



VCU

Human Research Protection Program

Plan¹

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Scope

Throughout this document “Institution” refers to Virginia Commonwealth University, and includes VCUarts Qatar, the branch located at Education City in Doha, Qatar.

Purpose

This Institution is committed to protecting the rights and welfare of subjects in Human 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 Research.

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 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 a formal written agreement is in place prior to involving an independent investigator (not acting as agents/employees of VCU, the VCU Health System, or any other institution or facility) who is “engaged” in non-exempt VCU human subjects research, regardless of the funding source, or when an alternate reliance agreement is in place.

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 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 is considered engaged in Human Research when this Institution’s employees or agents for the purposes of the Human 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 guidance

on “Engagement of Institutions in Research”² to apply this definition and exceptions to this definition.

Human Research:

Any activity that either:

- Is “Research” as defined by DHHS and involves “Human Subjects” as defined by DHHS (“DHHS Human Research”); or
- Is “Research” as defined by FDA and involves “Human Subjects” as defined by FDA (“FDA Human 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 are 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 on whose specimen (identified or unidentified) a medical device is used.

² <http://www.hhs.gov/ohrp/policy/engage08.html>

Investigator

The person responsible for the conduct of the Human Research at one or more sites. If the Human 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.³

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

³ 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.

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.

Mission

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 (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/Deputy Institutional Official (IO/DIO), 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
- Justice

Legal Requirements

This Institution commits to apply its ethical standards to all Human Research regardless of funding.

All Human Research must undergo review by 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 is engaged in DHHS Human 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 commits to apply the regulations of that agency relevant to the protection of Human Subjects.

When this Institution is engaged in FDA Human 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 Research should be referred to the IRB Office who will provide a determination.

Other Requirements

When reviewing research that involves community-based research, the IRB obtains consultation or training.

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 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 commits to apply the “International Conference on Harmonisation – Good Clinical Practice E6” (ICH-GCP) when required by industry-sponsored studies.

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 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 D (see table below). 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.

Quick applicability table for DHHS Subparts:

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

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 443.1C which includes the requirements to apply 10 CFR §745 and Subparts B, C, and D of 45 CFR §46, as applicable, and additional DOE requirements outlined in HRP-318 – WORKSHEET – Additional Federal Agency Criteria.

DOE requirements apply to all research conducted with DOE funding, at DOE institutions (regardless of funding source), or by DOE or DOE contractor personnel (regardless of funding source or location conducted), whether done domestically or in an international environment, including classified and proprietary research.

When research involves contractors, DOE “Contractor Requirements Document” describing contractor responsibilities for protecting human research participants must be included in contracts.

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.

When Human Research is subject to Veterans Administration (VA) oversight, this Institution commits to apply VHA Directive 1200.05 requirements, which includes 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 pertained to non-veteran subjects enrolled in Veterans Administration (VA) approved research.

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.

Research conducted internationally, including at the VCUarts Qatar branch, may be subject to additional oversight, including local ethics committee review and/or oversight by the Qatar Ministry of Public Health, as applicable to the research. Contact the HRPP Office for more information.

Sponsored Human Research

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

Scope of Human Research Protection Program

The categories of Human Research overseen include:

- 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.)
- International research.
- Research conducted or funded by the Veteran Administration (VA).
- Research conducted or funded by the Department of Defense (DOD).
 - DOD research involving Experimental Subjects.

- DOD classified research.
- Research on DOD personnel.
- DOD research involving chemical or biological agents under an exception.
- 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).
 - Department of Energy (DOE) human terrain mapping research.
- Research conducted, funded, or subject to oversight by the Environmental Protection Agency (EPA).
- Federally funded research.
- Research involving fetuses.
- Research involving *in vitro* fertilization.
- FDA-regulated research.
- Research involving drugs that require an IND.
- Research involving devices that require an abbreviated IDE.
- Research involving devices that require an IDE issued by FDA.
- Investigator held abbreviated IDE.
- Investigator held IND or IDE.
- Research involving pregnant women as subjects.
- Research involving non-viable neonates.
- Research involving neonates of uncertain viability.
- 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.
- Research involving a waiver of consent for planned emergency research.
- 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.

Human Research Protection Program Policies and Procedures

Policies and procedures for the Human Research Protection Program are available on the following Web site: <https://research.vcu.edu/human-research>.

Human Research Protection Program Components

Institutional Official/Deputy Institutional Official (IO/DIO)

The Vice President for Research and Innovation is designated as the IO.

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

- Review and sign federal assurances (FWA) and addenda.
- Complete recommended Assurance training for the IO.
- Create the Human Research Protection Program budget.
- Allocate resources within the Human Research Protection Program budget.

- Ensure that the HRPP has sufficient resources, space, and staff, including IRBs appropriate for the volume and types of Human Research to be reviewed, so that reviews are accomplished in a thorough and timely manner.
- Appoint and remove IRB members and IRB chairs.
- Ensure that the IRB Chair(s) and members have direct access to the Institutional Official if they have any concerns about the function of the IRB, undue influence, or any issue related to the protection of human research subjects.
- Hire and fire 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 Research.
- Suspend or terminate research approved by one of the Institution's IRBs.
- Disapprove research approved by one of the Institution's IRBs.
- 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.

The DIO, upon appointment by the IO, has been delegated the responsibility to:

- Oversee the review and conduct of Human Research under the jurisdiction of the Human Research Protection Program.
- "Set the tone" by promoting an institutional culture of respect and conscience, so that the ethical conduct of Human Research is supported at the highest levels of the organization.
- Periodically review this plan to assess whether it is providing the desired results and recommend amendments as needed.
- Follow up on findings of serious or continuing non-compliance of IRB staff and IRB members.
- Investigate and remediate identified systemic problem areas, and where necessary remove individuals from involvement in the HRPP.
- Remain current with knowledge of human participant protection regulations to ensure the safe and ethical conduct of research.
- Serve as a liaison between the HRPP Program, IRB, and various University departments, divisions, centers and committees on issues related to research ethics.
- Review questions from research compliance or quality assurance units regarding the seriousness of research non-compliance in studies that are being reviewed.
- Present educational sessions on human studies research as requested at meetings at University locations and representing the University at national and international meetings as requested.
- Partner with IRB leadership to address issues both within the IRB and more broadly at the University that may be related to regulatory compliance or issues negatively affecting research participants.
- Partner with the HRPP Executive Director, Institutional Official, and other research leaders in maintaining full accreditation status of the University's HRPP.

- Partner with HRPP Executive Director and other University leaders to set strategic direction for enhancing the institution's HRPP and research portfolio.
- Make final decisions on IRB membership in collaboration with the HRPP director.
- Participate in the establishment of policies and procedures designed to increase the likelihood that Human Research will be conducted in accordance with ethical and legal requirements.
- Institute regular, effective, educational and training programs for all individuals involved with the Human Research Protection Program.
- Ensure a process is maintained to receive and act on complaints and allegations regarding the Human Research Protection Program.
- Ensure an auditing program is supported to monitor compliance and improve compliance in identified problem areas.
- Ensure a contingency plan exists 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 studies in an emergency/disaster scenario (e.g., natural disasters, man-made disasters, infectious disease pandemics, etc.).
- Maintains a COI management plan and will refer review of any items for which the DIO is conflicted to the IO instead.

Department of Energy (DOE) Institutional Official

The DOE IO:

- Oversees and monitors Departmental implementation of the requirements of DOE O 443.1C, 10 CFR §745, 45 CFR §46 (Other Subparts), as well as related Executive Orders, Presidential Memoranda, and other Presidential directives and international requirements, as applicable, in consultation with the NNSA, as appropriate.
- Reports to the Secretary of Energy for purposes of this function and determines what constitutes Departmental HSR, in consultation with the NNSA.
- Allocates resources for the DOE HSPP.
- Assures policies are in place that require that the research review process be independent and free of coercion and undue influence.
- Implements a process to receive and act on complaints and allegations regarding the DOE HSPP.
- Oversees the Central DOE IRBs and formally appoints all members of the Central DOE IRBs.
- Must approve classified research to be conducted at DOE sites/laboratories after IRB approval and prior to initiation.
- Must concur on all requests for partial or full exemptions from the requirements of DOE O 443.1C.
- Approves and rescinds authorization agreements with other DOE and outside institutions for IRB review.

Department of Energy (DOE) Human Subjects Protection (HSP) Program Manager

The DOE HSP Program Manager:

- Resides within the DOE Office of Biological and Environment Research (BER) and reports to the DOE IO.
- Develops procedures for the HSP program in consultation with the NNSA HSP Program Manager, as appropriate.
- Prepares and updates guidance to be followed for obtaining approval for HSR in consultation with the NNSA HSP Program Manager, as appropriate.
- Reviews and approves (or when an NNSA element is involved, reviews and may recommend approval of) local plans to correct noncompliance or mitigate adverse events and unanticipated problems involving risks to participants or others.
- Reviews and approves statements of work for Human Terrain Mapping (HTM) projects submitted by DOE's non-NNSA sites.
- Provides advice and guidance on evolving Departmental and national bioethics and regulatory issues regarding human research subject protection and helps identify and resolve program/project concerns in consultation with the NNSA HSP Program Manager, as appropriate.
- Develops and conducts educational programs on bioethics and human research subjects protection requirements, practices, and procedures relevant to DOE employees, DOE contractor personnel, financial assistance recipients, and the public in consultation with the NNSA HSP Program Manager, as appropriate.
- Regularly (at least every three years) conducts institutional performance reviews, or quality assurance consultations, to assess compliance with human research subject protection requirements, in consultation with the NNSA HSP Program Manager, as appropriate.
- Serves as the Chair of the DOE Human Subjects Working Group and as official DOE representative to groups with bioethics and HSP interests. The NNSA HSP Program Manager shall co-chair meetings, as appropriate.
- Reviews and, in coordination with the NNSA HSP Program Manager and the Office of Intelligence and Counterintelligence (IN), approves requests for waivers, on a project by project basis, from the DOE requirements for classified research if the reviewing IRB determines that a project that is classified, in whole or in part, can be reviewed in an unclassified manner.
- Makes recommendations to the Secretary after concurrence from the IO, regarding exemptions from any other requirements of DOE O 443.1C, and satisfies the advance notice and publication requirements of 10 CFR §745.101(i) prior to the granting of any exemption (in consultation with the NNSA HSP Program Manager, as appropriate).
- Concurs on human participant provisions in interagency agreements, in consultation with the NNSA HSP Program Manager, as appropriate.

- Maintains the DOE HSR Projects Database and an unclassified list of classified projects.
- Serves as the Co-Chair of the Central DOE IRB-C.

Department of Energy (DOE) National Nuclear Security Administration Human Subjects Protection Program Manager

When an NNSA element or project is involved, the responsibilities of the NNSA HSP Program Manager are identical to those of the DOE HSP Program Manager. The NNSA HSP Program Manager:

- Resides within NNSA NA-10.1, the Office of Strategic Partnership Programs, and reports functionally to the DOE IO.
- Ensures compliance with the DOE/NNSA requirements.
- Works with the DOE HSP Program Manager, as outlined above.
- Serves as the Co-Chair of the Central DOE IRB-C.

Responsibilities of the other DOE HRPP components are described in DOE Order 443.1C.

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 this facility, the resources of this facility, and the size and complexity of the research program at this 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 Directive 1058.03);
- Obtaining approval of the Chief Research and Development Officer (CRADO) if the VA facility wants to establish a new HRPP or change their IRB of Record.
- Ensuring that detailed SOPs are developed and implemented to satisfy all requirements of VHA Directive 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.
 - Each VA-approved human subjects research study must be completely audited in accordance with VHA Directive 1058.01.
 - Each study must be audited for compliance with the regulations and policies on informed consent in accordance with VHA Directive 1058.01.
- Approve the request for permission to conduct international research at this VA facility and ensuring 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 ensuring 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 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.
- Report in writing to the Office of Research Oversight (ORO) within 5 business days after being notified of a failure of a VA medical facility to achieve or maintain full accreditation of its HRPP if such accreditation is sought by the VA medical facility per VHA Directive 1058.01.
- 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:
 - IRB changes in number of IRBs and changes in membership rosters.
 - 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 this 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 not a commercial IRB and is established in accordance with the requirements of the VHA Directive 1200.05 and registered through the ORO to 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 Directive 1058.03 and MOU Checklist: <http://www.va.gov/ORO/orochecklists.asp>); and
- Ensuring 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 Directive 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 apparent 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 apparent 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 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 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/DIO.
- 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/DIO.
- Report allegations or finding of non-compliance with the requirements of the Human Research Protection Program 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, apparent serious or continuing non-compliance, suspension of IRB approval, and termination of IRB approval. This requirement is in addition to other applicable reporting requirements (e.g., reporting to the sponsor under FDA requirements.)
- Ensure oral notification is provided to the appropriate IRB of Record and ACOS/R&D immediately (i.e., within one hour) upon becoming aware of any local research death of a human subject that is believed to be both unexpected and related or possibly related to participation in a VA non-exempt human subjects research study. VA personnel must also ensure that follow-up written notification is provided to the appropriate IRB of Record within one (1) business day of becoming aware of such a death.

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

IRBs

The list of IRBs designated by the IO/DIO 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 available from the IRB Office. IRB members and IRB staff have the responsibility to follow Human Research Protection Program policies and procedures that apply to IRB members and staff. The IRB Chair has the responsibility for designating reviewers, finalizing the meeting agenda, and facilitating the meeting.

Relying on an External IRB

This Institution may rely upon IRBs of another institution or organization provided one of the following is true:

- The IRBs are part of an AAHRPP accredited institution or organization.
- The IRBs are not part of an AAHRPP accredited institution or organization, but where reasonable steps have been taken to ensure that subjects are adequately protected. For example, for research that is no greater than Minimal Risk, there may be an assurance that the IRBs will adhere to applicable ethical standards and regulations. For research that is greater than Minimal Risk, the institutions may agree on more extensive oversight.
- The IRBs are part of an established reliance network (e.g., Smart IRB) that has established contractual and SOP-level procedures to clarify the roles and responsibilities associated with IRB reliance and to establish mechanisms to ensure quality and consistency in the review process among institutions.
- The sIRB has been pre-determined by study sponsor or grant or established by prior arrangement.
- 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.)

Reliance on an external IRB requires an Authorization Agreement and an active Institutional Profile, as well as a local review for compliance with local policies of the Institution. When Human 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.

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

- Approve, require modifications to secure approval, and disapprove all Human Research overseen and conducted by the Institution. All Human Research must be

approved by one of the IRBs designated by the IO/DIO. Officials of this Institution may not approve Human Research that has not been approved by one of the Institution's IRBs.

- Suspend or terminate approval of Human Research not being conducted in accordance with an IRBs' requirements, including when the PI has made no attempt to remediate the protocol in response to a suspension or to provide required modifications within 30 days, or that has been associated with unexpected serious harm to subjects.
- Observe, or have a third party observe, the consent process and the conduct of the Human Research.
- 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 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.

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 in which they have a conflict of interest; and that the IRB separates business functions from ethical review.

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

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

Investigators and Research Staff

Investigators and research staff have the responsibility to:

- Follow the Human Research Protection Program requirements described in HRP-103 - INVESTIGATOR MANUAL.
- Comply with all determinations and additional requirements of the IRB, the IRB chair, and the IO/DIO.
- Develop and implement emergency/disaster response procedures for their research depending on location and nature of the research.

Legal Counsel

Legal Counsel has the responsibility to:

- Provide advice upon request to the IO/DIO, IRB, 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 Research is conducted in jurisdictions not covered by policies and procedures.
- Resolve conflicts among applicable laws.
- Determine whether any Human 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 Research in their department or school.
- Forward complaints and allegations regarding the Human Research Protection Program to the IO/DIO.
- Ensure that each Human Research study conducted in their department or school has adequate resources.

Office of Sponsored Programs

The Office of Sponsored Programs has the responsibility to review contracts and funding agreements for compliance with Human Research Protection Program policies and procedures.

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. The Veterans Administration (VA) Research and Development Committee has delegated its responsibility to conduct scientific review to the IRB.

Education and Training

This plan is made available to the human 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 various email list-serve groups targeted to appropriate audiences.

IRB members, IRB staff, and others involved in the review of Human Research, including the IO/DIO, must complete initial and continuing training utilizing the Collaborative Institutional Training Initiative (CITI) human subjects online training program. Training is valid for a two-year period, after which time refresher training must be completed. Refresher training may be repeated for a total of 3 times, at which point the Basic Training Course should be repeated.

Investigators and research staff must complete the initial and continuing training described in HRP-103 - INVESTIGATOR MANUAL.

HRPP staff will coordinate with organizational officials in the development and implementation of training materials related to emergency preparedness and response plans specific to human research conducted at the organization. The HRPP emergency preparedness plan will be made available to the human research community via the IRB website. The organization is responsible for notifying research teams when the organization's emergency response plan is activated.

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:

Treatment for injuries due to non-compliance by a subject with study procedures.

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

Care for VA research subjects under this Paragraph 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.

Emergency Preparedness

The organization routinely assesses potential emergency scenarios and threats to the institution to improve its emergency preparedness and response plan. The HRPP Director, or their designee, collaborates with organizational leadership to develop, implement, and assess emergency preparedness procedures for the HRPP.

Depending on the nature of the event, the HRPP Director will collaborate with institutional leadership to determine the types of research that might continue and the types that the organization may need to temporarily postpone. The organization proactively identifies external IRBs on which it can rely on temporarily during an emergency.

The IRB staff will work with IT resources and/or electronic system vendors to ensure continuity of operations in the event that electronic systems are inaccessible or not operational for extended periods of time during an emergency/disaster. The HRPP Director will collaborate with the vendor of the IRB's electronic system to ensure that records are maintained on a secure server that is accessible in the event of an emergency.

The organization will implement alternative review procedures, including leveraging online and virtual platforms, to ensure that IRB meetings can continue in scenarios where the IRB cannot meet in person. In instances where the convened IRB is unable to meet and IRB approval for a study may lapse, the IRB Chair can determine whether subjects can continue to participate in research activities if it is in the best interest of already enrolled subjects.

Questions and Additional Information for the IRB

The IRB Office wants your questions, information, and feedback.

Contact and location information for the IRB Office is:

Sanjur Brooks, DPS
Director, VCU Human Research Protection Program

Office of the Vice President for Research and Innovation
800 East Leigh Street, Suite 3000
Richmond, VA 23298
Email: HRPP@vcu.edu
804-828-0868

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 IRB Chair, IRB Office, IO/DIO, Legal Counsel, Deans, or Department Chairs.

The IRB has the responsibility to investigate allegations and findings of non-compliance and take corrective actions as needed. The IO/DIO 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/DIO or designee.

To make such reports, contact the IO:

Srirama Rao, Ph.D.
Vice President for Research and Innovation
Office of the Vice President for Research and Innovation
800 East Leigh Street, Suite 3000
Richmond, VA 23219
Email: vpresearch@vcu.edu
(804) 827-2262

Or, DIO:

F. Gerard Moeller, M.D.
Associate Vice President
Division of Clinical Research
800 East Leigh Street, Suite 3000
Richmond, VA 23219
Email: frederick.moeller@vcuhealth.org
(804) 828-4134

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 will 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/DIO may place limitations or conditions on an investigator's or research staff's privilege to conduct Human Research whenever in the opinion of the IO/DIO such actions are required to maintain the Human Research Protection Program.

Approval and Revisions to the Plan

This Human Research Protection Program Plan is to be approved by the VP for Research and Innovation. This plan is intended to be flexible and readily adaptable to changes in regulatory requirements. The IO/DIO has the responsibility to review this plan to assess whether it is providing the desired results. At the request of the IO/DIO, the HRPP Director has the authority to amend this plan as deemed necessary.

Approved:

P. Srirama Rao, Ph.D

Vice President for Research and Innovation

Appendix A-1: IRB Charter

Virginia Commonwealth University's Institutional Review Board (IRB) Charter

Origination Date: January 1, 2024

1. Introduction

This Charter outlines the establishment, responsibilities, and operations of the Virginia Commonwealth University (VCU) Institutional Review Board (IRB). The VCU IRB is dedicated to ensuring the ethical conduct of research involving human participants and compliance with all relevant regulations, including but *not limited to* the Common Rule (45 CFR 46) and the principles outlined in the Belmont Report.

The IRB reviews federally supported research proposals and non-federal funded research proposals that involve human subjects. The IRB is charged with evaluating each project's compliance with ethical standards in regard to issues such as informed consent, confidentiality, and any risk to the participants per 46 CFR 46 subpart A_.111. Criteria for IRB Approval. In short, the IRB acts to ensure that the individuals involved in the project are treated ethically.

Principal Investigators (PIs), Co-Investigator(s), and/or designee seeking to conduct federally supported, non-federal supported, or unfunded research proposals involving human subjects may not solicit subject participation or begin data collection until they have obtained approval and/or clearance from the VCU IRB or Human Research Protection Program when relying on an external IRB of Record. Some research projects involving human subjects are exempt from IRB approval requirements, and others might only need an expedited, rather than a full review.

1. Institutional Authority

This Charter and Standard Operating Procedures via the VCU Policy Toolkit formalize the structure and operations of the VCU IRB. The VCU IRB is registered as a single panel, denoted as Panel A, which encompasses two distinct subcommittees: (1) Clinical Trials and (2) Biomedical and Social Behavioral. The federal Office for Human Research Protections (OHRP) recognizes this structure under the registration numbers IRB00000410 (IORG0000244) and Federal Wide Assurance # FWA00005287. In subsequent references, this composite structure, including the single panel and its subcommittees, will be collectively termed "the IRB."

1. Mission and Purpose of the IRB

The purpose of the VCU IRB is to protect the rights, safety, and well-being of human participants in research conducted under the auspices of VCU. The mission of the IRB is to:

- Review and approve, modify, or disapprove research protocols involving human participants.

- Ensure that all research conducted at VCU complies with ethical principles and regulatory requirements.
- Provide education and guidance to researchers, staff, and the institution to promote ethical research practices.

1. Structure and Composition

The VCU IRB is designed to incorporate key members in accordance with AAHRPP Accreditation Standards, ensuring a comprehensive and well-rounded structure:

4.1.1. Chairperson(s): The Chairperson assumes a critical role in leading IRB meetings, ensuring strict adherence to proper review procedures, and serving as the primary liaison between the IRB and VCU administration.

4.1.2. Vice Chairperson(s): Collaborating closely with the Chairperson, the Vice Chairperson supports the leadership of IRB meetings and assumes responsibilities in their absence, ensuring continuous operational efficacy.

4.1.3. IRB Members: Those serving as IRB Members contribute diverse backgrounds and expertise, including scientists, clinicians, ethicists, and community representatives. Actively engaged in the comprehensive review of research protocols, they significantly contribute to the decision-making process.

4.1.4. IRB Administrator(s): Playing a pivotal role, the IRB Administrator manages administrative functions, provides crucial assistance with protocol submissions, and ensures that the IRB operates in strict compliance with regulatory standards. This role is indispensable for the day-to-day operations of the IRB.

4.1.5. Community Representative(s): In alignment with AAHRPP Accreditation Standards, the inclusion of community members, unaffiliated with the institution, ensures a comprehensive and diverse perspective. This representation effectively champions the interests of the broader community in the IRB's decision-making processes.

4.1.6. Human Research Protection Program (HRPP) Director: The HRPP Director holds overarching responsibility for managing and coordinating the institution's human research protection program, overseeing both the IRB and related activities. Duties include:

- 4.1.6.1. Overseeing and ensuring the effectiveness of the IRB.
- 4.1.6.2. Developing and implementing HRPP policies and procedures.
- 4.1.6.3. Liaising with institutional leadership and regulatory agencies.
- 4.1.6.4. Managing HRPP staff, including the IRB Administrator and Deputy Director.

4.1.7. Nonaffiliated Member: In compliance with AAHRPP Accreditation Standards, a nonaffiliated member enhances the diversity and independence of the IRB, contributing to the ethical review of research protocols.

4.1.8. Deputy Director of the HRPP: Collaborating closely with the HRPP Director, the Deputy Director of the HRPP manages day-to-day operations. Responsibilities encompass:

- 4.1.8.1. Assisting in the development and implementation of HRPP policies and procedures.
- 4.1.8.2. Managing HRPP staff and resources.
- 4.1.8.3. Ensuring compliance with regulations and ethical standards.
- 4.1.8.4. Serving as a point of contact for the IRB Administrator and research community representatives.

This meticulously structured framework ensures the effective and comprehensive functioning of the VCU IRB, incorporating leadership, expertise, and community representation, while aligning with the rigorous standards set forth by AAHRPP Accreditation.

It should be noted that to fulfill regulatory requirements for a quorum to convene a full board meeting, an IRB member may hold more than one role within the committee structure.

1. Responsibilities and Duties

The VCU IRB has the following responsibilities:

- 5.1. Review research protocols to assess and verify their ethical, scientific, and regulatory aspects.
- 5.2. Approve, modify, or disapprove research protocols.
- 5.3. Conduct continuing reviews of ongoing research.
- 5.4. Review and approve informed consent processes and documents.
- 5.5. Monitor and review unanticipated problems, adverse events, and protocol deviations.
- 5.6. Educate and provide guidance to researchers, staff, and students on ethical and regulatory matters.
- 5.7. Maintain accurate records of IRB activities and decisions.
- 5.8. Report to relevant authorities as required by regulations.
- 5.9. Establish and maintain policies and procedures for IRB operations.

1. Meetings and Decision-Making

The VCU IRB will convene regularly to review research protocols. A quorum, consisting of a majority of members, must be present for decisions to be made. Decisions will be made by a majority vote, with abstentions allowed.

1. Confidentiality and Conflict of Interest

All IRB members, administrators, and support staff must adhere to strict confidentiality regarding research protocols and discussions. Any member with a conflict of interest related to a particular research protocol must recuse themselves from the review and decision-making process.

1. Review Procedures

The VCU IRB will follow the policies and standardized procedures for the submission, review, and approval of research protocols, as outlined in the VCU Toolkit materials.

1. Compliance and Monitoring

The IRB will engage in ongoing self-assessment and may be subject to external audits. Non-compliance with ethical standards or regulatory requirements will be addressed promptly.

1. Amendment and Review of the Charter

This Charter may be amended by a majority vote of the IRB. A periodic review of the Charter will be conducted to ensure alignment with best practices and regulatory changes.

1. Conclusion

The VCU IRB Charter serves as the foundation for the ethical and responsible conduct of research involving human participants. It reflects the commitment of VCU to uphold the highest ethical standards and to protect the rights and well-being of research participants.

Approved by the VCU Institutional Review Board Chairs and Deputy Institutional Official on 4/11/2024

DocuSigned by:

Ronald Evans

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Ronald K. Evans, Ph.D.

Chair of the Social Behavioral and Biomedical Subcommittee

DocuSigned by:

Jill Opalesky

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Jill Opalesky, M.S

Interim Chair of the Clinical Trials Subcommittee

DocuSigned by:

Frederick Moeller

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F. Gerard Moeller, MD

Deputy Institutional Official

Disclaimer:

This Institutional Review Board (IRB) Charter serves as a formal documentation of the existing practices and principles upheld by Virginia Commonwealth University (VCU) IRB. The VCU IRB has been actively reviewing and overseeing research involving human participants prior to the establishment of this Charter. The creation of this Charter is part of the VCU Human Research Protection Program (HRPP) Transformation and serves as a formality to align with evolving institutional structures and regulatory requirements.

The content of this Charter reflects the ongoing commitment of the VCU IRB to uphold ethical standards, protect the rights and well-being of human participants, and ensure compliance with relevant regulations, including but not limited to the Common Rule (45 CFR 46) and the principles outlined in the Belmont Report.

The VCU IRB acknowledges that its responsibilities, processes, and procedures have been in effect and operational before the development of this formal Charter. This document is intended to provide transparency, clarity, and alignment with the broader HRPP Transformation initiatives within VCU

Any references to the establishment or origination of the IRB within this Charter should be understood in the context of this formal documentation process and the institutional commitment to continuous improvement and alignment with best practices in human research protection.

This disclaimer is issued to clarify that the creation of the IRB Charter is not indicative of a new establishment but rather a formalization of existing practices and an integral component of the ongoing HRPP Transformation at VCU.