TITLE: Evaluation and Quality Improvement of the VA Central IRB

1.0 PURPOSE

The purpose of this standard operating procedure is to describe the overall mechanisms to evaluate the VA Central IRB to ensure compliance is achieved and maintained pertaining to VA and other requirements for the protection of human subjects and to ensure a program of continuous quality improvement is in place. It also addresses the review and receipt of audit reports from the local participating sites in projects overseen by the VA Central IRB.

2.0 REVISION HISTORY

Date of Initial Approval	March 25, 2010
Revision Dates	September 17, 2010 February 14, 2011 August 10, 2011 December 9, 2011

3.0 SCOPE

This standard operating procedure applies to the VA Central IRB, local participating sites who list the VA Central IRB as an IRB of Record, and study teams on projects overseen by the VA Central IRB, as well as any other related quality improvement activities overseen by the VHA Central Office HRPP.

4.0 POLICY

4.1 It is the policy of the VA Central IRB to conduct activities designed to enhance understanding of human research by participants, prospective participants, or their communities, when appropriate, and evaluate such activities on a regular basis for improvement.

4.2 The VA Central IRB must have sufficient resources to protect the rights and welfare of research participants for research activities that it oversees. The Director of PRIDE annually evaluates the resources allocated for the VA Central IRB, makes adjustments as needed, and determines whether allocated resources are sufficient to meet all of the needs of the VHA Central Office HRPP.

4.3 The VA Central IRB conducts audits, surveys, or uses other methods, such as data collection tools to objectively assess and improve, when necessary:

- Compliance with organizational policies and procedures
- Compliance with applicable laws, regulations, codes, and guidance
- Compliance with accreditation standards of agency approved by ORD to conduct accreditation activities for VA facilities
- Quality effectiveness and efficiency of the VHA Central Office HRPP
- Strengths and weaknesses of the VHA Central Office HRPP

- Customer satisfaction

4.4 The VA Central IRB has open communications with VA Researchers under its oversight and is responsive to questions, concerns, and suggestions. Researchers and research staff may bring forward to the VA Central IRB concerns or suggestions regarding the VHACO HRPP, including the ethics review process.

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 coordinating the mechanisms to evaluate the VA Central IRB and ensure continuous quality improvement on a regular basis, as well as for presenting findings to the VA Central IRB. The VA Central IRB Administrator coordinates activities with local site liaisons when evaluating or obtaining feedback from VA facilities and non-VA Institutions described in the MOU. The VA Central IRB Administrator works with the VA Central IRB Co-Chairs and the Director, PRIDE, to determine the schedule, frequency, focus, and type of evaluations. When determining the scope and direction of the evaluation mechanisms the VA Central IRB Administrator and VA Central IRB Co-Chairs may consider the following:

- Outcome measures
- Details of the MOU with local VA facilities
- Strategic planning
- Reports of ongoing issues or complaints or expressions of concern
- Implementation of new processes, policies, or procedures
- IRB member and staff workload
- Items of interest that are routinely monitored on an annual basis, including community outreach activities

6.2 The VA Central IRB provides input on evaluation mechanisms, provides feedback, reviews evaluations, and takes corrective actions when appropriate. The VA Central IRB members participate in designing evaluation techniques. Non-voting staff members and IRB coordinators may assist in auditing or conducting other evaluation techniques.

6.3 VA facilities that have entered into an MOU with the VHA Central Office HRPP to use the VA Central IRB as an IRB of Record will cooperate in the evaluation process and provide feedback when requested.

6.4 Supervisors of IRB Staff routinely evaluate their staff using the VA Performance Appraisal system.

6.5 Prior to conducting a Quality Improvement Activity, such as survey or focus

group, the VA Central IRB must make a determination whether the activity is human subjects research that requires oversight by the VA Central IRB. See SOP 122, Determining Applicability of the Regulations.

7.0 PROCEDURES

7.1 Annual Evaluation of the VHA Central Office HRPP. An annual evaluation of the VHA Central Office HRPP will take place on a no less than yearly basis in accordance with VHA Handbook 1200.01, Research and Development (R&D) Committee. This evaluation will include but not be limited to the following

7.1.1 Reporting of Metrics. The VA Central IRB Administrator will gather and report on the numbers of the following activities as an assessment of workload:

- Turnaround time for review of initial projects from time of receipt of a completed PI/SC Application; separate times will be determined forr projects reviewed by the convened IRB and those processed using expedited review procedures, with reason for any delays that would have substantially affected the mean explained
- Number of lapsed projects if any and reasons for the lapse
- Number of serious adverse events, unanticipated problems involving risks to subjects or others, and protocol deviations
- Number of complaints from investigators and participants
- Number of validated reports of serious and continuing non-compliance
- Number of events that required reporting to ORO and other external agencies

7.1.2 VA Central IRB Project File Audits. The VA Central IRB Administrator will arrange for an audit of a subset of VA Central IRB records to determine the accuracy and effectiveness of VA Central IRB actions, records, and minutes. The non-voting IRB members serving in the capacity as regulatory advisors, voting members of the VA Central IRB, or other knowledgeable personnel may conduct these audits.

7.1.2.1 The auditors as a group will randomly select a minimum of five protocol files that were approved during the prior year. The auditors will also review the VA Central IRB minutes associated with the project files, along with any reviewer checklists.

7.1.2.1.1 The auditors pull files until each of the following characteristics are included in the audit process:

- A project reviewed by the expedited process
- A project reviewed by the convened IRB
- A project that has undergone continuing review (in the prior year)
- A project reviewed which consists of an FDA regulated activity
- A project reviewed which involves vulnerable subjects

7.1.2.1.2 One protocol may satisfy multiple characteristics. For example, the first randomly selected file might be a protocol reviewed by the convened IRB at continuing review and consist of an activity that is FDA regulated. The auditor should keep pulling files at random until he/she has a set of at least five files that meet all of the characteristics. Even if one project meets two or more of the above characteristics, a minimum of 5 projects must be included in the audit.

7.1.2.1.3 If the characteristic of interest was not submitted for IRB review in the prior year, it does not have to be included in the audit. For example, if the IRB did not review research pertaining to a vulnerable population in the prior year, it does not need to be included in the audit.

7.1.2.1.4 If the auditor has trouble pulling a complete set of files, the VA Central IRB Administrator may assist with identification of appropriate files to include in the audit process.

7.1.2.2 An auditor may compare the documentation against the expectations listed in the VA Central IRB SOPs, VA Policy, and federal regulations or use a checklist created for the audit. Alternatively, the auditor may use the VA Central IRB Form 139, Internal Audit Tool for Approved PI/SC Applications (Attachment 1).

7.1.2.3 The auditor documents the findings of the audit and presents the information to the VA Central IRB Administrator who will then present the findings to the VA Central IRB with the VA Central IRB Administrator taking any corrective actions that may be needed.

7.1.3 Resource Review. The VA Central IRB budget is reviewed by the Director of PRIDE to ensure the VA Central IRB has sufficient resources to protect the rights and welfare of research participants for research activities that it oversees. The Director of PRIDE determines whether allocated resources are sufficient to meet all of the needs of the VHA Central Office HRPP. When resource needs are identified the Director of PRIDE works with the Chief Research and Development Officer to request additional resources. Resources include but are not limited to: adequate numbers of qualified staff, consultants, establishing additional IRBs, obtaining necessary equipment and supplies, ensuring adequate information systems support, and having sufficient space to conduct business in a secure environment. The Director of PRIDE ensures space is adequate to store records securely, permit private conversations, accommodate computer and office equipment and conduct meetings.

7.1.4 Survey of Investigators, Local Sites, and VA Central IRB Members. Feedback from members, local sites, study teams will be obtained as follows:

7.4.1.1 On a biennial basis, the VA Central IRB conducts surveys of the investigators who have active studies being overseen by the VA Central IRB. In addition, the VA Central IRB will survey the VA Central IRB Liaisons of VA facilities that have active MOUs with the VHA Central Office for the use of the VA Central IRB as an IRB of record and that have an active PI/SC or LSI Application that has been approved. The

VA Central IRB may also use other methods to measure, assess, and improve, when necessary the VA Central IRB's:

- Compliance with organizational policies and procedures
- Compliance with applicable laws, regulations, codes, and guidance
- Communications with local sites, investigators, and study teams
- Quality effectiveness and efficiency
- Strengths and weaknesses
- Customer satisfaction

7.4.1.1.1 Results will be compiled by the VA Central IRB Administrator. Any issues identified as apparent serious or continuing noncompliance will be reported in accordance with VA Central IRB SOP 118, Serious and Continuing Noncompliance.

7.4.1.1.2 Researchers and local VA facility staff may communicate with the VA Central IRB at anytime via phone, e-mail, or written correspondence to provide feedback and this is actively encouraged at all phases of interaction. If researchers and research staff bring forward to the VA Central IRB concerns or complaints that require an immediate resolution, those are processed in accordance with VA Central IRB SOP 120, Community Outreach.

7.1.5 The VA Central IRB membership will be evaluated, as well as surveyed on an annual basis as follows:

7.1.5.1 The VA Central IRB members will be surveyed using VA Central IRB Form 150, IRB Member Self-Evaluation (Attachment 2) and VA Central IRB Form 151, IRB Co-Chair Evaluation (Attachment 3) regarding both their own performance, the performance of the VA Central IRB as a whole, the performance of VA Central IRB staff, and to obtain feedback and suggestions for improvement. Results will be compiled by the VA Central IRB Administrator and reported to the VA Central IRB and the Director, PRIDE.

7.1.5.2 The VA Central IRB membership will also be evaluated as to composition and if the members have the appropriate mix of expertise for review of the kinds of projects being submitted to the VA Central IRB.

7.1.6 In addition to the metrics as required in paragraph 7.1.1, a summary of noncompliance issues that required reporting will also be included.

7.2 Annual Review of VA Central IRB by Local Sites. All local sites for which the VA Central IRB serves as an IRB of Record must include the VA Central IRB in the annual review of the local HRPP that is conducted by the local Research and Development Committee.

7.2.1 The VA Central IRB will make available to all local sites a copy of the VHA Central Office HRPP annual review on the VA Central IRB SharePoint site upon completion of the report. The VA Central IRB Administrator will send an e-mail to all VA Central IRB Local Site Liaisons informing them that this report is available and reminding them to ensure that the review of the VA Central IRB is included in the annual review of the local site HRPP by the local R&D Committee.

7.2.2 In addition, any additional requirements or questions that a local R&D Committee has should be forwarded by the Local Site Liaison or the Local R&D Coordinator to the VA Central IRB Administrator. The VA Central IRB Administrator will provide requested information or access to documents as needed for the local R&D Committee to complete its review.

7.3 Review of Submitted Audit Reports. Research Compliance Officers (RCOs) submit copies of their routine regulatory and informed consent audits of studies being conducted at their sites to the VA Central IRB for review as required by the MOU. In addition, audit reports from other agencies are also required per the MOU to be submitted to the VA Central IRB for review. The submitted audit reports will be processed and reviewed as follows:

7.3.1 Routine audits for which no action is required by the VA Central IRB may be submitted with the continuing review report for the study. An exception to this is for the Million Veteran Program in which routine reports of informed consent audits for which no review and/or action is required by the VA Central IRB, are reported to ORO Central Office. ORO Central Office will then provide on a quarterly basis, the results of these audits. These results will then be reviewed and an information item at a convened meeting of the VA Central IRB.

7.3.2 All other audit reports requiring review and action will be submitted immediately to the VA Central IRB upon completion of the report and logged into the VA Central IRB Form 131, Reports of Noncompliance Log.

7.3.2.1 The VA Central IRB Administrator will review all audit reports that are not submitted as part of continuing review. Any audit report that identifies apparent serious or continuing noncompliance will be processed and reviewed in accordance with VA Central IRB SOP 118, Serious and Continuing Noncompliance. . Items of an administrative nature that can be clarified or resolved by VA Central IRB staff will be corrected and/or information provided to the applicable RCO. A written response summarizing the action taken will be sent to the Research and Development (R&D) Committee of the local site by the VA Central IRB Administrator through the local RCO with a copy to the local site liaison. The audit report and response will be provided to the VA Central IRB as information at the next convened meeting.

7.3.2.2 Issues that cannot be resolved administratively will be referred to one of the VA Central IRB Co-Chairs using VA Central IRB Form 152, Documentation of Review by a VA Central IRB Co-Chair or Other Designated Reviewer (Attachment 4). The Co-Chair can request additional information from the

investigators, the local sites, or the RCOs through the VA Central IRB Administrator or assigned VA Central IRB Coordinator, or request that the Primary or Expedited Reviewer review the report as needed to fully evaluate any issues.

7.3.2.3 If the Co-Chair or Reviewer can resolve the issue, a written response signed by the Co-Chair will be sent to the R&D Committee of the site and the audit report and response reported as information at the next convened VA Central IRB meeting.

7.3.2.4 If the Co-Chair does not resolve the issue, depending upon the nature of the report, the Co-Chair may elect to call a special convened meeting of the IRB to review the report or instruct the VA Central IRB Administrator to add the report to the agenda of the next regularly scheduled meeting.

7.3.2.5 If a report is reviewed at the convened meeting, the Primary Reviewer of the study will conduct a review of the issue prior to the meeting and present any recommendations for corrective action to the VA Central IRB. The VA Central IRB may exercise all its regulatory authority in deciding upon a required course of action. The results of the review will be reported in writing to the R&D Committee of the local site and to the investigators involved if applicable. If the VA Central IRB determines that the issue should be processed as an unanticipated serious adverse event, a serious unanticipated problem involving risks to subjects or others, or as serious or continuing non-compliance, the issue will then be processed under those SOPs.

7.3.3 The VA Central IRB may require more frequent audits by the RCOs or other means in order to more fully assess the level of risk, any issues of noncompliance, adequate protections for vulnerable populations, and any data safety concerns. In addition, the VA Central IRB may request more frequent audits if there has been a new FDA safety warning or the labeling on a drug has changed and there may be increased risk. There also may be other issues for which the VA Central IRB determines more frequent audits are needed. The reasons for the decision to have more frequent audits will be documented in the minutes. The VA Central IRB Administrator will prepare a memorandum for the signature of the Co-Chair requesting the more frequent audits. Upon signature, the memorandum will be forwarded to the local facility Medical Center Director, with a copy to the local R&D Committee Chair, the Local Site Investigators, Local Site Liaisons, and the Principal Investigator/Study Chair.

8.0 REFERENCES

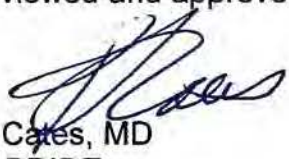
8.1 VHA Handbook 1200.01, Research and Development Committee Handbook

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

4 Attachments
1. VA Central IRB Form 139, Internal Audit Tool for Approved PI/SC Project Applications

2. VA Central IRB Form 150, IRB Member Self-Evaluation
3. VA Central IRB Form 151, IRB Co-Chair Self-Evaluation
4. VA Central IRB Form 152, Documentation of Review By a VA Central IRB Co-Chair or Other Designated Reviewer

I have reviewed and approved the content of this SOP.



K. Lynn, Cates, MD
Director, PRIDE

Date: 12/9/11

Internal Audit Tool for Approved PI/SC Project Applications

VA Central IRB
VA Institutional Review Board for Multisite Studies

Project and Reviewer Identification

VA Central IRB Number:	
Title of Project:	
Principal Investigator/Study Chair:	
VA Central IRB Final Approval Date:	
Local R&D Approval Date:	
Internal Auditor:	

SECTION 1: Review of Approved PI/SC New Project Application Package

1. Contents of Approved PI/SC New Project Application Package Present and Filed in Appropriate Order?

Document	Hard Copy	Shared Drive	NA	Comments
Final Approval Letter (Signed & Dated)	☐	☐	☐	
Final Privacy Officer Compliance Review (Signed & Dated)	☐	☐	☐	
Final Information Security Officer Compliance Review (Signed & Dated)	☐	☐	☐	
PI/SC New Project Application *(VA Central IRB Form 108)*	☐	☐	☐	

Document	Hard Copy	Shared Drive	NA	Comments
Co-PI/SC New Project Application Supplement(s) *(VA Central IRB Form 108a)*	☐	☐	☐	
CSP Coordinating Center PI/SC New Project Application Supplement(s) *(VA Central IRB Form 108b)*	☐	☐	☐	
PI/SC Documents (COI, CV, & LEIE)	☐	☐	☐	
Co-PI/SC Documents (COI, CV, & LEIE)	☐	☐	☐	
Additional Study team Documents (COI, CV, & LEIE)	☐	☐	☐	
Request for Expedited Review of New Project *(VA Central IRB Form 126)*	☐	☐	☐	
Vulnerable Population Supplement(s) *(110 Series)*	☐	☐	☐	
Request for Waiver of HIPAA Authorization *(VA Central IRB Form 103)*	☐	☐	☐	
Model HIPAA Authorization	☐	☐	☐	
Request for Waiver or Alteration of the Informed Consent Process *(VA Central IRB Form 112a)*	☐	☐	☐	
Request for Waiver of Documentation of Informed Consent *(VA Central IRB Form 112b)*	☐	☐	☐	
Model Informed Consent Form (Stamped) *(VA Form 10-1086)*	☐	☐	☐	
Model Consent for Use of Picture and/or Voice *(VA Form 10-3203)*	☐	☐	☐	
Model Recruitment Materials Specify Type:	☐	☐	☐	

Document	Hard Copy	Shared Drive	NA	Comments
Model Questionnaires/Surveys Specify Type:	☐	☐	☐	
Case Report Forms (Not Required – Optional)	☐	☐	☐	
Investigational Drug Information Record *(VA Form 10-9012)*	☐	☐	☐	
Investigational Drug Brochure	☐	☐	☐	
Investigational Device Information	☐	☐	☐	
HRC Minutes *(CSP Studies Only)*	☐	☐	☐	
Scientific Merit Review Letter or Minutes	☐	☐	☐	
Protocol Version #, date:_____ Are version numbers consistent with submissions and is the most recent version on the shared drive as part of the approved PI/SC package? ☐ **Yes** ☐ **No**	☐	☐	☐	
Correspondence between the study team and VA Central IRB Administrative Office is present and filed in chronological order?	☐	☐	☐	

2. Was the Administrative Pre-Screening Checklist (VA Central IRB Form 109b) completed for this approved application package?

☐ Yes

Date completed by VA Central IRB Coordinator:_____

☐ No

3. Was this project approved by expedited review?

☐ Yes. Please complete the information below.

☐ No. *(If this project was reviewed by the convened VA Central IRB, please continue to Question #4.)*

Please complete the following information regarding the expedited review process.

Documents Present	Hard Copy	Shared Drive	NA	Comment
Expedited Review Eligibility Determination *(VA Central IRB Form 121)*	☐	☐	☐	
Reviewer Checklist for PI/SC New Project Application *(VA Central IRB Form 111a)*	☐	☐	☐	
Reviewer Checklist for Informed Consent *(VA Central IRB Form 113)*	☐	☐	☐	
Regulatory Reviewer Checklist or Comments	☐	☐	☐	

Was this approval action reported on the expedited review procedures list as part of the VA Central IRB meeting minutes of the regularly scheduled IRB meeting following the approval date?

☐ Yes. Please specify meeting date (i.e. month year):_____

☐ No.

4. Please complete the following information for projects reviewed by the convened VA Central IRB.

☐ Not Applicable. *(This project was reviewed by expedited review procedures.)*

Document Present	Hard Copy	Shared Drive	NA	Comment
Primary Reviewer Checklist for PI/SC New Project Application *(VA Central IRB Form 111a)*	☐	☐	☐	
Secondary Reviewer Checklist for PI/SC New Project Application *(VA Central IRB Form 111a)*	☐	☐	☐	
Reviewer Checklist for Informed Consent *(VA Central IRB Form 113)*	☐	☐	☐	
Regulatory Reviewer Checklist or Comments	☐	☐	☐	

Was the review by the convened VA Central IRB documented within the meeting minutes?

☐ Yes. Please specify meeting date (i.e. month year):_____

☐ No.

5. Have the Master VA Central IRB Project Log been updated with the applicable reviewer, approval, and processing dates?

☐ Yes.

☐ No. Specify deficiencies: _____

6. If the study is active, has the current version of all approved documents been posted appropriately on SharePoint?

☐ NA. Project is no longer active.

☐ Yes.

☐ No. Specify deficiencies: _____

SECTION 2: Continuing Review Application Package

1. Has a Project Closure Report (VA Central IRB Form 117) been submitted?

☐ Yes.
Available in hard copy file: ☐ *(Please continue to Question #7.)*

Available in shared drive: ☐

☐ No. (*Please continue to Question #2.*)

2. Has there been a continuing review performed on the PI/SC application?

☐ Yes. (*Please continue to Question #3.*)

☐ No. Specify when next continuing review is due: _____ *(Please continue to SECTION 3.)*

3. Contents of Approved Continuing Review Application Package

Document	Hard Copy	Shared Drive	NA	Comments
Final Approval Letter (Signed & Dated)	☐	☐	☐	
Application for Continuing Review *(VA Central IRB Form 115b)*	☐	☐	☐	
Current Version of the Protocol Version Number and Date:	☐	☐	☐	
Current Model HIPAA Authorization	☐	☐	☐	
Current Model Informed Consent Form *(VA Form 10-1086)*	☐	☐	☐	
Other *Specify:*	☐	☐	☐	

4. Was an Administrative Screening Checklist for Continuing Review (VA Central IRB Form 109d) completed for this continuing application package?

☐ Yes.

Date completed by VA Central IRB Coordinator:_____

☐ No.

Was a Table of Documents for Continuing Review Prepared for this study? ☐ Yes ☐ No

5. Was the continuing review application package approved by expedited review?

☐ Yes. Please complete the information below and then skip to question 7.

☐ No. *(If this project was reviewed by the convened VA Central IRB, please continue to Question #6.)*

Document	Hard Copy	Shared Drive	NA	Comment
Expedited Review Eligibility Determination *(VA Central IRB Form 121)*	☐	☐	☐	
Reviewer Checklist for Continuing Review (PI/SC Application) *(VA Central IRB Form 114a)*	☐	☐	☐	

Was this action reported on the expedited review procedures list as part of the VA Central IRB meeting minutes?

☐ Yes. Please specify meeting date (i.e. month year):_____

☐ No.

6. Was a Reviewer Checklist for Continuing Review (PI/SC Application), VA Central IRB Form 114a, completed? ***(Convened reviews)***

☐ Yes.

Available in hard copy file: ☐

Available in shared drive: ☐

☐ No.

Was this action reported within the VA Central IRB meeting minutes?

☐ Yes. Please specify meeting date (i.e. month year):_____

☐ No.

7. Has the Master VA Central IRB Continuing Review Log been updated with the applicable reviewer, approval, processing, and closing dates?

☐ Yes.

☐ No. Specify deficiencies: _____

8. Has the current version of the continuing review package been posted appropriately on SharePoint?

☐ Yes.

☐ No. Specify deficiencies: _____

SECTION 3: Amendment or Modifications to an Approved Project

1. Has there been any amendments or modifications approved for the PI/SC application?

☐ Yes. (*Please continue to Question #2.*)

☐ No. *(Please continue to SECTION 4.)*

2. Contents of an Approved Amendment or Modification to an Approved Project

Document	Hard Copy	Shared Drive	NA	Comments
Final Approval Letter (Signed & Dated)	☐	☐	☐	
Request to Amend or Modify an Approved Project *(VA Central IRB Form 116)*	☐	☐	☐	
Specify Amendment # and Date:	☐	☐	☐	
Specify Amendment # and Date:	☐	☐	☐	
Specify Amendment # and Date: *Add additional rows as necessary*	☐	☐	☐	
Correspondence between the study team and VA Central IRB Office present and filed in chronological order?	☐	☐	☐	

3. Was a Reviewer Checklist for Amendments (VA Central IRB Form 120) completed?

☐ Yes.
Available in hard copy file: ☐ Available in shared drive: ☐

☐ No

4. If reviewed by expedited review procedures, was this action reported on the expedited review procedures list as part of the VA Central IRB meeting minutes?

☐ NA. Project reviewed by the convened VA Central IRB. *(Please continue to Question #4.)*

☐ Yes. Please specify (i.e. month year):_____

☐ No.

5. If reviewed by the convened VA Central IRB, was this action reported within the VA Central IRB meeting minutes?

☐ Yes. Please specify meeting date (i.e. month year):_____

☐ No.

6. Have the Master VA Central IRB Amendment Log been updated with the applicable reviewer, approval, and processing dates?

☐ Yes.

☐ No. Specify deficiencies: _____

7. Has the approved amendment package been posted appropriately on SharePoint?

☐ Yes.

☐ No. Specify deficiencies: _____

SECTION 4: Serious Adverse Events and Unanticipated Problems or Protocol Deviations

1. Have there been any serious adverse events (SAE), unanticipated problems (UAPs), or protocol deviations?

☐ Yes.

SAE or Unanticipated Problem: ☐ *(Please continue to Question #2.)*

Protocol Deviation: ☐ *(Please continue to Question #3.)*

☐ No.

2. Was a Reviewer Checklist for Serious Adverse Events or Unanticipated Problems (VA Central IRB Form 125) completed?

☐ Yes.

Available in hard copy file: ☐

Available in shared drive: ☐

☐ No.

3. Was a Report of Protocol Deviation or Violations (VA Central IRB Form 129) completed?

☐ Yes.

Available in hard copy file: ☐

Available in shared drive: ☐

☐ No.

4. Have the SAE, UAP, and/or protocol deviation logs been updated with the applicable reviewer, approval, and processing dates?

☐ Yes.

☐ No. Specify deficiencies: _____

5. Are copies of all review documentation located in the master hard copy file and shared drive?

☐ Yes.

☐ No. Specify deficiencies: _____

6. Have all actions been reported within the VA Central IRB meeting minutes or on the expedited review procedures list as part of the VA Central IRB meeting minutes?

☐ Yes. Please specify meeting date (i.e. month year):_____

☐ No.

SECTION 5: Audit Reports

1. Has an informed consent audit report been received?

☐ NA. *(Check this item if informed consent or documentation of informed consent has been waived or if the PI/SC site is not obtaining informed consent.)*

☐ Yes. Specify date of report: _____

Is this report over 1 year old?

☐ Yes. *(Please list as a deficiency in SECTION 6.)*

☐ No.

☐ No. Has it been one year since the PI/SC application was approved by the Local R & D?

☐ Yes. *(Please list as a deficiency in SECTION 6.)*

☐ No.

2. Has a regulatory audit report been received?

☐ Yes. Specify date of report: _____

Is this report over three years old?

☐ Yes. *(Please list as a deficiency in SECTION 6.)*

☐ No.

☐ No.*

** A deficiency should also be listed in Section 6 if the Local R&D approval date is over 3 years ago and a regulatory audit has not been performed.*

SECTION 6: Summary of Findings

☐ **There are no deficiencies identified.**

☐ **The following deficiencies require resolution.**

1)

2)

3)

Additional Rows can be added as necessary.

Additional Comments:

_____ _____

Signature of Internal Auditor **Date**

SECTION 7: Resolution of Deficiencies

All deficiencies listed above were resolved on _____.
(Date)

_____

Signature of VA Central IRB Coordinator

IRB Member Self-Evaluation

VA Central IRB
VA Institutional Review Board for Multisite Studies

The following tool was created to obtain information about your experience as an IRB member in order to improve our training and education function for IRB members and to ensure that IRB members have what is needed to perform their committee roles. This self-evaluation form will also be used as part of the annual evaluation of the IRB membership. Please evaluate yourself in the following areas:

IRB Member Name: _____

Date: _____

Please complete the following evaluation criteria:

Description	Rating	Comments/Suggestions
Knowledge and application of the federal regulations and ethical principles.	Check one box: ☐ Expert knowledge ☐ Working knowledge ☐ Familiar ☐ Need education	
Knowledge and application of VA-specific regulations and requirements in the review of research projects.	Check one box: ☐ Expert knowledge ☐ Working knowledge ☐ Familiar ☐ Need education	
Active discussion in the meeting discussions.	Check all that apply: ☐ Facilitate discussion as primary, secondary, or informed consent reviewer. ☐ Actively participate in discussion. ☐ Willing to disagree with consensus or majority opinion. ☐ Participate only as needed. ☐ Uncomfortable participating in discussion.	

Description	Rating	Comments/Suggestions
Attendance at IRB monthly meetings (in person or by teleconference).	Check one box: ☐ Attended 9-12 meetings in last 12 months. ☐ Attended 6-8 meetings in last 12 months. ☐ Attended fewer than 6 meetings in last 12 months.	
Utilizes the appropriate VA Central IRB checklists and documents determinations as required when serving as a primary, secondary, or informed consent reviewer.	Check all that apply: ☐ Uses and documents consistently on applicable checklists. ☐ Uses checklists but does not document consistently on applicable checklists. ☐ Uses checklist to aid in review of protocols. ☐ Does not use checklists. ☐ Have not served as a primary, secondary, or informed consent reviewer.	
Willingness to contact IRB Co-Chairs or IRB Administrative Staff for additional information or to make queries prior to scheduled meetings.	Check one box: ☐ Comfortable ☐ Hesitant, but will contact ☐ Reluctant	
Reviews all materials in depth and provides and contributes to the discussion.	Check one box: ☐ Have sufficient time to review all materials prior to meeting. ☐ Have sufficient time to review materials to which I have been assigned as a primary, secondary, or informed consent reviewer. ☐ Do not have sufficient time to review all materials prior to meeting. ☐ Need additional time to review all materials prior to meeting. ☐ Review would be facilitated in VA Central IRB meetings if materials sent earlier prior to convened meetings. *If not sufficient time, please indicate in the Comments and Suggestions Section ideas for improving processing.*	

Description	Rating	Comments/Suggestions
Recused self from convened meetings or as an assigned reviewer if a conflict of interest exists.	Check all that apply: ☐ Removes self as reviewer or during convened meeting if conflict of interest exists. ☐ Unsure when a financial conflict of interest exists for a VA Central IRB member. ☐ Unsure when a personal conflict of interest exists for a VA Central IRB member.	
As a Primary or Secondary Reviewer, processes all actions processed under expedited review procedures in a timely manner within established timeframes.	Check one box: ☐ Have sufficient time to review all materials within established timeframe or deadline . ☐ Do not have sufficient time to review materials to which I have been assigned within established timeframe or deadlines. *If not sufficient time, please indicate in the Comments and Suggestions section ideas for improving processing.*	

Do you have any suggestions for educational topics you would like presented at VA Central IRB meetings during the next calendar year?

☐ **Yes** ☐ **No**

If yes, please indicate these here:

Additional Comments/Suggestions:

IRB Co-Chair Self-Evaluation

VA Central IRB
VA Institutional Review Board for Multisite Studies

The following tool was created to obtain information about your experience as an IRB Co-Chair in order to improve our training and education function for the IRB membership and to ensure that IRB Co-Chairs have what is needed to perform their committee roles. This self-evaluation form will also be used as part of the annual evaluation of the IRB Co-Chairs. Please evaluate yourself in the following areas:

IRB Co-Chair Name: _____

Date: _____

Please complete the following evaluation criteria:

Description	Rating	Comments/Suggestions
Knowledge and application of the federal regulations and ethical principles.	Check one box: ☐ Expert knowledge ☐ Working knowledge ☐ Familiar ☐ Need education	
Knowledge and application of VA-specific regulations and requirements in the review of research projects.	Check one box: ☐ Expert knowledge ☐ Working knowledge ☐ Familiar ☐ Need education	
Ability to lead IRB members during convened IRB meetings abiding by federal regulations, including VA-specific requirements and applicable state and local requirements.	Check all that apply: ☐ Facilitate discussion. ☐ Actively participate in discussion. ☐ Willing to disagree with consensus or majority opinion. ☐ Participate only as needed. ☐ Uncomfortable leading discussion.	

Description	Rating	Comments/Suggestions
Meeting management and time management skills.	Check one box: ☐ Excellent ☐ Good ☐ Fair ☐ Need help	
Attendance at IRB monthly meetings (in person or by teleconference).	Check one box: ☐ Attended 9-12 meetings in last 12 months. ☐ Attended 6-8 meetings in last 12 months. ☐ Attended fewer than 6 meetings in last 12 months.	
Utilizes the appropriate VA Central IRB checklists and documents determinations as required when serving as a primary, secondary, or informed consent reviewer.	Check all that apply: ☐ Uses and documents consistently on applicable checklists. ☐ Uses checklists but does not document consistently on applicable checklists. ☐ Uses checklist to aid in review of protocols. ☐ Does not use checklists. ☐ Have not served as a primary, secondary, or informed consent reviewer.	
Willingness to contact other IRB Co-Chair or IRB Administrative Staff for additional information or to make queries prior to scheduled meetings.	Check one box: ☐ Comfortable ☐ Hesitant, but will contact ☐ Reluctant	
Recused self from convened meetings as IRB Co-Chair or as an assigned reviewer if a conflict of interest exists.	Check all that apply: ☐ Removes self as IRB Co-Chair or reviewer during convened meeting if conflict of interest exists. ☐ Unsure when a financial conflict of interest exists for a VA Central IRB member. ☐ Unsure when a personal conflict of interest exists for a VA Central IRB member.	

Description	Rating	Comments/Suggestions
Reviews all materials in depth and provides and contributes to the discussion.	Check one box: ☐ Have sufficient time to review all materials prior to meeting. ☐ Have sufficient time to review materials to which I have been assigned as a primary, secondary, or informed consent reviewer. ☐ Do not have sufficient time to review all materials prior to meeting. ☐ Need additional time to review all materials prior to meeting. ☐ Review would be facilitated in VA Central IRB meetings if materials sent earlier prior to convened meetings. *If not sufficient time, indicate suggestions for improvement in the Comments and Suggestions box.*	
Processes all expedited actions, to include review of serious adverse events, unanticipated problems, and protocol deviations in a timely manner consistent with the action required.	Check one box: ☐ Have sufficient time to review all materials within established timeframe or deadline . ☐ Do not have sufficient time to review materials to which I have been assigned within established timeframe or deadlines. *If not sufficient time, please indicate in the Comments and Suggestions section ideas for improving processing.*	

Have you had the time to comment on the draft VA Central IRB Member Handbook?

☐ **Yes** ☐ **No**

If no, please comment now by providing on the next page or commenting on the draft handbook and submitting a marked up copy to the VA Central IRB Administrator. Please ensure that you comment on whether any additional information needs to be included. Handbook is meant to be a quick reference guide to ensure that a member knows where to go to look something up in necessary.

Additional Comments/Suggestions:

Audit Reports Received and Action Taken

Calendar Year _____

Date Received	VA Central IRB #	Program Number	Facility	Type of Audit	POC at Facility	Response Required?	Response Sent	Resolution Code	Reported to IRB	Comments

Resolution Codes: ***1****-Project modified*
2*-Informed consent modified*
3*-Information to current participants*
4*-Information to past participants*
5*-Reconsenting*
6*- Continuing Review Interval Altered*
7 *- Observation of Consent Process*
8 *- Additional Investigator Training*
9 *- Approval Suspended*
10 *- Approval Terminated*
11*-Reported to Federal Agencies*
12*-No Action Taken*
13*-Other*

VA Central IRB Form 148
Log of Audit Reports Received and Action Taken
Updated: September 17, 2010

Documentation of Review By a VA Central IRB Co-Chair or Other Designated Reviewer

VA Central IRB
VA Institutional Review Board for Multisite Studies

Section 1: Project Identification *(To be completed by VA Central IRB Coordinator)*

VA Central IRB Number	
Title of Project	
Principal Investigator/Study Chair	
Local Site Investigator/Site (if applicable)	

Section 2: Information Received *(To be completed by VA Central IRB Coordinator)*

Copy Attached	☐ **Yes** ☐ **No**
Type of Information	☐ Information requested by VA Central IRB during review of PI/SC or LSI Application when it become available, i.e., DMC charter ☐ RCO Audit Report ☐ Other Audit Report *Specify agency:* _____ ☐ Response to Request for Information or Corrective Plan for a reported SAE or Protocol Deviation ☐ Closure Report – Check One - ☐ PI/SC ☐ Local Site Participation ☐ Other: *Specify:* _____
Additional Comments by VA Central IRB Coordinator if Applicable	

Section 3: Reviewer Recommendation *(To be completed by Reviewer)*

Please check the boxes below as applicable:

☐ **No action is required; the information should be filed in the project folder**

☐ **No further review is needed; the information should be filed in the project folder; however, report to VA Central IRB as an informational item.**

☐ **Review by another reviewer or entity is required. *Please specify:***

☐ **Review by Convened VA Central IRB is required.**

☐ **Additional information is needed as specified below**

Comments:

I do not have any conflict of interest concerning the above study.

_____ _____

Co-Chair or Designated Reviewer
VA Central IRB

Date