

**TITLE: Maintaining VA Central IRB Membership Files****1.0 PURPOSE**

This Standard Operating Procedure (SOP) sets forth the policies and procedures for maintaining VA Central IRB Membership files and for ensuring all required documentation for each member is kept up-to-date. It also includes procedures for reimbursing facilities for member time.

**2.0 REVISION HISTORY**

Date of Initial Approval	March 26, 2010
Revision Dates	August 10, 2011

**3.0 SCOPE**

This SOP applies to the VA Central IRB administrative staff and the VA Central IRB members.

**4.0 POLICY**

4.1 It is the policy of the VA Central IRB that VA Central IRB members will submit required documentation to the VA Central IRB Administrative Office as required by VA Central IRB SOP 102, VA Central IRB Membership Policies, and that they will ensure all documentation is kept up to date.

4.2 It is also the policy of the VA Central IRB that VA Central IRB Administrative staff will remind investigators when documents need to be updated and to keep the membership files current and organized to ensure ease of reference and retrieval of required information.

**5.0 DEFINITIONS**

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

**6.0 RESPONSIBILITIES**

6.1 VA Central IRB members are required to submit all required documentation to the VA Central IRB upon request and in a timely manner.

6.2 The VA Central IRB Membership Coordinator is responsible for the following:

- Creating a file for each newly appointed VA Central IRB member, to include nonvoting members, educating new members on all appointment

requirements, to include conflict of interest, and for ensuring the file is kept up-to-date

- Notifying members at least one month in advance of any requirement that needs to be renewed or updated
- Managing and updating the VA Central IRB members' contact information on a regular basis and making sure it is readily available to other VA Central IRB administrative staff for quick reference as needed
- Managing and updating the various VA Central IRB member databases to include appointment expiration dates, WOC appointment expiration dates, VA required training due dates, and member representative characteristics

## 7.0 PROCEDURES

7.1 Membership Files. The VA Central Membership Coordinator creates a file for each newly appointment member. Each file will contain the following sections:

### 7.1.1 For Without Compensation (WOC) Members:

- Section 1 – CV/Resume and IRB Member Application documents (voting members only)
- Section 2 – Appointment Letters/COI Attestation/Reviewer/Expedited Review Appointment Letter if Applicable
- Section 3 – WOC Package/Awards/Security Clearance Info/Letters of Appreciation
- Section 4 – Training Certificates (Table listing dates of completion on top)
- Section 5 – Travel Documents
- Section 6 – Other Documents and Correspondence (Reviewer Survey)

7.1.2 For paid VA Employee Members (both voting and non-voting) the same as for the WOC members will be set-up but Section 3 will contain time Logs and facility reimbursement requests/Letters of Appreciation/Security Clearance Info if applicable.

7.1.3 Nonvoting member files will mainly consist of appointment letters, training certificates, and security clearance information if applicable. CVs or resumes can be filed if available.

7.2 Notifying Members of Requirements. The VA Central IRB Membership Coordinator notifies members of required documentation that must be submitted as follows:

7.2.1 Upon an individual being identified for potential appointment to the VA Central IRB, the VA Central IRB Membership Coordinator calls or sends an e-mail to the members advising them of all documentation that must be submitted in accordance with VA Central IRB SOP 102 and follows-up to ensure all documentation is received.

7.2.2 In addition, the Membership Coordinator performs a List of Excluded Individuals/Entities (LEIE) check on each new member, informs the VA Central IRB Administrator of the results, and files the results in the member's file.

7.2.3 Once all documentation has been received, the Membership Coordinator prepares an appointment letter for signature of the applicable signatory official (the IO for the Co-Chairs and the Director, PRIDE, for all other appointees). Upon approval, a copy is sent to the member and a copy is filed in the member's folder. The Membership Coordinator will follow-up as needed to ensure that any new members who have not completed initial VA training requirements, complete them within 90 days of appointment.

7.2.4 The VA Central IRB Membership Coordinator notifies the members and the VA Central IRB Administrator at least 90 days in advance of an appointment expiration date.

7.2.4.1 For VA Central IRB member re-appointments, the VA Central IRB Administrator will discuss with the member their future plans and will consult with the Director, PRIDE, as to whether the member will be offered re-appointment. If the member is to be offered re-appointment, the Membership Coordinator will prepare the appointment letter and process it for signature. If the member does not wish or can't continue to serve on the VA Central IRB, the Director, PRIDE, and the VA Central IRB Administrator will initiate recruitment efforts in accordance with VA Central IRB SOP 102.

7.2.2.2 For WOC appointments, if the member desires re-appointment and the VA Central IRB Administrator and the Director, PRIDE, concur, the VA Central IRB Membership Coordinator initiates a new WOC agreement and obtains the member's signature. Upon receipt of the signed agreement, it will be forwarded to the PRIDE Personnel Liaison who will forward the agreement to the VHA Personnel Office for review and approval. A WOC appointment expiration date does not always correspond to the VA Central IRB member appointment date. Both appointments must be in place for a member to remain in an active voting status on the Board.

7.2.3 No later than 30 days prior to a required training expiration date, the member will be reminded via e-mail that the Membership Coordinator must receive documentation of completed training prior to the expiration date. The Membership Coordinator will send another e-mail reminder two weeks prior to the due date. One week prior to the due date the Membership Coordinator will


call the member and also inform the VA Central IRB Administrator and the Director, PRIDE. If the documentation has not been received by the day after the due date, the Membership Coordinator will inform the Director, PRIDE. Upon receipt of the training documentation, the tracking log will be updated with the new due date.

7.2.4 The Membership Coordinator updates the VA Central IRB member contact list on a regular basis and prints out a new contact list all the other VA Central IRB staff members when a change is made. At least once a year, the VA Central IRB Membership Coordinator queries the members to determine if they have updated their curriculum vitae and, if they have, obtains a copy for the file.

## 8.0 REFERENCES

VA Central IRB SOP 102, VA Central IRB Membership Policies

I have reviewed and approved the contents of this SOP.

  
K. Lynn Cates, MD  
Director, PRIDE

Date: 8/10/11