

TITLE: Logistical Preparations for a Convened Board Meeting**1.0 PURPOSE**

The purpose of this administrative Standard Operating Procedure (SOP) is to set forth the administrative guidelines and procedures that must be followed when preparing for a meeting of the convened VA Central IRB.

2.0 REVISION HISTORY

Date of Initial Approval	August 7, 2009
Revision Dates	March 26, 2010 February 14, 2011 August 10, 2011

3.0 SCOPE

This SOP applies to all VA Central IRB administrative staff, other PRIDE staff members assisting with the logistics of the convened VA Central IRB meetings, and the VA Central IRB members.

4.0 POLICY

4.1 It is the policy of the VA Central IRB to make agenda packages available to all VA Central IRB members who have indicated they can attend a convened meeting at least approximately 10 work days prior to a convened meeting to allow the members enough time to perform a thorough review of the materials. Members who have not indicated whether or not they can attend by the time the agenda packages are due are also given access to the materials.

4.2 The assigned VA Central IRB Coordinator performs an administrative screening of each new project action in accordance with VA Central IRB SOP 104, Application Requirements for New Projects Funded or Sponsored by the Office of Research and Development (ORD) Services prior to making a project application package available to the members for review. Any additional information received for the meeting after the agenda packages are initially made available are uploaded to the secure SharePoint site at least five workdays prior to the convened meeting. For documents that are received after the additional materials have been loaded to SharePoint, hard copies will also be available at the meeting for the members attending the meeting. For members attending via teleconference, copies will be sent via Express mail or sent by encrypted e-mail. These can include items such as investigator responses to reviewer questions, copies of the agenda tools to be used at a given meeting, minutes of previous meetings, and revised final agendas.

4.3 All members attending in person are to forward their travel estimates to the VA Central IRB Administration Office by the stated deadline date using the on-line system, except for WOC employees who may contact the Meeting

Coordinator directly to make travel arrangements. The VA Central IRB Administrative Office forwards each member's travel authorization to the member no later than 3 work days prior to the convened meeting or conference.

5.0 DEFINITIONS

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

6.0 RESPONSIBILITIES

6.1 The VA Central IRB Administrator is responsible for preparing a draft of the meeting agenda to be included in the agenda packages made available to members. The draft agenda is prepared in accordance with VA Central IRB SOP 108. The VA Central IRB Administrator is responsible for ensuring that all required meeting preparation milestones, as indicated in the enclosed table, VA Central IRB Meeting Preparation Milestones (Attachment 1), are met.

6.2 The VA Central IRB Coordinators are responsible for ensuring that an administrative pre-screening of their assigned projects is completed in accordance with VA Central IRB SOP 108. In addition, they are responsible for ensuring that all the reviewer checklists and certification forms for their project actions are filled out appropriately and have been made available to all Reviewers who have an action for review on the agenda. The Coordinators are also responsible for preparing and uploading the electronic files of all documents for their agenda packages onto the secure SharePoint Site by the deadline specified by the VA Central IRB Administrator.

6.3 The VA Central IRB Meeting Coordinator is responsible for coordinating all the logistical requirements concerning an upcoming convened meeting. These requirements include but are not limited to the following:

- Sending out meeting notices and audio/video communication requirements to members
- Tracking responses to meeting notices and keeping the membership attendance spreadsheet up-to-date
- Preparing the travel authorizations to allow member travel and distributing them to members upon approval
- Assisting WOC members in making flight arrangements and filing expense reports for payment
- Collating and mailing agenda packages via express delivery to VA Central IRB members who do not have access to the secure SharePoint site.
- Preparing Conflict of Interest Declaration forms (VA Central IRB Form 127) for all members attending the meeting, including them in the agenda packages, and collecting them from all attending members prior to the meeting

- Sending an e-mail to VA Central IRB members informing them when the agenda materials are available for review on the secure SharePoint site.
- Ensuring all audio and video teleconferencing equipment is in good working order prior to each meeting.
- Preparing the member voting matrix tracking sheet to track the votes of members participating via audio conference prior to the meeting.

6.4 VA Central IRB members are responsible for advising the VA Central IRB Administrative Office in a timely manner if they will not be able to attend a scheduled meeting either in-person or by video or audio conference. Members attending the meeting in-person are responsible for submitting their travel estimates, if applicable, by the stated deadline date in order to receive an approved travel authorization prior to commencement of their travel. Members are also responsible for completing their conflict of interest forms, and reviewing all materials prior to the meeting.

7.0 PROCEDURES

7.1 Meeting Invitation and Responses. The VA Central IRB Meeting Coordinator sends out an e-mail to all members announcing the monthly meeting time and date no later than three weeks (15 calendar days) prior to the scheduled meeting.

7.1.1 The invitation includes the following at a minimum:

- Meeting time and date
- Whether the meeting will be in person or only via video and/or audio
- Deadline date for responding to the invitation
- Link to on-line VA Central IRB member travel estimate database

7.1.2 The VA Central IRB Meeting Coordinator tracks all responses on the VA Central IRB Form 207, Monthly Meeting Attendance Worksheet (Enclosure 2), which is kept on the shared drive. The worksheet is annotated as follows:

- Whether the member can attend in person, via video or audio conference, or cannot attend.
- Whether a travel estimate was received if applicable
- The date the member's agenda package was shipped if the member does not have access to the secure SharePoint site.
- Date the VA Central IRB Form 102, Conflict of Interest Attestation, is received from the member for that particular meeting

7.1.3 If the member has not responded by the deadline date the Meeting Coordinator follows-up via e-mail and phone until a response is received.

7.1.4 The Meeting Coordinator also ensures that the VA Central IRB Conference Room has been appropriately booked for the day of the meeting, as well as the afternoon prior to the meeting so the room can be set-up if needed.

7.2 Travel Procedures. A travel authorization must be issued for each member attending the meeting in-person who is not from the local area.

7.2.1 Members attending in-person must submit an estimate of their travel costs.

7.2.1.1 VA members who are assigned to a local VA facility and who file a travel request through their local travel office must submit an estimate of their travel expenses through the VA Central IRB on-line travel database. The link to this database is sent with each meeting invitation and is also available on the VA Central IRB website. Members must complete and submit their travel estimates by the date indicated in the meeting invitation. The Meeting Coordinator follows-up with members via e-mail and /or phone call that have not met the deadline.

7.2.1.2 For WOC members for whom the Meeting Coordinator makes flight reservations in Fed Traveler, they must contact the Meeting Coordinator to indicate their flight preferences. The Meeting Coordinator prepares a travel plan for each traveler and has it signed by an authorized signatory authority and then turns it into ORD Finance.

7.2.2 Once all members have submitted their estimates the Meeting Coordinator downloads and saves the information to an Excel spreadsheet. The estimates are reviewed and scrubbed for accuracy by the Meeting Coordinator. Using the mail merge function of Microsoft Word, the travel estimate information is then merged with the travel authorization template. A travel authorization is then printed for each member.

7.2.3 A cover sheet for the travel authorizations is then prepared by the Meeting Coordinator for the signature of the Chief Research and Development Officer (CRADO) and included with the individual twxs. Upon signature of the CRADO, copies of the approved twxs are made for the VA Central IRB administrative files.

7.2.4 Each member is then sent a copy of their individual travel authorization and a copy of the signed cover letter via fax or e-mail.

7.2.5 Upon completion of travel, members who submitted a travel authorization through their local VA, also submit their expense report through their local facility. Their facility then requests reimbursement through ORD Finance. Members for whom the Meeting Coordinator made travel arrangements must submit their expenses to the Meeting Coordinator, who will then enter an expense report in Fed Traveler to be processed by ORD Finance.

7.3. Meeting Agenda Package Preparation. The draft agenda and the individual project actions, reviewer checklists, and certification forms are prepared in accordance with VA Central IRB SOP 108 by the VA Central IRB Coordinator and the VA Central IRB Administrator.

7.3.1 The link for the upcoming monthly meeting is set-up by the SharePoint Coordinator and made available to all members of the VA Central IRB administrative staff.

7.3.2 Each VA Central IRB Coordinator prepares the documents for each project they have been assigned that will be reviewed at the convened meeting as follows:

7.3.2.1 A folder is created with the name of the study as indicated on the draft agenda.

7.3.2.2 Within this folder subfolders are then created in a logical manner to group documents for ease of reference for the VA Central IRB members. The number and type of subfolders will depend upon the type of action being reviewed.

7.3.2.2.1 For initial reviews, the subfolders should be organized along the following lines but may be customized by each VA Central IRB Coordinator depending upon the type of documents submitted and the format of the electronic files:

- VA Central IRB Form 108, PI/SC New Project Application; 108a, Co-PI/C Supplement to New Project Application, and Investigator CVs and COI determinations
- Protocol and any appendices or attachments. Also include survey instruments, questionnaires, case report forms etc.
- Informed Consent documents and waiver requests, as well as HIPAA authorization and waiver requests
- Recruitment materials
- Drug or device information if applicable

7.3.2.2.2. For continuing reviews, the subfolders should be organized following the below example:

- VA Central IRB Form 115b, Request for Continuing Review; PI/SC Application, and new documents submitted
- All prior approved documents
- Each Local Site should have its own subfolder to include the VA Central IRB Form 115a, Request for Continuing Review, Local Site Investigator Application, and new informed consent documents as applicable

7.3.2.2.3 For amendments, subfolders are not required unless the amendment is substantive and can be broken down per paragraph 7.3.2.2.1.

7.3.3 The VA Central IRB Administrator will create folders for any other actions required, such as review of audit reports, reports of noncompliance, or review of serious adverse events or serious unanticipated problems involving risks to subjects or others.

7.3.4 After all materials are ready for review the assigned VA Central IRB Coordinator or the VA Central IRB Administrative Assistant will create a PDF file of all the documents loaded in the system in the order as specified on the agenda. The members will be able to access either the PDF file for review or the individual documents per their preference. A hard copy printout will then be made of the entire agenda package and copies made and distributed to all VA Central IRB administrative members and the VA Central IRB Regulatory Advisors.

7.3.5 The VA Central IRB Meeting Coordinator then sends an e-mail to the members letting them know the materials are available and provides a link to the SharePoint site. Hard copies are also sent via express delivery to those members who do not have access to the secure SharePoint site.

7.3.6 All documents that are loaded after the initial message has gone out to the members will be loaded in a subfolder named "Additional Documents" and the date. Members will be e-mailed letting them know that new documents are available. Members who do not have access will be sent hard copies via overnight express delivery.

7.3.7 Upon publication of the final agenda, the VA Central IRB Administrative Assistant will prepare a voting matrix based on the attendance worksheet. Each item having a vote will be listed as a column heading in place. This will be used as a tool for the VA Central IRB administrative staff to keep track of votes by members participating in the meeting via teleconference and to track member attendance throughout the meeting to ensure quorum is maintained. This is a temporary worksheet and can be shredded once the minutes of the meeting at which they were used are approved.

7.4. Conference Room and Communication Equipment Preparations. The Meeting Coordinator ensures the conference equipment is kept in good working order at all times. If any issues are discovered, a work order for equipment service will be immediately placed.

7.5.1 At least one week prior to the meeting, the Meeting Coordinator arranges for the VANTS video and audio conferencing line as applicable. In addition, the Meeting Coordinator will set up a second VANTS audio line only for investigators to call into the meeting as needed to answer member questions.

Each VA Central IRB Coordinator will set-up a time window with the study team as to when they will be available to call in during the time their study is slated to be discussed at the meeting. This second line will be set-up to accommodate at least ten personnel and will have the notice of someone entering the conference kept on for the duration of the meeting.

7.5.2 The afternoon prior to the meeting, all equipment is set-up and tested, and any presentations loaded and brought up to ensure they can be viewed. Internet connectivity is also tested if applicable. The conference room is cleaned, if applicable, and name tents are set out if there are new members.

7.5.3 On the day of the meeting, the Meeting Coordinator ensures all connections are made (video and audio) and remains available to handle any issues that arise in the communication systems. Upon conclusion of the meeting, the Meeting Coordinator ensures all equipment is disconnected and secured.

7.6 Materials Disposition. Hard copies of agenda packages may be retained by the members after the meeting or collected for shredding. If the members keep the packages, they are advised that the packages must be kept secure and then shredded when no longer needed.

7.6.1 Prior to the meeting the Meeting Coordinator sets out boxes labeled "For shredding." Members may drop off any items from their packages they do not want to hold in these boxes at any time during or after the meeting. Meeting materials will remain on the SharePoint site for a minimum four months as long as space is available for reference by the members if needed. After six months, they may be deleted due to site space restrictions.

7.6.2 After the meeting, the Meeting Coordinator secures the boxes for shredding. When the Meeting Coordinator is ready, but no less than monthly, the Meeting Coordinator completes a VA Form 7468, Request for Disposition of Records, with the following information:

- Contact information of the person completing the form, telephone number, address where the materials are to be picked up, and destination
- Description of the records to be shredded
- Amount of containers to be picked up
- Dates of records
- When the records need to be destroyed
- Requested method of destruction

The form must be signed by the VA Central IRB Administrator or other authorized individual. The form will then be sent to the VHA Central Office Records Manager who will arrange for pick-up of the boxes for shredding.

7.6.3 Depending on the amount of materials that need to be destroyed, the shredding process may also take place within the VA Central IRB Office, using a special shredder that complies with the security requirements for disposal of sensitive information.

8.0 REFERENCES

VA Central IRB SOP 108, VA Central IRB Convened Meeting Preparation.

2 Encl

1. VA Central IRB Meeting Preparation Milestones
2. VA Central IRB Form 207, Monthly Meeting Attendance Worksheet

I have reviewed and approved the content of this SOP.


K. Lynn Cates, MD
Director, PRIDE

Date: 8/10/11

VA Central IRB Meeting Preparation Milestones

15 Working Days to Meeting

- Reviewers assigned to all new projects submitted for initial review
- Meeting Coordinator sends out meeting invitation via e-mail and responses tracked

12 Working Days to Meeting

- Draft agenda prepared by VA Central IRB Administrator
- Each VA Central IRB Coordinator prepares assigned individual protocol project packages and prepares them for upload to SharePoint
- The VA Central IRB Meeting Coordinator prepares the following documents for the agenda packages:
 - Conflict of Interest Forms
 - Pre-Meeting Review Instructions
 - Training materials

10 Working Days to Meeting

- Individual project applications or other actions uploaded into SharePoint
- Draft Agenda is uploaded into SharePoint.
- Each VA Central IRB Coordinator ensures the applicable reviewer checklists are placed in the appropriate SharePoint subfolders for assigned reviewers or sent to them by encrypted e-mail.
- The VA Central IRB Meeting Coordinator:
 - Sends an e-mail to members letting them know materials are available for review on SharePoint and provides link
 - FEDEX's hard copies to members not having access to SharePoint
 - Prepares twxs for approval by the CRADO
 - Makes travel arrangements for WOC members

5 Working Days to Meeting

- Each IRB coordinator contacts reviewers for assigned studies to determine whether they have any questions for study team and arranges a time for the investigator to call in to the meeting on VANTS line
- Meeting Coordinator forwards signed twxs to members

24 Hours to Meeting

- Investigator responses to reviewer comments and any other last minute items uploaded to SharePoint and sent by fax to members not having access; hard copies also made to be available at the meeting.
- VA Central IRB Meeting Coordinator performs check of conferencing

VA Central IRB Project Review Action Package Contents

PI/SC New Project Application

Study packets loaded to SharePoint may include but not be limited to:

- VA Central IRB Form 108 (PI New Project Application)
- Protocol
- ORD funding Letter
- PI Biosketch
- PI Local findings on COI
- Model VA Research Informed Consent Form (VA Form 10-1086)
- Request for waiver or alteration of informed consent (VA Central IRB Form 112a)
- HRC Committee Meeting Minutes (CSP Studies Only)
- Prior Informed Consents (if is a follow-up study)
- HIPAA Authorization
- Request for waiver of HIPAA Authorization (VA Central IRB Form 103)
- Investigator's Drug Brochure
- Investigational Device Information (if applicable)
- Request for Waiver of Documentation of Informed Consent (VA Central IRB Form 112b)
- Vulnerable Population Supplement (VA Central IRB Form 110 Series)
- Model Recruitment Materials
- Model Participant's Instructions
- Model Questionnaires or Surveys
- Model Scripts
- Model VA Investigational Drug Information Record (VA Form 10-1092)
- Local site comments (30-day) if applicable

Reviewers will always receive copies of their applicable checklists and, for continuing reviews, copies or access to the entire project file. Reviewers may also need additional documents amendment review.

Local Site Investigator Application

Study packets on SharePoint may include but not be limited to:

- Copy of approved VA Central IRB 108
- VA Central IRB Form 104 (Local Site Investigator Application) and all applicable associated documents to include COI determinations, local investigator biosketches or CVs, and local documents based on model documents detailed under the PI/SC New Project Application Table
- Comparison Table to model documents

Continuing Review Application

Study packets on SharePoint may include but not be limited to:

- VA Central IRB forms 115a and 115b as applicable
- Comparison table of local site documents with model site and previously approved forms
- Copy of current Informed Consent Forms
- Copy of current HIPAA Authorizations
- DSMB/DMC reports as applicable
- Local audit reports as applicable

Additional documents may be required as determined by reviewers. Reviewers receive or have access to the entire project file.

Modifications to Previously Approved Research

Study packets on SharePoint may include but not be limited to:

- VA Central IRB form 116
- Copies of all modified documents with tracked changes

