VCU Research and Innovation

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Human Research Protection Program

Plan[1]

Revised 11/12/2024

[1] This document satisfies AAHRPP elements I.1.A-G, I-2, I-3, I.4.B-C, I.5.A, I.5.C, I.5.D, I.6.B, I.7.A, I.7.C, I-9, II.1.B, II.2.C, II.2.G, II.2.H, II.2.E-II.2.E.2, II.3.C-II.3.C.1, II.3.E, II.3.F, III.1.A, III.1.C, III.2.A, III.2.D

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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:

[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.

- Must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act

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

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 the research team or other clinicians in exchange for referrals of potential research subjects ("finder's fees") and payments (including offers for unrestricted grants/gifts) to the research team or the institution designed to accelerate recruitment that were tied to the rate or timing of enrollment ("bonus recruitment 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.

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- 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.

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- 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.

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- 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 1200.05and 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).

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- 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.

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- 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.

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- 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 an 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 the refresher course must be completed. After 9 refresher courses, a basic course must be taken again. 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:

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

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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.

HRP-103 | 11/26/2024 | Author: T. Bechert | Approver: J. Opalesky

Investigator Manual[1]

[1]This document satisfies AAHRPP element I.1.A, I.1.C-I.1.E, I-3, I.4.C, I.5.C, I.5.D, I.6.B, I.7.A-I.7.C, I-9, II.2.A, II.2.C, II.2.G, II.2.E-II.2.E.2, II.2.F-II.2.F.3, II.2.I, II.3.C-II.3.C.1, II.3.E, II.3.F, II.3.G, II.4.A, II.4.B, II.5.A, II.5.B, III.1.A, III.1.B, III.1.D, III.1.E, III.1.F, III.2.A, III.2.C, III.2.D

Table of Contents

Scope

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

What is the purpose of this manual?

This document, HRP-103 - INVESTIGATOR MANUAL, is designed to guide you through policies and procedures related to the conduct of Human Research that are specific to this institution.

General information regarding Human Research protections and relevant federal regulations and guidance is incorporated into the required human protections training. For additional information see below: “What training do my staff and I need in order to conduct Human Research?”

What is Human Research?

HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN defines the activities that this institution considers to be “Human Research.” An algorithm for determining whether an activity is Human Research can be found in HRP-310 - WORKSHEET - Human Research Determination, located in the IRB Policies & Procedures section of the IRB website. Use this document for guidance as to whether an activity meets either the DHHS or FDA definition of Human Research, keeping in mind that the IRB makes the ultimate determination in questionable cases as to whether an activity constitutes Human Research subject to IRB oversight.

You are responsible not to conduct Human Research without prior IRB review and approval (or an institutional review and determination of exempt Human Research). If you have questions about whether an activity is Human Research, contact the IRB Office who will provide you with a determination. If you wish to have a written determination, submit a request for determination in RAMS-IRB using HRP-503b - TEMPLATE NHSR.

What is the Human Research Protection Program?

HRP-101 – HUMAN RESEARCH PROTECTION PROGRAM PLAN describes this institution’s overall plan to protect subjects in Human Research.

- The mission of the Human Research Protection Program.
- The ethical principles that the institution follows governing the conduct of Human Research.
- The applicable laws that govern Human Research.
- When the institution becomes “engaged in Human Research” and when someone is acting as an agent of the institution conducting Human Research.
- The types of Human Research that may not be conducted.
- The roles and responsibilities of individuals within the institution.

Who can serve as Principal Investigator and what training do my staff and I need to conduct Human Research?

The PI must be available to devote adequate time and attention to the study to ensure its responsible conduct. In light of these responsibilities, the VCU Institutional Review Board (IRB) requires the individual holding the title of PI for a human research protocol be:

● A permanent, full-time or part-time employee of VCU or the VCUHSA; OR

● A non-employee with a VCU faculty appointment who will conduct research within the scope of their appointment and provides the following to the Institutional Review Board (IRB):

o A copy of the current appointment letter

o The PI Eligibility Request form available on the HRPP website (completed and signed by both the appropriate Department Chair and Dean).

Those ineligible to serve as PI include:
● Employees who are also students and are submitting their student projects
● Undergraduate and graduate students
● Post-doctoral students
● Fellows, residents
● House staff
● Hourly and PRN staff (“pro re nata” or “as the situation demands”)
● Volunteers

This section describes the training requirements imposed by the IRB. You may have additional training imposed by other federal, state, or institutional policies.

Investigators and staff conducting research must complete the Collaborative Institutional Training Initiative (CITI) human subjects online training program. The course that applies to the majority of research conducted or supported by the individual should be taken.

The CITI site can be accessed at http://www.citiprogram.org/.

Training is valid for a 2-year period, after which time the refresher course must be completed. After 9 refresher courses, a basic course must be taken again.

All members of the research team involved in the design, conduct, or reporting of the research must complete training. Members of the research team who have not completed human research protections training may not take part in aspects of the research that involve human subjects.

CITI training completion certificates must be uploaded for the Principal Investigator (and Medically or Psychologically Responsible Investigator, and Lead Student/Trainee Investigator, if applicable) for each new submission, continuing review, or newly added investigator.

What financial interests do my staff and I need to disclose to conduct Human Research?

Individuals involved in the design, conduct, or reporting of research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards are considered to have an institution responsibility.

Personnel who are involved in the design, conduct, or reporting of research, and have been designated by the PI as COI Investigators, are required to disclose the financial interests in the New Study SmartForm in RAMS-IRB and RAMS-AIRS.

- On submission of an initial review.
- At least annually as part of continuing review.
- Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest.

Individuals with reimbursed or sponsored travel by an entity other than a federal, state, or local government agency, higher education institution or affiliated research institute, academic teaching hospital, or medical center are required to disclose the purpose of the trip, the identity of the sponsor or organizer, the destination, and the duration of the travel.

Individuals subject to this policy are required to complete financial conflicts of interest training initially, at least every four years, and immediately when:

- Joining the institution
- Financial conflicts policies are revised in a manner that changes investigator requirements
- Non-compliant with financial conflicts policies and procedures

Additional details can be found in the VCU Conflicts of Interest in Research policy available at:

https://vcu.public.doctract.com/doctract/documentportal/08DA32A63EDBCC96C898EA6EC61CFF0A.

Additional information about the VCU Conflict of Interest in Research Program may be found at: https://research.vcu.edu/integrity-and-compliance/integrity-and-ethics/conflicts-of-interest-in-research/.

How do I submit new Human Research to the IRB?

Complete the New Study SmartForm in the electronic IRB system and attach all requested supplements, have the SmartForm submitted by the PI by clicking the “Submit” activity. Maintain electronic copies of all information submitted to the IRB in case revisions are required. Before submitting the research for initial review, you must:

- Obtain the financial interest status (“yes” or “no”) of each research staff.
- Obtain the agreement of research staff to his/her role in the research.

How do I submit a request to use a Humanitarian Use Device (HUD) for clinical use?

This Institution utilizes the IRB to review and approve the use of a HUD before it can be used at a facility for clinical care. You can refer to HRP-323 - WORKSHEET - Criteria for Approval HUD for additional information regarding the criteria that the IRB uses to review and approve HUD uses. The clinical use of a HUD is not considered Human Research but must still be submitted for review and approval by the IRB prior to clinical use (with the exception of emergency use). An informed consent form is not required by the IRB for the clinical use of an HUD. Informed consent is required for HUDs used for research.

Complete the New Study SmartForm in the electronic IRB system and attach all requested supplements, have the SmartForm submitted by the PI by clicking the "Submit" activity. Maintain electronic copies of all information submitted to the IRB in case revisions are required. Before submitting the research for initial review, you must:

- Obtain the financial interest status ("yes" or "no") of each research staff.
- Obtain the agreement of research staff to his/her role in the research.

When is single IRB review required?

Any cooperative nonexempt human subjects research subject to the Common Rule requires use of single IRB. This requirement applies to that portion of the research that is conducted in the United States. See Appendix A-10.

When will this IRB serve as the IRB of record (sIRB) or rely on an external IRB?

For criteria used to determine whether this institution will serve as the sIRB, refer to HRP-833 - WORKSHEET – Considerations for Serving as the sIRB. For criteria used to determine whether this institution will rely on an external IRB, refer to HRP-832 – WORKSHEET – Considerations for Relying on an External IRB. An Authorization Agreement(s) must be in place before this IRB can serve as the sIRB or rely on an external IRB.

When should I submit a request to rely on an External IRB?

For studies where this institution is a participating site (pSite), requests to rely on an external IRB should be submitted after the reviewing IRB (sIRB) has approved the study (e.g., lead site protocol), including consent templates and other document templates.

How do I request to rely on an external IRB?

Complete the New Study SmartForm in the electronic IRB system, indicate that an External IRB will serve as the IRB of Record and attach all requested supplements. Have the SmartForm submitted by the PI by clicking the "Submit" activity. Maintain electronic copies of all information submitted to the IRB in case revisions are required.

When should I consult with this IRB when planning a study for which this IRB will be asked to serve as the IRB of record (sIRB)?

If you will request this IRB to serve as the reviewing IRB (sIRB) for cooperative research, contact the IRB Office prior to submitting grant or other funding applications to determine whether this IRB will agree to serve as the sIRB for the study.

How do I request that this IRB serve as the IRB of record (sIRB) for my collaborative or multi-site research study?

When proposing VCU serve as the reviewing IRB, study teams MUST consult with irbreliance@vcu.edu prior to submitting grant or other funding applications. VCU cannot guarantee it will serve as the reviewing IRB without prior consultation. If VCU is not able to serve as the reviewing IRB, VCU HRPP will assist you in identifying another IRB that can serve as the single IRB.

If the study is a multicenter study where all sites have their own PI and will follow a standardized protocol, your initial submission in RAMS-IRB should not identify any relying sites. The VCU IRB will approve the protocol and template forms, such as informed consent. After the initial submission is approved, you should submit an amendment to add non-VCU sites.

How do I write an Investigator Protocol?

Use HRP-503 – TEMPLATE PROTOCOL as a starting point for drafting a new Investigator Protocol, and reference the instructions in italic text for the information the IRB looks for when reviewing research. Here are some key points to remember when developing an Investigator Protocol:

- The italicized bullet points in HRP-503 - TEMPLATE PROTOCOL serve as guidance to investigators when developing an Investigator Protocol for submission to the IRB. All italicized comments are meant to be deleted prior to submission.
- For any items described in the sponsor's protocol or other documents submitted with the application, investigators may simply reference the page numbers of these documents within the Investigator Protocol rather than repeat information.
- When writing an Investigator Protocol, always keep an electronic copy. You will need to modify this copy when making changes to the Investigator Protocol.
- If you believe your activity may not be Human Research, contact the IRB Office prior to developing your Investigator Protocol.
- Note that, depending on the nature of your research, certain sections of the template may not be applicable to your Investigator Protocol. Indicate this as appropriate.
- You may not involve any individuals who are members of the following populations as subjects in your research unless you indicate this in your inclusion criteria as the inclusion of subjects in these populations has regulatory implications.

    - Adults unable to provide legally effective consent
    - Individuals who are not yet adults (infants, children, teenagers)
    - Pregnant women
    - Prisoners
- If you are conducting investigator-initiated treatment (IIT), consult with the OVPRI Regulatory Affairs FDA Program staff in advance of submission to FDA. IIT protocols must add an institutionally-required monitor.
- If you utilize investigational drugs and/or biologics in the research, Investigational Drug Services Pharmacy must be consulted; use of outpatient study drugs may require a Drug Management Plan.
- If you are conducting community-based participatory research, you may contact the IRB Office for information about:
    - Research studies using a community-based participatory research design
    - Use of community advisory boards
    - Use of participant advocates
    - Partnerships with community-based institutions or organizations
- If you are conducting international research, additional review requirements and regulations may apply. This includes research conducted at the VCUarts Qatar branch, where oversight may be required by the Qatar Ministry of Public Health, as applicable to the research. Contact the HRPP Office for more information.

How do I create a consent document?

Use HRP-502 – TEMPLATE CONSENT DOCUMENT to create a consent document.

Note that all long form consent documents and all summaries for short form consent documents must contain all of the required and all additional appropriate elements of informed consent disclosure. Review the “Long Form of Consent Documentation” section in HRP-314 – WORKSHEET – Criteria for Approval, to ensure that these elements are addressed. When using the short form of consent documentation, the appropriate signature block from HRP-502 – TEMPLATE CONSENT DOCUMENT should be used on the short form.

If your research study meets the requirements for an exemption and there are interactions with subjects, you may use an abbreviated process for obtaining consent. Consent can be verbal, but you must provide the following information to participants through an information sheet or written script:

- The subject is being asked to participate in a research study;
- A description of the procedure(s) the participant will be asked to complete;
- Participation is voluntary; and
- The investigator’s name and contact information.

Translated consent documents should be submitted to the IRB along with a signed statement by the translator attesting that they understand English and the target language; the translator's credentials should be included. For minimal risk research, the PI may instead describe the qualifications of the translator (e.g., native speaker, experience living where the language is spoken, college-level preparation in the language) and the IRB will determine whether additional verification is required.

The Division of Sponsored Programs must review subject injury language included in the consent document for industry-funded studies. More information is available on their website: https://research.vcu.edu/forms/.

Payments to research subjects must comply with VCU Office of Procurement Services procedures available on their website: https://procurement.vcu.edu/i-want-to/pay-an-individual/compensate-a-research-participant/. Payments must be described in both the protocol and consent or information documents.

We recommend that you date the revisions of your consent documents to ensure that you use the most recent version approved by the IRB.

Do I need to obtain informed consent, including HIPAA authorization, in order to screen, recruit, or determine the eligibility of prospective subjects?

The IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:

> (1) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, OR
>
> (2) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

The research protocol should include information about how potential subjects will be identified and recruited in order for the IRB to be able to determine whether informed consent for these activities is required.

Certain preparatory to research activities by VCU covered entities (e.g., VCUHS, VCU School of Dentistry) may be conducted without obtaining HIPAA authorization and/or waiver or alteration of HIPAA. This provision allows a researcher to identify prospective research participants for purposes of seeking their authorization to use or disclose protected health information for a research study. This may include activities to aid study recruitment; for example, review of records while on-site at the covered entity, contacting prospective research subjects, or discussion of the option of enrolling in a clinical trial with prospective subjects. Under the

provision, a researcher may not remove protected health information from the covered entity's site.

Contact the IRB Office with additional questions or for further guidance regarding the requirement to obtain HIPAA authorization or a waiver to obtain HIPAA authorization for recruitment purposes.

What are the different regulatory classifications that research activities may fall under?

Submitted activities may fall under one of the following four regulatory classifications:

- Not "Human Research": Activities must meet the institutional definition of "Human Research" to fall under IRB oversight. Activities that do not meet this definition of are not subject to IRB oversight or review. Review the IRB Office's HRP-310 – WORKSHEET – Human Research Determination for reference. Contact the IRB Office in cases where it is unclear whether an activity is Human Research.
- Exempt: Certain categories of Human Research may be exempt from regulation but require IRB review. It is the responsibility of the institution, not the investigator, to determine whether Human Research is exempt from IRB review. Review the IRB Office's HRP-312 – WORKSHEET – Exemption Determination for reference on the categories of research that may be exempt.
- Review Using the Expedited Procedure: Certain categories of non-exempt Human Research may qualify for review using the expedited procedure, meaning that the project may be approved by a single designated IRB reviewer, rather than the convened board. Review the IRB Administration's HRP-313 – WORKSHEET – Expedited Review for reference on the categories of research that may be reviewed using the expedited procedure.
- Review by the Convened IRB: Non-Exempt Human Research that does not qualify for review using the expedited procedure must be reviewed by the convened IRB.

What are the decisions the IRB can make when reviewing proposed research?

The IRB may approve research, require modifications to the research to secure approval, table research, defer research or disapprove research:

- Approval: Made when all criteria for approval are met. See "How does the IRB decide whether to approve Human Research?" below.
- Modifications Required to Secure Approval: Made when IRB members require specific modifications to the research before approval can be finalized.
- Tabled: Made when the IRB cannot approve the research at a meeting for reasons unrelated to the research, such as loss of quorum. When taking this action, the IRB automatically schedules the research for review at the next meeting.

- Deferred: Made when the IRB determines that the board is unable to approve research and the IRB suggests modifications that might make the research approvable. When making this motion, the IRB describes its reasons for this decision, describes modifications that might make the research approvable, and gives the investigator an opportunity to respond to the IRB in person or in writing.
- Disapproval: Made when the IRB determines that it is unable to approve research and the IRB cannot describe modifications that might make the research approvable. When making this motion, the IRB describes its reasons for this decision and gives the investigator an opportunity to respond to the IRB in person or in writing.

How does the IRB decide whether to approve Human Research?

The criteria for IRB approval can be found in HRP-312 – WORKSHEET – Exemption Determination for exempt Human Research and HRP-314 – WORKSHEET – Criteria for Approval for non-exempt Human Research. The latter worksheet references other checklists that might be relevant. All checklists and worksheets can be found on the IRB Web site.

These checklists are used for initial review, continuing review, and review of modifications to previously approved Human Research.

You are encouraged to use the checklists to write your Investigator Protocol in a way that addresses the criteria for approval.

What will happen after IRB review?

The IRB will provide you with a written decision indicating that the IRB has approved the Human Research, requires modifications to secure approval, or has disapproved the Human Research.

- If the IRB has approved the Human Research: The Human Research may commence once all other institutional approvals have been met. IRB approval is usually good for a limited period of time which is noted in the approval letter.
- If the IRB requires modifications to secure approval and you accept the modifications: Make the requested modifications and submit them to the IRB. If all requested modifications are made, the IRB will issue a final approval. Research cannot commence until this final approval is received. If you do not accept the modifications, write up your response and submit it to the IRB.
- If the IRB defers the Human Research: The IRB will provide a statement of the reasons for deferral and suggestions to make the study approvable and give you an opportunity to respond in writing. In most cases if the IRB's reasons for the deferral are addressed in a modification, the Human Research can be approved.
- If the IRB disapproves the Human Research: The IRB will provide a statement of the reasons for disapproval and give you an opportunity to respond in writing.

In all cases, you have the right to address your concerns to the IRB directly at an IRB meeting.

What are my obligations after IRB approval?

1) Do not start Human Research activities until you have the final IRB approval letter.
2) Do not start Human Research activities until you have obtained all other required institutional approvals, including approvals of departments or divisions that require approval prior to commencing research that involves their resources.
3) Ensure that there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space.
4) Ensure that Research Staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials, protocol requirements and, when relevant, privileges) to perform procedures and duties assigned to them during the study.
5) Update the IRB office with any changes to the list of study personnel.
6) Personally conduct or supervise the Human Research. Recognize that the investigator is accountable for the failures of any study team member.
    a) Conduct the Human Research in accordance with the relevant current protocol as approved by the IRB, and in accordance with applicable federal regulations and local laws.
    b) When required by the IRB ensure that consent or permission is obtained in accordance with the relevant current protocol as approved by the IRB.
        i) Assessment of decision making capacity tool (for reference only): https://research.vcu.edu/media/office-of-research-and-innovation/humanresearch/ICEval.doc
    c) Do not modify the Human Research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects.
    d) Protect the rights, safety, and welfare of subjects involved in the research.
7) Submit to the IRB:
    a) Proposed modifications as described in this manual. (See "How do I submit a modification?")
        i) Single subject protocol exceptions should be submitted via the modification process.
        ii) Modifications requested in response to a Suspension of IRB Approval must be submitted within 30 days. Studies with no remediation attempt will be referred to the convened IRB for Termination of IRB Approval.
    b) A continuing review application as requested in the approval letter. (See "How do I submit continuing review?")
    c) A continuing review application when the Human Research is closed. (See "How Do I Close Out a Study?")
8) Complete the Report New Information SmartForm within 5 business days of becoming aware of any of the following information items:
    a) Information that indicates a new or increased risk, or a new safety issue. For example:
        i) New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor report, or investigator finding) indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk.

ii) An investigator brochure, package insert, or device labeling is revised to indicate an increase in the frequency or magnitude of a previously known risk, or describe a new risk
iii) Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol
iv) Protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm
v) Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm
vi) Any changes significantly affecting the conduct of the research

b) Harm experienced by a subject or other individual, which in the opinion of the investigator are **unexpected** and **probably related** to the research procedures.
   i) A harm is "unexpected" when its specificity or severity are inconsistent with risk information previously reviewed and approved by the IRB in terms of nature, severity, frequency, and characteristics of the study population.
   ii) A harm is "probably related" to the research procedures if in the opinion of the investigator, the research procedures more likely than not caused the harm.
c) Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such non-compliance.
d) Audit, inspection, or inquiry by a federal agency and any resulting reports (e.g. FDA Form 483.)
e) Written reports of study monitors that represent information described in 8(a) or (b) above; all other study monitor reports (e.g., reflects administrative changes or updates only) may be submitted at the time of continuing review.
f) Failure to follow the protocol due to the action or inaction of the investigator or research staff that represents a potential increase in risk of harm to subjects.
g) Breach of confidentiality.
h) Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject.
i) Incarceration of a subject in a study not approved by the IRB to involve prisoners.
j) Complaint of a subject that cannot be resolved by the research team.
k) Premature suspension or termination of the protocol by the sponsor, investigator, or institution.
l) Unanticipated adverse device effect (any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects).

9) Submit an updated disclosure of financial interests per VCU requirements within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest.
10) Do not accept or provide payments to the research team or other clinicians in exchange for referrals of potential research subjects ("finder's fees.")

11) Do not accept payments (including offers for unrestricted grants/gifts) to the research team or the institution designed to accelerate recruitment that were tied to the rate or timing of enrollment ("bonus recruitment payments.")
12) See additional requirements of various federal agencies in Appendix A. These represent additional requirements and do not override the baseline requirements of this section.
13) If the study is subject to the revised 2018 Common Rule, a clinical trial, and is supported by a Common Rule agency, one IRB-approved version of a consent form that has been used to enroll participants must be posted on a public federal website designated for posting such consent forms. The form must be posted after recruitment closes, and no later than 60 days after the last study visit. Please contact the study sponsor with any questions.
    a) If certain information should not be made publicly available on a Federal website (e.g. confidential commercial information), the supporting Federal department or agency may permit or require redactions to the information posted. Contact the Federal department or agency supporting the clinical trial for a formal determination.
    b) Contact the supporting Federal department or agency sponsor with any other questions regarding consent form posting obligations.
    c) The VCU Post Approval Monitoring and Education (PAM&E), when applicable, performs routine or for-cause audits.

What are my obligations as the overall study PI for an sIRB study?

1) Coordinate with HRPP personnel to determine whether this institution's IRB can act as the single IRB for all or some institutions participating in the study or if an external IRB will assume oversight.
2) Identify whether any IRB fees will be charged for this study and address any budget considerations.
3) Identify all sites that will be engaged in the human research and require oversight by the IRB.
4) Ensure that all sites receive a request to rely on the reviewing IRB and that all institutional requirements are satisfied before a study is activated at a relying site.
5) Collaborate with the reviewing IRB to document roles and responsibilities for communicating and coordinating key information from study teams and the IRB or HRPP at relying sites.
6) Respond to questions or information requests from study teams or the IRB or HRPP staff at relying sites.
7) Provide relying site investigators with the policies of the reviewing IRB.
8) Provide relying site investigators with the IRB-approved versions of all study documents, including an approved consent template.
9) Help prepare and submit IRB applications on behalf of all sites. This includes initial review, modifications, personnel updates, reportable new information and continuing review information for all sites.
10) Establish a process for obtaining and collating information from all sites and submitting this information to the reviewing IRB. This includes site-specific variations in study conduct, such as the local consent process and language, subject identification and recruitment processes and local variations in study conduct.
11) Provide pSites with HRP-103p – pSite Manual.

12) Fulfill any communication responsibilities as outlined in HRP-830 – WORKSHEET – Communication and Responsibilities.
13) Use HRP-811- FORM – Basic Site Information, HRP-812 – FORM – Site Continuing Review, HRP-813 – FORM – Site Modification, and 814 – FORM – Site Reportable New Information to collect information from participating sites.
14) Ensure that consent forms used by pSites follow the consent template approved by the reviewing IRB and include required language as specified by the pSites.
15) Provide site investigators with all determinations and communications from the reviewing IRB.
16) Submit reportable new information from pSites to the reviewing IRB in accordance with the terms outlined in the authorization agreement or communication plan.
17) Report the absence of continuing review information from pSites if they do not provide the required information prior to submission of the continuing review materials to the reviewing IRB. Notifying the pSite of their lapse in approval and applicable corrective actions.
18) Provide study records to the relying institution, reviewing IRB or regulatory agencies upon request.

What are my obligations as investigator when relying on an external IRB?

1) Obtain appropriate approvals from this institution prior to seeking review by another IRB.
2) Comply with determinations and requirements of the reviewing IRB.
3) Prepare consent and other study documents that are consistent with those approved by the sIRB (e.g., use the approved consent template to create site-specific documents).
4) Provide the reviewing IRB with requested information about local requirements or local research context issues relevant to the IRB's determination prior to IRB review, including HRP-508 Site Supplement.
5) Notify the reviewing IRB when local policies that impact IRB review are updated.
6) Cooperate in the reviewing IRB's responsibility for initial and continuing review, record keeping and reporting and providing all information requested by the reviewing IRB in a timely manner.
7) Disclose conflicts of interest as required by the reviewing IRB and complying with management plans that may result.
8) Promptly report to the reviewing IRB any proposed changes to the research and not implement those changes to the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to the participants.
9) When enrolling participants, obtain, document and maintain records of consent for each participant or each participant's legally authorized representative.
10) Promptly report to the reviewing IRB any unanticipated problems involving risks to participants or others according to the requirements specified in the reliance agreement.
11) Provide the reviewing IRB with data safety monitoring reports in accordance with the reviewing IRB's reporting policy.
12) Report non-compliance, participant complaints, protocol deviations or other events according to the requirements specified in the reliance agreement.

13) Specify the contact person and provide contact information for researchers and research staff to obtain answers to questions, express concerns, and convey suggestions regarding the use of the reviewing IRB.
14) Fulfill any communication responsibilities as outlined in HRP-830 - WORKSHEET - Communication and Responsibilities.
15) Determine which institutional requirements apply to your study and ensure all are met. Refer to HRP-309 – WORKSHEET – Ancillary Review Matrix.
16) Submit as a follow-on submission in RAMS-IRB prior to submitting to the reviewing IRB:
    a. PI and personnel changes to VCU for approval
    b. Changes to HIPAA pathways
    c. Addition of drugs or devices
    d. Change in research funding
14) Submit as a report in RAMS-IRB when any of the following occur at the VCU site:
    e. An unanticipated problem
    f. The reviewing IRB determined that noncompliance occurred
15) Close the study in RAMS-IRB when the reviewing IRB closes the VCU site.

How do I document consent?

Use the signature block approved by the IRB. Complete all items in the signature block, including dates and applicable checklists.

The following are the requirements for long form consent documents:

- The subject or representative signs and dates the consent document.
  - If the subject/representative is physically unable to sign the consent form, note this on the consent form and document the method used for communication with the prospective subject/representative and the specific means by which their agreement was communicated.
- The individual obtaining consent signs and dates the consent document.
- Whenever the IRB or the sponsor require a witness to the oral presentation, the witness signs and dates the consent document.
- For subjects who cannot read and whenever required by the IRB or the sponsor, a witness to the oral presentation signs and dates the consent document.
- A copy of the signed and dated consent document is to be provided to the subject.

The following are the requirements for short form consent documents:

- The subject or representative signs and dates the short form consent document.
- The person obtaining consent signs and dates the summary.
- The impartial witness (fluent in both English and the language spoken by the subject/representative) to the oral presentation signs and dates the short form consent document and the summary. The witness and the interpreter may be the same person.
- Copies of the signed and dated consent document and summary are provided to the person(s) signing those documents.

How do I submit a modification?

Complete the Modification SmartForm in the electronic IRB system and attach all requested supplements, have the SmartForm submitted by the PI by clicking the “Submit” activity. Maintain electronic copies of all information submitted to the IRB in case revisions are required. Please note that research must continue to be conducted without inclusion of the modification until IRB approval is received. Updates to the list of study personnel will be acknowledged unless the update represents a modification to the research.

How do I submit continuing review?

Complete the Continuing Review SmartForm in the electronic IRB system and attach all requested supplements and have the SmartForm submitted by the PI by clicking the “Submit” activity. Maintain electronic copies of all information submitted to the IRB in case revisions are required.

If the continuing review involves modifications to previously approved research, submit those modifications either as a combined Modification and Continuing Review or as a separate request for modification using the Modification SmartForm the electronic system.

If the continuing review application is not received by the date requested in the approval letter, you will be restricted from submitting new Human Research until the completed application has been received.

If the approval of Human Research expires all Human Research procedures related to the protocol under review must cease, including recruitment, advertisement, screening, enrollment, consent, interventions, interactions, and collection or analysis of private identifiable information. Continuing Human Research procedures is a violation of institutional policy. If current subjects will be harmed by stopping Human Research procedures that are available outside the Human Research context, provide these on a clinical basis as needed to protect current subjects. If current subjects will be harmed by stopping Human Research procedures that are not available outside the Human Research context, immediately contact the IRB chair and provide a written list of the currently enrolled subjects and why they will be harmed by stopping Human Research procedures.

How do I close out a study?

Complete the Continuing Review SmartForm in the electronic IRB system and attach all requested supplements and have the SmartForm submitted by the PI by clicking the “Submit” activity. Maintain electronic copies of all information submitted to the IRB in case revisions are required. If you fail to submit a continuing review form to close out Human Research, you will be restricted from submitting new Human Research until the completed application has been received.

How long do I keep records?

Maintain your Human Research records, including signed and dated consent documents, in compliance with institutional policy issued by VCU Technology Services, and for no less than three years after completion of the research. Maintain signed and dated HIPAA authorizations and consent documents that include HIPAA authorizations no less than six years after completion of the research.

Consult with VCU IT before disposing of any research records to ensure institutional policy is followed.

If your Human Research is sponsored, contact the sponsor before disposing of Human Research records.

What if I need to use an unapproved drug, biologic, or device and there is no time for IRB review?

Contact the IRB Office or IRB chair immediately to discuss the situation. If there is no time to make this contact, see HRP-322 – WORKSHEET – Emergency Use for the regulatory criteria allowing such a use and make sure these are followed. Use HRP-506 – TEMPLATE CONSENT DOCUMENT – Expanded Access to prepare your consent document. You will need to submit a report of the use to the IRB within five working days of the use.

Include in the report a description of how the use meets the criteria outlined in HRP-322 - WORKSHEET – Emergency Use, a summary of the patient's diagnosis and treatment history, and date and time of the use. Attach to the report the consent document templates used (if applicable), approval of the use from the FDA (drugs and biologics), or concurrence letter from an independent physician that the use of the device is warranted and no other alternative treatments are/were available (devices).

If you fail to submit the report within five working days, you will be restricted from submitting new Human Research until the report has been received.

Emergency use of an unapproved drug or biologic in a life-threatening situation without prior IRB review is "research" as defined by FDA, the individual getting the test article is a "subject" as defined by FDA, and therefore is governed by FDA regulations for IRB review and informed consent. FDA contacts for obtaining an emergency IND may be found here: Emergency Use of an Investigational Drug or Biologic | FDA.

Emergency use of an unapproved device without prior IRB review is not "research" as defined by FDA and the individual getting the test article is not a "subject" as defined by FDA. However, FDA guidance recommends following similar rules as for emergency use of an unapproved drug or biologic. FDA must be notified within 5 days of emergency use of a medical device that has an IDE or where no IDE exists. FDA guidance for emergency use of a medical device may be found here: Expanded Access for Medical Devices | FDA.

Individuals getting an unapproved drug, biologic, or device without prior IRB review cannot be considered a "subject" as defined by DHHS and their results cannot be included in prospective "research" as that term is defined by DHHS.

FDA regulations require that any subsequent use of a test article at the institution have prospective IRB review and approval. If it is anticipated that this test article may be used again (for the same patient, a different patient, or for any indication), submit a protocol and consent document(s) to the IRB for review so that an approved protocol will be in place when the next need arises.

How do I submit a non-emergency expanded access request for an unapproved drug, biologic, or device to the IRB?

There are five different types of non-emergency use expanded access:

1. Individual patient expanded access use of an investigational drug

Individual patient drug expanded access requests should be submitted to the IRB as a new study. If the study team checked "Request for Authorization to Use Alternative IRB Review Procedures" on FDA Form 3926 (field 10.b.) or has a separate waiver request included with FDA Form 1571 for the purpose of obtaining concurrence from an IRB Chair or designee, this information should be included in the application. Instead of uploading a protocol, the submission should include the following:

- A thorough patient history and treatment plan, included in the Form FDA 3926 or in a separate document that includes:
    - The proposed daily dose, route, and frequency of administration of planned treatment; duration of planned treatment; criteria for discontinuation of treatment; and planned dose modifications for adverse events;
    - The planned monitoring for adverse events, response to treatment, and changes in clinical status, as well as proposed modifications to the treatment plan to mitigate risks to the patient if appropriate;
    - The key details of the patient's history, including diagnosis and summary of prior therapy (including response to such therapy); the reason for request, including an explanation of why the patient lacks other therapeutic options; and information regarding a patient's relevant clinical characteristics (such as comorbid conditions and concomitant medications) that is necessary to assess the potential for increased risks of the drug; and
    - A summary of known risks of the drug

Use HRP-506 - TEMPLATE CONSENT DOCUMENT - Expanded Access to prepare your consent document. A Continuing Review application must be submitted to the IRB at least annually, and any modifications or new information should be reported accordingly.

2. Compassionate Use (Individual patient/small group access) of a device

Requests for compassionate use of a device should be submitted to the IRB as a new study. See HRP-325 - WORKSHEET - Device Compassionate Use for the regulatory criteria allowing such a use and make sure these are followed. The FDA does not consider the compassionate use of an unapproved device to be a clinical investigation, however it is expected that informed consent be obtained. Use HRP-506 - TEMPLATE CONSENT DOCUMENT - Expanded Access to prepare your consent document.

Instead of uploading a protocol, the submission should include a summary of the conditions constituting the compassionate use, other relevant details of the case, approval from the device manufacturer, device/product manual, FDA authorization, and any other relevant information (i.e., patient-facing materials, etc.). Continuing review is not required for compassionate use, however if any problems occurred as a result of device use, these should be discussed in the follow-up report and reported to the IRB as soon as possible.

3. Intermediate-size patient population access of a drug
4. Expanded access for widespread use of a drug
5. Treatment use of a device

Requests for any of these three (3) types of expanded access use should be submitted to the IRB as a new study. Submissions should include the protocol, consent form, and other pertinent information (i.e., Investigator's Brochure, device/product manual, patient-facing materials, etc.). Use HRP-502 - TEMPLATE CONSENT DOCUMENT to prepare your consent document. A Continuing Review application must be submitted to the IRB at least annually, and any modifications or new information should be reported accordingly.

How do I transfer responsibility to a new principal investigator?

Changes of PI often prompt changes to other parts of the study. Review all consent/assent forms, recruitment materials and other documents to make certain they have been updated to reflect the change. The current PI may transfer responsibility to a new PI by creating a Modification in RAMS-IRB and updating the Principal Investigator field on the "Study Information" page of the SmartForm. (See "How do I submit a modification?") Additionally, update the "Personnel" page to add or change the role of the new PI to "Principal Investigator", update the Principal Investigator's FIR and COI status in the submission, upload a copy of the new PI's CV/resume, and correspondence between the current PI to the new PI (e.g., an email) confirming the transfer of responsibilities.

If the current PI is leaving the institution but will remain a study team member, please contact irbreliance@vcu.edu to determine if a reliance agreement is appropriate.

If the current PI is leaving the institution and plans to take research data or specimens with them, there are contractual agreements that may be needed in order to share individual level human subjects research data/specimens. Please contact the Office of Sponsored Programs.

If a PI goes on an unanticipated leave or there is an abrupt departure from the institution, a Report to IRB should be submitted in RAMS-IRB by a current member of the study team as soon as possible. The Report should include whether the unanticipated leave is temporary or permanent, and whether responsibilities will be transferred to a new PI. If there is no appropriate replacement for the PI and the department wishes to close the study, a member of the study team may complete the closure request indicating that the PI is no longer affiliated with the institution, study activities are complete, and the study should be closed.

How do I get additional information and answers to questions?

This document and the policies and procedures for the Human Research Protection Program are available on the IRB Web Site at https://research.vcu.edu/human-research.

If you have any questions or concerns, about the Human Research Protection Program, contact the IRB Office at:

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

If you have questions, concerns, complaints, allegations of undue influence, allegations or findings of non-compliance, or input regarding the Human Research Protection Program that cannot be addressed by contact the IRB Office, follow the directions in HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN under “Reporting and Management of Concerns.”

Appendix A-1 *Additional Requirements for DHHS-Regulated Research*[2] [3]

1. When a subject decides to withdraw from a clinical trial, the investigator conducting the clinical trial should ask the subject to clarify whether the subject wishes to withdraw from all components of the trial or only from the primary interventional component of the trial. If the latter, research activities involving other components of the clinical trial, such as follow-up data collection activities, for which the subject previously gave consent may continue. The investigator should explain to the subject who wishes to withdraw the importance of obtaining follow-up safety data about the subject.
2. Investigators are allowed to retain and analyze already collected data relating to any subject who chooses to withdraw from a research study or whose participation is terminated by an investigator without regard to the subject's consent, provided such analysis falls within the scope of the analysis described in the IRB-approved protocol. This is the case even if that data includes identifiable private information about the subject.
3. For research not subject to regulation and review by FDA, investigators, in consultation with the funding agency, can choose to honor a research subject's request that the investigator destroy the subject's data or that the investigator exclude the subject's data from any analysis.
4. When seeking the informed consent of subjects, investigators should explain whether already collected data about the subjects will be retained and analyzed even if the subjects choose to withdraw from the research.
5. When research is covered by a certificate of confidentiality, researchers:
    a. May not disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or
    b. May not disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.
    c. May disclose information only when:
        i. Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding.

[2] http://www.hhs.gov/ohrp/policy/subjectwithdrawal.html

[3] These requirements apply to all VCU human research.

ii. Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;
iii. Made with the consent of the individual to whom the information, document, or biospecimen pertains; or
iv. Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human participants in research.

d. Researchers must inform participants of the protections and limitations of certificates of confidentiality (see language in HRP-502 - TEMPLATE CONSENT DOCUMENT).
    i. For studies that were previously issued a Certificate and notified participants of the protections provided by that Certificate, NIH does not expect participants to be notified that the protections afforded by the Certificate have changed, although IRBs may determine whether it is appropriate to inform participants.
    ii. If part of the study cohort was recruited prior to issuance of the Certificate, but are no longer activity participating in the study, NIH does not expect participants consented prior to the change in authority, or prior to the issuance of a Certificate, to be notified that the protections afforded by the Certificate have changed, or that participants who were previously consented to be re-contacted to be informed of the Certificate, although the IRB may determine whether it is appropriate to inform participants.
e. Researchers conducting research covered by a certificate of confidentiality, even if the research is not federally funded, must ensure that if identifiable, sensitive information is provided to other researchers or organizations, the other researcher or organization must comply with applicable requirements when research is covered by a certificate of confidentiality.

Appendix A-2 *Additional Requirements for FDA-Regulated Research*

1. When a subject withdraws from a study:[4]
    a. The data collected on the subject to the point of withdrawal remains part of the study database and may not be removed.
    b. An investigator may ask a subject who is withdrawing whether the subject wishes to provide continued follow-up and further data collection subsequent to their withdrawal from the interventional portion of the study. Under this circumstance, the discussion with the subject would distinguish between study-related interventions and continued follow-up of associated clinical outcome information, such as medical course or laboratory results obtained through non-invasive chart review, and address the maintenance of privacy and confidentiality of the subject's information.
    c. If a subject withdraws from the interventional portion of the study, but agrees to continued follow-up of associated clinical outcome information as described in the previous bullet, the investigator must obtain the subject's informed consent for this limited participation in the study (assuming such a situation was not described in the original informed consent form). IRB approval of informed consent documents is required.
    d. If a subject withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the investigator must not access for purposes related to the study the subject's medical record or other confidential records requiring the subject's consent.
    e. An investigator may review study data related to the subject collected prior to the subject's withdrawal from the study, and may consult public records, such as those establishing survival status.
2. For FDA-regulated research involving investigational drugs:
    a. Investigators must abide by FDA restrictions on promotion of investigational drugs:[5]
        i. An investigator, or any person acting on behalf of an investigator, must not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug.
        ii. This provision is not intended to restrict the full exchange of scientific information concerning the drug, including dissemination of scientific findings in scientific or lay media. Rather, its intent is to restrict promotional claims of safety or effectiveness of the drug for a use for which it is under investigation and to preclude commercialization of the drug before it is approved for commercial distribution.

[4] http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126489.pdf

[5] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.7

iii. An investigator must not commercially distribute or test market an investigational new drug.

b. Follow FDA requirements for general responsibilities of investigators[6]
   i. An investigator is responsible for ensuring that an investigation is conducted according to the signed investigator statement, the investigational plan, and applicable regulations; for protecting the rights, safety, and welfare of subjects under the investigator's care; and for the control of drugs under investigation.
   ii. An investigator must, in accordance with the provisions of 21 CFR §50, obtain the informed consent of each human subject to whom the drug is administered, except as provided in 21 CFR §50.23 or §50.24 of this chapter.
   iii. Additional specific responsibilities of clinical investigators are set forth in this part and in 21 CFR §50 and 21 CFR §56.

c. Follow FDA requirements for control of the investigational drug[7]
   i. An investigator must administer the drug only to subjects under the investigator's personal supervision or under the supervision of a sub-investigator responsible to the investigator.
   ii. The investigator must not supply the investigational drug to any person not authorized under this part to receive it.

d. Follow FDA requirements for investigator recordkeeping and record retention[8]
   i. Disposition of drug:
      1. An investigator is required to maintain adequate records of the disposition of the drug, including dates, quantity, and use by subjects.
      2. If the investigation is terminated, suspended, discontinued, or completed, the investigator must return the unused supplies of the drug to the sponsor, or otherwise provide for disposition of the unused supplies of the drug under 21 CFR §312.59.
   ii. Case histories.
      1. An investigator is required to prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation.
      2. Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital charts, and the nurses' notes. The case history for each individual must document that informed consent was obtained prior to participation in the study.

[6] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.60
[7] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.61
[8] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.62

iii. Record retention: An investigator must retain required records for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified.

e. Follow FDA requirements for investigator reports[9]
   i. Progress reports: The investigator must furnish all reports to the sponsor of the drug who is responsible for collecting and evaluating the results obtained.
   ii. Safety reports: An investigator must promptly report to the sponsor any adverse effect that may reasonably be regarded as caused by, or probably caused by, the drug. If the adverse effect is alarming, the investigator must report the adverse effect immediately.
   iii. Final report: An investigator must provide the sponsor with an adequate report shortly after completion of the investigator's participation in the investigation.
   iv. Financial disclosure reports:
      1. The clinical investigator must provide the sponsor with sufficient accurate financial information to allow an applicant to submit complete and accurate certification or disclosure statements as required under 21 CFR §54.
      2. The clinical investigator must promptly update this information if any relevant changes occur during the course of the investigation and for 1 year following the completion of the study.

f. Follow FDA requirements for assurance of IRB review[10]
   i. An investigator must assure that an IRB that complies with the requirements set forth in 21 CFR §56 will be responsible for the initial and continuing review and approval of the proposed clinical study.
   ii. The investigator must also assure that he or she will promptly report to the IRB all changes in the research activity and all unanticipated problems involving risk to human subjects or others, and that he or she will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

g. Follow FDA requirements for inspection of investigator's records and reports[11]
   i. An investigator must upon request from any properly authorized officer or employee of FDA, at reasonable times, permit such officer or employee to have access to, and copy and verify any records or reports made by the investigator pursuant to 312.62.

[9] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.64

[10] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.66

[11] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.68

ii. The investigator is not required to divulge subject names unless the records of particular individuals require a more detailed study of the cases, or unless there is reason to believe that the records do not represent actual case studies, or do not represent actual results obtained.

h. Follow FDA requirements for handling of controlled substances[12]
    i. If the investigational drug is subject to the Controlled Substances Act, the investigator must take adequate precautions, including storage of the investigational drug in a securely locked, substantially constructed cabinet, or other securely locked, substantially constructed enclosure, access to which is limited, to prevent theft or diversion of the substance into illegal channels of distribution.

3. For FDA-regulated research involving investigational devices:
    a. General responsibilities of investigators.[13]
        i. An investigator is responsible for ensuring that an investigation is conducted according to the signed agreement, the investigational plan and applicable FDA regulations, for protecting the rights, safety, and welfare of subjects under the investigator's care, and for the control of devices under investigation. An investigator also is responsible for ensuring that informed consent is obtained in accordance with 21 CFR §50.
    b. Specific responsibilities of investigators[14]
        i. Awaiting approval: An investigator may determine whether potential subjects would be interested in participating in an investigation, but must not request the written informed consent of any subject to participate, and must not allow any subject to participate before obtaining IRB and FDA approval.
        ii. Compliance: An investigator must conduct an investigation in accordance with the signed agreement with the sponsor, the investigational plan, and other applicable FDA regulations, and any conditions of approval imposed by an IRB or FDA.
        iii. Supervising device use: An investigator must permit an investigational device to be used only with subjects under the investigator's supervision. An investigator must not supply an investigational device to any person not authorized to receive it.
        iv. Financial disclosure:
            1. A clinical investigator must disclose to the sponsor sufficient accurate financial information to allow the applicant to submit complete and accurate certification or disclosure statements required under 21 CFR §54.

[12] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.69

[13] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.100

[14] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.110

2. The investigator must promptly update this information if any relevant changes occur during the course of the investigation and for 1 year following completion of the study.

v. Disposing of device: Upon completion or termination of a clinical investigation or the investigator's part of an investigation, or at the sponsor's request, an investigator must return to the sponsor any remaining supply of the device or otherwise dispose of the device as the sponsor directs.

c. Maintain the following accurate, complete, and current records relating to the investigator's participation in an investigation:[15]

i. All correspondence with another investigator, an IRB, the sponsor, a monitor, or FDA, including required reports.

ii. Records of receipt, use or disposition of a device that relate to:

1. The type and quantity of the device, the dates of its receipt, and the batch number or code mark.
2. The names of all persons who received, used, or disposed of each device.
3. Why and how many units of the device have been returned to the sponsor, repaired, or otherwise disposed of.

iii. Records of each subject's case history and exposure to the device. Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital charts, and the nurses' notes. Such records must include:

1. Documents evidencing informed consent and, for any use of a device by the investigator without informed consent, any written concurrence of a licensed physician and a brief description of the circumstances justifying the failure to obtain informed consent.
2. Documentation that informed consent was obtained prior to participation in the study.
3. All relevant observations, including records concerning adverse device effects (whether anticipated or unanticipated), information and data on the condition of each subject upon entering, and during the course of, the investigation, including information about relevant previous medical history and the results of all diagnostic tests.
4. A record of the exposure of each subject to the investigational device, including the date and time of each use, and any other therapy.

iv. The protocol, with documents showing the dates of and reasons for each deviation from the protocol.

[15] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.140

v. Any other records that FDA requires to be maintained by regulation or by specific requirement for a category of investigations or a particular investigation.

d. Inspections[16]
   i. Entry and inspection: A sponsor or an investigator who has authority to grant access must permit authorized FDA employees, at reasonable times and in a reasonable manner, to enter and inspect any establishment where devices are held (including any establishment where devices are manufactured, processed, packed, installed, used, or implanted or where records of results from use of devices are kept).
   ii. Records inspection: A sponsor, IRB, or investigator, or any other person acting on behalf of such a person with respect to an investigation, must permit authorized FDA employees, at reasonable times and in a reasonable manner, to inspect and copy all records relating to an investigation.
   iii. Records identifying subjects: An investigator must permit authorized FDA employees to inspect and copy records that identify subjects, upon notice that FDA has reason to suspect that adequate informed consent was not obtained, or that reports required to be submitted by the investigator to the sponsor or IRB have not been submitted or are incomplete, inaccurate, false, or misleading.

e. Prepare and submit the following complete, accurate, and timely reports[17]
   i. Unanticipated adverse device effects. An investigator must submit to the sponsor and to the reviewing IRB a report of any unanticipated adverse device effect occurring during an investigation as soon as possible, but in no event later than 10 working days after the investigator first learns of the effect.
   ii. Withdrawal of IRB approval. An investigator must report to the sponsor, within 5 working days, a withdrawal of approval by the reviewing IRB of the investigator's part of an investigation.
   iii. Progress. An investigator must submit progress reports on the investigation to the sponsor, the monitor, and the reviewing IRB at regular intervals, but in no event less often than yearly.
   iv. Deviations from the investigational plan:
      1. An investigator must notify the sponsor and the reviewing IRB of any deviation from the investigational plan to protect the life or physical well-being of a subject in an emergency.
      2. Such notice must be given as soon as possible, but in no event later than 5 working days after the emergency occurred.
      3. Except in such an emergency, prior approval by the sponsor is required for changes in or deviations from a plan, and if these

[16] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.145

[17] http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.150

changes or deviations may affect the scientific soundness of the plan or the rights, safety, or welfare of human subjects, FDA and IRB also is required.

v. Informed consent. If an investigator uses a device without obtaining informed consent, the investigator must report such use to the sponsor and the reviewing IRB within 5 working days after the use occurs.

vi. Final report. An investigator must, within 3 months after termination or completion of the investigation or the investigator's part of the investigation, submit a final report to the sponsor and the reviewing IRB.

vii. Other. An investigator must, upon request by a reviewing IRB or FDA, provide accurate, complete, and current information about any aspect of the investigation.

Appendix A-3 ***Additional Requirements for Clinical Trials (ICH-GCP)***

1. Investigator's Qualifications and Agreements
    a. The clinical trial should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with good clinical practice and the applicable regulatory requirements.
    b. The investigator should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial, should meet all the qualifications specified by the applicable regulatory requirements, and should provide evidence of such qualifications through up-to-date curriculum vitae and/or other relevant documentation requested by the sponsor, the IRB, and/or the regulatory authorities.
    c. The investigator should be thoroughly familiar with the appropriate use of the investigational product, as described in the protocol, in the current Investigator's Brochure, in the product information and in other information sources provided by the sponsor.
    d. The investigator should be aware of, and should comply with, GCP and the applicable regulatory requirements.
    e. The investigator/institution should permit monitoring and auditing by the sponsor, and inspection by the appropriate regulatory authorities.
    f. The investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.
2. Adequate Resources
    a. The investigator should be able to demonstrate (e.g., based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period.
    b. The investigator should have sufficient time to properly conduct and complete the trial within the agreed trial period.
    c. The investigator should have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely.
    d. The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product, and their trial-related duties and functions.
3. Medical Care of Trial Subjects
    a. A qualified physician (or dentist, when appropriate), who is an investigator or a sub-investigator for the trial, should be responsible for all trial-related medical (or dental) decisions.
    b. During and following a subject's participation in a trial, the investigator/institution should ensure that adequate medical care is provided to a subject for any adverse events, including clinically significant laboratory values, related to the trial. The investigator/institution should inform a subject when medical care is needed for intercurrent illnesses of which the investigator becomes aware.

c. It is recommended that the investigator inform the subject's primary physician about the subject's participation in the trial if the subject has a primary physician and if the subject agrees to the primary physician being informed.
d. Although a subject is not obliged to give his/her reasons for withdrawing prematurely from a trial, the investigator should make a reasonable effort to ascertain the reasons, while fully respecting the subject's rights.

4. Communication with IRB
    a. Before initiating a trial, the investigator/institution should have written and dated approval opinion from the IRB for the trial protocol, written informed consent form, consent form updates, subject recruitment procedures (e.g., advertisements), and any other written information to be provided to subjects.
    b. As part of the investigator's/institution's written application to the IRB, the investigator/institution should provide the IRB with a current copy of the Investigator's Brochure. If the Investigator's Brochure is updated during the trial, the investigator/institution should supply a copy of the updated Investigator's Brochure to the IRB.
    c. During the trial the investigator/institution should provide to the IRB all documents subject to review.
5. Compliance with Protocol
    a. The investigator/institution should conduct the trial in compliance with the protocol agreed to by the sponsor and, if required, by the regulatory authorities and which was given approval opinion by the IRB. The investigator/institution and the sponsor should sign the protocol, or an alternative contract, to confirm agreement.
    b. The investigator should not implement any deviation from, or changes of the protocol without agreement by the sponsor and prior review and documented approval opinion from the IRB of an amendment, except where necessary to eliminate an immediate hazards to trial subjects, or when the changes involves only logistical or administrative aspects of the trial (e.g., change in monitors, change of telephone numbers).
    c. The investigator, or person designated by the investigator, should document and explain any deviation from the approved protocol.
    d. The investigator may implement a deviation from, or a change of, the protocol to eliminate an immediate hazard to trial subjects without prior IRB approval opinion. As soon as possible, the implemented deviation or change, the reasons for it, and, if appropriate, the proposed protocol amendments should be submitted: a) to the IRB for review and approval opinion, b) to the sponsor for agreement and, if required, c) to the regulatory authorities.
6. Investigational Product
    a. Responsibility for investigational product accountability at the trial site rests with the investigator/institution.
    b. Where allowed/required, the investigator/institution may/should assign some or all of the investigator's/institution's duties for investigational product

accountability at the trial site to an appropriate pharmacist or another appropriate individual who is under the supervision of the investigator/institution.

c. The investigator/institution and/or a pharmacist or other appropriate individual, who is designated by the investigator/institution, should maintain records of the product's delivery to the trial site, the inventory at the site, the use by each subject, and the return to the sponsor or alternative disposition of unused product. These records should include dates, quantities, batch/serial numbers, expiration dates (if applicable), and the unique code numbers assigned to the investigational product and trial subjects. Investigators should maintain records that document adequately that the subjects were provided the doses specified by the protocol and reconcile all investigational product received from the sponsor.
d. The investigational product should be stored as specified by the sponsor and in accordance with applicable regulatory requirements.
e. The investigator should ensure that the investigational product is used only in accordance with the approved protocol.
f. The investigator, or a person designated by the investigator/institution, should explain the correct use of the investigational product to each subject and should check, at intervals appropriate for the trial, that each subject is following the instructions properly.
g. Randomization Procedures and Unblinding: The investigator should follow the trial's randomization procedures, if any, and should ensure that the code is broken only in accordance with the protocol. If the trial is blinded, the investigator should promptly document and explain to the sponsor any premature unblinding (e.g., accidental unblinding, unblinding due to a serious adverse event) of the investigational product.

7. Informed Consent of Trial Subjects
    a. In obtaining and documenting informed consent, the investigator should comply with the applicable regulatory requirements, and should adhere to GCP and to the ethical principles that have their origin in the Declaration of Helsinki. Prior to the beginning of the trial, the investigator should have the IRB's written approval opinion of the written informed consent form and any other written information to be provided to subjects.
    b. The written informed consent form and any other written information to be provided to subjects should be revised whenever important new information becomes available that may be relevant to the subject’s consent. Any revised written informed consent form, and written information should receive the IRB's approval opinion in advance of use. The subject or the subject’s legally acceptable representative should be informed in a timely manner if new information becomes available that may be relevant to the subject’s willingness to continue participation in the trial. The communication of this information should be documented.
    c. Neither the investigator, nor the trial staff, should coerce or unduly influence a subject to participate or to continue to participate in a trial.

d. None of the oral and written information concerning the trial, including the written informed consent form, should contain any language that causes the subject or the subject's legally acceptable representative to waive or to appear to waive any legal rights, or that releases or appears to release the investigator, the institution, the sponsor, or their agents from liability for negligence.
e. The investigator, or a person designated by the investigator, should fully inform the subject or, if the subject is unable to provide informed consent, the subject's legally acceptable representative, of all pertinent aspects of the trial including the written information and the approval opinion by the IRB.
f. The language used in the oral and written information about the trial, including the written informed consent form, should be as non-technical as practical and should be understandable to the subject or the subject's legally acceptable representative and the impartial witness, where applicable.
g. Before informed consent may be obtained, the investigator, or a person designated by the investigator, should provide the subject or the subject's legally acceptable representative ample time and opportunity to inquire about details of the trial and to decide whether or not to participate in the trial. All questions about the trial should be answered to the satisfaction of the subject or the subject's legally acceptable representative.
h. Prior to a subject's participation in the trial, the written informed consent form should be signed and personally dated by the subject or by the subject's legally acceptable representative, and by the person who conducted the informed consent discussion.
i. If a subject is unable to read or if a legally acceptable representative is unable to read, an impartial witness should be present during the entire informed consent discussion. After the written informed consent form and any other written information to be provided to subjects, is read and explained to the subject or the subject's legally acceptable representative, and after the subject or the subject's legally acceptable representative has orally consented to the subject's participation in the trial and, if capable of doing so, has signed and personally dated the informed consent form, the witness should sign and personally date the consent form. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject or the subject's legally acceptable representative, and that informed consent was freely given by the subject or the subject's legally acceptable representative.
j. Both the informed consent discussion and the written informed consent form and any other written information to be provided to subjects should include explanations of the following:
    i. That the trial involves research.
    ii. The purpose of the trial.
    iii. The trial treatments and the probability for random assignment to each treatment.
    iv. The trial procedures to be followed, including all invasive procedures.

v. The subject's responsibilities.
vi. Those aspects of the trial that are experimental.
vii. The reasonably foreseeable risks or inconveniences to the subject and, when applicable, to an embryo, fetus, or nursing infant.
viii. The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this.
ix. The alternative procedures or courses of treatment that may be available to the subject, and their important potential benefits and risks.
x. The compensation and/or treatment available to the subject in the event of trial related injury.
xi. The anticipated prorated payment, if any, to the subject for participating in the trial.
xii. The anticipated expenses, if any, to the subject for participating in the trial.
xiii. That the subject's participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled.
xiv. That the monitors, the auditors, the IRB, and the regulatory authorities will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject's legally acceptable representative is authorizing such access.
xv. That records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential.
xvi. That the subject or the subject's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in the trial.
xvii. The persons to contact for further information regarding the trial and the rights of trial subjects, and whom to contact in the event of trial-related injury.
xviii. The foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated.
xix. The expected duration of the subject's participation in the trial.
xx. The approximate number of subjects involved in the trial.

k. Prior to participation in the trial, the subject or the subject's legally acceptable representative should receive a copy of the signed and dated written informed consent form and any other written information provided to the subjects. During a subject's participation in the trial, the subject or the subject's legally acceptable representative should receive a copy of the signed and dated consent form

updates and a copy of any amendments to the written information provided to subjects.

l. When a clinical trial (therapeutic or non-therapeutic) includes subjects who can only be enrolled in the trial with the consent of the subject's legally acceptable representative (e.g., minors, or patients with severe dementia), the subject should be informed about the trial to the extent compatible with the subject's understanding and, if capable, the subject should sign and personally date the written informed consent.

m. Except as described above, a non-therapeutic trial (i.e. a trial in which there is no anticipated direct clinical benefit to the subject), should be conducted in subjects who personally give consent and who sign and date the written informed consent form.

n. Non-therapeutic trials may be conducted in subjects with consent of a legally acceptable representative provided the following conditions are fulfilled: a) The objectives of the trial cannot be met by means of a trial in subjects who can give informed consent personally. b) The foreseeable risks to the subjects are low. c) The negative impact on the subject's well-being is minimized and low. d) The trial is not prohibited by law. e) The approval opinion of the IRB is expressly sought on the inclusion of such subjects, and the written approval opinion covers this aspect. Such trials, unless an exception is justified, should be conducted in patients having a disease or condition for which the investigational product is intended. Subjects in these trials should be particularly closely monitored and should be withdrawn if they appear to be unduly distressed.

o. In emergency situations, when prior consent of the subject is not possible, the consent of the subject's legally acceptable representative, if present, should be requested. When prior consent of the subject is not possible, and the subject's legally acceptable representative is not available, enrolment of the subject should require measures described in the protocol and/or elsewhere, with documented approval opinion by the IRB, to protect the rights, safety and well-being of the subject and to ensure compliance with applicable regulatory requirements. The subject or the subject's legally acceptable representative should be informed about the trial as soon as possible and consent to continue and other consent as appropriate should be requested.

8. Records and Reports

a. The investigator should ensure the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the CRFs and in all required reports.

b. Data reported on the CRF, that are derived from source documents, should be consistent with the source documents or the discrepancies should be explained.

c. Any change or correction to a CRF should be dated, initialed, and explained (if necessary) and should not obscure the original entry (i.e. an audit trail should be maintained); this applies to both written and electronic changes or corrections. Sponsors should provide guidance to investigators and/or the investigators' designated representatives on making such corrections. Sponsors should have

written procedures to assure that changes or corrections in CRFs made by sponsor's designated representatives are documented, are necessary, and are endorsed by the investigator. The investigator should retain records of the changes and corrections.

d. The investigator/institution should maintain the trial documents as specified in Essential Documents for the Conduct of a Clinical Trial and as required by the applicable regulatory requirements. The investigator/institution should take measures to prevent accidental or premature destruction of these documents.
e. Essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period however if required by the applicable regulatory requirements or by an agreement with the sponsor. It is the responsibility of the sponsor to inform the investigator/institution as to when these documents no longer need to be retained.
f. The financial aspects of the trial should be documented in an agreement between the sponsor and the investigator/institution.
g. Upon request of the monitor, auditor, IRB, or regulatory authority, the investigator/institution should make available for direct access all requested trial-related records.

9. Progress Reports
    a. The investigator should submit written summaries of the trial status to the IRB annually, or more frequently, if requested by the IRB.
    b. The investigator should promptly provide written reports to the sponsor, the IRB and, where applicable, the institution on any changes significantly affecting the conduct of the trial, and/or increasing the risk to subjects.
10. Safety Reporting
    a. All serious adverse events (SAEs) should be reported immediately to the sponsor except for those SAEs that the protocol or other document (e.g., Investigator's Brochure) identifies as not needing immediate reporting. The immediate reports should be followed promptly by detailed, written reports. The immediate and follow-up reports should identify subjects by unique code numbers assigned to the trial subjects rather than by the subjects' names, personal identification numbers, and/or addresses. The investigator should also comply with the applicable regulatory requirements related to the reporting of unexpected serious adverse drug reactions to the regulatory authorities and the IRB.
    b. Adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations should be reported to the sponsor according to the reporting requirements and within the time periods specified by the sponsor in the protocol.

c. For reported deaths, the investigator should supply the sponsor and the IRB with any additional requested information (e.g., autopsy reports and terminal medical reports).
d. Premature Termination or Suspension of a Trial If the trial is prematurely terminated or suspended for any reason, the investigator/institution should promptly inform the trial subjects, should assure appropriate therapy and follow-up for the subjects, and, where required by the applicable regulatory requirements, should inform the regulatory authorities. In addition:
    i. If the investigator terminates or suspends a trial without prior agreement of the sponsor, the investigator should inform the institution where applicable, and the investigator/institution should promptly inform the sponsor and the IRB, and should provide the sponsor and the IRB a detailed written explanation of the termination or suspension.
    ii. If the sponsor terminates or suspends a trial, the investigator should promptly inform the institution where applicable and the investigator/institution should promptly inform the IRB and provide the IRB a detailed written explanation of the termination or suspension.
    iii. If the IRB terminates or suspends its approval opinion of a trial, the investigator should inform the institution where applicable and the investigator/institution should promptly notify the sponsor and provide the sponsor with a detailed written explanation of the termination or suspension.

11. Final Reports by Investigator: Upon completion of the trial, the investigator, where applicable, should inform the institution; the investigator/institution should provide the IRB with a summary of the trial's outcome, and the regulatory authorities with any reports required.

Appendix A-4 *Additional Requirements for Department of Defense (DOD) research*

1. When appropriate, research protocols must be reviewed and approved by the IRB prior to the Department of Defense approval. Consult with the Department of Defense funding component to see whether this is a requirement.
2. Civilian researchers attempting to access military volunteers should seek collaboration with a military researcher familiar with service-specific requirements.
3. Employees of the Department of Defense (including temporary, part-time, and intermittent appointments) may not be able to legally accept payments to participate in research and should check with their supervisor before accepting such payments. Employees of the Department of Defense cannot be paid for conducting research while on active duty.
4. Service members must follow their command policies regarding the requirement to obtain command permission to participate in research involving human subjects while on-duty or off-duty.
5. Components of the Department of Defense might have stricter requirements for research-related injury than the DHHS regulations.
6. There may be specific educational requirements or certification required.
7. When assessing whether to support or collaborate with this institution for research involving human subjects, the Department of Defense may evaluate this institution's education and training policies to ensure the personnel are qualified to perform the research.
8. When research involves U.S. military personnel, policies and procedures require limitations on dual compensation:
    a. Prohibit an individual from receiving pay of compensation for research during duty hours.
    b. An individual may be compensated for research if the participant is involved in the research when not on duty.
    c. Federal employees while on duty and non-Federal persons may be compensated for blood draws for research up to $50 for each blood draw.
    d. Non-Federal persons may be compensated for research participating other than blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research.
9. Surveys performed on DOD personnel must be submitted, reviewed, and approved by the DOD Information Management Control Officer (IMCO) after the research protocol is reviewed and approved by the IRB. When a survey crosses DOD components, additional review is required. Consult the Department of Defense funding component to coordinate this review.
10. When research involves large scale genomic data (LSGD) collected on DOD-affiliated personnel, additional protections are required:
    a. Additional administrative, technical, and physical safeguards to prevent disclosure of DoD-affiliated personnel's genomic data commensurate with risk (including secondary use or sharing of de-identified data or specimens)

    b. Research will apply an HHS Certificate of Confidentiality
    c. DoD Component security review
11. Data or information sent to a DOD component under a pledge of confidentiality for exclusively statistical purposes must be used exclusively for statistical purposes and may not be disclosed in identifiable form for any other purpose, except with the informed consent of the respondent.
12. When conducting multi-site research, a formal agreement between institutions is required to specify the roles and responsibilities of each party.
13. The following must be reported to the applicable DOD Component Office of Human Research Protections within 30 days:
    a. When significant changes to the research protocol are approved by the IRB or EC:
        i. Changes to key investigators or institutions.
        ii. Decreased benefit or increased risk to participants in greater than minimal risk research.
        iii. Addition of vulnerable populations as participants.
        iv. Addition of DOD-affiliated personnel as participants.
        v. Change of reviewing IRB.
    b. When the organization is notified by any federal body, state agency, official governing body of a Native American or Alaskan native tribe, other entity, or foreign government that any part of an HRPP is under investigation for cause involving a DOD-supported research protocol.
    c. Any problems involving risks to participants or others, suspension or termination of IRB approval, or any serious or continuing noncompliance pertaining to DOD-supported human participant research.
    d. The results of the IRB's continuing review, if required.
    e. Change in status when a previously enrolled participant becomes pregnant, or when the researcher learns that a previously enrolled participant is pregnant, and the protocol was not reviewed and approved by the IRB in accordance with 45 CFR 46, Subpart B.
    f. Change in status when a previously enrolled participant becomes a prisoner, and the protocol was not reviewed and approved by the IRB in accordance with 32 CFR 219, Subpart C.
    g. Closure of a DOD-supported study.
14. For human participant research that would not otherwise be approved but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates, written approval from the DOD Office for Human Research Protections must be obtained through the DOD Component Office of Human Research Protections prior to research starting.
15. Other specific requirements of the Department of Defense research be found in the "Additional Requirements for Department of Defense (DOD) Research" section in the IRB's HRP-318 - WORKSHEET - Additional Federal Agency Criteria.

Appendix A-5 *Additional Requirements for Department of Energy (DOE) Research*

(See DOE Order 443.1C)

1. Research that involves one or more of the following must be submitted to the appropriate IRB for human subjects research review and determination :
    a. Study of humans in a systematically modified environment. These studies include but are not limited to intentional modification of the human environment:
        i. Study of human environments that use tracer chemicals, particles or other materials to characterize airflow.
        ii. Study in occupied homes or offices that:
            1. Manipulate the environment to achieve research aims.
            2. Test new materials.
            3. Involve collecting information on occupants' views of appliances, materials, or devices installed in their homes or their energy-saving behaviors through surveys and focus groups.
    b. Use of social media data.
    c. Human Terrain Mapping (HTM).
    d. All exempt HSR determinations must be made by the appropriate IRB and/or IRB office.
2. Personally identifiable information collected and/or used during HSR projects must be protected in accordance with the requirements of DOE Order 206.1, Department of Energy Privacy Program, current version. The Central DOE IRBs require submission of DOE's HRP- 490-CHECKLIST-Reviewing Protocols that use Personally Identifiable Information (PII) if your research includes PII.
3. You must report the following to the DOE human subjects research Program Manager (and, when an NNSA element is involved, the NNSA HSP Program Manager) prior to initiation of any new human subjects research project, even if it meets the regulatory definition of exempt human subjects research as outlined in 10 CFR Part 745.104, involving:
    a. An institution without an established Institutional Review Board (IRB);
    b. A foreign country;
    c. The potential for significant controversy (e.g., negative press or reaction from stakeholder or oversight groups);
    d. Research subjects in a protected class (prisoners, children, individuals with impaired decision making capability, or DOE/NNSA federal or DOE/NNSA contractor employees as human subjects, who may be more vulnerable to coercion and undue influence to participate) that is outside of the reviewing IRB's typical range/scope; or
    e. The generation or use of classified information.
4. The IRB must be notified immediately and the DOE HSP Program Manager (and, when an NNSA element is involved, the NNSA HSP Program Manager) must be notified within 48 hours and consulted regarding planned corrective actions if any of the following occur:

a. Adverse events. Notify the IRB for all adverse events and the DOE/NNSA HSP Program Manager if the IRB determines them to be significant, as defined in DOE Order 443.1C.
b. Unanticipated problems and complaints about the research.
c. Any suspension or termination of IRB approval of research.
d. Any significant non-compliance with HSP Program procedures or other requirements.
e. Any finding of a suspected or confirmed data breach involving PII in printed or electronic form. Report immediately to the IRB, the DOE/NNSA HSP Program Manager(s), and the DOE-Cyber Incident Response Capability, in accordance with the requirements of the CRD associated with DOE O 206.1.
f. Serious adverse events and corrective actions taken must be reported immediately to the IRB and the DOE/NNSA HSP Program Manager(s). The time frame for "immediately" is defined as upon discovery.

5. Requirements for human participant protections for classified research apply to all classified research conducted or supported by the DOE and its national laboratories, including contracts, and including Human Terrain Mapping research.
6. Researchers conducting human subjects research in any other country or on citizens or other individuals residing in that country must be cognizant of country-specific human subjects research requirements and consult the IRB regarding applicability of such requirements.
7. No human subjects 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, may be initiated without both a Federalwide Assurance (FWA) or comparable assurance (e.g., Department of Defense assurance) of compliance and approval by the cognizant Institutional Review Board (IRB) in accordance with 10 CFR §745.103. Human subjects research involving multiple DOE sites (e.g., members of the research team from more than one DOE site and/or data or human subjects from more than one DOE site) must be reviewed and approved by one of the Central DOE IRBs prior to initiation, or if authorized by the DOE and/or NNSA HSP Program Manager, other appropriate IRB of record. In all cases, an IRB Authorization Agreement (IAA) or Memorandum of Understanding (MOU) must be in place between the organization(s) conducting the HSR and the organization responsible for IRB review.
8. Human subjects research that involves DOE Federal and/or contractor employees must first be reviewed and approved by the appropriate DOE IRB (the DOE site IRB or one of the Central DOE IRBs), or if deemed more fitting by the Federally assured DOE site or Headquarters, other appropriate IRB of record, in accordance with an IAA or MOU negotiated between the DOE site or Headquarters and the organization responsible for IRB review.
9. Classified and unclassified human subjects research that is funded through the Strategic Intelligence Partnership Program (SIPP) must be reviewed and approved by the Central DOE IRB-Classified.

10. If applicable, federally funded HSR must comply with the requirements of the Paperwork Reduction Act.
11. Other specific requirements of the DOE research can be found in the “Additional Requirements for Department of Energy (DOE) Research” section in the IRB’s HRP-318 - WORKSHEET - Additional Federal Agency Criteria.

Appendix A-6 *Additional Requirements for Department of Justice (DOJ) Research*

Additional Requirements for DOJ Research conducted in the Federal Bureau of Prisons

1. Implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research.
2. The project must not involve medical experimentation, cosmetic research, or pharmaceutical testing.
3. The research design must be compatible with both the operation of prison facilities and protection of human subjects.
4. Investigators must observe the rules of the institution or office in which the research is conducted.
5. Any investigator who is a non-employee of the Bureau of Prisoners must sign a statement in which the investigator agrees to adhere to the requirements of 28 CFR §512.
6. The research must be reviewed and approved by the Bureau Research Review Board.
7. Incentives cannot be offered to help persuade inmate subjects to participate. However, soft drinks and snacks to be consumed at the test setting may be offered. Reasonable accommodations such as nominal monetary recompense for time and effort may be offered to non-confined research subjects who are both: No longer in Bureau of Prisons custody. Participating in authorized research being conducted by Bureau employees or contractors.
8. A non-employee of the Bureau may receive records in a form not individually identifiable when advance adequate written assurance that the record will be used solely as a statistical research or reporting record is provided to the agency.
9. Except as noted in the consent statement to the subject, you must not provide research information that identifies a subject to any person without that subject's prior written consent to release the information. For example, research information identifiable to a particular individual cannot be admitted as evidence or used for any purpose in any action, suit, or other judicial, administrative, or legislative proceeding without the written consent of the individual to whom the data pertain.
10. Except for computerized data records maintained at an official Department of Justice site, records that contain non-disclosable information directly traceable to a specific person may not be stored in, or introduced into, an electronic retrieval system.
11. If you are conducting a study of special interest to the Office of Research and Evaluation but the study is not a joint project involving Office of Research and Evaluation, you may be asked to provide Office of Research and Evaluation with the computerized research data, not identifiable to individual subjects, accompanied by detailed documentation. These arrangements must be negotiated prior to the beginning of the data collection phase of the project.
12. Required elements of disclosure additionally include:
    a. Identification of the investigators.

b. Anticipated uses of the results of the research.
c. A statement that participation is completely voluntary and that the subject may withdraw consent and end participation in the project at any time without penalty or prejudice (the inmate will be returned to regular assignment or activity by staff as soon as practicable).
d. A statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law. For example, an investigator may not guarantee confidentiality when the subject indicates intent to commit future criminal conduct or harm himself or herself or someone else, or, if the subject is an inmate, indicates intent to leave the facility without authorization.
e. A statement that participation in the research project will have no effect on the inmate subject's release date or parole eligibility.

13. You must have academic preparation or experience in the area of study of the proposed research.
14. The IRB application must include a summary statement, which includes:
    a. Names and current affiliations of the investigators.
    b. Title of the study.
    c. Purpose of the study.
    d. Location of the study.
    e. Methods to be employed.
    f. Anticipated results.
    g. Duration of the study.
    h. Number of subjects (staff or inmates) required and amount of time required from each.
    i. Indication of risk or discomfort involved as a result of participation.
15. The IRB application must include a comprehensive statement, which includes:
    a. Review of related literature.
    b. Detailed description of the research method.
    c. Significance of anticipated results and their contribution to the advancement of knowledge.
    d. Specific resources required from the Bureau of Prisons.
    e. Description of all possible risks, discomforts, and benefits to individual subjects or a class of subjects, and a discussion of the likelihood that the risks and discomforts will actually occur.
    f. Description of steps taken to minimize any risks.
    g. Description of physical or administrative procedures to be followed to: Ensure the security of any individually identifiable data that are being collected for the study.
    h. Destroy research records or remove individual identifiers from those records when the research has been completed.
    i. Description of any anticipated effects of the research study on institutional programs and operations.
    j. Relevant research materials such as vitae, endorsements, sample consent statements, questionnaires, and interview schedules.

16. The IRB application must include a statement regarding assurances and certification required by federal regulations, if applicable.
17. You must assume responsibility for actions of any person engaged to participate in the research project as an associate, assistant, or subcontractor.
18. At least once a year, you must provide the Chief, Office of Research and Evaluation, with a report on the progress of the research.
19. At least 12 working days before any report of findings is to be released, you must distribute one copy of the report to each of the following: the chairperson of the Bureau Research Review Board, the regional director, and the warden of each institution that provided data or assistance.
20. You must include an abstract in the report of findings.
21. In any publication of results, you must acknowledge the Bureau's participation in the research project.
22. You must expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau.
23. Prior to submitting for publication the results of a research project conducted under this subpart, You must provide two copies of the material, for informational purposes only, to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons.
24. Other specific requirements of the Department of Justice (DOJ) Research Conducted within the Federal Bureau of Prisons (BOP) can be found in the “Additional Requirements for Department of Justice (DOJ) Research Conducted within the Federal Bureau of Prisons (BOP)” section in the IRB’s HRP-318 - WORKSHEET - Additional Federal Agency Criteria.

Additional Requirements for DOJ Research Funded by the National Institute of Justice

1. The project must have a privacy certificate approved by the National Institute of Justice Human Subjects Protection Officer.
2. All investigators and research staff are required to sign employee confidentiality statements, which are maintained by the responsible investigator.
3. The confidentiality statement on the consent document must state that confidentiality can only be broken if the subject reports immediate harm to subjects or others.
4. Under a privacy certificate, investigators and research staff do not have to report child abuse unless the subject signs another consent document to allow child abuse reporting.
5. A copy of all data must be de-identified and sent to the National Archive of Criminal Justice Data, including copies of the informed consent document, data collection instruments, surveys, or other relevant research materials.
    a. At least once a year, the researcher shall provide the Chief, Office of Research and Evaluation, with a report of the progress of the research.
    b. At least 12 working days before any report of findings is to be released, the researcher shall distribute one copy of the report to each of the following: the chairperson of the Bureau Research Review Board, the regional director, and the warden of each institution that provided data or assistance. The researcher shall include an abstract in the report of findings.

c. In any publication of results, the researcher shall acknowledge the Bureau's participation in the research project.
d. The research shall expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau.
e. Prior to submitting for publication the results of a research project conducted under this subpart, the researcher shall provide two copies of the material, for informational purposes only, to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons

6. Other specific requirements of the Department of Justice (DOJ) Research Funded by the National Institute of Justice can be found in the “Additional Requirements for Department of Justice (DOJ) Research” section in the IRB’s HRP-318 - WORKSHEET - Additional Federal Agency Criteria.

Appendix A-7 *Additional Requirements for Department of Education (ED) Research*

1. Each school at which the research is conducted must provide an assurance that they comply with the Family Educational Rights and Privacy Act (FERPA) and the Protection of Pupil Rights Amendment (PPRA).
2. Provide a copy of all surveys and instructional material used in the research. Upon request parents of children[18] involved in the research[19] must be able to inspect these materials.
3. The school in which the research is being conducted must have policies regarding the administration of physical examinations or screenings that the school may administer to students.
4. Other specific requirements of the Department of Education (ED) Research can be found in the "Additional Requirements for Department of Education (ED) Research" section in the IRB's HRP-318 - WORKSHEET - Additional Federal Agency Criteria.

[18] Children are persons enrolled in research not above the elementary or secondary education level, who have not reached the age or majority as determined under state law.

[19] Research or experimentation program or project means any program or project in any research that is designed to explore or develop new or unproven teaching methods or techniques.

Appendix A-8 *Additional Requirements for Environmental Protection Agency (EPA) Research*

1. Research conducted, supported, or intended to be submitted to EPA is subject to Environmental Protection Agency Regulations.
2. Intentional exposure of pregnant women or children to any substance is prohibited.
3. Observational research involving pregnant women and fetuses are subject to additional DHHS requirements for research involving pregnant women (45 CFR §46 Subpart B) and additional DHHS requirements for research involving children (45 CFR §46 Subpart D.)
4. Research involving children must meet category #1 or #2.
5. Other specific requirements of the Environmental Protection Agency (EPA) Research can be found in the "Additional Requirements for Environmental Protection Agency (EPA) Research and Research Intended to be Submitted to the Environmental Protection Agency" section in the IRB's HRP-318 - WORKSHEET - Additional Federal Agency Criteria.

Appendix A-9 *Additional Requirements for Veterans Administration (VA) Research*

- The investigator must 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 (local SAEs or serious problems that are unanticipated and related to the research), apparent serious or continuing non-compliance, suspension of IRB approval, termination of IRB approval. Any unanticipated problem involving risks to subjects or others that is a local research death must be reported orally to the IRB immediately upon becoming aware of the information.
- VA research is research that is conducted by researchers (serving on VA compensated, WOC, or IPA appointments) while on VA time or on VA property. The research may be funded by VA, by other sponsors, or be unfunded. VA research must have Research and Development (R&D) Committee approval before it is considered VA Research and before it can be initiated. All research activities approved by the R&D Committee are considered VA Research.
    - VA-affiliated nonprofit research and education corporations (NPC) are authorized by Congress under 38 U.S.C. 7361-7366 to provide flexible funding mechanisms for the conduct of research and education at one or more VA facilities. Research approved by a facility R&D Committee are considered to be a VA research project or a VA education activity respectively, regardless of the source of funding, the entity administering the funds, or the research or education site (see VHA Handbook 1200.17, Department of Veterans Affairs Nonprofit Research and Education Corporations Authorized by Title 38 U.S.C. Sections 7361 Through 7366, dated April 27, 2016 and revised May 9, 2017).
    - VA research includes VA-approved research conducted at international sites not within the United States, its territories, or Commonwealths; and includes research where human tissues are sent outside the United States.
- The investigator must give first priority to the protection of research subjects, uphold professional and ethical standards and practices, and adhere to all applicable VA and other federal requirements, including the local VA facility's policies and procedures, regarding the conduct of research and the protection of human subjects. The investigator must hold a current VA appointment to conduct VA research.
- The responsibilities of the investigator may be defined in the protocol or IRB application. Specifically, the principal investigator's and local site investigator's responsibilities include, but are not limited to
    - Qualifications to Conduct Human Subjects Research. VA investigators must have the appropriate training, education, expertise, and credentials to conduct the research according to the research protocol.
        - PIs must ensure that all research staff are qualified (e.g., including but not limited to appropriate training, education, expertise, and credentials) to perform procedures assigned to them during the course of the study.
        - 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.
    - Investigators and co-investigators must be identified on the IRB application and must provide credentials, conflict of interest statements or other documentation required by VA and local facility policies.
    - All individuals involved in conducting VA human subjects research 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).
    - Investigators must prospectively document their research with their supervisor in writing.
    - Investigators must submit exempt protocols that require limited IRB review to the IRB for limited IRB review/approval.
- Research Protocol. The investigator must develop and submit a research protocol that is scientifically valid, describes the research objectives, background and methodology, provides for fair and equitable recruitment and selection of subjects, minimizes risks to subjects and others, and describes a data and safety monitoring plan consistent with the nature of the study. The research must be relevant to the health or welfare of the Veteran population. When relevant, the protocol must include the following safety measures:
    - The type of safety information to be collected including AEs;
    - Frequency of safety data collection;
    - Frequency or periodicity of review of cumulative safety data;
    - Statistical tests for analyzing the safety data to determine if harm is occurring; and
    - Conditions that trigger an immediate suspension of the research, if applicable.
- Approvals. The investigator must submit the protocol for initial review and obtain written approvals from the IRB, other applicable committees, and from the R&D Committee. In addition, the investigator must receive written notice from the ACOS/R&D that the research may commence before initiating the research.
    - An investigator may not self-certify that a study is exempt.
    - Once approved by the IRB, the protocol must be implemented as approved. All modifications to the approved research protocol or consent form must be approved by the IRB prior to initiating the changes except when necessary to eliminate apparent immediate hazards to the subject.
    - The investigator must also obtain continuing review and approval at a frequency established by the IRB, but not less than once every year and is expected to submit all materials required for continuing review in sufficient time to assure

approval prior to the expiration date. No research activities may be conducted at any time without a currently valid IRB approval.

- Conflict Of Interest. The investigator must disclose to the IRB any potential, actual, apparent, or perceived conflict of interest of a financial, professional, or personal nature that may affect any aspect of the research, and comply with all applicable VA and other federal requirements regarding conflict of interest.
- Initial Contact. During the recruitment process, members of the research team must make initial contact with potential subjects in person or by letter prior to initiating any telephone contact, unless there is written documentation that the subject is willing to be contacted by telephone about the study in question or a specific kind of research as outlined in the study. (NOTE: This does not apply to situations where a Veteran calls in response to an advertisement. If existing information from sources such as a medical record or database, research or non-research, are used to identify human subjects, there must be an IRB approved HIPAA waiver for this activity in the new protocol.)
  - Any initial contact by letter or telephone must provide a telephone number or other means that the potential subject can use to verify that the study constitutes VA research.
  - If a contractor makes the initial contact by letter, the VA investigator must sign the letter.
- Informed Consent for Research. The investigator must obtain and document legally effective informed consent of the subject or the subject's LAR prospectively (i.e., no screening or other interaction or intervention involving a human subject can occur until after the IRB-approved informed consent requirements have been met) that is in alignment with ethical principles that govern informed consent for research. The only exceptions are if the IRB determines the research is exempt, or approves a waiver of the informed consent process, or approves a waiver of the signed informed consent document.
  - If the investigator does not personally obtain informed consent, the investigator must delegate this responsibility in writing (e.g., by use of a delegation letter) to research staff sufficiently knowledgeable about the protocol and related concerns to answer questions from prospective subjects, and about the ethical basis of the informed consent process and protocol.
    - If the investigator contracts with a firm, e.g., a survey research firm, to obtain consent from subjects, collect private individually identifiable information from human subjects, or are involved in activities that would institutionally engage the firm in human subjects research, the firm must have its own IRB oversight of the activity. In addition, the PO must determine that there is appropriate authority to allow the disclosure of individual names and other information to the contracted firm.
    - The investigator must ensure that all original signed and dated informed consent documents are maintained in the investigator’s research files, readily retrievable, and secure.

- HIPAA Authorization. The investigator or designee must obtain HIPAA authorization for the use and disclosure of the subject's PHI, or obtain an IRB-approved waiver of HIPAA authorization unless there is a limited data set and appropriate DUA. The written HIPAA authorization may either be a standalone document or combined with the research informed consent approved by the IRB. If a standalone document is used as the written HIPAA authorization, VA Form 10-0493: Authorization for Use and Release of Individually Identifiable Health Information Collected for VHA Research, must be used to document the authorization.

- Reporting. The investigator is responsible for reporting unanticipated problems involving risks to subjects or others, serious unanticipated problems involving risks to subjects or others, apparent serious or continuing noncompliance, any termination or suspension of research; and privacy or information security incidents related to VA research, including: any inappropriate access, loss, or theft of PHI; noncompliant storage, transmission, removal, or destruction of PHI; or theft, loss, or noncompliant destruction of equipment containing PHI, in accordance with local facility or IRB SOPs and VHA Handbook 1058.01.
    - VA personnel must ensure that the appropriate IRB of Record is notified, in writing, within five (5) business days after becoming aware of any apparent serious and/or continuing noncompliance with applicable laws, regulations, policies, and agreements pertaining to non-exempt human participants research. This includes, but is not limited to, serious or continuing noncompliance with the Common Rule, local VA medical facility policies and SOPs related to human participants research, if developed, IRB-approved protocols, and the requirements or determinations of the IRB.
    - In the event of a local research participant death, VA personnel must ensure that the appropriate IRB of Record is notified:
        - Immediately (i.e., within one hour) upon becoming aware of any local research death of a human participant that is believed to be both unexpected and related or possibly related to participating in a VA non-exempt human participant study. VA personnel must also provide follow-up written notification to the IRB within one (1) business day.
- In the event of any apparent UPIRTSO, VA personnel must ensure that the appropriate IRB of Record is notified, in writing, within five (5) business days after becoming aware of any apparent UPIRTSO.

- Research Records. All written information given to subjects must be in the investigator's research file along with the consent form(s). All records regardless of format (paper, electronic, electronic systems) must be managed per NARA approved records schedules found in VHA RCS 10-1 and therefore must be retained until disposition instructions, as approved by NARA, are published in VHA RCS 10-1. NOTE: Once the disposition schedule is determined, records should be disposed in accordance with VHA RCS 10-1. If the investigator leaves VA, all research records must be retained by the VA facility where the research was conducted.

- VHA Health Record. A VHA health record must be created or updated, and a progress note created, for all research subjects (Veterans or Non-Veterans) who receive research procedures or interventions as inpatients or outpatients at VA medical facilities that are either used in or may impact the medical care of the research subject at a VA medical facility or at facilities contracted by VA to provide services to Veterans (e.g., Community-Based Outpatient Clinics or nursing homes). Informed consent and HIPAA authorization documents are not required to be in the health record. The name and contact information of the researcher conducting the study should be included.
- Investigational Drugs and Devices. The investigator must conduct VA human subjects research involving investigational drugs and devices in accordance with all applicable VA policies and other federal requirements including, but not limited to: VHA Directive 1200.05, VHA Handbook 1108.04, and applicable FDA regulations. The storage and security procedures for test articles used in research must be reviewed and approved by the IRB and follow all applicable federal rules.
  - The PI or Local Site Investigator (LSI) must provide the Pharmacy Service with the following:
    - Written approval letter signed by the ACOS for R&D that all relevant approvals have been obtained and that the study may be initiated at the site (VHA Directive 1200.01);
    - An IRB approval letter;
    - A copy of the approved study protocol;
    - A copy of VA Form 10-9012, when appropriate;
    - An IB, when appropriate;
    - Any sponsor-provided documents relating to the storage, preparation, dispensing, and accountability of the investigation products;
    - Copies of all correspondence addressed to the Researcher from the FDA specific to the investigational drugs as appropriate;
    - A copy of the consent document for each participating participant with all appropriate signatures;
    - Protocol revisions, amendments, and updates after IRB approval and after the IRB approved the amendment;
    - Updates and changes to authorized prescribers after IRB approval;
    - Documentation of IRB continuing review approval;
    - Notice to the Chief, Pharmacy Service, the research pharmacy when applicable and the IRB in writing and the Research and Development Committee when a study involving investigational drugs has been suspended, terminated, or closed.
  - The PI or LSI must provide Pharmacy Service and/or the Research Service Investigational Pharmacy, investigational drug information on each patient receiving an investigational drug through the electronic medical record or other locally-approved means. This documentation is to include allergies, toxicities, or adverse drug events related to the investigational drug, or the potential for

interaction with other drugs, foods, or dietary supplements (herbals, nutriceuticals).
    - The PI or LSI must place the completed VA Form 10-9012, or electronic equivalent, in the subject's medical record.
    - The PI must comply with all dispensing and documentation requirements and the dispensing log must be made accessible to the investigational drug pharmacist upon request.
  - Initiation of Research Projects. IRB approval is for a specified time period based on the degree of risk of the study, not to exceed 1 year except for research subject to the 2018 Requirements where continuing review is not required. The IRB determines the expiration date based upon its date of review and communicates that date to the investigator in the written approval letter. The investigator must not initiate the IRB approved research protocol until all applicable requirements in VHA Directive 1200.01 have also been met including obtaining R&D Committee approval.
  - Expiration of IRB Approval. There is no provision for any grace period to extend the conduct of research beyond the expiration date of IRB approval. Therefore, continuing review and re-approval of research must occur on or before the date when IRB approval expires. If approval expires, the investigator must:
    - Stop all research activities including, but not limited to, enrollment of new subjects, analyses of individually identifiable data, and research interventions or interactions with currently participating subjects, except where stopping such interventions or interactions could be harmful to those subjects; and
    - Immediately submit to the IRB Chair a list of research subjects who could be harmed by stopping specified study interventions or interactions. The IRB Chair must determine within 2 business days whether or not such interventions or interactions may continue.
  - Documentation of Informed Consent
      - When documentation of informed consent is not waived by IRB, the investigator or designee must ensure that the informed consent document is signed and dated by the subject or the subject's legally authorized representative,
    - If consent is obtained electronically, the following must be met:
      - Authentication controls on electronic consent provide reasonable assurance that such consent is rendered by the proper individual; and
      - The subject dates the consent as is typical or that the software provides the current date when signed.
- Vulnerable Subjects
  - The following populations are considered categorically vulnerable and have specific VA requirements for their inclusion in research:
    - Pregnant Women, Human Fetuses and Neonates
    - Prisoners
    - Children
    - Subjects who Lack Decision-making Capacity.
- Research Involving Prisoners

- Research involving prisoners cannot be conducted by VA investigators while on official VA duty, at VA facilities, or at VA-approved off-site facilities unless a waiver has been granted by the CRADO.
- Waiver requests must be submitted electronically to the CRADO by the VA medical facility Director with the following documents:
  1. A letter from the VA medical facility Director supporting the conduct of the VA study involving prisoners;
  2. Rationale for conducting the research involving prisoners to include additional ethical protections taken by the proposed research for prisoners to make voluntary and uncoerced decisions whether or not to participate as subjects in research;
  3. Documentation of the VA investigator's qualifications to conduct the research involving prisoners, such as a biosketch and a list of all research team members;
  4. Location of institutions where the research is proposed to be conducted;
  5. A copy of the IRB approval letter specifically documenting its review determinations according to 45 CFR 46.305(a);
  6. A copy of the IRB minutes approving the research with documentation that at least one member of the IRB included a prisoner or a prisoner representative for the review of the research;
  7. A copy of the IRB-approved research study;
  8. A copy of the IRB-approved informed consent document; and
  9. A copy of the written HIPAA authorization.
- If such a waiver is granted, the research must comply with the requirements of 45 CFR 46.301 - 46.306.

- Research Involving Children
  - Research involving children must not present greater than minimal risk.
  - The VA medical facility Director must approve participation in the proposed research that includes children.
  - Research involving biological specimens or data obtained from children is considered to be research involving children even if de-identified. If the biological specimens or data were previously collected, they must have been collected under applicable policies and ethical guidelines.
  - The IRB must have the appropriate expertise to evaluate VA research involving children and must comply with the requirements of 45 CFR 46.401 - 46.404 and 46.408.
- Research Involving Pregnant Women, Human Fetuses and Neonates as Subjects
  - Neonates: Interventional research enrolling neonates cannot be conducted by VA investigators while on official duty, or at VA facilities, or at VA approved off-site facilities. VA investigators may conduct research involving noninvasive monitoring of neonates if the research is determined by the IRB to be minimal risk. Prospective observational and retrospective record review studies that involve neonates or neonatal outcomes are permitted. The VA medical facility Director must certify that the medical facility has sufficient expertise in neonatal health to conduct the proposed research.

- Pregnant Women: The VA medical facility Director must certify that the medical facility has sufficient expertise in women's health to conduct the proposed research if the research includes interventional studies or invasive monitoring of pregnant women as subjects.
- Research that involves provision of in vitro fertilization services can be conducted by VA investigators while on official VA duty, at VA facilities, or at VA-approved off-site facilities. This includes prospective and retrospective research involving provision of or the enhancement of FDA-approved methods of in vitro fertilization for studies involving consenting subjects, both male and female, undergoing or who have undergone in vitro fertilization for the treatment of certain forms of human infertility. In vitro fertilization is any fertilization of human ova that occurs outside the body of a female, either through a mixture of donor human sperm and ova or by any other means.
- Prospective and retrospective studies that enroll or include pregnant subjects who conceived through in vitro fertilization or other artificial reproductive technologies are permitted.
- Research that uses human fetal tissue or that focuses on either a fetus, or human fetal tissue, in-utero or ex-utero cannot be conducted by VA investigators while on official VA duty, at VA facilities, or at VA-approved off-site facilities. Use of stem cells shall be governed by the policy set by NIH for recipients of NIH research funding.

- Research Involving Persons Who Lack Decision-Making Capacity
  - The protocol must include a plan, that it is appropriate given the population and setting of the research, for how investigators will determine when a legally authorized representative will be required to provide informed consent. In general, the research staff must perform or obtain and document a clinical assessment of decision-making capacity for any subject suspected of lacking decision-making capacity.
  - When the potential subject is determined to lack decision-making capacity, investigators must obtain consent from the LAR of the subject (i.e., surrogate consent). NOTE: Investigators and IRBs have a responsibility to consult with the Office of General Counsel (OGC) regarding state or local requirements for surrogate consent for research that may supersede VA requirements.
  - The following persons are authorized to consent on behalf of persons who lack decision-making capacity in the following order of priority:
    - (1) Health care agent (i.e., an individual named by the subject in a Durable Power of Attorney for Health Care);
    - (2) Legal guardian or special guardian;
    - (3) Next of kin: a close relative of the patient 18 years of age or older, in the following priority: spouse, child, parent, sibling, grandparent, or grandchild; or
    - (4) Close friend.
  - If feasible, the investigator must explain the proposed research to the prospective research subject even when the legally authorized representative gives consent. Although unable to provide informed consent, some persons may resist participating in a research protocol approved by their representatives. Under no circumstances

may a subject be forced or coerced to participate in a research study even if the LAR has provided consent.
    - Legally authorized representatives must be told that their obligation is to try to determine what the subjects would do if able to make an informed decision. If the potential subjects' wishes cannot be determined, the legally authorized representatives must be told they are responsible for determining what is in the subjects' best interest.
- Research Involving Certificates of Confidentiality
    - If information about the subject's participation will be included as part of the VHA medical record that information must be given to the prospective subject as part of the informed consent process that information regarding study participation will be included in the medical record.
    - In instances where a written informed consent form is used, inclusion of a statement that the study has been issued a CoC is required.
    - Investigators should work with the research office in their facility to assure that when Veterans are enrolled in a study protected by a Certificate of Confidentiality, they are not simultaneously enrolled in other interventional studies unless it is absolutely clear that this enrollment does not raise safety issues.
- Collaborative Research
    - This addresses collaborations between VA and non-VA investigators. Collaboration is encouraged when VA investigators have a substantive role in the design, conduct, and/or analysis of the research. VA may also serve as a Coordinating Center for collaborative studies. NOTE: Collaborative studies do not include studies conducted under a CRADA with pharmaceutical companies or other for-profit entities.
    - IRB of Record Approval. Each institution is responsible for safeguarding the rights and welfare of human subjects and providing oversight of the research activities conducted at that institution.
        - Each collaborating institution engaged in human subjects research must obtain approval from its IRB of Record and hold a FWA or another assurance acceptable to VA, e.g. DoD assurance.
        - VA investigators must submit a protocol or other documentation to their VA IRB of Record that delineates which research activities will be conducted by VA.
        - Each institution engaged in the collaborative research must use the informed consent document and HIPAA authorization required by their respective institutional policies for subjects recruited from that institution, or procedures requiring participation of the subject at that institution. The informed consent document may contain information on the project as a whole as long as the document clearly describes which procedures will be performed at VA and which will be performed at other institutions.
            - The VA informed consent document must clearly state when procedures mentioned at other institutions are part of the VA's portion of the study.
            - The informed consent document and HIPAA authorization must be consistent and include information describing the following:

        - PHI to be collected and/or used by the VA research team;
        - PHI to be disclosed to the other institutions; and
        - Purpose for which the PHI may be used.
    - Waivers. PHI obtained in research for which the IRB of Record has waived the requirements to obtain a HIPAA authorization and a signed informed consent document may not be disclosed outside VA unless the VA facility Privacy Officer ensures and documents VA's authority to disclose the PHI to another institution. A waiver of HIPAA authorization is not sufficient to fulfill the requirements of other applicable privacy regulations such as the Privacy Act of 1974 (5 U.S.C. 552a).
    - Research Data. The protocol, addendum, and/or IRB of Record application must describe the data to be disclosed to collaborators, the entity(ies) to which the data are to be disclosed, and how the data are to be transmitted. This includes data from individual subjects as well as other data developed during the research such as the analytic data and the aggregate data.
        - Each VA facility must retain a complete record of all data obtained during the VA portion of the research in accordance with privacy requirements, the Federal Records Act, and VHA Records Control Schedule (RCS) 10-1.
        - All disclosures and data transmission must meet privacy and security requirements per VA Directive 6500, VHA Handbook 6500, and VHA Handbook 1605.1.
    - Written agreements. Collaborative research involving non-VA institutions may not be undertaken without a signed written agreement (e.g., a CRADA or a Data Use Agreement (DUA)) that addresses such issues as the responsibilities of each party, the ownership of the data and the reuse of the data for other research. NOTE: Any reuse must be consistent with the protocol, the informed consent document, and the HIPAA authorization.
- Photography, Video and/or Audio Recording for Research Purposes
    - The informed consent for research must include information describing any photographs, video, and/or audio recordings to be taken or obtained for research purposes, how the photographs, video, and/or audio will be used for the research, and whether the photographs, video, and/or audio will be disclosed outside the VA.
        - An informed consent to take a photograph, video, and/or audio recording cannot be waived by the IRB.
        - The consent for research does not give legal authority to disclose the photographs, video, and/or audio recordings outside the VA. A HIPAA authorization is needed to make such disclosures.
- International Research
    - VA international research is defined as any VA-approved research conducted at international sites (i.e., not within the United States (U.S.), its territories, or Commonwealths), any VA-approved research using either identifiable or de-identified human biological specimens or identifiable or de-identified human data originating from international sites, or any VA-approved research that entails sending such specimens or data out of the U.S. This definition applies regardless of the funding source (funded or unfunded) and to research conducted through any mechanism of

support including MOUs, CRADAs, grants, contracts, or other agreements. NOTE: Research conducted at U.S. military bases, ships, or embassies is not considered international research.
    - Sending specimens or data to individuals with VA appointments at international sites (e.g., a WOC appointment, a VA investigator on sabbatical at an international site) is considered international research. Remote use of data that is maintained on VA computers within the U.S. or Puerto Rico and accessed via a secure connection is not considered international research.
    - International research includes multi-site trials involving non-U.S. sites where VA is the study sponsor, a VA investigator is the overall study-wide PI, VA holds the Investigational New Drug (IND), or the VA manages the data collection and the data analyses.
    - International research does not include studies in which VA is only one of multiple participating sites where the overall study-wide PI is not a VA investigator (i.e., the PI for the study as a whole is not a VA investigator).
  - Before approving international research involving human subjects research, the IRB must ensure that human subjects outside of the U.S. who participate in research projects in which VA is a collaborator receive equivalent protections as research participants inside the U.S. (see OHRP guidance at http://www.hhs.gov/ohrp/international/index.html). NOTE: The VA medical facility Director must approve participation in the proposed international research.
  - All international research must also be approved explicitly in a document signed by the VA medical facility Director, except for Cooperative Studies Program activities which must be approved by the CRADO.
- Use Preparatory To Research
  - VA investigators may use individually-identifiable health information to prepare a research protocol prior to submission of the protocol to the IRB for approval without obtaining a HIPAA authorization or waiver of authorization.
    - VA investigators must not arbitrarily review PHI based on their employee access to PHI until the investigator documents the following required information as “Preparatory to Research” in a designated file that is readily accessible for those required to audit such information (e.g., Health Information Manager or PO):
      - Access to PHI is only to prepare a protocol;
      - No PHI will be removed from the covered entity (i.e., VHA); and
      - Access to PHI is necessary for preparation of the research protocol.
    - Non-VA researchers may not obtain VA information for preparatory to research activities without appropriate VA approvals (see VHA Directive 1605.01).
    - During the preparatory to research activities the VA investigator:
      - Must only record aggregate data. The aggregate data may only be used for background information to justify the research or to show that there are adequate numbers of potential subjects to allow the investigator to meet enrollment requirements for the research study;

        - Must not record any individually identifiable health information; and
        - Must not use any individually identifiable information to recruit research subjects.
        - Preparatory activities can include reviewing database output (computer file or printout) containing identifiable health information generated by the database owner, if the investigator returns the database output to the database owner when finished aggregating the information.
    - Contacting potential research subjects and conducting pilot or feasibility studies are not considered activities preparatory to research.
    - Activities preparatory to research only encompass the time to prepare the protocol and ends when the protocol is submitted to the IRB.
- Posting of Clinical Trial Consent Forms
    - For studies subject to the 2018 Requirements, if a VA research study is a clinical trial, one IRB-approved informed consent form used to enroll subjects, unless the IRB waived documentation of informed consent, must be posted by either the investigator or the Federal department or agency conducting or supporting the study. The informed consent form must be posted after the clinical trial is closed to recruitment and no later than 60 days after the last study visit by any subject as described in the IRB-approved protocol. For multi-site studies, it applies when the entire study has closed to subject recruitment. Any proprietary or personal information (such as names and phone numbers) must be redacted prior to posting the informed consent form.
        - For any ORD-funded clinical trial, the applicable ORD funding service will be responsible for posting the informed consent form.
        - For a clinical trial funded or supported by a Federal agency or department other than VA, the awardee is responsible for posting the informed consent form.
        - For a clinical trial funded or supported by a non-Federal agency or department (e.g., university, industry, nonprofit organization) or not funded, the VA Investigator conducting the clinical trial is responsible for ensuring that the informed consent form is posted. If the clinical trial includes multiple sites engaged in the clinical trial, an agreement must exist specifying who is responsible for posting the informed consent form.
- Other specific requirements of Veterans Administration (VA) research can be found in the “Additional Requirements for Veterans Administration (VA) Research” section in the IRB’s HRP-318 – WORKSHEET – Additional Federal Agency Criteria

Appendix A-10 ***Single IRB Studies***

1. That National Institutes of Health expects that all sites participating in multi-site studies involving non-exempt human subjects research funded by the NIH will use a single Institutional Review Board (sIRB) to conduct the ethical review required by the Department of Health and Human Services regulations for the Protection of Human Subjects at 45 CFR Part 46.
    a. This policy applies to the domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research, whether supported through grants, cooperative agreements, contracts, or the NIH Intramural Research Program. It does not apply to career development, research training or fellowship awards.
    b. This policy applies to domestic awardees and participating domestic sites. Foreign sites participating in NIH-funded, multi-site studies will not be expected to follow this policy.
    c. Exceptions to the NIH policy will be made where review by the proposed sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy. Requests for exceptions that are not based on a legal, regulatory, or policy requirement will be considered if there is a compelling justification for the exception. The NIH will determine whether to grant an exception following an assessment of the need.
2. The Office for Human Research Protections expects that all sites located in the United States participating in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.

    The following research is not subject to this provision:

    a. Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or
    b. Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.
    c. For research not subject to paragraph (b) of this section, an institution participating in a cooperative project may enter into a joint review arrangement, rely on the review of another IRB, or make similar arrangements for avoiding duplication of effort.

Appendix A-11 *Additional Requirements for Research Subject to EU General Data Protection Regulations (GDPR)*

1. Human Research involving personal data about individuals located in (but not necessarily citizens of) European Union member states, Norway, Iceland, Liechtenstein, and Switzerland is subject to EU General Data Protection Regulations.
2. For all prospective Human Research subject to EU GDPR, contact institutional legal counsel or your institution's Data Protection Officer to ensure that the following elements of the research are consistent with institutional policies and interpretations of EU GDPR:
    a. Any applicable study design elements related to data security measures.
    b. Any applicable procedures related to the rights to access, rectification, and erasure of data.
    c. Procedures related to broad/unspecified future use consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens.
3. Where FDA or DHHS regulations apply in addition to EU GDPR regulations, ensure that procedures related to withdrawal from the research, as well as procedures for managing data and biospecimens associated with the research remain consistent with Appendices A-1 and A-2 above.

Appendix A-12 *Emergency/Disaster Preparedness Considerations for Investigators Conducting Human Research*

Investigators conducting human research should be aware of the following additional considerations associated with managing Human Research during an emergency/disaster scenario (e.g., extreme weather events, natural disasters, man-made disasters, infectious disease pandemics, etc.) related to investigators' ongoing interactions with research subjects and the institutional review board (IRB) in such cases.

During Emergency/Disaster Scenarios: Deciding Whether a Study-Specific Risk Mitigation Plan for Ongoing Research Is Needed

In general, investigators should develop a study-specific emergency/disaster risk mitigation plan for their research unless one of the following is true:

- Research does not involve in-person interaction with research subjects.
- Research can be conducted as written while adhering to additional institution-level and HRPP-level guidance and requirements regarding the emergency/disaster event.
- The research is externally sponsored, and the sponsor has developed a protocol-specific risk mitigation plan for the research.
- The research has been voluntarily placed on hold for recruitment and all research procedures (except for necessary follow-up procedures to be done consistently with additional institution-level and HRPP-level guidance and requirements regarding the emergency/disaster event).

Tools and Resources for Developing Study-Specific Emergency/Disaster Risk Mitigation Plans for Ongoing Research

Review "HRP-108 - FLOWCHART - Study-Specific Emergency-Disaster Risk Mitigation Planning" and "HRP-351 - WORKSHEET - Protocol-Specific Emergency-Disaster Risk Mitigation Planning" for general guidance on developing study-specific risk mitigation plans.

Voluntary Holds on Human Research Activities

Investigators may voluntarily elect to place all recruitment, enrollment and research procedures on temporary hold during emergency/disaster scenarios if doing so will better ensure the safety of research subjects and would not create any additional risks to the safety and welfare of research subjects. Such voluntary holds on research activity do not require IRB notification or review.

Submitting Study-Specific Emergency/Disaster Risk Mitigation Plans for IRB Review

If immediate modification of the research is necessary to eliminate an apparent immediate hazard to a subject, take action and notify the IRB within five business days following the standard pathway to submit reportable new information.

For all other study modifications made to ensure the ongoing safety of research subjects during emergency/disaster scenarios, submit a study amendment and all relevant new or modified study materials to the IRB.

Other Reportable New Information Considerations During Emergency/Disaster Scenarios

The IRB's list of reportable events includes two items for which additional clarification and guidance may be helpful during emergency/disaster scenarios:

- ***"Failure to follow the protocol due to the action or inaction of the investigator or research staff."*** Emphasis on action or inaction of the investigator or research staff has been added because this requirement does not include action or inaction of the research subject. For example, study teams may notice an increase in the number of subjects who do not arrive for scheduled research visits under emergency/disaster circumstances. Failure of a research participant to appear for a scheduled research visit is not noncompliance due to action or inaction by the investigator or research staff, and therefore does not require reporting to the IRB.
- ***"Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject."*** During emergency/disaster scenarios, there will be cases where there is sufficient time to receive IRB approval of any proposed modifications to previously approved research, and in such cases, investigators should follow standard IRB procedures for submitting modifications. However, there will be other cases where investigators must make more immediate changes to the protocol or investigational plan to minimize or eliminate immediate hazards or to protect the life and well-being of research participants. Such changes may be implemented without IRB approval, but are required to be reported to the IRB within five business days afterward in accordance with IRB policies and procedures for submitting reportable new information.

HRP-103p | 11/12/2024 | Author: T. Bechert | Approver: J. Opalesky

pSite Investigator Manual[1]

(For Single IRB Review of Multi-Site or Collaborative Research)

[1]This document satisfies AAHRPP element I-9

Table of Contents

Scope

Throughout this document “local institution” refers to the Participating Site (pSite).

What is the purpose of this manual?

This document, HRP-103 – pSite INVESTIGATOR MANUAL, is designed to guide you through policies and procedures related to the conduct of Human Research that are specific to the institution that is serving as the sIRB.

General information regarding Human Research protections and relevant federal regulations and guidance is incorporated into the required human protections training. For additional information see below: “What training does my staff and I need in order to conduct Human Research?”

What training does my staff and I need to conduct Human Research?

This section describes the training requirements imposed by the IRB. You may have additional training imposed by other federal, state, or institutional policies.

Personnel affiliated with an institution or entity with an IRB must complete human protections training as required by their local institution.

Personnel affiliated with an organization without an IRB or not affiliated with any entity (e.g., independent consultant) must complete human participant protection training as described below.

Investigators and staff conducting research must complete the Collaborative Institutional Training Initiative (CITI) human subjects online training program. The course that applies to the majority of research conducted or supported by the individual should be taken.

The CITI site can be accessed at http://www.citiprogram.org/.

Training is valid for a two-year period, after which time refresher training must be completed. After 9 refresher courses, a basic course must be taken again.

All members of the research team involved in the design, conduct, or reporting of the research must complete training. Members of the research team who have not completed human research protections training may not take part in aspects of the research that involve human subjects.

CITI training completion certificates must be uploaded for the Principal Investigator (and Medically or Psychologically Responsible Investigator, and Lead Student/Trainee Investigator, if applicable) for each new submission, continuing review, or newly added investigator.

What financial interests do my staff and I need to disclose to the sIRB to conduct Human Research?

You should follow your local institution’s processes and policies regarding financial interest disclosures. You must provide the sIRB with the local institution’s evaluation when any

personnel (or an immediate family member of personnel) involved in the design, conduct, or reporting of the research are determined to have a financial interest Related to the Research.

What are my responsibilities as the Participating Site (pSite) Investigator?

The lead study team will provide the forms below to the pSite study team. The pSite study team is then responsible for completing and returning the following documents to the lead study team at initial review:

- HRP-811 – FORM – Basic Site Information
- Site-specific study documents, including consent, authorization form if requested, and recruitment material

The documents below are tools to report ongoing submissions to the lead study team, who will submit to the sIRB on your behalf:

- HRP-812 – FORM – Site Continuing Review
- HRP-813 – FORM – Site Modification
- HRP-814 – FORM – Site Reportable New Information

pSite investigators are responsible for ensuring safe and appropriate performance of the research at their site and following their own local institution's processes and requirements for relying on an external IRB, including completion of local institutional ancillary reviews.

How do I create a consent document?

Use the sIRB approved consent template document and revise it to include applicable site-specific required language.

We recommend that you date the revisions of your consent documents to ensure that you use the most recent version approved by the IRB.

What are my obligations after sIRB approval of my site?

1) Do not start Human Research activities until you have the final IRB approval letter.
2) Do not start Human Research activities until you have obtained all other required local institutional approvals.
3) Ensure that there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space.
4) Ensure that Research Staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials, protocol requirements and, when relevant, privileges) to perform procedures and duties assigned to them during the study.
5) Personally conduct or supervise the Human Research. Recognize that the investigator is accountable for the failures of any study team member.

a) Conduct the Human Research in accordance with the relevant current protocol as approved by the IRB, and in accordance with applicable federal regulations and local laws.
b) When required by the IRB ensure that consent or permission is obtained in accordance with the relevant current protocol as approved by the IRB.
    i) Assessment of decision making capacity tool (for reference only): https://research.vcu.edu/media/office-of-research-and-innovation/humanresearch/ICEval.doc
c) Do not modify the Human Research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects.
d) Protect the rights, safety, and welfare of subjects involved in the research.

6) Submit to the lead study team and sIRB:
    a) Proposed modifications as described in this manual. (See "What are my responsibilities as the pSite Investigator?")
        i) Single subject protocol exceptions should be submitted via the modification process.
        ii) Modifications requested in response to a Suspension of IRB Approval must be submitted within 30 days. Studies with no remediation attempt will be referred to the convened IRB for Termination of IRB Approval.
    b) A continuing review application as requested in the approval letter. (See "What are my responsibilities as the pSite Investigator?")
    c) A continuing review application when the Human Research is closed. (See "What are my responsibilities as the pSite Investigator?")
7) Complete HRP-814 – FORM – Site Reportable New Information and provide to the lead study team so that it can be submitted to the sIRB within five business days of becoming aware of any of the following information items:
    a) Information that indicates a new or increased risk, or a new safety issue. For example:
        i) New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor report, or investigator finding) indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk.
        ii) An investigator brochure, package insert, or device labeling is revised to indicate an increase in the frequency or magnitude of a previously known risk, or describe a new risk
        iii) Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol
        iv) Protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm
        v) Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm
        vi) Any changes significantly affecting the conduct of the research
    b) Harm experienced by a subject or other individual, which in the opinion of the investigator are **unexpected** and **probably related** to the research procedures.
        i) A harm is "unexpected" when its specificity or severity are inconsistent with risk information previously reviewed and approved by the IRB in terms of nature, severity, frequency, and characteristics of the study population.

ii) A harm is "probably related" to the research procedures if in the opinion of the investigator, the research procedures more likely than not caused the harm.

c) Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such non-compliance.

d) Audit, inspection, or inquiry by a federal agency and any resulting reports (e.g. FDA Form 483.)

e) Written reports of study monitors that represent information described in 8(a) or (b) above; all other study monitor reports (e.g., reflects administrative changes or updates only) may be submitted at the time of continuing review.

f) Failure to follow the protocol due to the action or inaction of the investigator or research staff that represents a potential increase in risk of harm to subjects.

g) Breach of confidentiality.

h) Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject.

i) Incarceration of a subject in a study not approved by the IRB to involve prisoners.

j) Complaint of a subject that cannot be resolved by the research team.

k) Premature suspension or termination of the protocol by the sponsor, investigator, or institution.

l) Unanticipated adverse device effect (any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects).

8) Complete HRP-813 – FORM – Site Modification and provide to lead study team to report an updated disclosure of financial interests per VCU requirements within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest. Attach the pSite institution's evaluation of the financial interest.

9) Do not accept or provide payments to the research team or other clinicians in exchange for referrals of potential research subjects ("finder's fees.")

10) Do not accept payments (including offers for unrestricted grants/gifts) to the research team or the institution designed to accelerate recruitment that were tied to the rate or timing of enrollment ("bonus recruitment payments.")

11) See sIRB requirements of federal agencies in Appendix A.

12) If the study is subject to the revised 2018 Common Rule, a clinical trial and supported by a Common Rule agency, one IRB-approved version of a consent form that has been used to enroll participants must be posted on a public federal website designated for posting such consent forms. The form must be posted after recruitment closes, and no later than 60 days after the last study visit. Please contact the study sponsor with any questions.

a) If certain information should not be made publicly available on a Federal website (e.g. confidential commercial information), the supporting Federal department or agency may permit or require redactions to the information posted. Contact the Federal department or agency supporting the clinical trial for a formal determination.

b) Contact the supporting Federal department or agency sponsor with any other questions regarding consent form posting obligations.

13) The VCU Post Approval Monitoring and Education (PAM&E), when applicable, performs routine or for-cause audits.

How do I document consent?

Use the signature block approved by the sIRB on the consent form(s). Complete all items in the signature block, including dates.

The following are the requirements for long form consent documents:

- The subject or representative signs and dates the consent document.
- If the subject/representative is physically unable to sign the consent form, note this on the consent form and document the method used for communication with the prospective subject/representative and the specific means by which their agreement was communicated.
- The individual obtaining consent signs and dates the consent document.
- Whenever the sIRB or the sponsor require a witness to the oral presentation, the witness signs and dates the consent document.
- For subjects who cannot read and whenever required by the IRB or the sponsor, a witness to the oral presentation signs and dates the consent document.
- A copy of the signed and dated consent document is to be provided to the subject.

The following are the requirements for short form consent documents:

- The subject or representative signs and dates the short form consent document.
- The person obtaining consent signs and dates the summary.
- The impartial witness (fluent in both English and the language spoken by the subject/representative) to the oral presentation signs and dates the short form consent document and the summary. The witness and the interpreter may be the same person.
- Copies of the signed and dated consent document and summary are provided to the person(s) signing those documents.

How do I get additional information and answers to questions?

This document and the policies and procedures for the Human Research Protection Program are available on the IRB Web Site at https://research.vcu.edu/human-research/hrppirb/hrpp-policies-and-guidance/.

If you have any questions or concerns, about the Human Research Protection Program, contact the IRB Office at:

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

You may also contact your local institution IRB Office or Human Research Protection Program.

Appendix A-1 ***Single IRB Studies***

1. That National Institutes of Health expects that all sites participating in multi-site studies involving non-exempt human subjects research funded by the NIH will use a single Institutional Review Board (sIRB) to conduct the ethical review required by the Department of Health and Human Services regulations for the Protection of Human Subjects at 45 CFR Part 46.
    a. This policy applies to the domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research, whether supported through grants, cooperative agreements, contracts, or the NIH Intramural Research Program. It does not apply to career development, research training or fellowship awards.
    b. This policy applies to domestic awardees and participating domestic sites. Foreign sites participating in NIH-funded, multi-site studies will not be expected to follow this policy.
    c. Exceptions to the NIH policy will be made where review by the proposed sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy. Requests for exceptions that are not based on a legal, regulatory, or policy requirement will be considered if there is a compelling justification for the exception. The NIH will determine whether to grant an exception following an assessment of the need.
2. The Office for Human Research Protections expects that all sites located in the United States participating in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.

    The following research is not subject to this provision:

    a. Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or
    b. Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.
    c. For research not subject to paragraph (b) of this section, an institution participating in a cooperative project may enter into a joint review arrangement, rely on the review of another IRB, or make similar arrangements for avoiding duplication of effort.

Should I take part in a research study?[1]

Here are some things you should know.

What is an IRB?
The Institutional Review Board (IRB) is a group of people who review and approve human research. The IRB includes medical people, scientists, and people from the local community. They review human research to make sure it is well-planned and ethical.

The IRB serves to protect your rights and your welfare before and during the research study. For example, the IRB makes sure that any risks are as small as possible. The IRB does not decide for you. The IRB decides whether it is right to ask people whether they want to take part in a research study. The IRB also reviews each research study while it is going on to make sure volunteers are protected.

Should I take part in a research study?
Thousands of research studies are being conducted each year. These research studies have contributed to health improvements for many people from every walk of life.

None of the advances in health care would be possible without people willing to volunteer to take part in research study. You may be asked to volunteer for a research study approved by this IRB. This pamphlet aims to help you understand your rights as a research study volunteer. It will help you to decide if you should take part in a research study. It will try to help you understand some of what is needed for a good research study. We urge you to review this information and discuss it with other people you trust.

Who will see my records?
Like your medical record, the information in your research study record will be confidential. Information will be given only to the people who need it. This includes researchers and staff who carry out the research study. This includes the Institutional Review Board (IRB), the company or group funding the research study, and various government oversight agencies. It is important for these groups to be able to look at your records, so they can ensure that the research study is conducted using acceptable research practices.

What is a research study?
A research study is an organized activity to learn more about a problem or answer questions. Scientists conduct many different kinds of studies. For example, a research study may test if a treatment is safe and effective. A research study may be done to find out what health care practices work best. A research study may be done to determine the best way to prevent an illness. A research study may use a survey or an interview to understand feelings people have about their health. One type of research study is a clinical trial. A clinical trial is a research study that will try to decide whether new treatments are safe and effective. In clinical trials, treatments are often compared with placebos to check the effectiveness of that treatment. A placebo is an inactive substance which may resemble

[1] This document satisfies AAHRPP elements I.4.A-B, I.5.D

an active substance. However, it typically has no value to treat or prevent an illness.

Who will answer my questions?
The research team will explain the research study to you. The consent form includes this explanation. You should take your time when you read the consent form.

If you have any questions, ask the research staff. If you don't understand something, ask them to explain it to you so you do understand. The information will be given to you in a language that you know. If English isn't your native tongue, ask for an interpreter to be present when you are discussing the research study with the research staff.

You can take the information home. You can discuss it with your family, friends, a health care provider, or others before you decide whether or not to take part in the research study. If you decide to take part in the research study, you will be asked to sign the consent form.

The informed consent process is more than just signing a piece of paper. It is a process that goes on throughout the research study. During the research study, you may be told of new findings, benefits or risks. At that time, you can decide whether or not to continue to take part in the research study. You may decide not to take part. You may change your mind and leave the research study before it starts. You may also leave at any time during the research study or the follow-up period.

Why should I volunteer for a research study?
There are many reasons to participate in research study.

You may want to:

- Help find a cure for an illness
- Help other people who are sick
- Help find ways to provide better care
- Help scientists find out more about how the human body and mind work
- Take part in a research study that is trying to find a better treatment for a condition that you have.

If you decide to take part in a research study, you do so as a VOLUNTEER. That means YOU decide whether or not you will take part. If you choose to do so, you have many important rights.

What is informed consent?
Informed consent is the process of learning the key facts about a research study before you decide whether or not to volunteer. Your agreement to volunteer should be based upon knowing what will take place in the research study and how it might affect you. Informed consent begins when the research staff explains the facts to you about the research study.

The research staff will assist you with the "informed consent form" that goes over these facts, so you can decide whether or not you want to take part in the research study. These facts include details about the research study, tests or procedures you may receive, the benefits and risks that could result, and your rights as a research volunteer.

Are there benefits to being in a research study?
There may or may not be a direct benefit to you if you take part in a research study. For example, your health or a health condition you have may get better as a result of your participation in the research study. It may stay the same. It may get worse. No one can predict what will happen with a research study or how it might affect you. The research study may not help you personally.

The research study may result in information that will help others in the future.

Are there risks or side effects in a research study?

Sometimes research procedures and treatments may cause discomfort and bad side effects. The questions being asked could make you uncomfortable. The risks and side effects of the research study may not be known completely when you start the research study. The research staff will discuss with you known possible risks, so you can decide if you want to volunteer. If you do volunteer, the research staff will tell you about any new risks that they learn about during the research study for as long as you take part in the research study.

What questions should I ask before I agree to take part in a research study?

Before you decide to volunteer to take part in a research study, you need to know as much as possible about the research study. If there are any issues that concern you, be sure to ask questions. You might want to write your questions down in advance or take this booklet with you. The following is a list of sample questions. Not every question will apply to every research study.

- Who is doing this research study and what question might it answer?
- Will this research study help in understanding my condition? If so, how?
- What tests or procedures will be done?
- Is it possible that I will receive a placebo (inactive substance)?
- Will I have to make extra trips?
- What could happen to me, good and bad, if I take part in the research study?
- How long will this research study last?
- What will happen to any specimens that I give?
- Who has reviewed and approved this research study?
- Could my condition get worse during the research study?
- What will happen if it does?
- What other options or choices do I have if I decide not to take part in this research study?
- Who will be in charge of my care? Will I be able to continue to see my own doctor?
- Will I be charged anything or paid anything to be in this research study?
- If I decide to participate in this research study, how will it affect my daily life?
- What will happen to me at the end of the research study?
- Will I be told the results of the research study?
- Who will find out that I am taking part in this research study?
- How do I end my participation in this research study if I change my mind?
- Whom do I contact for questions and information about the research study?

Remember, if you do not understand the answer to any of your questions, ask again. Ask the person to explain the answer in a way you can understand it. If you forget the answers to the questions during the research study, just ask them again.

What if I do not want to take part in a research study?

If anyone asks you to take part in a research study, you have the right to say "no."

Remember:

- Your decision will not affect how we treat you.
- You need to weigh both the risks of the research study and the benefits.
- It may be helpful to talk with family members, friends, or your health care providers.

- If you decide to volunteer for a research study, you can change your mind and stop or leave the research study at any time. Your decision will not affect how we treat you.

Who will answer my questions?

If you have questions about research at Virginia Commonwealth University, please contact:

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

Please call this number if you have concerns or complaints, or just want to talk to someone about research at this organization.

VCU Research and Innovation

HRP-105 | 02/01/2024

OHRP FDA WRITTEN PROCEDURE CROSSWALK

The purpose of this document is to provide cross reference between IRB written procedure guidance prepared jointly by the Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA)[1] as published in May 2018 and the standard delivered HRPP Toolkit. This document is to be used for the purposes of determining what information should be covered in written procedures rather than a tool for assessing compliance. It may be utilized for HRPP self-evaluation and/or as audit/inspection support.

I. IRB Initial and Continuing Review of Research; Reporting IRB Findings and Actions

REGULATORY REQUIREMENT – Each IRB must follow written procedures for conducting initial and continuing review of research and for reporting IRB findings and actions to the investigator and the institution [45 CFR 46.103(b)(4)(i), 21 CFR 56.108(a)(1)]

RECOMMENDATIONS - Operational details should include the following to address HHS and FDA requirements for IRB written procedures:

Activity as Defined by Guidance	Relevant HRPP Toolkit ID Numbers and Notes
1. Conducting reviews at a meeting of the convened IRB[2] including:	
Documents submitted to the IRB for review (e.g., protocol, informed consent form, recruitment materials).	HRP-040 - SOP - IRB Meeting Preparation
Reviewer system utilized by the convened IRB (e.g., primary reviewer(s)).	HRP-040 - SOP - IRB Meeting Preparation
Documents routinely distributed to all IRB members and those that may be distributed to specific IRB members (e.g., primary reviewer(s)).	HRP-040 - SOP - IRB Meeting Preparation
Range of possible actions the convened IRB can take.	HRP-041 - SOP - IRB Meeting Conduct
Format of a convened meeting (e.g., in person, videoconferencing, other mechanism).	HRP-041 - SOP - IRB Meeting Conduct

[1] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#toc

[2] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn4

Defining and maintaining quorum and the process followed if quorum is lost.[3]	HRP-042 - SOP - IRB Meeting Attendance Monitoring
Managing IRB members/alternates with conflicting interests.	HRP-050 - SOP - Conflicting Interests of IRB Members
2. Conducting review via expedited review procedures[4] including:	
Documents submitted to the IRB for review.	HRP-021 - SOP - Pre-Review
Reviewer system utilized for expedited review (e.g., IRB chairperson or other experienced reviewer(s) designated by the chairperson from among the members of the IRB).	HRP-030 - SOP - Designated Reviewers
Range of possible actions the designated expedited reviewer can take.	HRP-032 - SOP - Non-Committee Review Conduct
Method used for keeping all IRB members advised of research proposals approved via expedited review.	HRP-043 - SOP - IRB Meeting Minutes
3. Determining that the criteria for IRB approval of research are met.[5]	HRP-314 – WORKSHEET – Criteria for Approval
4. Information about reviewing the informed consent form and the informed consent process[6] including:	
Consideration of the required and additional elements of informed consent.	HRP-314 - WORKSHEET - Criteria for Approval
Translation of the informed consent form for non-English speaking subjects, when applicable.	HRP-090 - SOP - Informed Consent Process for Research
For HHS-conducted or -supported research, consideration of a waiver or alteration of the consent procedure.[7]	HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process
For both HHS-conducted or -supported research and FDA-regulated research, consideration of a waiver of documentation of consent.	HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent
5. Considering whether the study involves subjects that are likely to be vulnerable to coercion or undue influence, and, if so, whether additional	HRP-314 - WORKSHEET - Criteria for Approval

[3] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn5
[4] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn7
[5] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn6
[6] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn8
[7] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn9

safeguards have been included to protect the rights and welfare of these subjects[8]	
6. Reviewing studies requesting exceptions from informed consent requirements for emergency research[9]	HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research
7. For FDA-regulated research, assessing whether the investigator and/or sponsor determined that an investigational new drug application (IND) or investigational device exemption (IDE) is required for the proposed study, if applicable, and the basis for this determination[10]	HRP-306 - WORKSHEET - Drugs and Biologics HRP-307 - WORKSHEET - Devices
8. For FDA-regulated medical device research, making and documenting the significant/nonsignificant risk (SR/NSR) determination[11]	HRP-418 - CHECKLIST - Non-Significant Risk Device
9. For HHS-conducted or -supported research, determining the applicability of additional protections for pregnant women, human fetuses and neonates, and for prisoners[12]	HRP-412 - CHECKLIST - Pregnant Women HRP-413 - CHECKLIST - Non-Viable Neonates HRP-414 - CHECKLIST - Neonates of Uncertain Viability HRP-415 - CHECKLIST - Prisoners
10. Reviewing research involving children as subjects in accordance with applicable regulations.[13]	HRP-416 – CHECKLIST - Children
11. Reviewing the qualifications of the investigator(s) and study staff, and the adequacy of the site where the research will be conducted, including any institutional requirements for sponsor-investigator studies, if applicable.	Note: HRP-314 - WORKSHEET - Criteria for Approval requires that the research has the resources necessary to protect subjects (i.e. time to conduct and complete the research; adequate facilities, subject pool, and medical/psychosocial resources; qualified investigators and research staff; appropriate qualifications for international research.). However, as the parameters of these resources will vary based on institutional capabilities and research protocol requirements, institutionally specific language should be incorporated into HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN.

[8] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn10

[9] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn11

[10] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn12

[11] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn13

[12] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn14

[13] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn15

	HRP-103 - INVESTIGATOR MANUAL HRP-306 - WORKSHEET - Drugs and Biologics HRP-307 - WORKSHEET - Devices
12. Determining and documenting the effective date of initial approval and calculating the date for subsequent continuing review.	HRP-041 - SOP - IRB Meeting Conduct
13. Communicating the IRB's findings and actions to both the investigator and the institution[14], including:	
Which institutional office(s)/official(s) are notified.	HRP-052 - SOP - Post-Review
Communicating to the investigator any modifications or clarifications required by the IRB as a condition of approval.	HRP-052 - SOP - Post-Review HRP-303 - WORKSHEET - Communication of Review Results HRP-512 - LETTER - Mods Req to Secure Approval
Reviewing and acting on the investigator's response to any required modifications or clarifications required by the IRB as a condition of approval.	HRP-021 - SOP - Pre-Review
Communicating the reason(s) for a decision to disapprove, and the process followed to allow the investigator to respond.	HRP-052 - SOP - Post-Review
14. For FDA-regulated research, reviewing a request for expanded access or treatment use.[15]	HRP-023 - SOP - Emergency Use, Compassionate Use, Indiv Patient Expanded Access
15. For FDA-regulated research, reviewing the emergency use of a test article.[16]	HRP-023 - SOP - Emergency Use, Compassionate Use, Indiv Patient Expanded Access
16. For FDA-regulated research, reviewing a request for the use of a Humanitarian Use Device (HUD).[17]	HRP-323 - WORKSHEET - Criteria for Approval HUD

II. Frequency of IRB Review; Verification Regarding Material Changes

Regulatory Requirement - Each IRB must follow written procedures for determining which projects require review more often than annually and determining which projects need verification from sources other than the investigator that no material changes have occurred since previous IRB review [45 CFR 46.103(b)(4)(ii), 21 CFR 56.108(a)(2)]

[14] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#toc

[15] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn17

[16] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn18

[17] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn19

RECOMMENDATIONS - Operational details should include information about:

Activity as Defined by Guidance	Relevant HRPP Toolkit ID Numbers and Notes
17. Determining the approval period/continuing review interval of the proposed research, including:	HRP-302 - WORKSHEET - Approval Intervals
General criteria used to make these determinations (e.g., the nature of the study and risks posed by the study; the degree of uncertainty regarding the risks involved; the vulnerability of the subject population; the experience of the investigator; the IRB's previous experience with the investigator and/or sponsor; the projected rate of enrollment; whether the study involves novel therapies).	HRP-041 - SOP - IRB Meeting Conduct
Documenting the approval period/continuing review interval (e.g., in the IRB meeting minutes or elsewhere in the IRB records).	HRP-041 - SOP - IRB Meeting Conduct
Communicating the IRB's determinations regarding the approval period/continuing review interval to the investigator.	HRP-052 - SOP - Post-Review
18. Determining whether the proposed research requires verification from sources other than the investigator, such as the sponsor, or other third party, that no material changes have occurred since the last IRB review, including the general criteria utilized to make the determination (e.g., complex projects; investigators with previous compliance issues; continuing review report indicates changes not previously reported; randomly selected projects).	HRP-212 - FORM - Continuing Review

III. Reporting of Proposed Changes to the IRB; Prior IRB Review and Approval of Changes

REGULATORY REQUIREMENT – Each IRB must follow written procedures for ensuring prompt reporting to the IRB of proposed changes in a research activity, and ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects [45 CFR 46.103(b)(4)(iii), 21 CFR 56.108(a)(3) and (4)]

RECOMMENDATIONS - Operational details should include information about:

Activity as Defined by Guidance	Relevant HRPP Toolkit ID Numbers and Notes

19. Reporting changes in research to the IRB, including:	
Informing investigators that they may not initiate changes to research without prior IRB review and approval except when necessary to eliminate apparent immediate hazards to subjects (e.g., through training programs, materials for investigators, specific directives included in approval letters to investigators).	HRP-103 - INVESTIGATOR MANUAL
Ensuring that changes in research are being reported to the IRB before they are initiated (e.g., random audits of research records).	HRP-103 - INVESTIGATOR MANUAL HRP-430 - CHECKLIST - Investigator Quality Improvement Assessment
Process for notifying the IRB of any changes made to eliminate apparent immediate hazards to subjects that did not have prior IRB approval.	HRP-103 - INVESTIGATOR MANUAL
20. Reviewing changes in research, including:	
What might qualify as a minor change in research.	HRP-313 - WORKSHEET - Expedited Review
Documents submitted to the IRB for changes in research.	HRP-213 - FORM - Modification
Type of review (e.g., full board review vs. expedited review), and the range of possible actions the IRB may take.	HRP-041 - SOP - IRB Meeting Conduct HRP-402 - CHECKLIST - Non-Committee Review
Assessment of whether the IRB-approved informed consent form requires revision.	HRP-314 - WORKSHEET - Criteria for Approval
21. Communicating the IRB's findings and actions for changes in research to both the investigator and the institution[18], including:	
Which institutional office(s)/official(s) are notified.	HRP-052 - SOP - Post-Review
Communicating to the investigator and the institution any modifications or clarifications required by the IRB as a condition of approval.	HRP-041 - SOP - IRB Meeting Conduct HRP-043 - SOP - IRB Meeting Minutes HRP-052 - SOP - Post-Review

[18] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn20

Reviewing and acting on the investigator's response to any required modifications or clarifications required by the IRB as a condition of approval.	HRP-021 - SOP - Pre-Review
Communicating the reason(s) for a decision to disapprove, and the process followed to allow the investigator to respond.	HRP-041 - SOP - IRB Meeting Conduct HRP-043 - SOP - IRB Meeting Minutes

IV. Reporting of Unanticipated Problems, Serious or Continuing Noncompliance, and Any Suspension or Termination of IRB Approval

REGULATORY REQUIREMENT - Each IRB must follow written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and, as applicable, any department or agency head, OHRP, and/or FDA of any unanticipated problems involving risks to human subjects or others, any instance of serious or continuing noncompliance with the applicable HHS and/or FDA regulations, or the requirements or determinations of the IRB, and any suspension or termination of IRB approval [45 CFR 46.103(a) and (b)(5), 21 CFR 56.108(b)]

RECOMMENDATIONS - Operational details should include information about:

Activity as Defined by Guidance	Relevant HRPP Toolkit ID Numbers and Notes
22. Identifying who is responsible for promptly reporting to the IRB, appropriate institutional officials, and, as applicable, any department or agency head, OHRP, and/or FDA any[19]	HRP-024 - SOP - New Information
Unanticipated problems involving risks to human subjects or others.	HRP-024 - SOP - New Information
Serious or continuing noncompliance.	HRP-024 - SOP - New Information
Suspension or termination of IRB approval.	HRP-024 - SOP - New Information HRP-026 - SOP - Suspension or Termination Issued Outside of Convened IRB
23. Reviewing information about unanticipated problems involving risks to human subjects or others[20], including:	
What might qualify as an unanticipated problem involving risks to human subjects or others, including adverse events that should be considered unanticipated problems.	HRP-214 - FORM - Reportable New Information

[19] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn21

[20] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn22

Documents submitted to the IRB regarding an unanticipated problem (e.g., written summary of the unanticipated problem, the outcome, and any steps taken to prevent recurrence).	HRP-214 - FORM - Reportable New Information
Type of review (e.g., full board review vs. expedited review), and the range of possible actions the IRB may take, if any.	HRP-024 - SOP - New Information
24. Reviewing information about serious or continuing noncompliance with the regulations or IRB requirements or determinations[21], including:	
What might qualify as serious or continuing noncompliance.	HRP-001 - SOP - Definitions
Documents submitted to the IRB regarding serious or continuing noncompliance (e.g., written summary of the noncompliance, the outcome, and any steps taken to prevent recurrence).	HRP-214 - FORM - Reportable New Information
Type of review (e.g., full board review vs. expedited review), and the range of possible actions the IRB may take, if any.	HRP-024 - SOP - New Information
25. Suspending or terminating approval of research that is not being conducted in accordance with the IRB's requirements, or that has been associated with unexpected serious harm to subjects[22], including:	
Circumstances in which suspending or terminating IRB approval might be appropriate.	HRP-026 - SOP - Suspension or Termination Issued Outside of Convened IRB
Consideration of subjects already enrolled (e.g., informing subjects about the suspension or termination).	HRP-026 - SOP - Suspension or Termination Issued Outside of Convened IRB
Orderly termination of the study, or transfer of the study or study subjects, if applicable.	HRP-026 - SOP - Suspension or Termination Issued Outside of Convened IRB
Communicating the reason(s) for the IRB's decision to suspend or terminate approval of the research.	HRP-026 - SOP - Suspension or Termination Issued Outside of Convened IRB

[21] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn23

[22] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn24

V. Additional Topics the Institution/IRB May Consider

a. Scope and Authority

Activity	Relevant HRPP Toolkit ID Numbers and Notes
26. The development and scope of the written procedures (e.g., who is responsible for preparing and maintaining them, including writing, revising, and approving; how often they are reviewed and updated, who they apply to; what happens if they are not followed).	HRP-061 - SOP - Quarterly Evaluations of the HRPP
27. The institutional authority under which the IRB is established and authorized, and the independence afforded the IRB to carry out its duties.	HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN
28. The ethical principles that govern the IRB in assuring that the rights and welfare of human subjects are protected.	HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN
29. Important regulatory definitions that guide the IRB's review processes and procedures (e.g., the definition of research, clinical investigation, human subject, minimal risk).	HRP-001 - SOP - Definitions
30. Other relevant federal regulations that may apply to human subject research (e.g., Health Insurance Portability and Accountability Act regulations, Department of Defense regulations).	HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN
31. Which institutional office(s) or official(s), if any, is responsible for further review and approval, or disapproval, of research that is approved by the IRB.[23]	HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN
32. The IRB's relationship to the administration of the institution, the other committees and department chairpersons within the institution, the research investigators, other institutions, and the regulatory agencies.	HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN

b. IRB Membership

Activity	Relevant HRPP Toolkit ID Numbers and Notes

[23] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn25

33. The number of members on the IRB[24].	HRP-080 - SOP - IRB Formation and Registration
34. Ensuring diversity in IRB membership (e.g., representation of both genders, multiple professions, scientific and nonscientific members, nonaffiliated members)[25].	HRP-304 - WORKSHEET - IRB Composition HRP-601 - DATABASE - IRB Roster
35. Selecting and appointing the IRB chairperson, the members, and alternate members if any, including:	
The length of term or service, general description of duties, attendance requirements, performance evaluation, including removal if necessary.	HRP-082 - SOP - IRB Membership Addition HRP-083 - SOP - IRB Membership Removal
The qualifications of the IRB chairperson, members and any alternate members[26].	HRP-082 - SOP - IRB Membership Addition HRP-304 - WORKSHEET - IRB Composition
The criteria used to categorize members and alternate members as scientist, nonscientist, and nonaffiliated[27].	HRP-082 - SOP - IRB Membership Addition HRP-202 - FORM - IRB Member Information
36. Defining what constitutes a conflicting interest for the IRB chairperson, members, and alternate members, and managing any such conflicting interest, including recusal from a meeting to ensure that a chairperson, member, or alternate member with a conflicting interest does not vote or count towards the quorum[28].	HRP-050 - SOP - Conflicting Interests of IRB Members
37. Training and education provided to the IRB chairperson, IRB members, alternate members, administrative support staff, and investigators.	HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN

c. IRB Functions and Operations

Activity	Relevant HRPP Toolkit ID Numbers and Notes

[24] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn26
[25] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn27
[26] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn28
[27] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn29
[28] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn30

38. Determining whether a study is subject to IRB review (e.g., what types of studies must be reviewed, which regulations apply, who makes the determination).	HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN
39. Determining which HHS-conducted or -supported research studies qualify as exempt from the HHS regulations, including who makes the determination.	HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN
40. Implementing cooperative IRB review arrangements, when applicable, such as joint review, reliance on the review of another qualified IRB, or similar arrangements aimed at avoiding duplication of effort[29].	HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN
41. Process for reporting the emergency use of an FDA-regulated test article to the IRB[30].	HRP-023 - SOP - Emergency Use, Compassionate Use, Indiv Patient Expanded Access
42. The use of consultants by the IRB[31], including a description of the process to identify the need for a consultant, to choose a consultant, and the consultant's participation in the review of research.	HRP-041 - SOP - IRB Meeting Conduct
43. Identifying and managing an investigator with a conflicting interest.	VCU Conflicts of Interest in Research policy: https://vcu.public.doctract.com/doctract/documentportal/08DA32A63EDBCC96C898EA6EC61CFF0A
44. Determining the applicability of state and local laws[32].	**Note: As state and local law varies from institution to institution, local language should be incorporated into relevant Toolkit documents as needed.**
45. Tracking study approvals and scheduling continuing review to prevent lapses in IRB approval, including procedures to follow if IRB approval lapses.	HRP-062 - SOP - Periodic Tasks HRP-063 - SOP - Expiration of IRB Approval
46. Handling subject complaints, problems, concerns and questions about rights as a research subject.	HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN HRP-024 - SOP - New Information
47. Administrative support staff duties.	**Note:** Individual SOPs indicate the party responsible for carrying out procedures.

[29] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn31

[30] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn32

[31] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn33

[32] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn34

	HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN specifies additional duties and responsibilities in the Components section.
48. Keeping the IRB informed of study completion and close out to ensure record retention in compliance with 45 CFR 46.115(b) and/or 21 CFR 56.115(b).	HRP-103 - INVESTIGATOR MANUAL
49. Registering the IRB and maintaining IRB registration[33] via the HHS Internet-based registration system[34].	HRP-080 - SOP - IRB Formation and Registration
50. Providing access to information about IRB requirements and written procedures (e.g., posting the information on a website accessible to the investigators, sponsors, and others).	HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN
51. Contingency plans 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, natural disaster).	HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN

d. IRB Records

Activity	Relevant HRPP Toolkit ID Numbers and Notes
52. Maintaining records required to be retained[35], and other records (e.g., IRB member training records).	HRP-072 - SOP - IRB Records Retention
53. Where records are stored (e.g., on site, off-site archives), and the format for record storage (e.g., hard copy, electronic or both).	HRP-070 - SOP - IRB Records
54. Preparing and maintaining minutes of IRB meetings[36].	HRP-043 - SOP - IRB Meeting Minutes

[33] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn35
[34] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn36
[35] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn37
[36] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn38

55. Retaining records for at least 3 years after completion of the research, and ensuring records are accessible for inspection[37].	HRP-072 - SOP - IRB Records Retention

[37] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn39