

TITLE: Continuing Review and Approval Requirements**1.0 PURPOSE**

This Standard Operating Procedure (SOP) describes the policies and procedures of the VA Central Institutional Review Board (IRB) for conducting continuing review and approval as required by 38 CFR 109e. It includes continuing review responsibilities of Principal Investigators/Study Chairs (PI/SCs), Local Site Investigators (LSIs), Coordinating Centers, and VA Central IRB members and Administrative Staff.

2.0 REVISION HISTORY

Date of Initial Approval	June 23, 2008
Revision Dates	June 14, 2009 September 14, 2009 March 24, 2010 August 27, 2010 February 14, 2011 August 9, 2011 December 12, 2011

3.0 SCOPE

This SOP applies to all VA investigators and their project team members who have received approval from the VA Central IRB to conduct a research project involving human participants, to include Coordinating Center staff if applicable. It also applies to investigators who have been granted an exemption by the VA Central IRB. In addition, this SOP applies to all the VA Central IRB members and administrative support staff who are responsible for monitoring continuing review requirements, processing continuing review requests, reviewing and approving requests, and communicating the results to investigators and local sites..

4.0 POLICY

4.1 The VA Central IRB conducts continuing review at intervals appropriate to the level of risk, but not less than once per year for all non-exempt human research reviewed and previously approved by the VA Central IRB to ensure all IRB approval criteria as applicable are still being met. Sufficient information must be submitted by investigators to allow the VA Central IRB to perform a substantial and meaningful review to include the following:

- Review of the ongoing level of risks and benefits
- Assessment of the need for special safeguards to protect subjects
- Review of the adequacy of ongoing protection for potentially vulnerable subjects

4.2 VA Central IRB approved research projects involving human studies which

have been determined to be exempt are not subject to VA Central IRB continuing review requirements.

4.3 Continuing review approval of research must occur on or before the date when VA Central IRB approval expires. This includes a study team making and submitting any modifications required by the VA Central IRB during its review and the VA Central IRB reviewing and approving them prior to the expiration of the current approval period.

4.4 When continuing review is not completed prior to the expiration of the current approval period, there is an automatic lapse of IRB approval. All research must stop unless a VA Central IRB Co-Chair determines that it is in the best interests of individual participants to continue the research interventions or interactions. Approval of an amendment during the current approval period by the VA Central IRB does not alter the date by which continuing review must occur.

4.5 Continuing review of research is required if the research remains active for long-term follow-up of participants, even when the research is permanently closed to enrollment of new participants and all participants have completed all research-related interventions. Continuing review is also required if the remaining research activities include collection or analysis of private identifiable information as described in the VA Central IRB approved protocol.

4.6 The completion, suspension, or termination of a project is a change in study activity and must be reported to the VA Central IRB. It is the policy of the VA Central IRB that when a project is closed or terminated, that the PI/SC submit a closure report.

4.7 All Local Site Investigator Applications will receive the same continuing review date as the PI/SC Application, regardless of when the Local Site Investigator Application or Continuing Review Application was approved.

5.0 DEFINITIONS

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

6.0 RESPONSIBILITIES

6.1 Local Site Investigator (LSI). The LSI is responsible for:

6.1.1 Submitting continuing review applications and any supporting documentation to the PI/SC by the timeframe established by the PI/SC and prior to the VA Central IRB approval expiration date.

6.1.2 Stopping all research activities if VA Central IRB approval lapses unless otherwise notified by a VA Central IRB Co-Chair that the research can continue in the best interest of the participants.

6.2 Principal Investigator/Study Chair (PI/SC). The PI/SC is responsible for:

6.2.1 Submitting continuing review applications from all participating LSIs, along with the completed PI/SC continuing review application, to the VA Central IRB prior to the VA Central IRB approval expiration date.

6.2.2 Stopping all research activities if VA Central IRB approval lapses unless otherwise notified by a VA Central IRB Co-Chair that the research can continue in the best interest of the participants.

6.2.3 Submitting notification of suspension or termination of a study

6.2.4 Submitting a project closure report upon completion or termination of the study.

6.3 Coordinating Center. The assigned Coordinating Center, if applicable, is responsible for assisting the PI/SC in collecting and evaluating data from the sites; tracking adverse events and problems involving risks to subjects or others that require reporting to the VA Central IRB; and assisting the PI/SC in preparing and submitting the PI/SC Continuing Review Application.

6.4 VA Central IRB. The VA Central IRB is responsible for:

6.4.1 Applying the IRB approval criteria described in 38 CFR Part 16.111 and in VA Central IRB SOP 101, VA Central Institutional Review Board Authorities, Responsibilities, and Activities, during the continuing review and approval of non-exempt human research projects.

6.4.2 Monitoring the status of exempt studies to ensure that any changes in the study design do not result in the study becoming non-exempt.

6.4.3 Reviewing closure reports for impact on any related studies and to ensure there are no ongoing research activities which would require the study to remain open and subject to continuing review.

6.5 VA Central IRB Administrative Office. The VA Central IRB administrative staff is responsible for the following:

6.5.1 Notifying the PI/SC at least 90 days prior to the current VA Central IRB approval expiration date and providing them instructions for submitting a request for continuing review or a closure report.

6.5.2 Ensuring all required information is received prior to forwarding a request for continuing review to the convened VA Central IRB or VA Central IRB Reviewer conducting expedited review.

6.5.3 Notifying investigators in writing of the results of the VA Central IRB

review and documenting these in the VA Central IRB meeting minutes as applicable.

6.5.4 Notifying the PI/SC and/or LSI(s), the local site liaisons, and the sponsoring ORD funding service if VA Central IRB approval of a project lapses.

7.0 PROCEDURES

7.1 Notification of Continuing Review Requirements.

7.1.1 Notification of the requirement for continuing review will be conducted as follows:

7.1.1.1 The VA Central IRB administrative staff sends an electronic notice to the PI/SC and either sends continuing review application forms by e-mail or uploads them to the VA Central IRB SharePoint website, no earlier than 120 and no later than 90 days prior to the VA Central IRB expiration date of an approved research project. A copy of the notice is also sent to the Coordinating Center for CSP studies or any other study utilizing a Coordinating Center.

7.1.1.2 The initial notification consists at a minimum of:

- Name of Study and PI/SC
- Names of all approved sites that must submit a report
- Current approval expiration date
- Deadline for submission to the VA Central IRB in order to allow time for review at a convened meeting if applicable and/or for the submission and review and approval of any required modifications prior to the current approval period expiration date
- VA Central IRB Form 115a, Application for Continuing Review: Local Site Investigators (Attachment 1), if applicable.
- VA Central IRB Form 115b, Application for Continuing Review: Principal Investigator/Study Chair (Attachment 2)

7.1.1.3 A follow-up reminder notice is sent by e-mail if a continuing review request or closure report is not received 30 days after the initial electronic notice is sent.

7.1.2 Upon receipt of the notification, the PI/SC notifies the Local Site Investigators at all approved engaged sites of the submission requirement and sends them a copy of the VA Central IRB Form 115a, Application for Continuing Review: Local Site Investigator Application. The PI/SC must establish a submission deadline for the LSIs to submit the VA Central IRB Forms 115a to the PI/SC, while still allowing sufficient time for the PI/SC to review the submitted applications, prepare and submit the PI/SC Application to the VA Central IRB by the established deadline.

7.2 Local Site Investigator Applications. All participating LSIs must complete the VA Central IRB Form 115a, Application for Continuing Review: Local Site Investigator,

in its entirety and submit it to the PI/SC by the established deadline date, along with any additional documents required to complete the continuing review application. Additional documents to be included in the LSI's continuing review application include, but are not limited to the following, if applicable:

- Copy of the current VA Central IRB-approved informed consent document
- Copy of the current HIPAA authorization
- Copy of informed consent and/or regulatory audit(s) conducted by local RCO since the initial approval or last continuing review and any other reports from oversight agencies that have not been previously forwarded to the VA Central IRB

7.3 Principal Investigator/Study Chair Applications. The PI/SC must complete VA Central IRB Form 115b: Application for Continuing Review: Principal Investigator/Study Chair, which includes a protocol abstract, and submit it to the VA Central IRB along with any additional documents required to complete the continuing review application.

7.3.1 Additional documents to be included in the PI/SC's continuing review application include, but are not limited to the following, if applicable:

- Continuing review applications for all participating LSIs
- Current VA Central IRB-approved protocol
- Current VA Central IRB-approved model informed consent document (VA Form 10-1086), if applicable
- Current model HIPAA authorization
- Copy of informed consent or regulatory audits conducted at PI/SC's VA facility since the initial approval or last continuing review and any other reports from oversight agencies that have not been previously forwarded to the VA Central IRB

7.3.2 If the PI/SC has not received a particular LSI Application by the deadline date, the PI/SC should not hold the entire package. The PI/SC should submit the package without the missing LSI Application and provide a reason for the delay. Enrollment figures for the site should be included in the PI/SC Application with a note that these will be verified upon submission of the LSI Application.

7.4. Administrative Screening. The VA Central IRB Coordinator for the study performs an administrative screening of the continuing review applications upon receipt using VA Central IRB Form 109d, Administrative Screening Checklist for Continuing Review (Attachment 3).

7.4.1 If any information is incomplete, the PI is contacted and asked to send the missing information as soon as possible. A record of the contact is kept on the VA Central IRB Form 109d.

7.4.2 Once all the required documentation is received, the VA Central IRB Coordinator completes the VA Central IRB Form 109d and also prepares the VA Central IRB Form 114c, Table of Documents Provided for Continuing Review (Attachment 4) to assist the VA Central IRB and/or Reviewer in keeping track of all the documents that require review.

7.4.3 If the study requires review at a convened meeting, the VA Central IRB Administrator adds the review to the next regularly scheduled meeting agenda. If the approval period will lapse prior to the next regularly scheduled convened meeting, the VA Central IRB Administrator will consult with the VA Central IRB Co-Chair to determine if an unscheduled meeting should be held via teleconference to review the action.

7.4.4 The VA Central IRB Coordinator prepares the VA Central IRB Form 114a, Reviewer Checklist for Continuing Review (PI/SC Application) and VA Central IRB Form 114b, Continuing Review Checklist for Local Site Investigator Applications for completion by the Primary Reviewer. If the review will involve a large number of local site investigator applications, audit reports, amendments, or other documents requiring review, or there is a significant change in the study, i.e., in the risk level, the Primary Reviewer will be consulted as to whether additional assistance is needed to conduct the review. If additional assistance is needed, an additional set of checklists will be prepared for the Secondary Reviewer, if one was assigned, or if there is none, an additional Expedited Reviewer will be assigned.

7.4.5 The VA Central IRB Coordinator for the assigned study will then process the study for review in accordance with VA Central IRB SOP 108, VA Central IRB Convened Meeting Preparation, or VA Central IRB SOP 110, Expedited Review Process.

7.5. Continuing Review Approval Expiration Date. The VA Central IRB continuing review approval expiration date is the last date the study can be conducted without further VA Central IRB approval.

7.5.1 For new projects requiring review by the convened VA Central IRB, the date of the convened meeting at which the project is "Approved Contingent Upon Required Minor Modifications "or, if there are no modifications, "Approved Contingent Upon Receipt and Review of Local Site Comments", establishes the date by which the expiration period will be calculated for the approval period specified by the VA Central IRB.

7.5.2 For new projects undergoing expedited review, the date the Co-Chair approves the PI/SC New Project Application after receipt and review of local site comments and after any other required modifications are made if any, is the date by which the expiration date will be calculated for the approval period.

7.5.3 For approved projects undergoing continuing review, the new continuing review approval period will be set by one of the following depending upon the type of review being conducted:

7.5.3.1 For reviews by the convened Board, the date by which the expiration period will be calculated for the new approval period is the date the Application For Continuing Review: PI/SC Application is either "Approved" or "Approved Contingent upon Minor Modifications."

7.5.3.2 For reviews conducted by expedited review procedures, the date by which the expiration period will be calculated for the new approval period is the date the Application For Continuing Review: PI/SC Application is "Approved" by the Co-Chair.

7.5.3.3 As an option, when continuing review occurs annually and the VA Central IRB performs and completes the review within 30 days before the original expiration date of the current IRB approval period, the VA Central IRB can retain the original anniversary date (day and month) as the date for the next IRB approval expiration date of the study.

7.6 Lapse in Approval. If a PI/SC has not provided continuing review application materials to the VA Central IRB, or the VA Central IRB has not approved the PI/SC continuing review application by the IRB approval expiration date, the VA Central IRB approval automatically lapses and all research activities must stop, including data analysis of private identifiable information. No enrollment of participants can occur.

7.6.1 If the PI/SC continuing review application is not approved by the VA Central IRB approval expiration date, all research activities by the PI/SC and LSI(s) must stop.

7.6.2 If an LSI continuing review application is not approved by the VA Central IRB approval expiration date, all research activities under the study at that site only must stop.

7.6.3 The PI/SC, or LSI as applicable, must immediately submit to the VA Central IRB Co-Chair a list of participants for whom stopping or interrupting interventions or interactions would cause harm, as well as the name of the Chief of Staff at the participating VA Facility(s). The VA Central IRB Co-Chair will consult with the Chief of Staff(s) to determine whether it is in the best interests of individual participants to continue participating and document the consultation and determination in writing to the PI/SC or LSI(s).

7.6.4 The VA Central IRB will notify the PI/SC, the ORD service funding the project, affected participating sites, and affected LSIs of lapses of study approval. A sample lapse in approval letter is found at Attachment 5. Correspondence will be prepared by the VA Central IRB administrative staff to be reviewed and signed by the VA Central IRB Co-Chair. Correspondence will be sent by encrypted e-mail with a read

receipt requested and all notification documents will also be uploaded to the VA Central IRB SharePoint study site.

7.6.5 If the lapse occurred due to non-submission of the continuing review applications by the PI/SC or LSI, the PI/SC or LSI may submit the request for continuing review application, along with a justification for the delay in submission, up to 30 days after the expiration of approval date in order for the review to still be conducted by the VA Central IRB. If the lapse only affected a particular site(s), the LSI Application must be submitted through the PI/SC's office. After the 30 days have elapsed, the project will be closed, or closed at the affected site(s) and the ORD funding service, PI/SC and LSIs and local site liaisons as applicable informed of the closure. If study closure is not in the best interest of patients, the study may be continued until the participants have safely completed the study or can be withdrawn but no new enrollment can take place.

7.6.5.1 If the PI/SC wants to re-open a study that lapsed for more than 30 days a new PI/SC study application must be submitted or the PI/SC can consult with the VA Central IRB Administrative office regarding any documentation that may be required, in addition to the continuing review application, for the review to take place.

7.6.5.2 If an LSI wishes to re-open the study that lapsed at their site and it has been over 30 days since the lapse occurred, the PI/SC must concur and consult with the VA Central IRB Administrative Office regarding any additional submission requirements for that site, i.e., obtaining the signature of the local Associate Chief of Staff for Research and Development (ACOS/R&D).

7.6.6 If the PI/SC submitted all the required documents by the expiration date, but the approval period lapses, all the actions as described in paragraphs 7.6.1 through 7.6.4 must still take place. The VA Central IRB will review the submitted materials as soon as practicable. The investigator must respond to any modifications or comments made by the VA Central IRB as a result of its review within 30 days of receipt of the comments or requested modifications or the actions in paragraph 7.6.5 will occur.

7.7 Tracking IRB Approval Expiration Dates. Upon approval of a new study by the VA Central IRB, either at a convened IRB meeting or by expedited review procedures, the VA Central IRB Coordinator assigned to the project will enter the date of the IRB approval expiration on the VA Central IRB Form 136, Master VA Central IRB Continuing Review Log (Attachment 6).

7.7.1 This log will be used to track when notifications to investigators of the continuing review requirement must go out and is updated by the VA Central IRB Coordinator through the entire process of review through when continued approval is granted and notification to the study teams and investigators. Each VA Central IRB Coordinator will check this log at least once per month to ensure that all notifications have been made in a timely manner and that all other fields on the form are appropriately completed for a project that underwent continuing review.

7.7.2 Upon approval of the continuing review of a project, the VA Central IRB Coordinator or VA Central IRB Administrator will enter the new IRB approval expiration date on the applicable year spreadsheet on the VA Central IRB Form 136.

7.8 Project Closure. Upon completion or termination of an approved project, the principal investigator must submit a VA Central IRB Form 117a, Study Closure Report (Attachment 7), to the VA Central IRB.

7.8.1 The Study Closure Report is forwarded to one of the VA Central IRB Co-Chairs for review, through the Primary Reviewer. If the Co-Chair or Primary Reviewer has any questions concerning the report, these will be forwarded to the PI/SC for a response, either directly by the Co-Chair or by the VA Central IRB Coordinator.

7.8.2 Once the response is received, reviewed by the Primary Reviewer and Co-Chair, and there are no more questions, the VA Central IRB administrative staff sends the PI/SC an acknowledgement and concurrence memorandum indicating that the VA Central IRB considers the study to be closed. The VA Central IRB Coordinator updates the study logs and the closure action is reported at the next convened meeting of the VA Central IRB. The project files are then archived in accordance with VA Central IRB SOP 116, Maintenance of VA Central IRB Files.

7.8.3 If only the participation of a local site is closed or terminated, the LSI completes a VA Central IRB Form 117b, Local Site Project Participation Closure Report. The VA Central IRB Form 117b is reviewed by the Primary or Expedited Reviewer using VA Central IRB Form 152, Reviewer Checklist for Miscellaneous Information. If there are no further questions, the VA Central IRB administrative staff sends the PI/SC an acknowledgement and concurrence memorandum indicating that the VA Central IRB considers the study to be closed. The VA Central IRB Coordinator updates the study logs and the site closure action is reported at the next convened meeting of the VA Central IRB. The project files are then archived in accordance with VA Central IRB SOP 116, Maintenance of VA Central IRB Files.

7.8.4 If a closure report for a site is received as part of the continuing review submission for a study, the site closure notice can be included in the continuing review approval letter sent to the PI/SC of the main study with a copy to the LSI and Local Site Liaison at the site(s) that closed.

8.0 REFERENCES

8.1 38 CFR 16, Department of Veterans Affairs, Protection of Human Subjects

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

8.3 21 CFR 56, U.S. Food and Drug Administration, Institutional Review Boards

8.4 Office for Human Research Protections January Guidance on Continuing Review

8.5 FDA Information Sheet, Guidance for Institutional Review Boards and Clinical Investigators, 1998 Update, Continuing Review After Study Approval

7 Attachments

1. VA Central IRB Form 115a, Application for Continuing Review: Local Site Investigators
2. VA Central IRB Form 115b, Application for Continuing Review: Principal Investigator/Study Chair
3. VA Central IRB Form 109d, Administrative Screening Checklist for Continuing Review
4. VA Central IRB Form 114c, Table of Documents Provided for Continuing Review
5. Sample Notification Letter for Lapse in Project Approval
6. VA Central IRB Form 136, Master VA Central IRB Continuing Review Log
7. VA Central IRB Form 117a, Project Closure Report
8. VA Central IRB Form 117b, Local Site Project Participation Closure Report

I have reviewed and approved the content of this SOP.


K. Lynn Cates, MD
Director, PRIDE

Date: 12/12/11

Application for Continuing Review: Local Site Investigator



Date of VA Central IRB Approval Expiration:

VA Central IRB#:

VA Facility Name:

Local Site Investigator Name:

Name of Project:

Application Instructions

- The Local Site Investigator (LSI) must complete this form and submit it to the Principal Investigator/Study Chair (PI/SC) by the deadline established by the PI/SC. **The PI/SC is responsible for submitting it to the VA Central IRB.**
- The LSI must also submit the following documents, if applicable, with the continuing review application:
 - Copy of the current VA Central IRB-approved informed consent document
 - Copy of the current approved HIPAA authorization
 - Copy of Informed Consent or Regulatory Audit(s) conducted by local RCO or equivalent or any other reports of oversight agencies since last continuing review or initial VA Central IRB approval.
- Submit this entire application to the PI/SC in an electronic copy according to the PI/SC study team instructions. Each section must contain a response. Other documents submitted with this application as checked below must also be submitted as applicable.
 - The informed consent document and HIPAA authorization must be in MS Word. Other documents can be in PDF format.
 - The file name must include the LSI's last name, type of document, and the date (e.g., jones.informedconsent.032808).
- Please contact the assigned VA Central IRB Coordinator for your study if you have any questions.

Contents of Application Package

Please check all documents included in this package:

- Application for Continuing Review: Local Site Investigator
- Current VA Central IRB-approved Informed Consent Document (VA Form 10-1086)
- Current approved HIPAA authorization
- Copy of Informed Consent Audit(s) or Regulatory Audit(s) Conducted at Local Site

Please indicate below any other documents included with this continuing review application. If the documents have been modified from currently approved documents (e.g., informed consent document) please use the Microsoft Word track changes function to indicate modifications. Submit both tracked and untracked versions of the documents if changes were made.

- VA Central IRB Form 116, Request to Amend or Modify an Approved Project
- VA Central IRB Form 119, Report of Unanticipated Serious Adverse Event (SAE) and/or Unanticipated Problems (UAP) Involving Risks to Participants or Others
- Other:
- Other:
- Other:

I. Project and Investigator Identification

1. Title of Project	
2. VA Central IRB Project #	
3. Local Site Investigator (LSI)	a. Name: _____ c. Phone: _____ b. VA E-mail: _____
4. Local VA Facility Name:	

II. Project Team Members

Please list all local site project team members currently working on this project and indicate personnel added since the last review and approval by the VA Central IRB. Include CVs or biosketches and COI for new personnel added since the last review for which no amendment was submitted and approved. Check the applicable boxes if training is current for personnel listed and if COI has changed for any personnel. If COI has recently changed, a new COI determination must be attached if not previously reported.

Name	Project Role	Obtaining informed consent? Y/N	Check if Added Since Last Review	Check if all training is current	Check if any change in COI
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please list all personnel who have left the project since the last continuing review. Additional rows may be added as needed.

Name	Project Role	Date Departed

Note: Additional project members may be added by inserting more rows in the table.

III. Current Project Status

The Local Site Investigator must check one of the following:

<input type="checkbox"/>	1. Enrollment has not started.
<input type="checkbox"/>	2. Open to enrollment; no participants enrolled.
<input type="checkbox"/>	3. Open to enrollment; participants enrolled.
<input type="checkbox"/>	4. Active and open to enrollment; participants are undergoing interventions per approved project.
<input type="checkbox"/>	5. Closed to enrollment; participants continue to undergo interventions per approved project. Date Closed to Enrollment: _____
<input type="checkbox"/>	6. Closed to enrollment; participants are in follow-up (e.g. survival) only or ongoing data analysis of private identifiable information. Date Closed to Enrollment: _____
<input type="checkbox"/>	7. Other (Chart Reviews, etc.): _____

IV. Participant Enrollment Summary

Participant Data Element	Local Site Information	
<input type="checkbox"/> Check if your project utilizes records or specimens versus human participants. <i>When the application asks for the number of subjects, document the number of records or specimens that have been reviewed or collected.</i>		
1. Total Number of Participants Approved for this Project in Local Site Investigator Application		
2. Total Number of Additional Participants Approved for this Project in VA Central IRB-Approved Amendments for this site.		
3. Total Number of Participants Approved for this Project by VA Central IRB for this site.		
Note: If this is the first continuing review application, you need only complete the Column "Since Original VA Central IRB Approval". Otherwise, complete both columns.	Since Original VA Central IRB Approval	Since Last VA Central IRB Approval
4. Number of Participants Enrolled (Enrolled means participants who signed an informed consent form, gave consent but the VA Central IRB approved a waiver of documentation of informed consent, or were enrolled under a waiver of informed consent. This includes screen failures and participants who have withdrawn or were withdrawn by the study team.)		
5. Number of Participants Enrolled Who Failed Screening <input type="checkbox"/> Check here if your project does not have screening procedures.		
6. Number of Participants Withdrawn If there were withdrawals, indicate reasons:		

Note: If this is the first continuing review application, please complete any question in the remaining sections requesting information "since the last continuing review application" with information since the project was initially approved by the VA Central IRB.

V. Participant Recruitment Issues and Complaints

<p>1. Have there been any difficulties in the recruitment of participants since the last continuing review application?</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes. If yes, please explain any recruitment difficulties that were or are currently being experienced:</p>
<p>2. Have there been any complaints from participants or others since the last continuing review application?</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Yes. If yes, please explain and address whether the complaint(s) was resolved:</p>

VI. Participant Enrollment by Gender and Race or Ethnic Groups

Check if your study enrolled human subjects and gender and minority status were not collected

Enter the cumulative enrollment for your local site, to include the number of records reviewed and/or specimens collected if used in your study versus human participants.

	American Indian or Alaskan Native	Asian	Black or African American	Native Hawaiian or other Pacific Islander	White	Hispanic or Latino	Other	Total
Men								
Women								
Total								

VII. Participant Enrollment: Vulnerable Populations or Special Classes of Participants

Were any additional categories of vulnerable populations or special classes of participants enrolled at your local site since the last continuing review application?

- No
- Yes. If yes, please check all the below categories that apply:
- Employees or students
 - Individuals with impaired decision-making capability
 - Pregnant women
 - Economically and/or educationally disadvantaged persons
 - Patients for whom you provide care
 - Prisoners
 - Illiterate, limited, or no English language proficiency
 - Terminally ill patients

VIII. Informed Consent and HIPAA Authorization

1. Type of Informed Consent process approved by the VA Central IRB at your local site (check all that apply):

- None
- Waiver of informed consent for recruitment purposes
- Waiver of informed consent
- Waiver of documentation of informed consent
- Written documentation of informed consent.

2. Has an informed consent audit been completed by the RCO at your local site since the last continuing review application?

- N/A
- No. Continue to item 3.
- Yes: If yes, please indicate date:

Was this report previously submitted to the VA Central IRB for review? Yes No
If no, submit a copy with the continuing review report.

3. Did all participants enrolled at your local site and entered on the master list of subjects for the study sign and date a VA Central IRB-approved informed consent document prior to undergoing any study interactions or interventions unless the VA Central IRB granted a waiver of informed consent or a waiver of documentation of informed consent?

- N/A
- Yes Number of consent forms signed and dated by subjects:
- No: If no, please explain:

2. Are you requesting any changes in the informed consent process or documentation or HIPAA authorization?

- No
- Yes. If yes, please attach a VA Central IRB Form 116, Request to Amend or Modify an Approved Project, with this continuing review application.

IX. Data Safety Monitoring and Risk/Benefit Assessment

Please answer the following questions concerning adverse events, unanticipated problems, and complaints that have occurred since the last review of the project by the VA Central IRB.

1. Have all unanticipated serious adverse events and unanticipated problems involving risks to subjects or others occurring at your local site been reported to the VA Central IRB since the last continuing review application?

- No. If no, please attach VA Central IRB Form 119, Report of Unanticipated Serious Adverse Event (SAE) and/or Unanticipated Problem (UAP) Involving Risks to Participants or Others, with this continuing review application for each separate SAE or UAP
- Yes

2. Since the last continuing review application, have there been any adverse events and/or unanticipated problems involving risks to subjects or others that did not require immediate reporting?

- No
- Yes. If yes, please give overall total and summarize types of problems that occurred:

3. Have all protocol violations or deviations that met the requirement for immediate reporting been reported since the last continuing review?

- No. If no, please attach VA Central IRB Form 129, Report of Protocol Violation or Deviation.
- Yes. :

4. Since the last continuing review, have there been any other adverse events or protocol deviations/violations occurring at your local site that did not require immediate reporting?

- No
- Yes. If yes, please give overall total and summarize types of events that occurred:

5. Since the last continuing review application, has the profile of adverse events (in terms of frequency, severity or specificity) occurring at your local site changed from previous experience or from protocol expectation?

- No
- Yes. If yes, please explain:

6. Since the last continuing review application, has any new information affected the reasonableness of the risks associated with the research in relation to the anticipated benefits, and/or affected the willingness of the participants to enroll, or to continue in the research?

- No
- Yes. If yes, please explain:

7. Has the risk-potential benefits ratio changed at your local site compared to when the project was originally approved?

- No
- Yes. If yes, please explain:

X. Additional Information

1. Since the last continuing review application, have you submitted any amendments to the VA Central IRB for approval?

- No
- Yes. If yes, please complete the table below:

Amendment Number	Date of IRB Approval	Amendment Content

2. Since the last continuing review application, has your local RCO performed a Regulatory audit on this study at your site?

- No. Continue to item 3.
- Yes. If yes, please indicate date:

Was this report previously submitted to the VA Central IRB for review? Yes No
If no, submit a copy with the continuing review report.

3. Has an informed consent audit(s) been performed since the last continuing review?

- N/A
- No. Continue to item 4.
- Yes. If yes, please indicate date:

Was this report previously submitted to the VA Central IRB for review? Yes No
If no, submit a copy with the continuing review report.

4. Have any other audits been conducted by any other entities that have not been previously reported to the VA Central IRB?

- No
- Yes. If yes, please attach a copy or indicate that a copy has been previously provided to the VA Central IRB for review and/or comment.

5. Please provide any additional information **specific to your local site's participation in the project** not addressed in the above sections and/or supplementing the continuing review application (e.g., presentations or publications).

XI. Local Investigator Certification/Assurance

The Local Site Investigator must check each box and sign and date the form.

<input type="checkbox"/>	1. I have completed this continuing review application and included any applicable supplemental documents. All unidentified unanticipated internal or local unanticipated serious adverse events have been reported as required and applicable.
<input type="checkbox"/>	2. I will submit this document to the Principal Investigator/Study Chair and maintain a copy of this continuing review application form and supplemental documents in my research records.
<input type="checkbox"/>	3. I and my project team, to include additional project team members listed in Section II of this Application, continue to have no conflicts of interest in regard to the conduct of this project or, if a conflict has arisen, the conflict has been reviewed by my local site and a copy of the determination is attached.
<input type="checkbox"/>	4. All members of the local site project team, to include the additional project team members listed in Section II of this Application, are appropriately credentialed, privileged, and have completed all required VA training in the protection of human participants and Good Clinical Practice.
<input type="checkbox"/>	5. I certify that all participants entered on to the master list of participants for this study who were enrolled at this site signed the current VA Central IRB-approved informed consent form prior to undergoing any interactions or interventions unless the VA Central IRB granted a waiver of informed consent and/or a waiver of documentation of informed consent.
<input type="checkbox"/>	6. I understand it is my responsibility to submit all project changes to the VA Central IRB for approval prior to initiating such change, except when necessary to eliminate apparent immediate hazard to the participant.
<input type="checkbox"/>	7. I understand that if continuing review approval has not been completed prior to the VA Central IRB expiration date, I must stop all research activities at my local site immediately, including data analysis. If I have participants currently enrolled receiving interventions or interactions, I must immediately submit a list of names to the VA Central IRB Co-Chair who will determine, in consultation with the Chief of Staff, whether participants may continue receiving continuation of research interventions or interactions.

By signing below, I attest that the project continues to be scientifically and ethically sound. I and my project team have the competencies and resources to continue to conduct the research described in this continuing review application. I and my study team will continue to meet the ethical standards for research involving human participants and will comply with requirements for VA Central IRB approval of this project.

Local Site Investigator Signature

Date

Application for Continuing Review: Principal Investigator/Study Chair



Date of Current VA Central IRB Approval Expiration:

VA Central IRB#:

Name of Project:

PI/SC Name:

VA Facility Name:

Application Instructions

- The Principal Investigator/Study Chair (PI/SC) must complete this form and submit it to the VA Central IRB by the above Application Due date.
- The PI/SC must also submit the following documents with the continuing review application as applicable:
 - Continuing Review Applications from all participating Local Site Investigators
 - Protocol Abstract
 - VA Central IRB-approved Protocol
 - VA Central IRB-approved Amendments
 - Copy of the current VA CIRB-approved model informed consent document
 - Copy of the current approved model HIPAA authorization
 - Copy of Informed Consent or Regulatory Audit(s) conducted by RCO or equivalent at PI/SC's VA Facility since last continuing review application or any other reports from oversight agencies
- Upon completion of the entire application package, the documents must be uploaded to the secure VA Central IRB SharePoint site for your study. A continuing review submission sub-folder has been created under your study folder to accept your documents. Each section of the application must contain a response. Other documents submitted with this application as checked below must also be submitted.
 - The model informed consent document and model HIPAA authorization must be in MS Word format. Other documents can be in PDF format.
 - The file name must include the PI/SC last name, type of document, and the date (e.g., jones.informedconsent.032808).
- Please contact the assigned VA Central IRB Coordinator for your study if you have any questions.

Contents of Application Package

Please check all documents included in this package:

- Application for Continuing Review: Principal Investigator/Study Chair
- Continuing Review Applications from (insert number) Local Site Investigators
- Protocol Abstract
- VA Central IRB-Approved Protocol
- VA Central IRB-Approved Amendments
- Current VA Central IRB-approved Model Informed Consent Document (VA Form 10-1086)
- Current approved Model HIPAA authorization
- Copy of Informed Consent Audit(s) or Regulatory Audit(s) Conducted at PI/SC's VA Facility or any other report from an oversight agency.

Please include below a list of any other documents included as part of the continuing review application. If the documents have been modified from currently approved documents (e.g., informed consent document), please use the Microsoft Word track changes function to indicate modifications. Submit both tracked and untracked versions of the documents if changes were made.

- VA Central IRB Form 116, Request to Amend or Modify an Approved Project
- VA Central IRB Form 119, Report of Unanticipated Serious Adverse Event (SAE) and/or Unanticipated Problem (UAP) Involving risks to Participants or Others
- Other:
- Other:
- Other:
- Other:
- Other:
- Other:

I. Project Identification

1. Title of Project	
2. VA Central IRB Project #	
3. Principal Investigator/Study Chair (PI/SC)	Name: _____ Phone: _____ VA E-mail: _____
4. PI/SC VA Medical Facility	
5. Project Coordinator	Name: _____ Phone: _____ E-mail: _____

II. Project Team Members

Please list **all local** site project team members **currently** working on this project and indicate personnel **added** since the last review for which no amendment was submitted and approved by the VA Central IRB. Include CVs or biosketches and COI for new personnel as applicable. Check the applicable boxes if training is current for personnel listed and if COI has changed for any personnel. If COI has recently changed, a new COI determination must be attached if not previously reported.

Name	Project Role	Obtaining Informed Consent? Y/N	Check if added since last review	Check if all training is current	Check if any change in COI
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please list all personnel who have **left** the project since the last continuing review. Additional rows may be added as needed.

Name	Project Role	Date Departed

Note: Additional project members may be added by inserting more rows in the table.

III. Current Project Status

The PI/SC must check one of the following:	
<input type="checkbox"/>	1. Enrollment has not started.
<input type="checkbox"/>	2. Open to enrollment; no participants enrolled.
<input type="checkbox"/>	3. Open to enrollment; participants enrolled.
<input type="checkbox"/>	4. Active and open to enrollment; participants are undergoing interventions per approved project.
<input type="checkbox"/>	5. Closed to enrollment; participants continue to undergo interventions per approved project. Date Closed to Enrollment:
<input type="checkbox"/>	6. Closed to enrollment; participants are in follow-up (e.g. survival) only or ongoing data analysis of private identifiable information. Date Closed to Enrollment:
<input type="checkbox"/>	7. Other (Chart Reviews etc.):
Check this block if you are requesting expedited VA Central IRB review for this continuing review application. <input type="checkbox"/>	

Note: If this is the first continuing review application, please complete any question in the remaining sections requesting information "since the last continuing review application" with information since the project was initially approved by the VA Central IRB.

IV. Participant Enrollment Summary

<input type="checkbox"/> Check if your project utilizes records or specimens versus human participants. <i>When the application asks for the number of subjects, document the number of records or specimens that have been reviewed or collected.</i>	
1. Total Number of Participants Initially Approved for this Project or at Last Continuing Review	
2. Total Number of Additional Participants Approved for this Project in VA Central IRB-Approved Amendments	
3. Total Number of Participants Approved for this Project by VA Central IRB at this Time	

V. Participant Recruitment Issues and Complaints

1. Have there been any systemic difficulties in the recruitment of participants since the last continuing review application?
<input type="checkbox"/> No
<input type="checkbox"/> Yes. If yes, please explain any recruitment difficulties that were or are currently being experienced:
2. Have you received any complaints from participants or others since the last continuing review application not addressed by local site investigators?
<input type="checkbox"/> No
<input type="checkbox"/> Yes. If yes, please explain and address whether the complaint(s) was resolved:

3. Are you requesting any changes in the groups of individuals (e.g., vulnerable populations) recruited into the project with this continuing review application?

- No
 Yes. Please explain.

VI. Informed Consent and HIPAA Authorization

Are you requesting any changes in the informed consent process or documentation or HIPAA authorization?

- No
 Yes. If yes, please attach a VA Central IRB Form 116, Request to Amend or Modify an Approved Project, with this continuing review application.

VII. Data Safety Monitoring and Risk/Benefit Assessment

Please answer the following questions concerning adverse events, unanticipated problems, and complaints that have occurred since the last review of the project by the VA Central IRB. Do not duplicate reports previously submitted by local site investigators.

1. Does this project have a Data Safety and Monitoring Board (DSMB)?

- No, skip to question 2.
 Yes, answer the below questions.

a. If Yes, indicate when it last met or if it has not yet met, when it will have its first meeting. If a copy of the charter was not previously submitted, please include with this application.

b. Are there are there any reports or interim findings generated by the DSMB?

- No
 Yes. If yes, please attach a copy of the most recent report or interim findings.

2. Have all unanticipated serious adverse events and unanticipated problems involving risks to subjects or others been reported to the VA Central IRB since the last continuing review application?

- No. If no, please attach VA Central IRB Form 119, Report of Unanticipated Serious Adverse Event (SAE) and/or Serious Unanticipated Problem (UAP) Involving Risks to Participants or Others, with this continuing review application for each separate SAE or UAP.
 Yes

PLEASE NOTE: The PI/SC should not duplicate reporting of serious adverse events or serious unanticipated problems involving risks to participants or others if the reportable event or problem was previously reported to the VA Central IRB by the Local Site Investigator and no additional information needs to be conveyed. If the research project does not involve LSIs under the direction of the PI/SC (e.g., single site research project or multi-site research project not requiring LSIs), the PI/SC is responsible for fulfilling all LSI responsibilities.

3. Since the last continuing review application, have there been any other unanticipated problems involving risks to subjects or others?

No

Yes. If yes, please give overall total and summarize types below:

4. Since the last continuing review application, have there been any other adverse events occurring?

No

Yes. If yes, please give overall total and summarize types below:

5. Since the last continuing review application, has the profile of adverse events (in terms of frequency, severity, or specificity) changed from previous experience or from protocol expectation?

No

Yes. If yes, please explain:

6. Since the last continuing review application, has any new information affected the reasonableness of the risks associated with the research in relation to the anticipated benefits, and/or affected the willingness of the participants to enroll, or to continue in the research?

No

Yes. If yes, please explain:

7. Has the risk-potential benefits ratio changed compared to when the project was last approved by the VA Central IRB?

No

Yes. If yes, please explain:

VIII. Abstract

Include a 1-5 page (do not exceed 5 pages) abstract containing the following content (as applicable). Please attach a separate PDF document.

- Purpose
- Research question
- Study aim or Hypotheses
- Methods (eligibility criteria, interventions or interactions, evaluations, follow-up)
- Data Safety Monitoring Plan
- **Progress** to date to include data analysis/results if applicable

IX. Additional Information

1. Since the last continuing review application, have you submitted any amendments to the PI/SC Application to the VA Central IRB for approval?

- No
 Yes. If yes, please complete the table below:

Amendment Number	Date of IRB Approval	Amendment Content

Add additional rows as necessary.

2. Has a Regulatory Audit been conducted on this study by your local facility RCO since the last continuing review?

- No. Continue to item 3.
 Yes. If yes, please indicate date:

Was this report previously submitted to the VA Central IRB for review? Yes No
 If no, submit a copy with the continuing review report.

3. Has an informed consent audit(s) been performed since the last continuing review?

- N/A
 No. Continue to item 4.
 Yes. If yes, please indicate date:

Was this report previously submitted to the VA Central IRB for review? Yes No
 If no, submit a copy with the continuing review report.

4. Have any other audits been conducted by any other entities that have not been previously reported to the VA Central IRB?

- No
 Yes. If yes, please attach a copy or indicate that a copy has been previously provided to the VA Central IRB for review and/or comment.

5. Briefly describe the progress of the research since the last approval period.

6. Are there any significant preliminary observations/interim findings during the last approval period? (Do not duplicate information in a DSMB report if submitted with this continuing review application.)

- No significant preliminary observations or interim findings at this time
 Yes. Briefly describe the observations or findings below:

7. Has there been any recent (within the last year) literature from peer reviewed publications (if they exist) relevant to your research project?

- No
 Yes. Please summarize below and describe their relevance to your project.

8. Please provide any additional information specific to this project not addressed in the above sections and/or supplementing the continuing review application (e.g., presentations or publications).

X. Summary of Participating Local Sites

Local Site Investigator	VA Facility	Number of Enrolled Subjects Since Previous VA Central IRB Approval	Total Number of Enrolled Subjects Since Initial VA Central IRB Approval
Total Number of Enrolled Participants			

Note: Insert additional rows in the table as needed.

The term enrolled denotes those participants who signed informed consent forms. It includes screen failures and those participants who have withdrawn. The above figures should match those provided on the Local Site Investigator Continuing Review Applications. If they do not, please provide justification:

XI. Principal Investigator/Study Chair Certification/Assurance

The Principal Investigator/Study Chair must check each box and sign and date the form.

<input type="checkbox"/>	1. I have completed this continuing review application and included any applicable supplemental documents. All unanticipated SAEs, whether related or unrelated, that have been identified internally by the local participating sites have been reported to the VA Central IRB.
<input type="checkbox"/>	2. I have submitted continuing review applications from participating local site investigators and maintained a copy of the continuing review application forms and supplemental documents in my research records.
<input type="checkbox"/>	3. I and my project team, to include any additional team members added in Section II of this Application, have no conflicts of interest in regard to the conduct of this project or, if a conflict has arisen, the conflict has been reviewed by this site and a copy of the determination is attached.
<input type="checkbox"/>	4. All members of the project team, to include any additional team members added in Section II of this Application, are appropriately credentialed, privileged, and have completed all required VA training in the protection of human participants and Good Clinical Practice.

<input type="checkbox"/>	5. I certify that all participants entered on to the master list of participants for this study who were enrolled at identified participating sites signed the current VA Central IRB-approved informed consent form prior to undergoing any interactions or interventions unless the VA Central IRB granted a waiver of informed consent and/or a waiver of documentation of informed consent.
<input type="checkbox"/>	6. I understand it is my responsibility to submit all project changes to the VA Central IRB for approval prior to initiating such change, except when necessary to eliminate apparent immediate hazard to the participant.
<input type="checkbox"/>	7. I understand that if continuing review approval has not been completed prior to the VA Central IRB expiration date, I must stop all research activities, including data analysis. If I have participants currently enrolled receiving interventions or interactions, I must immediately submit a list of names to the VA Central IRB Co-Chair who will determine, in consultation with the Chief of Staff at participating facilities, whether participants may continue receiving the research interventions and interactions.

By signing below, I attest that the project continues to be scientifically and ethically sound. I and my project team have the competencies and resources to continue to conduct the research described in this continuing review application. I and my study team will continue to meet the ethical standards for research involving human participants and will comply with requirements for VA Central IRB approval of this project.

Principal Investigator/Study Chair Signature

Date

Administrative Screening Checklist for Continuing Review Applications



This form is used by VA Central IRB Administrative staff to perform an initial screening of applications submitted for continuing review.

Section 1: Principal Investigator and Project General Information

VA Central IRB Project Number Assigned:

Date Received:

Current Approval Expiration Date:

1. Project Title:
2. Name of Principal Investigators/Study Chairs (PI/SC):
3. Name of PI Site:
4. Is the PI Site a Local Participating Site: Yes No
5. Number of Local Participating Sites:
6. Does the study need to be reviewed at a convened Board meeting? Yes No

If yes, add to the draft agenda of the next scheduled convened meeting. If submission deadline has passed add to the following meeting if approval period will not lapse prior to the meeting date. If approval period will lapse, consult the VA Central IRB Administrator.

Section 2: Principal Investigator/SC Continuing Review Application

1. Have any additional personnel been added since the initial or last continuing review?
 No.
 Yes. If yes, CVs, biosketches, and COI determinations for each new study team member must be attached if not previously provided via an approved amendment. *Add to Section 5, Issues Requiring Resolution if any required documentation is not included.*
2. Has there been any change in the training or COI status of any study team members?
 No. File Local Conflict of Interest findings in protocol folder. Report no COI identified to Board.
 Yes. Ensure appropriate documentation is included with the application for review. *If any documentation is missing, add this to Section 4, Missing Documents.*
3. If this study involves a Coordinating Center, was the application package submitted through the applicable Coordinating Center?
 No
 Yes
4. Are the currently approved model informed consent document and HIPAA authorization attached if applicable?
 Yes.
 No. Ensure appropriate documentation is included with the application for review. *If any documentation is missing, add this to Section 4, Missing Documents.*

5. Are any changes being requested in the currently approved PI/SC project package?

- No.
- Yes. If yes, is a VA Central IRB Form 116, Request to Amend or Modify An Approved Project attached with all associated revised documents? *If no, add this and/or any missing associated documents to Section 4, Missing Documents.* For convened meetings, add amendment to agenda tool. For both convened and expedited reviews, add to Table of Documents Provided for Continuing Review (VA Central IRB Form 114c)

6. Please check if any of the following are included with the continuing review report. For both convened and expedited reviews, add to Table of Documents Provided for Continuing Review (VA Central IRB Form 114c).

- Data Safety and Monitoring Board or Data Monitoring Committee Report
- Regulatory Audit
- Informed Consent Audit
- SAE or other report of unanticipated problem in research
- Significant new findings
- Other: _____ (specify)

7. Is the protocol abstract sufficient to give an overall summary of the study and does it include a section on progress to date?

- Yes
- No. Add to Section 5, Issues Requiring Resolution.

Section 3: Local Site investigator Continuing Review Applications Check here if N/A

List each site for which a report is required and check the applicable boxes as indicated. Add a checked box as required to Sections 4 or 5 if there missing documents or issues requiring resolution. Add other checked boxes as required to the Table of Documents Provided for Continuing Review

Site	Missing Items	Added Personnel	Change in Training or COI	Amendment Submitted	Audit Report Submitted and Type	SAE/UAP Report	Other (Specify)

Add additional rows as needed depending upon the number of sites.

Section 4: Missing Required Documents

Check one of the following:

- No required documents are missing from either the PI/SC or Local Site Investigator Applications
- Based on an administrative review of the project, the following required documents were not submitted as part of this application.

Site	Document	Date PI/LSI Contacted	Form of Contact	Date Received

Add additional rows as needed

Section 5: Issues Requiring Resolution

Check one of the following:

- No issues require further resolution.
- Based on an administrative review of the continuing review applications, the following issues must be resolved prior to the continuing review being scheduled for Board review.

Issue	Date PI Contacted	Form of Contact	Date Resolved	What was resolution

Add additional rows as needed

Section 6: Assigned VA Central IRB Coordinator Actions

1. All documents and all administrative issues have been resolved for this continuing review application and it is ready for review by the VA Central IRB. The following type of review is appropriate with this project:

- Expedited Convened Board

2. The following documents have been prepared as applicable: ***(Check all that apply)***

- Reviewer Checklists for Primary Reviewer *Name:*
- Reviewer Checklists for Secondary Reviewer (If applicable) *Name*
- Expedited Review Eligibility Determination (VA Central IRB Form 121) if applicable
- Table of Documents Provided for Continuing Review

VA Central IRB Coordinator: _____

Date: _____

Correspondence



From: VA Central IRB

Date:

TO: (Principal Investigator/Study Chair and/or LSI as applicable)

(Facility Address)

SUBJECT: Notice of Lapsed VA Central IRB Approval

1. You are hereby notified that the approval period on the below listed project has lapsed since no continuing review and re-approval of the project was conducted by the expiration date of **(Date of Expiration)**. You have also been informed of this lapse by our VA Central IRB Administrative Office via e-mail and by phone. A copy of this letter is also being sent to the Associate Chief of Staff for Research and Development (ACOS/R&D) of your facility, to the ACOS/R&D of all the participating sites *(if applicable)*, and to your funding agency.

Title of Project:

2. No further research on this project may take place. If there are participants for whom stopping this research activity will cause harm, please immediately forward a list of the affected participants, along with written justification for their continued participation, to the VA Central IRB Administrative Office. One of the VA Central IRB Co-Chairs will contact you. For all active participants for whom discontinuance of their participation will not cause harm, you and your project team must notify them in writing that the project has been terminated. Please forward a sample copy of this termination letter to the VA Central IRB Administrative Office for inclusion in the project file.

3. **(Use this paragraph if a continuing review application has not been received)** You may still submit the Continuing Review Application with 30 days of receipt of this letter and the continuing review will be conducted by the VA Central IRB. Otherwise, please submit a VA Central IRB Form 117, Project Closure Report. A copy of this form was electronically forwarded to you with the e-mail notice of this lapse. This form can also be downloaded from the VA Central IRB website. Please note that until your project's continuing review has been approved by the VA Central IRB no further research on this project may take place. (See Paragraph 2 above.)

3. **(Use this paragraph if a continuing review application has been received but not yet reviewed and/or approved)** Your continuing review application has been received and is in the process of being reviewed. **(Insert current status, i.e., indicate date the VA Central IRB review will take place or that the VA Central IRB is still pending receipt of additional information from the investigator.)** We will keep you informed concerning the progress of the review.

4. Any questions pertaining to this project or the functions and responsibilities of the VA Central IRB can be addressed to the VA Central IRB Coordinator for this project at (Phone) or e-mail (address).

Signature Block of VA Central IRB Chair

CC:

PI/SC

LSI (of specific lapsed site or all LSI if PI/SC approval lapse)

ORD Funding Service

Local Site Liaison (of specific lapsed site or all liaisons if PI/SC approval lapse)

Project Closure Report



VA Institutional Review Board for Multisite Studies

This form is completed when a research project that was approved by the VA Central IRB is completed or ends for any reason or if the IRB approval has lapsed for over 30 days. When a Project Closure Report is submitted:

- *No interactions or interventions with subjects for the purposes of the research may take place*
- *No additional data may be collected*
- *Data may not be analyzed if it includes identifiable private information about the participants or any of the HIPAA identifiers*
- *No more individually identifiable specimens from the participants can be tested or analyzed.*

I. Project Identification

Title of Project			
Principal Investigator/Study Chair (PI/SC)			
VA Central IRB Project #			
PI Contact Information	Phone:	E-mail:	Assigned VAMC:
Date of Closure			
Reason for Closure (Check one)	<input type="checkbox"/> Project Completed	<input type="checkbox"/> Project Not Started or Cancelled	<input type="checkbox"/> VA Central IRB Approval Lapsed over 30 days
	<input type="checkbox"/> Study Inactive	<input type="checkbox"/> Project Transferred to another site	<input type="checkbox"/> Other (specify): _____

II. Number of Participants Enrolled and/or Subject Data Used

Participant/Subject Data Element <i>(Please complete all applicable fields)</i>	Number of Participants/Subjects
Since Last Continuing Review	
Total Enrolled	
Total Withdrawn/Dropped Out	
<i>The following must be completed if the data was collected:</i>	
Total Males	
Total Females	
Total From Vulnerable Population <i>(Specify Category: _____)</i>	
Total African-American	
Total Caucasian	
Total Asian/Pacific Islander	
Total American Indian/Alaska Native	
Total Hispanic Origin	
Total Other	

Please list the specific reasons for participant withdrawal or dropout and the number of participants withdrawing or dropping out for each reason since the last continuing review. Add as many lines as needed.

Reason for Withdrawal/Drop Out

Number Withdrawn or Dropped

For Entire Study	Number of Participants
Total Accrual Goal	
Total Enrolled	
Total Withdrawn/Dropped Out	
<i>The following must be completed if the data was collected:</i>	
Total Males	
Total Females	
Total From Vulnerable Population (<i>Specify Category: _____</i>)	
Total African-American	
Total Caucasian	
Total Asian/Pacific Islander	
Total American Indian/Alaska Native	
Total Hispanic	

III. Adverse Events, Unanticipated Problems, and Complaints

Have there been any adverse events, unanticipated problems, protocol deviations or violations, or complaints since the last continuing review approval that were not reported to the VA Central IRB? Please check one of the boxes below.

- N/A. This was an exempt study.
- No. All adverse events; unanticipated problems; protocol deviations or violations; and complaints have been previously reported.
- Yes. *(If yes, please attach a VA Central IRB Form 119, Report of Unanticipated Serious Adverse Event (SAE) and/or Unanticipated Problem (UAP) Involving Risks to Participants or Others, and/or VA Central IRB Form 129, Report of Protocol Deviations or Violations, as applicable. For other reports of adverse event, please provide the overall total and a summary of the types of events that occurred.)*

IV. Summary of Project Conclusions or Reasons for Closure/Lapse

Please provide a brief summary of your conclusions or the reasons for the project closure. If the results of the project were or are to be published please provide a copy of the publication or an abstract. If IRB approval has lapsed over 30 days, please provide the reason for lapse, whether any participants need to continue to be followed for health and safety reasons, and whether you intend to resubmit the study for IRB review and approval.

V. Data Analysis and Storage

Please answer the following questions concerning any remaining data analyses and how the data will be stored.

1. Do you plan to continue analysis of de-identified data? Yes No

If yes, answer the following additional questions:

- a. Please describe how the data will be de-identified or note where in the protocol it is described:

Note: Data must be de-identified according to both Common Rule and HIPAA requirements.

- b. Describe your plans to maintain data security and privacy of the de-identified data:

2. For all study data and specimens, please answer the following:

- a. How will the data and specimens be stored?
b. How long will the data and specimens be stored?
c. How and when will the data and specimens be destroyed?

3. Are you submitting any new or missed DSMB or other oversight reports?

Yes No Not applicable

If yes, please explain.

4. Were there any unexpected safety developments?

Yes No Not applicable

If yes, please explain.

5. If the protocol describes plans to share research results with the participants, was this done

Yes No Not applicable

If no, explain.

6. Will identifiable information be used to re-contact individuals to obtain or provide additional information?

Yes No

If yes, please explain.

7. Have there been any significant new findings (recent literature or other relevant information) that may affect the risks or benefits associated with the research that should be disclosed to the participants of the study?

Yes No

If yes, describe how you will notify research participants. Submit copies of any letter or materials that you will use.

8. Does the above information in this section differ from what was described in the approved protocol?

Yes No

If yes, submit a VA Central IRB Form 116, Request to Amend or Modify an Approved Project, with the above materials. This amendment must be reviewed and approved before you request closure of the study.

VI. Investigator Certification

The principal investigator must check one of the boxes below and sign and date the form.

<input type="checkbox"/>	I understand that I may submit this report only if none of the participants are receiving any research-related project interventions or interactions, including interactions or interventions related to collection of long-term follow-up data, at any of the local participating sites and the project is permanently closed to enrollment.
	If the project is being terminated early, orderly participant termination procedures are being implemented and followed as detailed in the approved protocol, informed consent and HIPAA authorization.
	Additional private identifiable information or identifiable specimens from or about the participants are not being obtained.
	The analysis of all study data that includes identifiable private information or identifiable specimens is complete.
	Any remaining data analysis or manuscript preparation only involves de-identified data analysis as described above and in the approved protocol.
	If any follow-up procedures are being done they are for clinical purposes only.

	No further contact with enrolled subjects is necessary, except as described in the informed consent for re-contact for additional studies.
	Specimens and/or data are not maintained in a repository that has been approved as part of this project.
	If any local Sites that had approved VA Central IRB Local Site Investigator Applications have not previously provided Local Site Closure reports, they are being provided with this report.
	All data and specimens generated as a part of this project are maintained in compliance with Federal Regulations, local laws, and VA policy, including requirements for privacy, information security, and repository activities.
	The study sponsor has provided permission to close the study.
<input type="checkbox"/>	No participants were enrolled and/or no private identifiable data or identifiable specimens were collected or generated.
	If any local Sites that had approved VA Central IRB Local Site Investigator Applications have not previously provided Local Site Closure reports, they are also being provided with this report.
	The study sponsor has provided permission to close the study.
<hr style="width: 50%; display: inline-block; vertical-align: middle;"/> Date	
<hr style="width: 50%; display: inline-block; vertical-align: middle;"/> Date	

VI. VA Central IRB Review

Please answer the following questions concerning any remaining data analysis and how the data will be stored.

1. Is any additional information needed?

Yes No

If yes, specify:

If no, is it okay to close the protocol?

Yes No

Comments:

Print Name

Title

Signature of VA Central IRB Co-Chair

Date

Local Site Project Participation Closure Report



This form is completed when the participation of a local site in a research project that was approved by the VA Central IRB is completed or ends for any reason or if the IRB approval of the project at the site has lapsed over 30 days. When a Local Site Project Participation Closure Report is submitted:

- *No interactions or interventions with subjects for the purposes of the research may take place at the site*
- *No additional data may be collected at the site*
- *Data may not be analyzed if it includes identifiable private information about the participants or any of the HIPAA identifiers at the site or by any of the site study team members*
- *No more individually identifiable specimens from the participants can be tested or analyzed at the site or by any of the site study team members.*

I. Project Identification

Title of Project			
Local Site Investigator (LSI)			
VA Central IRB Project #			
LSI Contact Information	Phone:	E-mail:	Assigned VAMC:
Date of Closure			
Reason for Closure (Check one)	<input type="checkbox"/> Project Completed	<input type="checkbox"/> Project Not Started or Cancelled	<input type="checkbox"/> VA Central IRB Approval Lapsed over 30 days
	<input type="checkbox"/> Study Inactive	<input type="checkbox"/> Project Transferred to another site	<input type="checkbox"/> Other (specify): _____

II. Number of Participants Enrolled and/or Subject Data Used

Participant/Subject Data Element <i>(Please complete all applicable fields)</i>	Number of Participants/Subjects
Since Last Continuing Review	
Total Enrolled	
Total Withdrawn/Dropped Out	
<i>The following must be completed if the data was collected:</i>	
Total Males	
Total Females	
Total From Vulnerable Population <i>(Specify Category: _____)</i>	
Total African-American	
Total Caucasian	
Total Asian/Pacific Islander	

Total American Indian/Alaska Native	
Total Hispanic Origin	
Total Other	
<p>Please list the specific reasons for participant withdrawal or dropout and the number of participants withdrawing or dropping out for each reason since the last continuing review. Add as many lines as needed.</p>	
<u>Reason for Withdrawal/Drop Out</u>	<u>Number Withdrawn or Dropped</u>

III. Adverse Events, Unanticipated Problems, and Complaints

Have there been any adverse events, unanticipated problems, or complaints since the last continuing review approval that were not reported to the VA Central IRB? Please check one of the boxes below.

- N/A. This was an exempt study.
- No. All adverse events, unanticipated problems, and complaints have been previously reported.
- Yes. (If yes, please attach a VA Central IRB Form 119, Report of Unanticipated Serious Adverse Event (SAE) and/or Unanticipated Problem (UAP) Involving Risks to Participants or Others, and/or VA Central IRB Form 129, Report of Protocol Deviations or Violations, as applicable. For other reports of adverse event, please provide the overall total and a summary of the types of events that occurred.)

IV. Summary of Local Site Participation or Reason for Lapse, Termination, or Withdrawal from Project

Please provide a brief summary of your site's participation. If IRB approval of the project at the site has lapsed over 30 days, please provide the reason for lapse, whether any participants need to continue to be followed for health and safety reasons, and whether you intend to resubmit the study for IRB review and approval.

V. Data Analysis and Storage

Please answer the following questions concerning any remaining data analyses and how the data will be stored.

1. Do you plan to continue analysis of de-identified data at this study or in conjunction with the PI/SC study team? Yes No

If yes, answer the following additional questions:

- a. Please describe how the data will be de-identified or note where in the protocol it is described:

Note: Data must be de-identified according to both Common Rule and HIPAA requirements.

- b. Describe your plans to maintain data security and privacy of the de-identified data:

2. For all study data and specimens, please answer the following:

- a. How will the data and specimens be stored?
b. How long will the data and specimens be stored?
c. How and when will the data and specimens be destroyed?

3. Are you submitting any new or missed oversight reports, i.e, local Research Compliance Officer (RCO) reports that were not previously submitted?

Yes No Not applicable

If yes, please explain.

4. Were there any unexpected safety developments at this site?

Yes No Not applicable

If yes, please explain.

5. If the protocol describes plans to share research results with the participants, was this or will this be done at this site or by the PI/CS study team?

Yes No Not applicable as there is no sharing of results in the study.

If yes, indicate how and when this will or was done.

6. Will identifiable information be used to re-contact individuals to obtain or provide additional information?

Yes No

If yes, please explain.

7. Have there been any significant new findings (recent literature or other relevant information) that may affect the risks or benefits associated with the research that should be disclosed to the participants of the study?

Yes No

If yes, describe how you will notify research participants. Submit copies of any letter or materials that you will use.

8. Does the above information in this section differ from what was described in the approved protocol?

Yes No

If yes, submit a VA Central IRB Form 116, Request to Amend or Modify an Approved Project, with the above materials or indicate that the PI/SC will be submitting an amendment to the approved PI/SC Application. This amendment must be reviewed and approved before you request closure of the study at your site.

VI. Investigator Certification

The principal investigator must check one of the boxes below and sign and date the form.

<input type="checkbox"/>	I understand that I may submit this report only if none of the participants are receiving any research-related project interventions or interactions, including interactions or interventions related to collection of long-term follow-up data, at this site and the project is permanently closed to enrollment at this site.
	If the project is being terminated early at this site, orderly participant termination procedures are being implemented and followed as detailed in the approved protocol, informed consent and HIPAA authorization.
	Additional private identifiable information or identifiable specimens from or about the participants are not being obtained at this site.
	The analysis of all study data that includes identifiable private information or identifiable specimens is complete at this site or did not take place at this site.
	Any remaining data analysis or manuscript preparation by local study team members only involves de-identified data analysis as described above and in the approved protocol.

	If any follow-up procedures are being done they are for clinical purposes only.
	No further contact with enrolled subjects is necessary at this site, except as described in the informed consent for re-contact for additional studies.
	All data and specimens generated as a part of this project are maintained in compliance with Federal Regulations, local laws, and VA policy, including requirements for privacy, information security, and repository activities.
<input type="checkbox"/>	No participants were enrolled and/or no identified data was collected or generated at this site.
<hr/> <div style="display: flex; justify-content: space-around;"> Signed Date </div>	