



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

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## 1 SCOPE AND APPLICABILITY

- 1.1 The scope and purpose of this standard operating procedure (SOP) 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).
- 1.2 This SOP applies to research involving human participants that is conducted and/or overseen by the VHACO HRPP and for which the VA Central IRB serves as the IRB of Record. It includes all components of the VHACO HRPP and the HRPPs of VA field facilities, as well as Non-Profit Corporations associated with the VA field facilities, when involved in the conduct and/or oversight of studies for which the VA Central IRB serves as the VA IRB of Record. This SOP applies to 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 Non-Profit Corporation IOs and their delegates; local Research Compliance Officers; and all individuals serving as study team members in studies overseen by the VA Central IRB. It also pertains to any other VA employees and students involved in the conduct and oversight of VA research involving human participants in studies overseen by the VA Central IRB.
- 1.3 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, and 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. The VHACO HRPP adheres to the basic ethical principles (respect for persons, beneficence, and justice) governing human research found in the Belmont Report which can be found at the following web link: <http://www.history.nih.gov/research/downloads/belmont.pdf>.
- 1.4 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.
  - 1.4.1 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. These requirements apply to VA research involving special populations such as pregnant women, children, and prisoners. The VHACO HRPP and the VA Central IRB also adhere to the following additional VA requirements:
    - 1.4.1.1 Statutory provisions for protection of VA patient rights, Title 38 United States Code (U.S.C.) Sections 501, 7331, and 7334.
    - 1.4.1.2 VA regulations pertaining to protection of patient rights, 38 CFR 17.33a and 17.34.
    - 1.4.1.3 VA regulations pertaining to research related injuries, 38 CFR 17.85.
    - 1.4.1.4 VA regulations pertaining to hospital care for research purposes and outpatient care for research purposes, 38 CFR 17.45 and 17.92.



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

1.5 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.

1.5.1 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.

1.5.2 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.

1.6 When the VA Central IRB reviews FDA-regulated clinical investigations, it applies and adheres to the FDA regulations pertaining to the protection of human participants and the conduct of IRBs. These include 21 CFR 11, 50, 54, and 56.

1.7 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)

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

1.9 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:

1.9.1 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.

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

1.10 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.



## 2 DEFINITIONS

- 2.1 **Assurance.** A written commitment by the institution to protect human subjects participating in research and to comply with the requirements of 38 CFR Part 16 (VHA Handbook 1058.03). For the purposes of the VA Central IRB SOPs, “assurance” is synonymous with “Federalwide Assurance.”
- 2.2 **Children.** Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted (45 CFR 46.402(a)).
- 2.3 **Federalwide Assurance (FWA).** See “Assurance.”
- 2.4 **Human Protections Administrator (HPA).** The individual named in an FWA as a primary contact responsible for directing, or having in-depth knowledge of, the daily operations of an Institution’s program for protecting human research subjects (VHA Handbook 1058.03).
- 2.5 **Human Research Protection Program (HRPP).** An HRPP is a comprehensive system to ensure the protection of human subjects participating in research. At a local VA facility the HRPP consists of a variety of individuals and committees including but not limited to: the VA Facility Director, Associate Chief of Staff (ACOS) for Research and Development (R&D), the Administrative Officer (AO) for R&D, Research Compliance Officer (RCO), the R&D Committee, the Institutional Review Board (IRB), other committees or subcommittees addressing human subjects protection (e.g., Subcommittee on Research Safety, Institutional Biosafety Committee, Radiation Safety Committee, Radioactive Drug Research Committee, Conflict of Interest Committee, investigators, IRB staff, research staff, health and safety staff (e.g., Biosafety Officer, Radiation Safety Officer) and research pharmacy staff. The objective of this system is to assist the institution in meeting ethical principles and regulatory requirements for the protection of human subjects (VHA Handbook 1200.05).

The VHA Central Office HRPP is composed of the VA Central IRB, the institutional leadership (the Principal Deputy Under Secretary for Health is the Institutional Official), ORD, investigators of VA multi-site projects approved by the VA Central IRB, local medical center directors and Research and Development Committee at participating local facilities, ORO, and many others who are involved in human subjects research. The VHA Central Office HRPP does not replace or duplicate the efforts of the local VA facilities’ HRPPs. Instead, it serves as the HRPP for VA multi-site projects that are reviewed and approved by the VA Central IRB. The VHA Office of Research Oversight (ORO) has oversight responsibility for the VHA Central Office HRPP.

- 2.6 **Human Subject.** The definition of human subject includes investigators, technicians and others assisting investigators, when they serve in a “subject” role by being observed, manipulated, or sampled. Title 38 CFR Part 16 defines a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains either:
- Data through intervention or interaction with the individual (interaction includes communication or interpersonal contact between the researchers and the subject), or
  - Identifiable private information (38 CFR 16.102(f)).



For research covered by the Food and Drug Administration (FDA) regulations, human subjects mean an individual who is or becomes a participant in a clinical investigation, either as a recipient of the test article or as a control. (21 CFR 50.3(g) and 21 CFR 66.102(c)). For research covered by FDA device regulations, subject means a human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control. A subject may be in normal health or may have a medical condition or disease (21 CFR 812.3(p)).

- 2.7 **Institutional Official (IO).** The IO is the individual legally authorized as Signatory Official to commit an institution to an Assurance. The IO serves as the official representative of the institution to external entities and oversight bodies and provides all written communication with external departments, agencies and oversight bodies. The Principal Deputy Undersecretary for Health Affairs is the IO for VHA Central Office and VA facility Directors are the IOs for local VA facilities (VHA Handbook 1200.05).
- 2.8 **Institutional Review Board (IRB).** A board, committee, or other group, formally designated by an institution to review, approve, require modification in, disapprove, and conduct continuing oversight of human research in accordance with 38 CFR 16 and other applicable VA and Federal requirements (VHA Handbook 1058.01).
- 2.9 **IRB of Record.** The IRB(s) designated under a VA facility's FWA for review and oversight of the facility's human subject research (VHA Handbook 1058.03, paragraph 4m).
- 2.10 **Local Site Liaison.** An individual who serves as the main point of contact between the VA Central IRB and the local facility Research and Development Service regarding studies that are being reviewed and overseen by the VA Central IRB.
- 2.11 **Memorandum of Understanding (MOU).** A written agreement between two VA facilities or between a VA facility and a non-VA Institution documenting their relationship and defining their respective roles and responsibilities within that relationship (VHA Handbook 1058.03, paragraph 4n).
- 2.12 **Non-Profit Corporation (NPC).** A VA non-profit research corporation is an independent, state-chartered non-profit organization affiliated with a VA medical facility that receives and administers funds to conduct research. VA-affiliated non-profit corporations are established for purposes of research and education, under the authority delegated from the Secretary to the Under Secretary for Health.
- 2.13 **Pregnancy.** The period of time from implantation until delivery. (VHA Handbook 1200.05).
- 2.14 **Prisoner.** Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing (VHA Handbook 1200.05).
- 2.15 **Research.** A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (38 CFR 16.102(d)). Activities meeting

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this definition constitute research for the purposes of VHA Handbook 1200.05, whether or not they are conducted or supported under a program which is considered research for other purposes.

### 3 RESPONSIBILITY

3.1 Institutional Official (IO). The IO is designated by the Under Secretary for Health to represent the VHACO HRPP, assume the obligations of the VHACO FWA as the Signatory Official, and to ensure compliance with its terms.

3.1.1 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 Human Protections Administrator for the VHACO HRPP. The VHACO IO is responsible for maintaining a current FWA, ensuring compliance with its terms, and establishing written procedures as required.

3.1.2 The following are the duties and responsibilities of the 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 VHACO 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.
- 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

3.2 The Human Protections Administrator (HPA) for the VHACO HRPP is responsible for ensuring that the VHACO HRPP carries out all functions and responsibilities of the HRPP as detailed in VHA Handbook 1200.05. The IO appoints the HPA in writing from among the senior management officials within the VA Office of Research and development (ORD). The HPA has been delegated the following specific duties by the IO:

- Managing and administering funds, personnel, space, and other resources allocated to the VHACO 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;



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- Suspending or terminating the VA Central IRB appointment 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 VA Central IRB Chair or 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 Co-Chairs;
- Performing an annual evaluation of the VHACO HRPP and reporting the results to the VHACO HRPP IO and to local VA facilities that have an active MOU with the VHACO HRPP; and
- Ensuring the VHACO HRPP is accredited by an organization approved by ORD to perform this function.

3.3 Local R&D Committees. The local R&D Committees are responsible for fulfilling all responsibilities required in VHA Handbook 1200.01, Research and Development Committee Handbook, for all research in which the local 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 facilities' HRPP if the VA Central IRB is listed as one of their IRBs of record.

3.4 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.

3.5 VA Central IRB Administrator. The VA Central IRB Administrator is responsible for overseeing the daily administrative activities of the VA Central IRB to include ensuring the FWA and IRB registration with OHRP are kept current, all written policies and procedures governing the operation of the VA Central IRB are up-to-date, and that the VA Central IRB operates according to approved policies and procedures. The VA Central IRB Administrator is also responsible for the following:

- 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;
- Assisting local VA facilities and Non-Profit Corporations if they do not have an approved MOU in place, and/or have not designated the VA Central IRB as an IRB of record on their respective FWA, in submitting and processing the required documents;
- Maintaining a database of all local VA facilities with approved MOUs and their renewal dates; and
- Educating and assisting local sites and study teams on meeting VA Central IRB and VHACO HRPP and other VA requirements concerning the conduct of human subjects research.

3.6 VA Central IRB Managers. The VA Central IRB Managers are responsible for conducting 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 Managers also maintain all required documentation, including but not limited to required records of all actions taken by the VA Central IRB in regard to each Manager's assigned projects.

- 3.7 VA Investigators and research staff. All VA investigators, research staff and students (including VA employees or students from a VA-affiliated academic institution) 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 are required to 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 for overseeing the conduct of the research. 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.
- 3.8 VA-affiliated Non-profit Corporations (NPCs). NPCs that are affiliated with local VA facilities for the purpose of providing a flexible funding mechanism for the conduct of and/or to facilitate functions related to the conduct of approved VA research and education, must have and keep up-to-date an FWA designating the VA Central IRB as an IRB of record. The NPC is responsible for ensuring that its FWA is kept current in accordance with VHA Handbook 1058.03. The NPC is also responsible for ensuring it enters into an MOU with the local VA facility and the VHA Central Office. This MOU sets forth the respective authorities, roles, and responsibilities of these three entities.
- 3.9 Local Site Liaison. Liaisons are responsible for facilitating communication with the VA Central IRB as needed and ensuring that all approved study documents on the VA Central IRB SharePoint site are made available for the site Research Office files, as applicable. Liaisons also assist other designated site personnel in performing review functions and relaying the results to the VA Central IRB. Liaisons ensure that the VA Central IRB is immediately informed of all local site actions involving such as restriction, suspension, or termination of research privileges for research team members associated with a VA Central IRB-approved project. Similarly, liaisons ensure that audits by local facility staff or outside agencies are provided by the study team or other local staff to the VA Central IRB in a timely manner on projects it oversees, and that records necessary to facilitate oversight, compliance, and monitoring are made available to the VA Central IRB as required. Local Site Liaisons also keep the VA Central IRB updated on changes in local Research Office and Institutional personnel in accordance with the MOU. This is extremely important in order to ensure that the appropriate individuals receive e-mail notifications when documents are uploaded to the VA Central IRB SharePoint site and for VA Central IRB staff to be able to make applicable notifications for reportable events and in maintaining up-to-date access controls for the site.

#### 4 PROCEDURE

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



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- 4.1.1 The 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.
- 4.1.2 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, need to be listed individually on the FWA.
- 4.1.3 The FWA and VA addendum are updated upon the appointment of a new Under Secretary of Health, Principal Deputy Under Secretary for Health, or HPA. 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 4.1.2, is added or deleted.
- 4.1.4 Upon appointment to their positions, the Under Secretary for Health, the Principal Deputy Under Secretary for Health, and HPA, 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>.
- 4.1.5 FWA updates are prepared as necessary by the VA Central IRB Administrator using the automated OHRP registration system. The update is then submitted through the HPA to the IO for signature through the VHA Central Office automated correspondence system. The VA Central IRB Administrator also coordinates the update through ORO, to include an updated VA addendum to the FWA (as specified in VHA Handbook 1058.03) which must be signed by the Under Secretary for Health, in addition to the VHACO IO. The OHRP electronic submission is not finalized until clearance is received by ORO and all signatures have been obtained as required on the FWA.
- 4.1.6 In addition, any letters of delegation and/or appointment that must be updated based on the FWA changes will also be prepared by the VA Central IRB Administrator and included as part of the package forwarded for signature to the offices of the Principal Deputy Under Secretary for Health and the Under Secretary of Health through the VHA Central Office electronic correspondence system.
- 4.2 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.
- 4.2.1 The VA Central IRB is registered with OHRP as a single IRB. Additional IRBs may 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 periodic basis, but no less than annually, by VA Central IRB staff, VA Central IRB members and Co-Chairs, as well as ORD stakeholders to ensure that all reviews are accomplished in a thorough and timely manner and that sufficient resources are available to adequately handle the workload.



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

4.2.2.1 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.

4.2.2.1.1 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.

4.2.2.1.2 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.

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

4.2.2.2 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. However, those changes will be posted on the listing maintained on the VA Central IRB website and also on the VA Central IRB SharePoint site.

4.2.3 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
- 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



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Non-voting members are listed on the roster per the request of ORO and are indicated as such in the "Comments." Rosters are maintained permanently.

4.2.4 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.

4.3 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 3.1.2).

4.3.1 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 HPA (see Paragraph 3.2).

4.3.2 All delegations of authority must be in writing and expire upon the appointment of a new IO. The HPA periodically keeps the IO informed on the status of the VHACO HRPP and immediately reports any issues or concerns that may require the attention of the IO.

4.4 Reporting Findings and Actions to the VHACO Institutional Official (IO). The HPA 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.

4.4.1 Copies of all periodic reports, and any other documentation presented to the IO, are kept on file electronically on the VA Central IRB shared drive.

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

4.5 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:

- Uploading the VA Central IRB meeting minutes to the VA Central IRB SharePoint site for access by local VA sites, to include sites with which VACO has an MOU;
- Formal (signed letters) and informal (e-mails) correspondence with both investigators, study team coordinators, and local site points of contact;
- Maintenance of a public reference website at: <http://www.research.va.gov/vacentralirb/> ;
- Informing Local Site Liaisons via e-mail whenever VA Central IRB policies and procedures change that affect the local site or study teams;
- Provision of a toll-free number at 1-877-254-3130;



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- Availability of a generic VA Central IRB global web address at [va.central.irb@va.gov](mailto: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 as budgetary and VA travel restrictions permit; and
  - Conduct of periodic VA Central IRB webinars and/or teleconferences to include the following:
    - For local VA facilities and associated Non-Profit Corporations regarding the MOU process and/or upcoming changes in MOU content;
    - For VA Central IRB Liaisons and other local site representatives concerning their duties and responsibilities, as well as VA Central IRB policies and procedures; and
    - For investigators and other study team members concerning topics such as the VA Central IRB new project submission and review process, continuing review and amendment submissions, and reporting unanticipated serious adverse events, and noncompliance.
- 4.5.1 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.
- 4.5.2 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:
- Report on the Annual Review of the VHACO HRPP;
  - Current VA Central IRB membership roster in format required by ORD approved accrediting agency; and
  - Accreditation documents for the VHACO HRPP as applicable.
- 4.5.3 Investigators, local sites, and other staff are encouraged to express any concerns and/or suggestions to the VHACO HPA, the VA Central IRB Administrator and VA Central IRB Managers as applicable. These staff members will bring any issues that cannot be resolved at their level to the attention of the appropriate official.
- 4.6 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, and associated NPCs as applicable, on entering into an MOU with the VHA Central Office 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, and associated NPCs as applicable, that have approved MOUs with the VHA Central Office
  - VA Central IRB SOPs and associated forms
  - Frequently Asked Questions (FAQs)



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- Information for Research Participants or Potential Participants
- Points of contact

4.6.1 The site will have a “What’s New” link for easy reference that will indicate the most recent changes on the site.

4.6.2 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.

4.7. 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 as an attachment to this SOP.

## 5 DOCUMENTATION REQUIREMENTS

5.1 All approved MOUs held by local VA facilities will be documented and maintained in VACO Central IRB database files (Paragraph 3.5).

5.2 Certificates of completion by the Under Secretary for Health, the Principal Deputy Under Secretary for Health, and the HPA, for each of the three modules of the OHRP Online FWA training, will be maintained in VA Central IRB files (See Paragraph 4.1.4).

5.3 All current VHA FWAs will be documented both in VHACO (ORO) files and in the OHRP registration system (See Paragraph 4.1.5).

5.4 The VA Central IRB membership roster, including all pertinent information, will be reported to OHRP and ORO (See Paragraph 4.2.3). Copies of all periodic reports of the findings and actions of the VA Central IRB will be electronically filed on the VA Central IRB shared drive (See Paragraph 4.4 and 4.4.1). A folder containing the Report on the Annual Review of the VHACO HRPP, IRB membership rosters, HRPP accreditation documents, and other files will be maintained on the VA SharePoint site for VA Central IRB Liaisons (See Paragraph 4.5.2).

## 6 REFERENCES

- 6.1 38 CFR 16, Department of Veterans Affairs, Protection of Human Subjects
- 6.2 38 CFR 17, Department of Veterans Affairs, Medical
- 6.3 VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research
- 6.4 VHA Handbook 1200.01, Research and Development (R&D) Committee
- 6.5 VHA Handbook 1058.03, Assurance of Protection for Human Subjects in Research
- 6.6 VHA Handbook 1605.1, Privacy and Release of Information
- 6.7 VHA Handbook 1605.2, Minimum Necessary Standards for Protected Health Information



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- 6.8 45 CFR 46, Subparts B-D, Department of Health and Human Services, Protection of Human Subjects, including subparts A through D.
- 6.9 45 CFR 160 and 164, General Administrative Requirements and Security and Privacy (The HIPAA Privacy Rule)
- 6.10 21 CFR 11, Electronic Records; Electronic Signatures
- 6.11 21 CFR 54, Financial Disclosure by Clinical Investigators
- 6.12 21 CFR 56, U.S. Food and Drug Administration, Institutional Review Boards
- 6.13 21 CFR 50, U.S. Food and Drug Administration, Protection of Human Subjects
- 6.14 21 CFR 312, U.S. Food and Drug Administration, Investigational New Drug Application
- 6.15 21 CFR 314, U.S. Food and Drug Administration, Applications for FDA Approval to Market a New Drug
- 6.16 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
- 6.17 21 CFR 812, U.S. Food and Drug Administration, Investigational Device Exemptions
- 6.18 21 CFR 814, Pre-Market Approval of Medical Devices
- 6.19 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/>
- 6.20 OHRP Terms of the FWA: These can be found at <http://www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm>



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

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**Revision History**

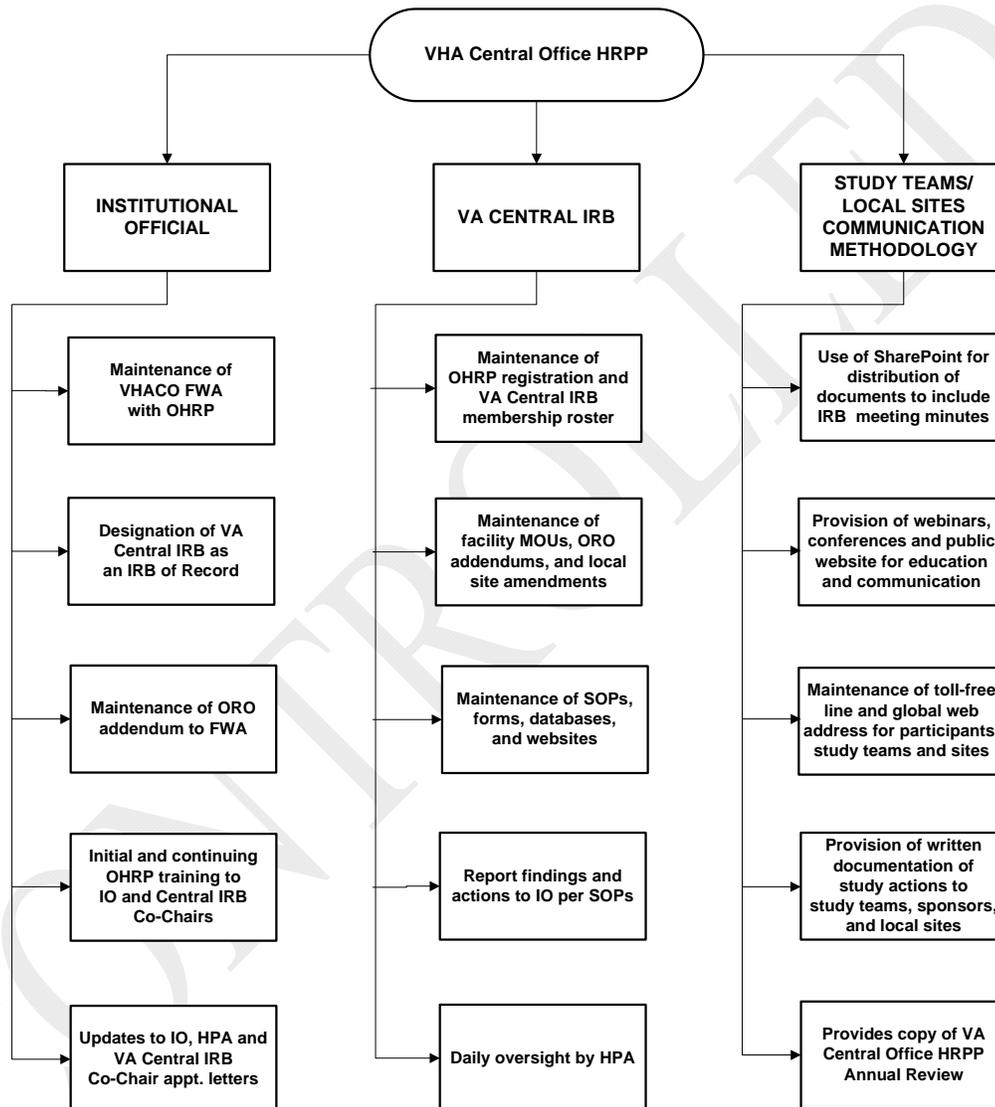
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**Attachment 1**

**VA CENTRAL IRB SOP 100 PROCESS CHART**



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**Attachment 2**

**VHA Central Office Human Research Protection Program Organizational Chart**

