



VA Central IRB Membership Policies

Document No.: RD-IRB-SOP-102

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1 SCOPE AND APPLICABILITY

- 1.1 The scope and purpose of this standard operating procedure (SOP) is to describe the policies and procedures the VA Central IRB uses in recruiting and appointing members to ensure that the composition of the VA Central IRB membership meets all VA and other requirements. It also details member training requirements and member performance evaluation criteria and procedures.
- 1.2 This SOP applies to all categories of VA Central IRB members. It also applies to staff members of the VA Central IRB Administrative Office and the Office of Research and Development (ORD) who are involved in the selection, appointment, training, and evaluation of VA Central IRB members. It also applies to the Institutional Official (IO) for the VHA Central Office (VHACO) Human Research Protection Program (HRPP).
- 1.3 It is the policy of the VA Central IRB that its membership is composed in accordance with all VA and other federal requirements and that all VA Central IRB members, Co-Chairs, and all VA Central IRB administrative staff involved in management of the VA Central IRB, have the knowledge, skills, and abilities necessary to carry out the functions of the VA Central IRB.
- 1.4 It is the policy of the VA Central IRB that no member of the Office of Research and Development (ORD) may serve as a voting member of the VA Central IRB. ORD employees may serve in non-voting advisory or consultant roles as needed and/or requested as set forth in this SOP. ORD leadership may attend meetings as guests but do not stay and observe actual study deliberations in order to ensure there is no appearance of undue influence. VA Central IRB administrative staff are not members of the VA Central IRB.

2 DEFINITIONS

- 2.1 **Ad Hoc Consultant.** An individual with select competence in special areas invited by the VA Central IRB to review certain protocols based on a specific or unique expertise and to render an opinion or make recommendations to the VA Central IRB. These individuals may not vote on the project.
- 2.2 **Alternate IRB Member.** A person officially appointed to serve in the absence of a specific primary voting member and authorized to deliberate and vote in the primary member's absence. The alternate member's specialty, qualifications and experience must be comparable to that of the primary member being replaced. An alternate can also be appointed for a non-voting member and can provide the same advice and guidance as the primary member in the primary member's absence.
- 2.3 **Conflict of Interest.** Any situation in which financial or personal obligations or interests may compromise or present the appearance of compromising an individual's or group's professional judgment in conducting, reviewing, or reporting research. An appearance of COI is when the circumstances would cause a reasonable person with knowledge of the relevant facts to question an employee's impartiality in the review and conduct of human research protocols.
- 2.4 **Employee.** Refers to any employee of the Department of Veterans Affairs to include Without Compensation (WOC) employees or appointment through an Intergovernmental Personnel Act (IPA) appointment. Status as an employee is unaffected by pay or leave status.
- 2.5 **Human Protections Administrator.** The individual named in an FWA as a primary contact



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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).

2.6 Institutional Official. 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 agencies and oversight bodies and provides all written communication with external departments, agencies, and oversight bodies. The Principal Deputy Under Secretary for Health is the IO for VHA Central Office and VA facility Directors are the IOs for local VA facilities. (VHA Handbook 1200.05).

2.7 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).

2.8 Nonaffiliated IRB Member. Nonaffiliated members are not otherwise affiliated with the Department of Veterans Affairs (VA) and are not part of the immediate family of a person who is affiliated with the VA (VHA Handbook 1200.05 and 38 CFR 16.107d.) Individuals who perform occasional volunteer activities without a WOC appointment are not affiliated. Employees of academic institutions that have a formal academic affiliation agreement with VA and employees of VA nonprofit research and educational foundations are affiliated. A Veteran whose only relationship with VA is receiving care at a VA facility or receiving benefits from the Veterans Benefits Administration may be considered nonaffiliated. However, any person serving in a VA Without Compensation (WOC) appointment in another role has an Intergovernmental Personnel Appointment (IPA), or who is retired from VA is considered to be otherwise affiliated and may not fulfill this role on the VA Central IRB. To be considered nonaffiliated, a WOC appointment can only be given to an otherwise nonaffiliated individual specifically for the purpose of liability protection for serving on an IRB.

2.9 Without Compensation (WOC). A category of VA employee who has been officially appointed to perform services for the Department of Veterans Affairs without any direct monetary compensation.

3 RESPONSIBILITY

3.1 The Principal Deputy Under Secretary for Health, as the IO for the VHA Central Office (VHACO), is responsible for ensuring the appointment of qualified and experienced members to the VA Central IRB. The VHACO IO is responsible for the following:

3.1.1 Directly appoints the VA Central IRB Co-Chairs and suspends or terminates the appointment of any Co-Chair who is not fulfilling the responsibilities and/or obligations of the Chair position.

3.1.2 Reviews the composition of the voting members of the VA Central IRB on a yearly basis as part of the VHA Central Office HRPP annual evaluation.

3.1.3 Meets with the VA Central IRB Co-Chairs on an annual basis to review their performance and that of the VA Central IRB.

3.2 The VHA Central Office Human Protections Administrator (HPA) is responsible for the following:



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- 3.2.1 Appointing VA Central IRB voting and non-voting members, with the exception of the Co-Chairs, as per current designation of authority letter from the VHA Central Office IO.
- 3.2.2 Suspending or terminating the VA Central IRB membership of any individual that is not fulfilling member responsibilities and/or obligations.
- 3.2.3 Annually reviewing the composition and performance of the VA Central IRB members and instituting any changes in membership composition as needed based on the performance of the members and the qualifications needed for the research being reviewed. The VHA Central Office HPA forwards any issues concerning the performance of the Co-Chairs to the VHA Central Office IO.
- 3.2.4 Recruiting qualified members in accordance with VA and other federal guidelines to include:
- 3.2.4.1 Seeking applications for VA Central IRB members from local VA facilities, VHA Central Office, Veterans, and pertinent fields of expertise in the lay community throughout the country.
- 3.2.4.2 Evaluating the qualifications of all potential candidates and appointing those individuals who have the required expertise and experience in research; human participant protection regulations; applicable laws; standards of professional conduct and practice; and/or knowledge of or experience with the community from which the participants are drawn.
- 3.2.5 Recruiting and/or approving ad hoc consultants requested by the Co-Chairs to ensure that the necessary expertise is available to the VA Central IRB when the current membership does not have the required ethical, scientific, or other expertise to review specific projects.
- 3.2.6 Approving or recommending travel or honoraria requests related to the services performed by these individuals.
- 3.2.7 Participating in the evaluation of the VA Central IRB. See SOP 123, Evaluation and Quality Improvement of the VA Central IRB.
- 3.3 The VA Central IRB Administrator is responsible for the following:
- 3.3.1 Ensuring that upcoming vacancies on the VA Central IRB are promptly identified, recruitment is initiated and new members appointed or current members re-appointed in order to maintain compositional requirements.
- 3.3.2 Working with the VHA Central Office Human Protections Administrator (HPA) to arrange for ad hoc consultants as requested by the Co-Chairs.
- 3.3.3 Ensuring that continuing education is provided to the members either through planned educational activities at convened meetings, attendance at educational conferences or completion



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of on-line training as applicable. All continuing education activities are documented in the minutes.

3.3.4 Updating the VA Central IRB registration when new members are appointed and provides an orientation as needed.

3.4 One or more VA Central IRB staff members are assigned responsibility for being the VA Central IRB member point of contact for membership-related issues. Depending upon the needs of the office and current workload, some of these duties may be split among designated staff members. This individual is responsible for the following:

3.4.1 Maintaining a folder on each VA Central IRB member that includes:

- Copies of VA Central IRB membership appointment letters
- Membership applications
- Local facility endorsement if applicable
- Completed conflict of interest attestations
- Curriculum vitae and resumes
- Training records
- Annual Self-Evaluations
- Facility Reimbursement Requests as applicable
- Member Hourly Tracking Logs

3.4.2 Maintaining up-to-date membership rosters on the VA Central IRB shared drive to include contact information, credentials and experience, reviewer category preferences, and training expiration dates.

3.4.3 Ensuring new members are given an orientation to the VA Central IRB SharePoint site and completing access permissions.

3.4.4 Ensuring all members complete training requirements by tracking training expiration dates and requesting updated certificates of completion as applicable.

3.4.5 Assisting members in coordinating travel requirements in conjunction with the ORD travel specialist.

3.4.6 Coordinating reimbursement of member time with their local facilities and with the Office of Research and Development (ORD) Finance Office.

3.5 VA Central IRB members, both voting and non-voting, are responsible for the following:

3.5.1 Submitting to the VA Central IRB Office Administrator Certificates of Completion for all required training in a timely manner.



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3.5.2 Tracking the time spent on VA Central IRB activities and providing an accounting to the VA Central IRB Administrative Office at least once per fiscal year.

3.5.3 Complying with all VA Central IRB membership requirements to include:

- Adherence to conflict of interest policies
- Meeting attendance requirements for scheduled meetings
- Completion of required training in a timely manner
- Timely performance of reviewer duties as assigned
- Adherence to all VA privacy and information security requirements

3.5.4 Applying the ethical standards of the Belmont Report when reviewing and overseeing research and ensuring all research approved complies with all VA and other requirements.

4 PROCEDURE

4.1 Composition of the VA Central IRB. In order to promote thorough ethical and scholarly review of research activities within the purview of the IRB, the VA Central IRB is composed of approximately 10-20 voting members of varying backgrounds from throughout the VA system and from the community at large, and five non-voting members. Two of the voting members serve as Co-Chairs. Ad hoc consultants are used as necessary.

4.1.1 Every non-discriminatory effort will be made to ensure the VA Central IRB voting membership is sufficiently diverse relative to race/ethnicity, gender, cultural background, and sensitivity to community attitudes to promote respect for the advice and counsel of the VA Central IRB in safeguarding the rights and welfare of human participants. In addition, the VA Central IRB will consist of members who are able to ascertain the acceptability of proposed research in terms of VA research goals and objectives, and the commitment and capability of local VA facilities to perform the research. If the VA Central IRB regularly reviews research that involves a vulnerable population of subjects, the voting membership will include one or more individuals who are knowledgeable about and experienced in working with those subjects. At a minimum, the VA Central IRB will include one or more voting members from each of the following categories of membership:

4.1.1.1 Scientific members from various disciplines who possess one of the following: 1) a medical degree and are board certified in their specialty; a doctoral degree in their scientific area of expertise, or 2) an allied health degree, i.e., pharmacy or nursing, and have significant experience in their field, to include experience in the conduct or review of human subjects research. At least one of the scientific members must be a licensed physician.

4.1.1.2 Nonscientific members who have expertise in such areas as regulatory affairs, legal affairs, medical ethics, civil rights, patient advocacy, community relations, or other areas that contribute to the complete and thorough review of human participant protections issues for the research projects submitted. At least one, and preferably more, nonscientific members will be appointed.



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- 4.1.1.3 Nonaffiliated members who are not otherwise affiliated with the VA and who are not part of the immediate family of a person who is affiliated with the VA. This category can include Veterans receiving Veteran's benefits or Veterans receiving care at a VA facility who have no other affiliation. All nonaffiliated members are appointed as VA Without Compensation (WOC) employees solely for their service on the VA Central IRB in accordance with VHA Handbook 1200.05, paragraph 12g. A nonaffiliated member can also serve in the capacity of a nonscientific member
- 4.1.2 The VA Central IRB has five standing non-voting members appointed by the VHA Central Office HPA to advise the VA Central IRB on matters pertaining to their area of expertise as follows:
- Information Security Officer (ISO)
 - Legal Advisor
 - Privacy Officer
 - Ethics Advisor
- 4.1.3 The VA Central IRB can consult ad hoc advisors as necessary to ensure the appropriate ethical, scientific, or other required expertise is available to the VA Central IRB when reviewing VA research.
- 4.1.4 The VHA Central Office HPA may appoint alternates for any of the voting members, with the exception of the Co-Chairs, or for any of the non-voting members. The appointments must be in writing and will include the name of the specific member or non-voting position for which that appointee can serve as an alternate. The alternate member's qualifications for service on the VA Central IRB must be comparable to those of the primary member to enable them to adequately fulfill the role of the member to be replaced. Alternate members may attend all VA Central IRB meetings and take part in all VA Central IRB activities. However, an alternate for a voting member can only vote in the absence of the specific primary member.
- 4.2 Recruitment of VA Central IRB Members. The VHA Central Office HPA recruits members from local VA facilities, VHA Central Office, the community of Veterans, other community groups, and from pertinent scientific fields as needed for the research reviewed.
- 4.2.1 Potential scientific members will have expertise in their field and be experienced in the conduct or review of human subjects' research studies. Also desirable is experience serving on a VA research-related committee or board.
- 4.2.2 Potential nonscientific members will not have scientific expertise. Prior experience as an IRB member is desirable but not mandatory. Nonscientific members should have an interest in protecting the health and welfare of Veterans and other human research participants.
- 4.2.3 Potential non-affiliated members may be either scientific or nonscientific members. Prior experience as an IRB member is desirable but not mandatory. Non-affiliated members should have an interest in protecting the health and welfare of Veterans and other human research participants.



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4.2.4 The VHA Central Office HPA and the VA Central IRB Administrator will make every effort to ensure that the membership of the VA Central IRB has adequate gender, racial, cultural, and geographic representation; as well as expertise in research involving vulnerable participants likely to participate in research overseen by the VA Central IRB, e.g., research with persons with impaired decision-making capability. However, no appointment to the VA Central IRB is made based solely on these criteria.

4.2.5 Individuals identified as potential voting members of the VA Central IRB are required to complete a VA Central IRB Form 100, Application to Become an IRB Member (Attachment 2) and be prepared to commit to the following:

- A three year appointment comprising approximately 1/8th of duty time or five hours per week for members, and a one year appointment comprising up to 4/8ths duty time or twenty hours per week for Co-Chairs;
- Travel to Washington, DC, for in-person meetings a minimum of twice per year if government travel restrictions permit;
- Attendance at a minimum of two-thirds of scheduled monthly meetings either in person or via teleconference or video conference; if members are absent due to extenuating circumstances, i.e., serious illness or military deployment, for three consecutive monthly meetings or more, the member's appointment will be terminated but the former member may be re-appointed upon resolution of the circumstances that caused the absence;
- Adherence to all VA requirements regarding the privacy and security of VA sensitive information,
- Completion of required training courses

4.2.6 The Co-Chairs of the VA Central IRB are recruited from among current members of the VA Central IRB or current and former Chairs of VA or university affiliate IRBs that serve as IRBs of record for VA facilities. The Co-Chairs are voting members.

4.2.6.1 The Co-Chairs must have extensive experience serving on or chairing an IRB that has reviewed multi-site VA-funded research.

4.2.6.2 Co-Chairs must be paid VA employees. The Co-Chair and the Co-Chair's facility must be willing to commit up to 4/8ths of the Co-Chair's duty time in performing VA Central IRB-related functions. VA ORD reimburses each Co-Chair's facility for up to 50 percent of the Co-Chair's VA salary plus fringe benefits. In addition, a Co-Chair must also be prepared to commit to all other requirements as specified in paragraph 4.2.5.

4.3 Appointment of Members. Member appointment requirements and the appointment process are as follows:

4.3.1 All voting members who are VA employees (with the exception of WOC employees) must submit an endorsement from their facility indicating that the employee will be given the amount of duty time needed to fulfill the obligations of a VA Central IRB member. This endorsement is documented on VA Central IRB Form 101, Endorsement for Appointment (Attachment 3). VA-ORD reimburses the member's facility for up to 1/8th of the member's VA salary per year



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and up to 4/8ths for the Co-Chairs. The VA member and the member's supervisor sign the form.

- 4.3.3 Non-affiliated members are required to complete additional paperwork for their appointments as VA WOC employees. This includes the signing of a formal WOC agreement. The VA Central IRB staff and the VA Central IRB Administrator assist all nonaffiliated members with the WOC appointment process.
- 4.3.4 All members must have a background check completed that meets VHA Central Office Human Resources recommendations and that is current within one year of their appointment date. If a member does not have these or they are out-of-date, VA Central IRB staff will assist the member in completing the paperwork and in arranging for the fingerprinting and checks to be performed as soon as the member is appointed.
- 4.3.5 All voting and nonvoting members can be appointed for a period of one to up to three years deepening upon the discretion of the VHA Central Office HPA, with the exception of the Co-Chairs, who are appointed/re-appointed on a yearly basis by the VHA Central Office IO. Members and Co-Chairs may be re-appointed to unlimited additional terms.
- 4.3.6 The original, signed appointment letter is sent to all members upon signature of the signatory authority and copies are maintained by the responsible VA Central IRB staff member in the IRB member's file.
- 4.3.7 Upon receipt of the appointment letter, all new members, regardless of member category or voting status, are given a new member orientation either in person or via teleconference. This orientation includes a review of the following as applicable depending upon the knowledge and experience of the new member:
- Pertinent VA and other federal regulations and policies,
 - VA Central IRB Standard Operating Procedures (SOPs), to include VA Central IRB member responsibilities in the review of human subjects research;
 - VA Central IRB Member Handbook, to include a tutorial on the use of the VA Central IRB secure SharePoint site for the distribution and review of project documents;
 - Belmont Report and other ethical guidelines,
 - Use of teleconferencing and video conferencing capabilities,
 - Use of the VA Central IRB website,
 - Training requirements,
 - Travel policy requirements,
 - Meeting attendance standards and reviewer turnaround time requirements, and
 - Conflict of Interest policies.
- 4.3.8 All members, regardless of voting status or member category, must also submit evidence of current completion of the following required training courses to the VA Central IRB administrative staff within 90 days of their appointment to the VA Central IRB. For all recurring training requirements, updated evidence of training completion must be submitted to



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demonstrate the member is up-to-date. A designated member of the VA Central IRB staff tracks the completion of all initial and recurring training requirements to include the following:

- VA Privacy Awareness or VHA Privacy Policy web training (yearly),
- VA Information Security Awareness (yearly),
- VA Information Security 201 (a one-time requirement),
- Good Clinical Practices and Human Subjects Protection ORD-approved course (CITI) (biennially),
- The three assurance modules on the OHRP website (Co-Chairs only), and
- Other required training as determined by the VA and other federal agencies.

4.4 Ongoing Training Provided to Members. VA Central IRB members are encouraged to attend the annual Public Responsibility in Medicine (PRIM&R) Conference, as well as other conferences, such as the VA IRB Chair Conference if approved by their local sites. Attendance at such conferences by VA Central IRB WOC members will be funded through the VA Central IRB budget if funds are available. Ongoing training opportunities are also provided through funded attendance at VA Central IRB training days if funding is available, as well as at regularly scheduled VA Central IRB meetings on at least a monthly basis.

4.5 Evaluation of VA Central IRB Member Performance. The VHA Central Office HPA annually reviews the performance of the VA Central IRB membership and re-evaluates its composition, as part of the VHA Central Office HRPP annual evaluation and recommending adjustments as needed to the VHACO IO in order to ensure that the IRB continues to meet VA and other requirements.

4.5.1 The individual performance of VA Central IRB voting members is evaluated by the VA Central IRB Co-Chairs based on the factors listed below.

- Attendance at convened IRB meetings, either in person or via audio or video conferencing;
- Active participation in meeting discussions,
- Knowledge and application of federal and VA-specific requirements for the review of human research,
- Completion of all required training, to include recurring training;
- Adherence to conflict of interest requirements
- Willingness to serve as a reviewer and utilization of the appropriate VA Central IRB checklists or certification forms, documenting determinations as required;
- Willingness to contact IRB Co-Chairs, IRB administrative staff, or study teams for additional information or to make queries prior to scheduled meetings;
- Reviews all materials in depth and comments are organized and understandable,
- Processes all actions reviewed using expedited review procedures in a timely manner within established timeframes, and
- Adherence to all VA and other applicable requirements in regard to the protection of human participants, including security and privacy of sensitive research information.



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4.5.2 The performance of the VA Central IRB Co-Chairs is also reviewed annually by the VHA Central Office HPA and the VHACO IO. The Co-Chairs are evaluated based on the following factors:

- Attendance at convened IRB meetings, both in person and via teleconference or video conference,
- Knowledge and application of federal and VA-specific requirements for the review of human research,
- Demonstrated ability to effectively facilitate convened meetings so that reviews are timely, thorough, and appropriately fulfill the IRB's responsibilities, as well as meet applicable state and local requirements for the studies and sites being reviewed;
- Meeting management and time management skills in adhering to the agenda and ensuring all required IRB approval criteria have been discussed,
- Completion of all required training, to include any recurring training,
- Adherence to conflict of interest requirements,
- Adequately identifies the need for Ad Hoc consultants,
- Willingness to contact IRB administrative staff or study teams for additional information or make queries prior to a convened meeting,
- Reviews all materials in depth and comments are organized and understandable,
- Processes all actions reviewed under expedited procedures in a timely manner within established timeframes,
- Ability to take necessary actions in response to unanticipated problems and/or serious adverse events,
- Timeliness in reviewing and signing meeting minutes and other project-related documents such as project review actions and continuing review approvals (electronically or manually),
- Willingness to meet via teleconference with study teams to discuss VA Central IRB determinations or actions, and
- Adherence to all VA and other requirements in regard to the protection of human participants, as well as security and privacy of sensitive research information.

4.5.3 The individual performance of VA Central IRB non-voting members is also evaluated based on the factors listed in paragraph 4.5.1 based on their particular role in reviewing studies and advising IRB members and administrative staff.

4.5.4 Feedback regarding the performance of VA Central IRB members and Co-Chairs will be provided as follows:

- 4.5.4.1 Group feedback will be provided by the VHA Central Office HPA and the Institutional Official regarding the overall performance of the VA Central IRB. This will be done annually at either a VA Central IRB in-person convened meeting or at a VA Central IRB training session. Group feedback will be provided orally in person and/or via teleconference and will consist of assessing the overall performance of the VA Central IRB over the past year in terms of quality metrics as specified in VA Central IRB SOP 123, Evaluation and Quality Improvement of the VA Central IRB.



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4.5.4.2 Individual feedback for the VA Central IRB members will be provided as necessary at the beginning of each fiscal year for those members who require improvement in one or more areas listed in paragraph 4.5.1. Co-Chairs will make recommendations for re-appointment, no offer of re-appointment, or termination of current appointment to the VHA Central Office HPA as applicable prior to the annual request for facility reimbursement letters being sent to members at the end of the calendar year.

4.5.4.3 Individual feedback for the VA Central IRB Co-Chairs will also be provided as needed by both the VHA Central Office HPA and the IO prior to the Co-Chairs re-appointment being approved by the IO.

4.6 Resignation of VA Central IRB Members. VA Central IRB members will notify both the VA Central IRB Co-Chairs and the VA Central IRB Administrator if they intend to resign from the VA Central IRB.

4.6.1 Members who resign prior to the expiration of their current term are asked to give at least a 60-day notice in writing via email or a memorandum or letter to allow sufficient time for an appropriate replacement to be named if needed.

4.6.2 Members whose terms are expiring and who do not wish to seek re-appointment are also asked to give at least a 60-day notice in writing of their intention to no longer serve after the end of their current term.

4.7 VA Central IRB Administrative Staff. While VA Central IRB administrative staff are not members of the VA Central IRB, the VA Central IRB Administrator and VA Central IRB Managers are expected to complete all the same required training that is required of the VA Central IRB members, as well as to take part in ongoing training that is provided to the members.

5 DOCUMENTATION REQUIREMENTS

5.1 Documentation of VA Central IRB membership policies, member appointment letters, member training completion certificates, CVs and resumes, WOC appointment paperwork, and travel documents will be stored on the secure VA Central IRB Shared Drive/SharePoint and in VA Central IRB files.

5.2 A separate file will be kept for each VA Central IRB member. These records will be archived upon expiration of the member's appointment or resignation from the IRB and maintained in accordance with the VHA Records Control Schedule.

6 REFERENCES

6.1 38 CFR 16, Department of Veterans Affairs, Protection of Human Subjects

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

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



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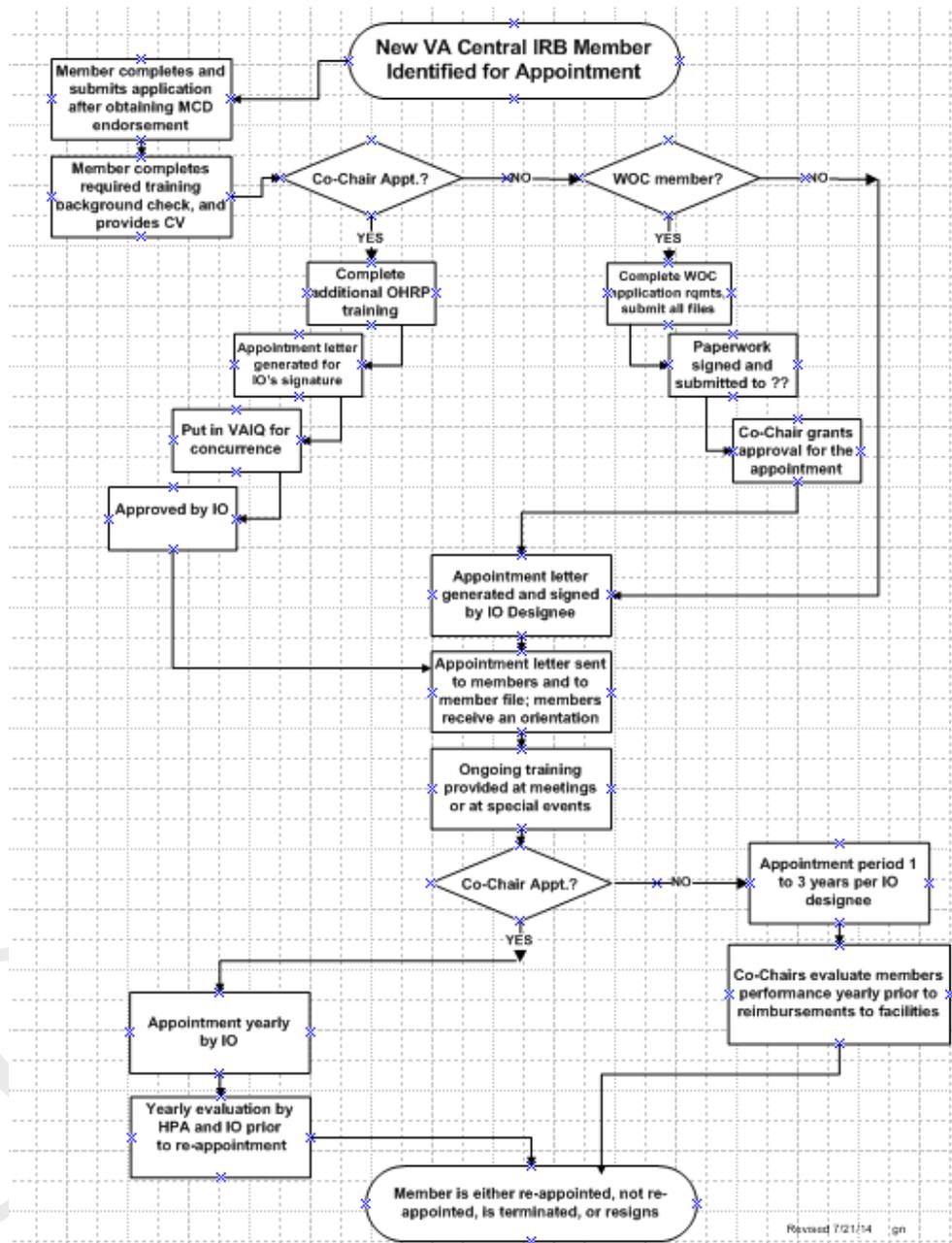
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Attachment 1: VA Central IRB SOP 102 Process Chart





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Attachments:

2. **VA Central IRB Form 100, Application to Become an IRB Member**
<http://vaww.vha.vaco.portal.va.gov/sites/comm/admin/quality/default.aspx>
3. **VA Central IRB Form 101, Endorsement for Appointment as a Member of the VA Central IRB**
<http://vaww.vha.vaco.portal.va.gov/sites/comm/admin/quality/default.aspx>

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Application to Become an IRB Member



Instructions:

The Department of Veterans Affairs, Office of Research and Development (ORD), is seeking individuals with IRB experience from across the country, to include current VA employees and non-VA-affiliated personnel, to apply to become a member of the VA Central Institutional Review Board (IRB). The purpose of the VA Central IRB is to ensure appropriate ethical and scientific review of selected ORD multi-site projects and to enhance the efficiency and timeliness of required reviews.

VA-affiliated applicants must ensure that they will be allowed time by their facilities to participate. Local VA facilities will be reimbursed for this time by ORD up to 1/8th of the VA-affiliated member's salary. Travel expenses for both VA and non-VA-affiliated members will be covered by ORD.

Applicants will be required to meet the following criteria **if selected** to become a member of the VA Central IRB:

- Up to a three year commitment comprising approximately 1/8th of duty time or approximately 5 hours a week on average for members
- Travel to Washington, DC, a minimum of twice per year to attend meetings.
- Attendance at two-thirds of monthly VA Central IRB meetings (in person or via audio/video conference).
- Completion of all required training courses.
- Submission of annual report of number of hours spent performing VA Central IRB duties
- For VA employees, submission of an Endorsement of Membership form from their local facility.
- For non-affiliated members, completion of any additional paperwork required for a VA Without Compensation (WOC) appointment.
- Completion of a successful background check current within one year of appointment

If you would like to serve as a member of the VA Central IRB, please complete the attached application form, attach a CV (or resume for non-scientists) and forward the application package to the Director, PRIDE, at the following address:

VA Office of Research and Development (10P9P)
Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420
FAX: 202-495-6155

Alternatively, the application package can be faxed to the fax number listed above. If you would like to send it via encrypted e-mail, please see below for phone number and e-mail address.

If you have any further questions concerning membership requirements or the goals and objectives of the VA Central IRB, please contact the VA Central IRB Administrator at 202-443-5649 or e-mail your inquiry to va.central.irb@va.gov.

APPLICATION TO BECOME A VA CENTRAL IRB MEMBER

I. DEMOGRAPHIC INFORMATION:

Name: <i>(First, Middle Initial, Last Name)</i>	Credentials/Degrees:
	Job Title:
Work Address: <i>(Home Address if Applicable)</i>	
<i>(Address Line 1)</i>	Telephone: Fax:
<i>(City, State, Zip)</i>	Cell Phone:
 <i>The following are requested but optional:</i>	
Age:	Sex:
Race:	Ethnicity:
Do you have a VA-owned laptop issued for your use or can you access VA systems from your personal computer? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Can you send and receive VA-encrypted e-mail? <input type="checkbox"/> Yes <input type="checkbox"/> No	

II. EXPERIENCE: *Please check all that apply in regard to your experience/status*

Veteran <input type="checkbox"/>	Physician <input type="checkbox"/>	Information Security Officer <input type="checkbox"/>
VA Employee <input type="checkbox"/>	Nurse <input type="checkbox"/>	Chief Information Officer <input type="checkbox"/>
Prior IRB Member <input type="checkbox"/>	Pharmacist <input type="checkbox"/>	Privacy/HIPAA <input type="checkbox"/>
Prior IRB Chair <input type="checkbox"/>	Public Health/ Epidemiology <input type="checkbox"/>	Health Services Research (HSR&D) <input type="checkbox"/>
FDA Experience <input type="checkbox"/>	Genomics <input type="checkbox"/>	Rehabilitation Research <input type="checkbox"/>
Quality/Compliance <input type="checkbox"/>	Biostatistician <input type="checkbox"/>	Social/ Behavioral Research <input type="checkbox"/>
Survey Design <input type="checkbox"/>	Ethicist <input type="checkbox"/>	VA Cooperative Studies Program (CSP) <input type="checkbox"/>
Non-Profit <input type="checkbox"/>	Economist <input type="checkbox"/>	VA CSP Human Rights Committee <input type="checkbox"/>
Non-Scientist <input type="checkbox"/>	Lawyer <input type="checkbox"/>	Non-Affiliated to VA <small>(Note: You are considered affiliated if an immediate family member is affiliated)</small> <input type="checkbox"/>
Scientist: <small>(Researcher)</small> <input type="checkbox"/>	For physicians, nurses, and other scientists, please indicate your specialty:	

III. HUMAN SUBJECTS PROTECTION EXPERIENCE: *Provide a brief response (less than two pages) to the following: (Text box will expand as needed.)*

1. Please describe your familiarity with human research, human research protections, and any related experience or qualifications:

2. Please describe any experiences with vulnerable populations (e.g., decisionally impaired subjects):

3. Please explain why you would like to serve on the VA Central IRB:

Please attach a current CV or resume. (*Please ensure your SSN is not included on your CV or resume*)

Please sign and date this application and provide your e-mail address.

Signature

Date Submitted: _____

Preferred E-mail Address: _____
(For VA employees this must be your VA e-mail address)

The Office of Research and Development, Department of Veterans Affairs, is collecting this information to evaluate an applicant's qualifications to serve on the VA Central IRB. It will be used to ensure that the VA Central IRB meets all VA and other federal requirements pertaining to IRB membership composition. It is estimated that the form will take approximately 20 minutes to complete. Responses are entirely voluntary. All information collected will remain confidential. The forms will be kept on file for a period of one year or for the duration of a member's appointment on the VA Central IRB.