institution or organization. Whether the Institution will rely on an IRB outside of the Institution is determined by the IRB Office based on a number of factors, including:

- Whether the use of a single IRB has been mandated by the study sponsor/supporting agency;
- The number of proposed studies involved in the collaboration;
- The anticipated level of risk associated with the proposed study;
- Whether the reviewing IRB’s policies and procedures meet USF HRPP standards. If the reviewing IRB is part of an AAHRPP-accredited HRPP, then it will be presumed that the USF HRPP’s standards are being met. However, AAHRPP accreditation in and of itself does not necessarily suffice as a basis for reliance;
- The location in which the majority of study procedures will take place;
- The Principal Investigator’s standing with this Institution and their role in the overall research;
- The ability of the reviewing IRB to be sufficiently informed about local context issues, including local laws and regulations; and
- The terms and conditions of the proposed IRB reliance agreement.

Reliance on an external IRB requires a reliance agreement and an active Institutional Profile, as well as a local review for compliance with local policies of the Institution. The scope of the review of these IRBs is delineated in reliance agreements, and available by request from the IRB Office.

When human subjects research carried out at this Institution or by its agents is reviewed by an IRB at another institution or organization, this HRPP will follow established policies and procedures that specify which studies are eligible for reliance, how reliance is determined, and will provide information to researchers about reliance criteria and the process for seeking IRB reliance. When this Institution cedes the ethical review of research to another organization, this Institution remains responsible for the oversight of the research and has the authority to audit/monitor the research.

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

- Approve, require modifications to secure approval, and disapprove all human subjects research overseen and conducted by the Institution. All human subjects research must be approved by one of the IRBs designated by the IO/OO. Officials of this Institution may not approve human subjects research that has not been approved by one of the Institution’s IRBs.
- Suspend or terminate approval of human subjects research not being conducted in accordance with an IRB’s 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 subjects research.
• Determine whether an activity is human subjects 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 subjects research to be approved.
• Serve as the Privacy Board, as applicable, to fulfill the requirements of the HIPAA Privacy Rule for use or disclosure of 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.

Investigators and Research Staff

Investigators and research staff have the responsibility to:

• Follow the HRPP requirements described in the HRP-103 - INVESTIGATOR MANUAL.
• Comply with all determinations and additional requirements of the IRB, the IRB Chair, and the IO/OO.

Legal Counsel

Legal Counsel has the responsibility to:

• Provide advice upon request to the IO/OO, IRB, and other individuals involved with the HRPP.
• Determine whether someone is acting as an agent of the Institution.
• Determine who meets the definition of “legally authorized representative” and “children” when human subjects research is conducted in jurisdictions not covered by policies and procedures.
• Resolve conflicts among applicable laws.
• Determine whether any human subjects research involving personal data about individuals located in (but not necessarily citizens of) European Union member states, Norway, Iceland, Liechtenstein, and Switzerland conforms with EU General Data Protection Regulations (GDPR).

Deans/Department Chairs

Deans and Department Chairs have the responsibility to:

• Oversee the review and conduct of human subjects research in their department or school.
• Forward complaints and allegations regarding the HRPP to the IO/OO.
• Ensure that each human subjects research study conducted in their department or school has adequate resources.
Sponsored Research and the Office of Clinical Research

Sponsored Research and the Office of Clinical Research have the responsibility to review Institutional contracts and funding agreements for compliance with HRPP policies and procedures. Contracts and funding agreements awarded outside of the Institution will be reviewed per the awardee’s policies.

The Quality Assurance/Quality Improvement (QA/QI) Program

The QA/QI Program evaluates the quality, efficiency and effectiveness of the HRPP through routine monitoring and for-cause audits of IRB-approved studies and the IRB in order to assess compliance with federal regulations, state and local laws, and this Institution’s HRPP policies and procedures. The Program also provides consultations, and conducts education and outreach with study teams. The QA/QI Program assists researchers with performing ethical, quality human subjects research by providing tools and templates to facilitate the conduct of research. When opportunities for improvement are identified, recommendations are presented to the appropriate program manager(s) and Research Integrity & Compliance Administration. The QA/QI Program completes a review for initial submissions involving research that may meet the definition of a clinical trial.

The IND/IDE Assistance Program

The IND/IDE Assistance Program provides regulatory support, guidance and education to USF Sponsor-Investigators who need to file an Investigational New Drug (IND) or Investigational Device Exemption (IDE) application with the Food and Drug Administration (FDA). The goal of the Program is to facilitate excellence in research by ensuring regulatory compliance in innovative research projects that utilize drugs, biologics or medical devices.

The HIPAA Research Compliance Program

The HIPAA Research Compliance Program ensures compliance with the HIPAA Privacy Rule (45 CFR Part 160 and Subparts A and E of Part 164) when human subjects research utilizes Protected Health Information (PHI). The HIPAA Research Privacy Officer and/or designee assists the Program with compliance issues related to HIPAA, serves as an alternate on the USF IRB, reviews requests for waivers of HIPAA authorization, and reviews preparatory to research requests as well as requests to use decedents’ PHI. The HIPAA Research Privacy Officer and/or designee completes a HIPAA checklist for any submissions for which an alteration or waiver of HIPAA authorization is requested.

The Institutional Biosafety Program/Committee (IBC)

The IBC ensures compliance with applicable federal, state and local laws. The IBC reviews and approves applications for the use of recombinant DNA, infectious agents or regulated toxins in humans. Approval by the IBC is required prior to issuance of final approval by the USF IRB. The IBC Program completes a review for any submissions involving use of recombinant DNA.
The Radiation Safety Program/Committee

The Radiation Safety Program approves all human subjects research that involve the use of radiation above standard of care with either radiation-producing machines or radioactive materials. The USF Radiation Safety Program Manager is also the USF Radiation Safety Officer (RSO) and is responsible for reviewing initial and continuing review applications and amendments for research involving use of radiation above standard of care. Approval by the RSO is required prior to issuance of final approval by the USF IRB.

The Conflict of Interest (COI) Program/Committee

The COI Program is charged with reviewing real or perceived individual and institutional financial conflicts of interest related to human subjects research and proposing and/or approving management plans for such conflicts. Submissions with a related individual financial conflict of interest or institutional conflict of interest are marked during the IRB’s pre-review of the submission for COI Program review. Management plans approved by the COI Program (administratively) or Committee are presented to the IRB for review. The IRB has the authority to accept the plan as submitted, require changes to the plan including the addition of additional controls, or disapprove the plan in its entirety. An application marked for COI Program review cannot be assigned to a Chair, Vice Chair, or for full Board review until the COI Program has completed its review.

The Technology Transfer Office (TTO)/Patents & Licensing

The TTO is charged with facilitating patents and licensing of inventions developed under the auspices of the University. The primary goals of the TTO are to facilitate the distribution of research results through commercial development and to generate revenue that rewards inventors for their creativity and support further research and educational programs at the University. The USF IRB works with TTO to ensure any and all conflicts of interest held by investigators conducting human subjects research are reported and managed appropriately.

Office of Community Engagement and Partnerships (OCEP):

USF has been designated as a community engaged institution by the Carnegie Foundation for the Advancement of Teaching. OCEP exists to expand and strengthen university-community engagement locally and globally in support of the University’s strategic priorities to: change lives for the better, improve health, foster sustainable development and positive societal change through high impact research and innovation; produce well-educated and highly skilled global citizens through a continued commitment to student success; and create new partnerships to build a strong and sustainable future for Florida in the global economy by establishing mutually beneficial partnerships (internal and external) that enhance student access to academic programs, research and employment opportunities.

Research and Development Committee (VA)

For Veterans Administration (VA) research, the Research and Development Committee has the responsibility for oversight of the local research program as defined in VHA Directive 1200.01.
Education and Training. This plan is made available to the human subjects research community via the IRB website. To maintain awareness of HRPP policies and procedures, new information, revised materials and opportunities for continuing education are communicated to the research community by way of the IRB Newsletter and/or special bulletins disseminated via e-mail.

IRB members, IRB staff, and others involved in the review of human subjects research, including the IO/OO, must complete initial and continuing training.

Investigators and research staff must complete initial and continuing human subjects protections training as described in HRP-103 - INVESTIGATOR MANUAL.

**Education and Training for Veterans Administration (VA) Research**

All individuals involved in conducting VA human subjects research, including the Institutional Official, are required to complete training in ethical principles on which human subjects research is to be conducted. Specific requirements regarding the type and frequency of training are found on ORD’s Web site at: http://www.research.va.gov/pride/training/options.cfm. All other applicable VA and VHA training requirements at the local and national level must be met (e.g. privacy and information security training).

**Treatment of Research-Related Injuries to Human Subjects at Veterans Administration (VA) Facilities**

VA medical facilities must provide necessary medical treatment to a research subject injured as a result of participation in a research study approved by a VA R&D Committee and conducted under the supervision of one or more VA employees. This does not apply to:

1) Treatment for injuries due to non-compliance by a subject with study procedures; or

2) Research conducted for the VA under a contract with an individual or a non-VA institution.

Care for injured VA research subjects must be provided in VA medical facilities, except in the following situations:

- If VA facilities are not capable of furnishing economical care or are not capable of furnishing the care or services required. Under these circumstances, VA facility Directors may contract for such care (38 CFR 17.85(b)(1)).
- If inpatient care must be provided to a non-Veteran under this paragraph, VA facility Directors may contract for such care.

The sponsor cannot bill the injured subject’s insurance company for the injury; however, the sponsor is responsible for reasonable and customary costs incurred for treatment of injury reasonably related to the subject’s participation in the study described in the scope of work except to the extent that:

- The injury is attributable to the negligence or willful misconduct of an indemnitee; or
• The injury is attributable to failure to administer the test article as required in the protocol or to otherwise substantially follow the protocol.
• If a research subject needs treatment in a medical emergency in a non-VA facility for a condition covered by this paragraph, VA facility directors must provide reasonable reimbursement for the emergency treatment in a non-VA facility.

**Credentialing and Privileging for Research at Veterans Administration (VA) Facilities**

Investigators and their staff conducting human subjects research must be credentialed and privileged as required by current local and VA requirements (see VHA Handbook 1100.19 and VHA Directive 2012-030, Credentialing of Health Care Professionals, or successor policy). Investigators and their research staff may only perform those activities in a research study for which they have the relevant credentials and privileges.

**Questions and Additional Information for the IRB**

The IRB Office appreciates questions, information, and feedback.

Contact and location information for the IRB Office is:
- University of South Florida Institutional Review Board
  - 3702 Spectrum Boulevard, Suite 165
  - Tampa, FL 33612
  - (813) 974-5638
  - RSCH-IRB@usf.edu

**Reporting and Management of Concerns**

Questions, concerns, complaints, allegations of undue influence, allegations or findings of non-compliance, or input regarding the HRPP may be reported orally or in writing. Employees are permitted to report concerns on an anonymous basis. Concerns may be reported to the IRB Chair, IRB Office, IO/OO, Legal Counsel, Deans, Department Chairs, or via EthicsPoint.

The IRB has the responsibility to investigate allegations and findings of non-compliance and take corrective actions as needed. The IO/OO has the responsibility to investigate all other reports and take corrective actions as needed.

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

To make such reports, contact the OO:
- Julie Moore, Director, Research Integrity & Compliance
  - juliemoore@usf.edu
**Monitoring and Auditing**

In order to monitor and ensure compliance, internal or external auditors who have expertise in federal and state statutes, regulations, and institutional requirements may conduct 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 IO may place limitations or conditions on an investigator’s or research staff’s privileges to conduct human subjects research, whenever in the opinion of the IO such actions are required to maintain the HRPP.

**Approval and Revisions to the Plan**

This HRPP Plan is to be approved by the Senior Vice President of Research, Innovation & Knowledge Enterprise. This plan is intended to be flexible and readily adaptable to changes in regulatory requirements. The IO/OO has the responsibility to review this plan to assess whether it is providing the desired results and amend this plan as deemed necessary.

Approved:

[Signature]

Dr. Paul R. Sanberg
Senior Vice President for Research, Innovation & Knowledge Enterprise

04/29/2020
Date