Human Research Protection Program

Plan[i]

HRP-101 | 5/14/2026 | Responsible Office: IRB

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Scope

Throughout this document “Institution” refers to University of Texas Health Science Center at San Antonio, also referred to as UT Health San Antonio.

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 the individual engages in research activities as defined by DHHS regulations and has signed an “Individual Investigator Agreement” which extends the UT Health SA FWA to the unaffiliated individual.

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”[ii] 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 is a live person and may be either a healthy human or a patient. A human subject includes an individual on whose specimen (identified or unidentified) a medical device is used.

Investigator

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.[iii]

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 living human subjects, and that meets any one of the following:

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

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/Organizational Official (IO/OO), and employees) follows the ethical principles outlined in the April 18, 1979 report of The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research titled "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," also known as "The Belmont Report":

- Respect for Persons
- Beneficence
- Justice

Legal Requirements

This Institution commits to apply its ethical standards to all Human Research regardless of funding or location. The Institution ensures compliance with applicable laws in the locations where research is conducted.

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. However, the IRB Office is available to assist in making determinations and will provide a determination letter for purposes of publication, presentation, etc.

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.

The Institution follows written policies and procedures to identify, manage, and minimize or eliminate financial conflicts of interest (COI) that could influence the conduct of research or the integrity of the Human Research Protection Program. The Institution's COI Committee oversees these efforts, and the IRB partners with the Committee to ensure COI management plans are effectively executed by investigators and study teams.

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

- Reviewing the scientific and scholarly validity of proposed research
- Post-approval monitoring
- Handling of complaints, non-compliance, and unanticipated problems involving risks to subjects or others, and reporting IRB findings or determinations, when required
- Consent process and other language issues
- Ensuring all necessary approvals are met
- Coordination and communication with local IRBs

For clinical trials, this Institution commits to apply the "International Conference on Harmonisation – Good Clinical Practice E6" (ICH-GCP) when required by industry-sponsored studies.

This Institution prohibits payments to professionals in exchange for referrals of potential subjects ("finder's fees") and payments designed to accelerate recruitment that were tied to the rate or timing of enrollment ("bonus payments.")

This Institution utilizes the IRB to review and approve the use of a Humanitarian Use Device (HUD) before it can be used at a facility for clinical care (with the exception of emergency use). The IRB reviews and approves research involving investigational or unlicensed test articles to ensure compliance with applicable regulations for their use.

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[iv]. This Institution will comply with the terms of the DFARS clause or comparable language used in the agreement with the Department of Defense (DOD) Component supporting the research involving human subjects.

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

When Human Research is subject to Veterans Affairs (VA) or Veterans Health Administration (VHA) 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 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.

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:

- 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
    - Research on DOD personnel
- Research conducted or funded by the Department of Education (ED)
- 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
- Exempt research requiring limited IRB review

Human Research Protection Program Policies and Procedures

Policies and procedures for the Human Research Protection Program are available within the Electronic Research Management System IRB Module (ERMS-IRB).

Human Research Protection Program Components

Institutional Official/Organizational Official (IO/OO)

The Senior Vice President for Research is designated as the IO/OO.

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

- Create the Human Research Protection Program budget.
- Allocate resources within the Human Research Protection Program budget.
- Recommend IRB members and chairs for appointment by the President of the Institution.
- 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.
- Create policies and procedures related to the Human Research Protection Program that are binding on the Institution.
- Suspend or terminate research approved by one of the Institution's IRBs.
- Disapprove research approved by one of the Institution's IRBs.
- Establish a contingency plan for transferring oversight of one or more studies to another institution or IRB in the event the IRB is unable to continue oversight of the studies in an emergency/disaster scenario (e.g., natural disasters, man-made disasters, infectious disease pandemics, etc.).

The IO/OO has the responsibility to:

- Oversee the review and conduct of Human Research under the jurisdiction of the Human Research Protection Program.
- Periodically review this plan to assess whether it is providing the desired results and recommend amendments as needed.
- Establish policies and procedures designed to increase the likelihood that Human 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 that the research review process is independent and free of coercion or undue influence, and ensure that officials of the Institution cannot approve research that has not been approved by one of the IRBs designated by the Institution.
- Ensure that the IRB Chair(s) and members have direct access to the IO/OO for appeal if they experience undue influence or if they have concerns about the function of the IRB.
- Implement a process to receive and act on complaints and allegations regarding the Human Research Protection Program.
- Follow up on findings of serious or continuing non-compliance of IRB staff and IRB members.
- Implement an auditing program to monitor compliance and improve compliance in identified problem areas.
- Investigate and remediate identified systemic problem areas, and where necessary, removal of individuals from involvement in the Human Research Protection Program.
- Ensure that the Human Research Protection Program has sufficient resources, 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.
- Review and sign federal assurances (FWA) and addenda.
- Fulfill educational requirements mandated by OHRP.

Department of Energy (DOE) Institutional Official

The DOE IO:

- Resides within Office of Science (SC) and serves both as the Associate Director of Science for Biological and Environmental Research (BER) and the Senior DOE Official responsible for overseeing and monitoring DOE-supported and conducted HSR (or for designated an SES-level manager in DOE to do so). Specifically, the DOE IO oversees the Departmental implementation of the requirements of DOE O 443.1C Chg.1, 10 CFR 745, 45 CFR 46 (Other Subparts), and related Executive Orders (E.O.s), 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 Human Subjects Protection Program (HSPP).
- Assures policies are in place that require that the research review process be independent and free of coercion and undue influence.
- Establishes 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.
- Reviews and adjudicates IRB member appeals of IRB approval determination for classified project.
- Must concur on all requests for partial or full exemptions from the requirements of DOE O 443.1C Chg. 1.
- 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 SC's 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 coordinates with DOE site Offices and site IRBs regarding plans to correct any noncompliance or mitigate adverse study events, ensuring they comply with applicable HSP requirements.
- Reviews and approves statements of work for Human Terrain Mapping (HTM) projects submitted by DOE's non-NNSA sites. Ensures compliance with DOE requirements, and, for HTM projects that are Strategic Partnership Projects (SPPs) and Strategic Intelligence Partnership Program (SIPP) projects, coordinates with

appropriate Headquarters SPP/SIPP leads prior to approving such statements of work for initiation. Ensures site Offices and M&O contractors are aware of decisions concerning proposed HTM work.

- 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 DOE-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 Chg. 1, 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 Database (HRSD), the list of unclassified intelligence-related HSR projects, and the unclassified list of classified HSR projects for DOE.
- 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 NA-1.1, the Office of Policy and Strategic Planning and reports functionally to the DOE IO.
- When a NNSA element or project is involved, the responsibilities of the NNSA HSP Program Manager are identical to those of the DOE HSP Program Manager.
- Ensures compliance with the DOE/NNSA requirements.

- Works with the DOE HSP Program Manager, as outlined above.
- Serves as one of the Co-Chair of the Central DOE IRB-C.

Responsibilities of the other DOE HRPP components are described in DOE Order 443.1C Chg. 1.

Veterans Administration (VA) Medical Facility Director

The VA Medical 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. This position also serves as the Institutional Official (IO) responsible for the VA medical facility's research program.

As the IO, the VA Medical Facility Director is responsible for overseeing the facility's research program, including but not limited to[v]:

- Ensuring that the institution's HRPP functions effectively and that the institution provides the resources and support necessary to comply with all requirements applicable to research involving human subjects.
- Overseeing the R&D Committee, IRB, and other applicable subcommittees of the R&D Committee, facility research office, and all VA investigators and VA research staff who conduct human subjects research at that facility.
- Delegating authority in writing for respective roles and responsibilities for the HRPP. This delegation of authority must provide the organizational structure and ensure leadership for oversight activities for all human subjects research conducted at or by the facility.
- Ensuring provision of adequate resources to support the operations of the HRPP.
- Ensuring independence of the IRB.
- Appointing the facility's IRB voting members in writing when the VA facility operates its own IRB.
- Appointing the Chair and, when applicable, Co-chair(s) or Vice Chair(s) for a term of up to 3 years when the VA facility operates its own IRB.
- Serving as the official representative of the institution to external agencies and oversight bodies, and providing all written communication with external departments, agencies, and oversight bodies.
- Ensuring that a procedure is in place to review and approve recruiting media, including documents, flyers, and advertisements for research that is not VA research prior to being posted or distributed in any form within or on the premises of a VA facility. Posting or distributing may include announcing, distributing, publishing, or advertising the study either electronically, by hard copy, or other means to anyone, including Veterans, clinicians, or other staff (see ORD guidance at http://www.research.va.gov/resources/policies/default.cfm).
- Ensuring that a documented procedure is in place for determining when a research activity approved by the IRB, prior to January 21, 2019, can transition to the 2018 Requirements, if applicable. The documented procedure must list what individuals or

groups are designated to make the determinations. NOTE: Investigators may not make a determination that their studies can be transitioned to the 2018 Requirements.

- Ensuring appropriate documentation of required actions and responsibilities pertaining to review, approval, conduct and oversight of research conducted at that facility set forth in VHA Directive 1200.05.
- Ensuring that any IRB operated by the VA facility is established in accordance with the requirements of VHA Directive 1200.05 and VHA Directive 1058;
- 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 or wants its internal IRB to serve as an IRB of record for a non-VA entity.
- Submitting waiver requests electronically to the CRADO for approval of research involving prisoners conducted by VA investigators while on official VA duty.
- Approving VA participation in proposed research that includes pregnant women, neonates, or children as described in VHA Directive 1200.05.

The VA Medical Facility Director is also responsible for[vi]:

- Ensuring that the VA medical facility holds a valid FWA approved by HHS-OHRP if the facility is engaged in non-exempt human subjects research covered by the requirements of the Federal Policy for the Protection of Human Subjects ("Common Rule"), which for VA is incorporated at 38 C.F.R. part 16.
- Ensuring that the VA medical facility's research review and oversight programs function effectively. This includes ensuring that there is adequate support at the facility to enable compliance with the reporting requirements of VHA Directive 1058 and the timely implementation of sustainable remedial actions to mitigate the risks of, correct, or otherwise prevent reoccurrence of the underlying issues or causes of the events covered by VHA Directive 1058.
- Notifying the Executive Director, ORO or applicable ORO workgroup in advance of the initiation of a research program or the substantial alteration of an existing research program that is related to the implementation, suspension, or termination of an Animal Care and Use Program (ACUP), HRPP, or Research Safety and Security Program (RSSP).
- Appointing at least one full-time VA medical facility RCO to conduct research informed consent and regulatory audits unless ORO has approved a written request from the VA medical facility Director to appoint a part-time VA medical facility RCO due to the facility having a small number of research studies such that the research auditing workload would not justify employing a full-time RCO.
- Ensuring that the VA medical facility Research Compliance Officer (RCO) (or a lead VA medical facility RCO if one designated in instances where a VA medical facility employs more than one RCO) reports directly to and is supervised by either the VA medical facility Director or a senior individual who both reports directly to and is supervised by the VA medical facility Director and whose primary responsibilities at the VA medical facility pertain directly to compliance.
- Ensuring that the RCO has direct access to the VA medical facility Director for purposes of reporting research noncompliance and other research-related concerns.

- Ensuring that VA medical facility RCO activities are not determined or managed by the ACOS/R&D or any other individual or research review committee in a VA medical facility's Research Service, regardless of to whom the VA medical facility RCO (or lead RCO if one has been designated) directly reports.
- Ensuring that the VA medical facility RCO's primary responsibilities at the VA medical facility pertain directly to compliance unless ORO has approved a written request from the VA medical facility Director otherwise.
- Ensuring that the VA medical facility RCO has the necessary education and experience at the time of hire or appointment to fulfill the duties of the RCO position.
- Ensuring that the VA medical facility RCO has ready access to research program and study documentation so that the VA medical facility RCO can effectively fulfill the responsibilities of the position, including access to documentation necessary to fulfill RCO research auditing requirements such as research review committee meeting minutes, study approval letters, approved study protocols, and investigator study documentation. NOTE: In situations where the VA medical facility relies upon a non-VA research review committee, the VA medical facility Director must ensure that the agreement (such as an MOU, reliance agreement, or service agreement) to rely on the committee requires that the VA medical facility's RCO be provided access to the non-VA research review committee's records to the extent necessary for the RCO to fulfill research auditing requirements.
- Ensuring that VA medical facility RCO audits are complete and timely and that the results of those audits are reported as required by VHA Directive 1058.
- Notifying ORO within 5 business days of an RCO annual quality assurance review determination that events covered by VHA Directive 1058 were not reported to ORO as required.
- Reporting any VA medical facility RCO appointment, resignation, or substantive change in duties or effort to ORO within 5 business days after the action takes effect.
- Implementing processes, consistent with all applicable VHA policy, to ensure that:
    - Events covered by VHA Directive 1058 are promptly reported to the VA medical facility Director so that the VA medical facility Director, or designee, can submit required notifications to ORO within the timeframes specified in VHA Directive 1058. NOTE: If the VA medical facility Director designates another individual to submit required notifications to ORO on their behalf, the VA medical facility Director must still be notified by VA medical facility personnel of the events covered by VHA Directive 1058 and the actions taken or to be taken to mitigate the risks of, correct, or otherwise prevent reoccurrence of the underlying issues/causes of the events.
    - Events covered by VHA Directive 1058 are reported to ORO within the specified timeframes.
    - The VA medical facility's RCO is copied on notifications to ORO required by VHA Directive 1058, unless the VA medical facility Director determines that it is inappropriate to do so.
- Ensuring that all research compliance reports from any state or Federal oversight entity (including ORO), as well as research accreditation reports and determinations, are provided to the VA medical facility ACOS/R&D or equivalent, the Research &

Development Committee (R&DC), any other relevant research review committees, and the VA medical facility RCO within 5 business days after receipt.

- Cooperating fully, and ensuring that VA medical facility personnel cooperate fully, with ORO's site reviews, investigations, and oversight activities, including ensuring that ORO requests for information (whether oral or in writing) are promptly and completely addressed.
- Ensuring that all applicable documents related to the review, approval, and ongoing oversight of VA research are promptly furnished to ORO in conjunction with ORO's research oversight activities.
- Ensuring timely implementation and documentation of remedial actions within the VA medical facility to mitigate the risks of, correct, or otherwise prevent reoccurrence of the underlying issues or causes of the events covered by VHA Directive 1058. NOTE: For the events that pose risk of harm to the safety, rights, or welfare of human research subjects or others as a result of participation in VA research, events that pose risk of harm to the safety of VA personnel conducting VA research, and events that pose risk to the welfare of animals used in VA research, appropriate actions to mitigate, correct, or otherwise prevent realization of such risks must be implemented as soon as practicable. This includes:
  - Ensuring that actions to remediate noncompliance identified by ORO are completed within 180 calendar days of notification by ORO, except where extenuating circumstances exist (e.g., remediation requires substantial renovation or fiscal expenditure, hiring, or legal negotiations).
  - Ensuring that actions to remediate, mitigate risks associated with, and otherwise prevent reoccurrence of events reportable to ORO pursuant to VHA Directive 1058 are completed within 180 calendar days of reporting to ORO, except where extenuating circumstances exist (e.g., remediation requires substantial renovation or fiscal expenditure, hiring, or legal negotiations).
  - When remedial actions cannot be completed within 180 calendar days, providing the appropriate ORO workgroup(s) with written justification and a reasonable timeline for completion for each action to the elapsing of the 180-calendar-day period for remediation. NOTE: This responsibility cannot be delegated.
- Ensuring accurate and timely completion of the VA medical facility Director's Certification of Research Oversight administered by ORO.

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 accepts audits conducted by the research compliance officer to fulfill the IRB's auditing requirements.

The Research Compliance Officer has the responsibility to:

- Promote awareness and understanding of VHA Directive 1058 among VA medical facility employees who administer the research program, VA medical facility employees who conduct or are otherwise engaged in VA research, internally operated research review committees, and, to the extent practicable, non-VA research review committees relied upon by the VA medical facility.
- Serve as a point of contact at the VA medical facility to whom VA personnel may submit research-related concerns, including initial reports of the occurrence of events addressed in VHA Directive 1058.
- Develop a written audit plan for performing informed consent and regulatory audits of approved study protocols and other post-approval monitoring activities as specified by ORO. The written audit plan must describe the VA medical facility RCO's auditing process, including:
    - Procedures for planning and executing audits.
    - Procedures for soliciting study investigators' responses to preliminary audit findings.
    - Procedures for reporting audit findings of noncompliance to relevant research review committees or committee coordinators with primary oversight of the research promptly, but no later than 30 calendar days after completion of an audit within findings.
- Audit VA medical facility research projects in accordance with the written audit plan, ensuring the accuracy of those audits, and ensuring the results of audits identifying noncompliance are promptly reported to relevant research review committees or committee coordinators with primary oversight of the research.
- Notify the VA medical facility Director and ORO within 5 business days of becoming aware that the auditing responsibilities described above cannot be fulfilled.
- Conduct a quality assurance review at least annually to determine whether events covered by VHA Director 1058 were reported to ORO as required, including whether such events were reported within the specified timeframes and submitting a written copy of the results to the VA medical facility Director and ACOS/R&D.
- Perform additional research compliance-related duties as assigned by their supervisor including assisting in research compliance education to investigators, research staff, and research committee members; assisting with research program accreditation activities; assisting with the completion of the VA medical facility Director's Certification of Research Oversight; conducting ad hoc audits of individual studies or programs; and conducting quality assurance activities designed to ensure that research compliance responsibilities at the VA medical facility are being satisfied.

The Research Compliance Officer has the authority to:

- Serve as a non-voting 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 (PO) and the Information System Security Officer (ISSO)

The PO and the IISO serve in an advisory capacity to the facility's IRB as either non-voting members or as consultants.

All members of the Institution

All individuals within the Institution have the responsibility to:

- Be aware of the definition of Human Research.
- Consult the IRB when there is uncertainty about whether an activity is Human Research.
- Not conduct Human Research or allow Human Research to be conducted without review and approval by an IRB designated by the IO/OO.
- Report allegations of undue influence regarding the oversight of the Human Research Protection Program or concerns about the Human Research Protection Program to the IO/OO.
- Report allegations or findings of non-compliance with the requirements of the Human Research Protection Program to the IRB.
- For 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. Additional guidance is in HOP 7.2.1 Human Research Protection Program Responsibilities.

IRBs

The IRBs designated by the IO/OO to be relied upon by the Human Research Protection Program, and the scope of review of these IRBs, are 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. Additional guidance is in HOP 1.6.6 Institutional Review Board and HOP 7.2.2 Institutional Review Board Responsibilities.

IRB members and chair

IRB members and chairs should complete the IRB member education within three months of being appointed to the board.

- IRB staff use the OIRB database to monitor IRB member training and provide regular reports to the members, chair and IRB Director of training status and impending expiration dates. If training lapses for extended periods, the chair and IRB Director will take this into account when providing annual member feedback and member re-appointments.
- Orientation of new IRB Members - following appointment as a member on the IRB and prior to serving as reviewers (primary or secondary), IRB members, ex officio members, and alternate members receive the following training:
    - The OIRB staff provides new and existing members with a general orientation. Following the annual assignment of members, the OIRB provides an orientation session for all new and current board members.
    - As new members are added to the board throughout the year, they will meet with the IRB Chair or designee to review roles and responsibilities either one-on-one or in a small group.
- Existing members may request one-on-one trainings or attend scheduled small group trainings as needed.
- IRB members are provided with continuing education as part of most meeting's standard agenda. The education topic is generally selected to coincide with an issue from one of the studies scheduled for review at the meeting.
- Additional educational materials containing ethical and regulatory guidance for the review of protocols involving a specialized area, (i.e., gene therapy or tissue banking) or selected vulnerable subject populations (i.e., prisoners) are provided specifically to primary/secondary reviewer or to all members as appropriate.
- The OIRB provides funding for the Chairs, members and/or regulatory specialists to attend national continuing education conferences, as budgets permit.

Relying on an External IRB

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. Local submission of an institutional research application is required, and submission to the external IRB occurs after the IRB Office receives the local application within ERMS-IRB and provides clearance for the external IRB submission.

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.

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/OO. Officials of this Institution may not approve Human Research that has been disapproved by the IRB of record.

- Suspend or terminate approval of Human Research not being conducted in accordance with an IRB's requirements or that has been associated with unexpected serious harm to subjects.
- Observe, or have a third party observe, the consent process and the conduct of the Human 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.

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

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.

The Institution's IRB office may determine whether serving as IRB of record is appropriate on a case-by-case basis. In general, however, the Institution's IRB will consider serving as the IRB of record in the following situations:

- The role of the external site or personnel is limited to activities such as data analysis, consultation, or other administrative roles;

- The study is minimal risk and the role of the external site or personnel is either limited or very straightforward (e.g., administration of a single survey, assisting with recruitment of subjects); and/or
- The study is eligible for review under an existing IRB authorization agreement (MOU, SMART, etc.).

The Institution's IRB may consider serving as IRB of record for another site or individual who does not have an appointment at the Institution, University Health, or STVHCS.

The Institution's IRB typically will not consider serving as the IRB of record in certain situations, including:

- The Institution is not engaged in research.
- The Institution's IRB does not have sufficient knowledge of the local context (as required by federal guidelines) to assume IRB oversight for external sites or personnel;
- The Institution's IRB does not feel it can adequately oversee the external site or personnel in a manner that will ensure the protection of human subjects; and/or
- Studies for which administrative or institutional policies otherwise prohibit or limit options for serving as IRB of record.

When the Institution's IRB agrees to serve as IRB of record for external personnel or collaborators, the external entity would be responsible for ensuring the completion of human subjects training. Institutional assurance will be documented during the reliance process.

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/OO.
- 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/OO, 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, Division Chiefs

Deans, Department Chairs and Division Chiefs 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/OO.
- Ensure that each Human Research study conducted in their department or school has adequate resources.

Office of Sponsored Programs (OSP)

The Grants and Contracts Office 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 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 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/OO, must complete initial and continuing training utilizing the Collaborative Institutional Training Initiative (CITI) human subjects online training program within three months of being employed. Training is valid for a three-year period, after which time refresher training must be completed.

IRB staff must complete individualized on-the-job training and orientation as determined by their job description. New staff must review all existing departmental policies and procedures.

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.

Alternate Training Options

Alternate research ethics training may be considered in lieu of CITI training on a case-by-case basis.

- The IRB Director or IRB Associate Director may determine that other research or ethical education programs (e.g., PRIM&R or FDA sponsored conferences, clinical research academic degree programs), or certifications (e.g., CIP, CRA) may count toward fulfilling minimum training or refresher requirements (for example, if community members have minimal involvement in minimal risk research other forms of ethics training may be acceptable).

- Documentation should be submitted to the OIRB by the trained individual as necessary to indicate that training was completed (or refresher training was completed at least once every three years).

- Documentation indicating that the IRB Director or IRB Associate Director determined the education to be appropriate education in research ethics, human research protections and regulatory policy should also be maintained by the Research Regulatory Reviewer.

Education and Training for VA Research

All individuals involved in conducting VA human subjects research, including the IO/OO, 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 website. 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 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, 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 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.

Continuing Planning for HRPP Disruptions

The organization routinely assesses potential emergency scenarios, disruptive events, and threats to the institution to improve its business continuity plan. The IRB Director, or their designee, collaborates with organizational leadership to develop, implement, and assess continuity planning procedures for the HRPP.

Depending on the nature of the event, the IRB Director will collaborate with the IO/OO, other institutional leadership, and vendors, as appropriate, to:

- Determine the types of research that might continue and the types that the organization may need to temporarily postpone.
- Identify external IRBs on which it can rely temporarily during an emergency.
- Ensure continuity of operations in the event that electronic systems and/or records are inaccessible or not operational.
- Implement alternative review procedures, including leveraging online and virtual platforms, to ensure that IRB meetings can continue in scenarios when 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:

IRB Director
Office of the Institutional Review Board
8403 Floyd Curl Drive, Mail Code 7830
San Antonio, TX 78229
Email: irb@uthscsa.edu
210-567-8250

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/OO, 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/OO has the responsibility to investigate all other reports and take corrective actions as needed.

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

To make such reports, contact the IO/OO:

Senior Vice President for Research
8403 Floyd Curl Drive
San Antonio, TX 78229
Email: vpr@uthscsa.edu
210-854-5671

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/OO 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/OO 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 reviewed and approved by the IO/OO. This plan is intended to be flexible and readily adaptable to changes in regulatory requirements. The IO/OO has the responsibility to review this plan to assess whether it is providing the desired results.

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[i] 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

[ii] http://www.hhs.gov/ohrp/policy/engage08.html

[iii] 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.

[iv] 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

[v] VHA Directive 1200.05(03), Amended July 13, 2023

[vi] VHA Directive 1058, November 8, 2024