

TITLE: Veterans Health Administration Central Office (VHACO) Human Research Protection Program (HRPP) Overview, Structure, and Responsibilities

1.0 PURPOSE

The purpose of this standard operating procedure is to describe the overall mission, values, organizational structure, responsibilities, and requirements of the VHACO HRPP, particularly in relation to the functioning of the VA Central Institutional Review Board (IRB).

2.0 REVISION HISTORY

Date of Initial Approval	June 16, 2008
Revision Dates	October 6, 2008 September 22, 2009 March 30, 2010 August 26, 2010 August 9, 2011 December 9, 2011

3.0 SCOPE

This standard operating procedure applies to research involving human participants that is conducted and/or overseen by the VHACO HRPP. It includes all components of the VHACO HRPP and the HRPPs of VA field facilities that use the VA Central IRB as an IRB of Record. This includes VA investigators participating in such research, to include students; VA Central IRB members and the VA Central IRB administrative staff; local VA Research and Development (R&D) Offices and Committees; the Institutional Official (IO) for the VHACO HRPP and his or her delegates; local participating VA facility IOs and their delegates; local Research Compliance Officers; and all other VA employees and students involved in the conduct and oversight of VA research involving human participants.

4.0 POLICY

4.1 It is the policy of the VHACO HRPP to ensure that all VA research under the purview of the VA Central IRB is conducted ethically and in accordance with all VA and other federal requirements for the protection of human research participants.

4.2 The VHACO HRPP adheres to the basic ethical principles governing human research participants research found in the Belmont Report which can be found at the following web link <http://ohsr.od.nih.gov/guidelines/belmont.html>. These principles are respect for persons, beneficence, and justice.

4.3 It is the policy of the VHACO HRPP to promote a culture of shared responsibility and accountability for the following goals: to protect the rights and welfare

of human research participants; to minimize the risks and maximize the benefits of participation; and to treat fairly the groups and individuals involved.

4.4 The VA is one of the 18 Federal departments and agencies that have agreed to follow the Federal Policy for the Protection of Human Subjects (the Common Rule.) This is incorporated in Title 38 Code of Federal Regulations (CFR) Part 16, Department of Veterans Affairs, Protection of Human Subjects.

4.4.1 The procedures followed by the VHACO HRPP for implementing 38 CFR Part 16 are defined in VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research.

4.4.2 VHA Handbook 1200.05 requirements apply to VA research involving special populations such as pregnant women, children, or prisoners.

4.5 The VHACO HRPP and the VA Central IRB also adhere to the following additional VA requirements:

4.5.1 Statutory provisions for protection of VA patient rights, Title 38 United States Code (U.S.C.) Sections 501, 7331, and 7334.

4.5.2 VA regulations pertaining to protection of patient rights, 38 CFR 17.33a and 17.34.

4.5.3 VA regulations pertaining to research related injuries, 38 CFR 17.85.

4.5.4 VA regulations pertaining to hospital care for research purposes and outpatient care for research purposes, 38 CFR 17.45 and 17.92

4.5.5 VA confidentiality of medical quality assurance records statute, 38 U.S.C. 5705.

4.6 Additionally, the VHACO HRPP adheres to statutes and regulations pertaining to the release of patient information. These include 5 USC 552a, 38 USC 5701a and 7332, and 45 CFR Parts 160-164.

4.6.1 VHA requirements are provided in VHA Handbook 1605.1, Privacy and Release of Information, and VHA Handbook 1605.2, Minimum Necessary Standards for Protected Health Information.

4.6.2 For the purposes of these requirements and in accordance with 45 CFR 164.512(i), the VA Central IRB may also approve a waiver of authorization as required by the Health Insurance Portability and Accountability Act (HIPAA) in regard to the research it reviews.

4.7 When FDA-regulated clinical investigations are conducted the VHACO HRPP also applies the FDA regulations pertaining to the protection of human participants and the conduct of IRBs, as does the VA Central IRB for the FDA-regulated research it reviews. These include 21 CFR 11, 50, 54, and 56.

4.8 The following additional FDA regulations are also applied when research involves the use of specific test articles as follows:

- Investigational New Drug Applications (IND) (21 CFR 312 and 314)
- Radioactive Drugs for Certain Research Uses (21 CFR 361)
- Biological Products (21 CFR 600)
- Investigational Device Exemptions (IDE) (21 CFR 812 and 814)

4.9 VA research supported by the Department of Health and Human Services (DHHS) must also adhere to the provisions in 45 CFR 46.

4.10 VA investigators are required to request and obtain permission from the Chief Research and Development Officer, or designee, in accordance with current Office of Research and Development (ORD) policy prior to initiating or conducting VA-approved research involving the following:

4.10.1 International research involving human subjects, human biological specimens, or human data. All individuals who participate as subjects in research at international sites must be provided appropriate protections that are in accord with those given to research subjects in the US, as well as protections considered appropriate by local authority and custom at the international site. Multi-site trials fall into this arena if any of the following apply: 1) VA is a sponsor, 2) VA functions as the Coordinating Center, 3) VA subcontracts to a foreign site, and 4) The PI for the overall study is a VA investigator or the VA investigator is specifically collaborating with an international investigator and the VA investigator sends data or human biological specimens outside the U.S.

4.10.2 Children and prisoners. See VA Central IRB SOP 106, Research Involving Vulnerable Populations and Other Special Categories of Participants.

4.11 VA research overseen by the VA Central IRB must comply with the state and local laws of the appropriate jurisdiction of the VA facility where research is conducted.

5.0 DEFINITIONS

See VA Central IRB SOP 128, Definitions Used in VA Central IRB SOPs.

6.0 RESPONSIBILITIES

6.1 Institutional Official (IO) – The IO is designated by the Under Secretary for Health to represent the VA Central Office HRPP, assume the obligations of the VHA

Central Office FWA as the Signatory Official, and ensure compliance with its terms. The VHA Principal Deputy Under Secretary for Health serves as the IO for the VHACO HRPP. The VHACO HRPP IO is advised by the Chief Research and Development Officer (CRADO); the Chief, Office of Research Oversight (ORO); and the Director, Program for Research Integrity Development and Education (PRIDE). The VHACO IO is responsible for maintaining a current FWA, ensuring compliance with its terms, and that written procedures have been established as required. The following are the duties and responsibilities of an IO that are inherent in the IO function and cannot be delegated:

- Fostering an institutional culture that supports the ethical conduct of human subjects research
- Serving as signatory authority for the VHA Central Office HRPP Federalwide Assurance (FWA)
- Completing required Assurance training
- Appointing the VA Central IRB Chair or Co-Chairs, and suspending or terminating the appointment of any Chair or Co-Chair who is not fulfilling the responsibilities and/or obligations of the Chair position.
- Approving the appointment of all VA Central IRB voting members
- Ensuring that the VA Central IRB functions independently and that its Chair, or Co-Chairs, and members have direct access to the IO for appeal if they experience undue influence or if they have concerns about the operations of the VA Central IRB
- Ensuring that resources, including funds, space, and personnel are provided to support the operation of the VHA Central Office HRPP

6.2 Director, Program for Research Integrity Development and Education (PRIDE) – The Director, PRIDE, serves as the HPA for the VHACO HRPP and is responsible for ensuring that the VHA HRPP carries out all functions and responsibilities of the HRPP as detailed in VHA Handbook 1200.05. The IO has delegated the following duties to the Director, PRIDE:

- Managing and administering funds, personnel, space and other resources allocated to the VHA Central Office HRPP in support of the VA Central IRB.
- Reviewing and approving the Standard Operating Procedures (SOPs) for the VA Central IRB
- Overseeing the daily operations of the VA Central IRB in accordance with its published SOPs
- Recruiting qualified applicants for membership on the VA Central IRB, to include expert ad hoc advisors

- Appointing VA Central IRB voting and nonvoting members, with the exception of the Chair or Co-Chairs
- Suspending or terminating the VA Central IRB membership of any individual for whom it is determined that he/she is not fulfilling VA Central IRB member responsibilities and/or obligations with the exception of the Co-Chairs
- Reviewing and signing Memoranda of Understanding between the VHA Central Office and local VA facilities concerning use of the VA Central IRB as an IRB of record for those facilities
- Being the point of contact for correspondence addressing human subjects research with the OHRP, the FDA, and VHA Central Office
- Developing and implementing an educational plan for VA Central IRB members, staff, and investigators that ensures they are appropriately knowledgeable to review and/or conduct research in accordance with ethical standards and all applicable VA and other requirements
- Performing an annual evaluation of the performance of the VA Central IRB members and Co-Chairs
- Performing an annual evaluation of the VHA Central Office HRPP and reporting the results to the VA Central Office HRPP IO and to local VA facilities that have an active MOU with the VHA HRPP
- Ensuring the VHA Central Office HRPP is accredited by an organization approved by ORD to perform this function

6.3 Local R&D Committees – The local R&D Committee is responsible for fulfilling all responsibilities required in VHA Handbook 1200.01, Research and Development Committee Handbook, for all research in which the facility is engaged, and for all research within other VA facilities for which it serves as the R&D Committee of record. The local R&D Committees also include the VA Central IRB in the annual review of their facility's HRPP if the VA Central IRB is listed as one of their IRBs of record.

6.4 VA Central IRB – The VA Central IRB is responsible for fulfilling all responsibilities and performing all functions of an IRB as specified in VHA Handbook 1200.05 and VA Central IRB SOP 101, VA Central IRB Authority, Responsibilities, and Activities.

6.5 VA Central IRB Administrator – The VA Central IRB Administrator is responsible for ensuring the FWA, IRB registration, and all written policies and procedures governing the operation of the VA Central IRB are kept current. The VA Central IRB Administrator ensures the VA Central IRB operates according to approved policies and procedures. The VA Central IRB administrator is responsible for overseeing the daily administrative activities of the VA Central IRB. This includes ensuring that all local VA sites participating in a VA-funded, multi-site project submitted to the VA Central IRB for review, have an approved MOU on file and that the VA Central IRB has been designated as an IRB of record on the local site's FWA. If the site does

not have an approved MOU in place, and/or is not designated as an IRB of record on the facility's FWA, the VA Central IRB Administrator works with the local facilities in submitting and processing these documents. The VA Central IRB Administrator also maintains a database of all local VA facilities with approved MOUs and their renewal dates.

6.6 VA Central IRB Coordinators – The VA Central IRB Coordinators are responsible for the daily activities of the VA Central IRB including but not limited to coordinating all project review functions of the VA Central IRB with the designated VA Central IRB reviewers, the VA Central IRB Co-Chairs, and the study teams in accordance with established policies and procedures. The VA Central IRB Coordinators maintain all required documentation, including but not limited to a record of all actions taken by the VA Central IRB in regard to their assigned projects.

6.7 VA Investigators and research staff – All VA investigators and research staff, to include students, are expected to adhere to the ethical standards required by the VA to conduct human subjects research. Investigators are responsible for completing all forms and documents required by the VA Central IRB in a timely manner and for promptly reporting any issues that require VA Central IRB review. VA Investigators sign an assurance upon submitting an initial application to the VA Central IRB, whether the investigator is a Principal Investigator/Study Chair (PI/SC) or a Local Site Investigator (LSI), acknowledging his/her responsibilities. In addition, PI/SCs and LSIs sign an acknowledgement of their responsibilities for the protection of human subjects each time they submit an amendment or continuing review request to the VA Central IRB.

7.0 PROCEDURES

7.1 Maintenance of VHACO FWA. VHACO will maintain a current FWA on file with both ORO and OHRP.

7.1.1 The Principal Deputy Under Secretary for Health has been appointed by the Under Secretary of Health to serve as the IO for the VHACO HRPP. As such, the Principal Deputy Under Secretary for Health serves as the Signatory Official for the VHACO FWA.

7.1.2 The FWA includes all components within the VHACO that conduct research. These offices do not have to be listed on the FWA. Only significant VHACO components where the program office is remotely located or OHRP would not recognize the office as a VHACO program are listed individually on the FWA.

7.1.3 FWA updates are submitted by the Director, PRIDE, acting in the capacity of the VHACO HPA, to OHRP through ORO, along with the VA addendum specified in VHA Handbook 1058.03. In addition to the VHACO IO, the Under Secretary for Health will sign the updated ORO addendum to the FWA.

7.1.4 The FWA and VA addendum are updated upon the appointment of a new Under Secretary of Health, Principal Deputy Under Secretary for Health, or the Director, PRIDE. The FWA is also updated if there is a change in the IRB of record or if a significant component of the VHACO that conducts research as defined in paragraph 7.1.2 is added or deleted.

7.1.5 Upon appointment to their positions, the Under Secretary for Health, the Principal Deputy Under Secretary for Health, and the Director, PRIDE, will complete the three OHRP FWA Online Training modules if they have not already done so. Copies of their Certificates of Completion for each of the three modules are forwarded to the VA Central IRB Administrator and kept in the files of the VA Central IRB. The OHRP Human Subjects Assurance Training module is located at: <http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp>

7.2 Designation of the VA Central IRB as the VHACO IRB of Record. The VA Central IRB is listed as the IRB of record on the VHACO FWA.

7.2.1 The VA Central IRB is registered with OHRP as a single IRB. Additional IRBs will be established as needed based on the volume and types of human research projects submitted. The turnaround time and workload of the IRB is evaluated on a regular basis by VA Central IRB and PRIDE staff to ensure that all reviews are accomplished in a thorough and timely manner.

7.2.2 The VA Central IRB Administrator ensures that the VA Central IRB registration is kept up-to-date.

7.2.2.1 If there is a change in the voting membership, the VA Central IRB Administrator submits an updated registration form to OHRP through ORO within 30 days of the change.

7.2.2.1.1 Registration updates are completed on-line through the OHRP website. Once the information is entered into the system by the VA Central IRB Administrator, ORO is informed and given the access codes for the updated registration.

7.2.2.1.2 ORO reviews the updated registration information on-line for completeness and accuracy and then informs the VA Central IRB Administrator when the review is complete. The update is then submitted to OHRP.

7.2.2.1.3 The VA Central IRB Administrator ensures that the VA Central IRB registration is renewed at least once every three years or within three years of the last previous update.

7.2.2.2 Changes in the non-voting membership do not need to be reported to OHRP or ORO until the next time there is a change in the voting

membership. Changes will be posted on the listing maintained on the VA Central IRB website.

7.2.3 The VA Central IRB membership roster as reported to OHRP and ORO contains the following information on the members:

- Name
- Gender
- Earned degrees
- Scientific status (scientist or non-scientist)
- Primary scientific or nonscientific specialty
- Affiliation status (whether the member or an immediate family member of the member is affiliated with the Department of Veteran Affairs)
- Indications of experience sufficient to describe each IRB member's chief anticipated contributions
- Employment or other relationship between each IRB member and the Department of Veterans Affairs
- Role on the IRB or representative capacity (i.e., vulnerable populations, prisoner representatives)
- IRB position (e.g., Co-chair)
- Voting Status
- Alternate Members
- The primary members or class of members for whom each alternate member could substitute

The role on the IRB, IRB position, and voting status are indicated in the "Comments" section of the roster as applicable. Rosters are maintained permanently.

7.2.4 The VA Central IRB Administrator periodically, but no less than once per year, queries current VA Central IRB members, both voting and non-voting, to identify any changes in their status, (e.g., additional degrees, added experiences) and updates the VA Central IRB Membership Roster if applicable. If any members have updated their curriculum vitae since the last update, they will be asked to submit an updated copy to the VA Central IRB Administrator.

7.3 VHACO Institutional Official (IO) Duties and Delegation of Authority. The IO may delegate the performance of certain duties to other responsible personnel within VHACO. However, responsibility for the program remains with the IO and the performance of some duties cannot be delegated (see Paragraph 6.1).

7.3.1 The VHACO HRPP IO also has certain other duties that may be delegated to other personnel to ensure appropriate oversight and efficient operations. The IO has currently delegated these duties to the Director, PRIDE (see Paragraph 6.2).

7.3.2 All delegations of authority must be in writing and expire upon the appointment of a new IO or Director, PRIDE, as applicable. The Director, PRIDE, keeps the IO informed on the status of the VHA Central Office HRPP and immediately report any issues or concerns that may require the attention of the IO.

7.4 Reporting Findings and Actions to the VHACO Institutional Official (IO). The Director, PRIDE, meets with the IO on a periodic basis to review the status of the VHA HRPP, to include the operations of the VA Central IRB. A report is prepared and presented to the IO as part of the periodic briefing and includes the status of projects reviewed by the VA Central IRB since the last report, to include new project approvals.

7.4.1 Copies of all periodic reports, the agenda for the briefings of the IO, and any other documentation presented to the IO are kept on file electronically on the PRIDE shared drive in the VA Central IRB folder. The monthly reports are also added to the IO SharePoint Site.

7.4.2 Upon appointment of a new IO, an orientation briefing is scheduled by the Director, PRIDE, to ensure the IO becomes familiar with his/her responsibilities.

7.5 Communication Methodology. Within the VHACO HRPP, communication is carried out in a number of different ways. These include but are not limited to the following:

- Distribution of the VA Central IRB meeting minutes to all relevant parties
- Formal and informal correspondence with both investigators, study team coordinators, and local site points of contact
- Maintenance of a reference website at <http://www.research.va.gov/programs/pride/cirb/default.cfm>
- Provision of a toll-free number at 1-877-25-3130
- Availability of a generic VA Central IRB global web address at va.central.irb@va.gov
- In-person interaction at local, regional, and national meetings, as well as other educational settings with local research office staff, compliance officers, and investigators
- Conduct of periodic VA Central IRB orientation webinars for local VA facilities regarding the MOU process, for VA Central IRB Liaisons concerning their duties and responsibilities, and for investigators preparing to submit projects to the VA Central IRB for review.

7.5.1 The VA Central IRB provides investigators and local participating VA facilities with written correspondence concerning their review and oversight responsibilities. Local VA facilities are responsible for training their personnel regarding the provisions of the Memorandum of Understanding (MOU) between the VHACO HRPP and their local facilities.

7.5.2 The VA Central IRB maintains a folder on the VA SharePoint site for VA Central IRB Liaisons. This folder will contain documents concerning issues pertaining to all sites and will include but not be limited to:

- Results of the annual review of the VHA Central Office HRPP Annual Review
- Current VA Central IRB membership roster in format required by accrediting agency
- Accreditation documents for the VHA Central Office

7.5.3 Investigators, local sites, and other staff are encouraged to express any concerns and/or suggestions to the Director, PRIDE, the VA Central IRB Administrator and Coordinators, or any other PRIDE staff. PRIDE staff will bring any issues that cannot be resolved at their level to the attention of the appropriate official.

7.6 VA Central IRB Website. To facilitate communication, a VA Central IRB website is maintained by the VA Central IRB Administrator. The information on the site will include, but not be limited to, the following information:

- Instructions for local facilities on entering into an MOU with the VHA Central Office HRPP and adding the VA Central IRB as an IRB of Record
- VA Central IRB member list
- VA Central IRB meeting dates
- Investigator guidelines and procedures
- Listing of VA facilities that have approved MOUs with the VHACO HRPP
- VA Central IRB SOPs and associated forms
- Frequently Asked Questions (FAQs)
- Information for Research Participants or Potential Participants
- Points of contact

7.6.1 The site will have a "What's New" link for easy reference that will indicate what is new or has been revised on the site.

7.6.2 More information on VA Central IRB communication methodology can be found in VA Central IRB SOP 111, VA Central IRB Communications with Investigators and Local Participating Sites.

7.7. VHA Central Office HRPP Organizational Chart. An organizational chart indicating the structure of the VHA Central Office HRPP and the relationship among the various components can be found at the Attachment to this SOP.

8.0 REFERENCES

8.1 38 CFR 16, Department of Veterans Affairs, Protection of Human Subjects

8.2 38 CFR 17, Department of Veterans Affairs, Medical

8.3 VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research

8.4 VHA Handbook 1200.01, Research and Development (R&D) Committee

8.5 VHA Handbook 1058.03, Assurance of Protection for Human Subjects in Research

8.6 VHA Handbook 1605.1, Privacy and Release of Information

8.7 VHA Handbook 1605.2, Minimum Necessary Standards for Protected Health Information

8.8 45 CFR 46, Subparts B-D, Department of Health and Human Services, Protection of Human Subjects, including subparts A through D.

8.9 45 CFR 160 and 164, General Administrative Requirements and Security and Privacy (The HIPAA Privacy Rule)

8.10 21 CFR 11, Electronic Records; Electronic Signatures

8.11 21 CFR 54, Financial Disclosure by Clinical Investigators

8.12 21 CFR 56, U.S. Food and Drug Administration, Institutional Review Boards

8.13 21 CFR 50, U.S. Food and Drug Administration, Protection of Human Subjects

8.14 21 CFR 312, U.S. Food and Drug Administration, Investigational New Drug Application

8.15 21 CFR 314, U.S. Food and Drug Administration, Applications for FDA Approval to Market a New Drug

8.16 21 CFR 361, U.S. Food and Drug Administration, Prescription Drugs for Human Use Generally Recognized as Safe and Effective and Not Misbranded: Drugs Used for Research

8.17 21 CFR 812, U.S. Food and Drug Administration, Investigational Device Exemptions

8.18 21 CFR 814, Pre-Market Approval of Medical Devices

8.19 OHRP Registration of an IRB: Instructions for registering and updating the current registration of an IRB can be found at <http://www.hhs.gov/ohrp/assurances/>

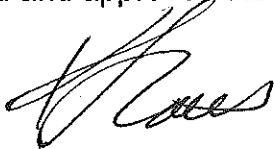
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8.20 OHRP Terms of the FWA: These terms can be found at
<http://www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm>

1 Attachment
VHA Central Office HRPP Organizational Chart

I have reviewed and approved the content of this SOP.



K. Lynn, Cates, M.D.
Director, PRIDE

Date: 12/9/11

VHA Central Office Human Research Protection Program Organizational Chart

