1 SCOPE AND APPLICABILITY

1.1 The scope and purpose of this standard operating procedure (SOP) is to describe the policies and procedures the VA Central IRB uses for conducting continuing review and approval as required by 38 CFR 109e. This SOP 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.

1.2 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. 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.

1.3 It is the policy of the VA Central IRB to conduct 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 that all IRB approval criteria 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, and
- Review of the adequacy of ongoing protection for potentially vulnerable subjects.

1.4 VA Central IRB-approved research projects involving human subjects that have been determined to be exempt are not subject to VA Central IRB continuing review requirements.

1.5 Continuing review approval of research must occur on or before the date when VA Central IRB approval expires. 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 interest of individual participants to continue the research interventions or interactions.

1.6 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.

1.7 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.

1.8 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, the PI/SC submit a closure report. This also pertains to local site closures or terminations.
1.9 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.

2 DEFINITIONS

2.1 Approval Period. The period of time the VA Central IRB determines the protocol may be approved prior to a requirement for another review. The VA Central IRB may approve a study for a period of up to one full calendar year, i.e., May 1, 2007 through April 30, 2008. The approval period would expire April 30th at midnight. If the approval period is for a shorter period of time, such as six months, the approval period would encompass the full six months, i.e., May 1, 2007 through October 31, 2007. The approval period would expire on October 31, 2007 at midnight.

2.2 Expiration or Lapse of IRB Approval. One minute after midnight on the day after the IRB approval expiration date. There is no provision for any grace period.

3 RESPONSIBILITY

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

3.1.1 Submitting continuing review applications and any supporting documentation to the PI/SC by the timeframe established by the PI/SC.

3.1.2 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.

3.1.3 Submitting a local site closure report to the VA Central IRB upon study activities ceasing at the site.

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

3.2.1 Submitting continuing review applications from all participating LSIs, along with the completed PI/SC continuing review application, to the VA Central IRB by the deadline established by the VA Central IRB in order for it to have sufficient time to review the applications and grant continued approval of the study prior to the expiration date.

3.2.2 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.

3.2.3 Submitting notification of suspension or termination of a study.

3.2.4 Ensuring sites submit local site closure reports upon closure of the project at a specific site and submitting a project closure report upon completion or termination of the study.

3.3 Coordinating Center. The assigned Coordinating Center, if applicable as part of their function for a particular study, is responsible for assisting the PI/SC in collecting and evaluating data from the sites; tracking adverse events, protocol deviations, 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. The Coordinating Center’s participation in the study will be reviewed as part of the PI/SC Application.

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

3.4.1 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.

3.4.2 Monitoring the status of exempt studies to ensure that any changes in the study design do not result in the study becoming non-exempt. See VA Central IRB SOP 107, Exempt Research.

3.4.3 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.

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

3.5.1 Notifying the PI/SC prior to the current VA Central IRB approval expiration date of the continuing review requirement and providing them instructions for submitting a request for continuing review or a closure report.

3.5.2 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.

3.5.3 Notifying investigators in writing of the results of the VA Central IRB review and documenting these as part of the VA Central IRB meeting minutes as applicable.

3.5.4 Notifying the PI/SC and/or LSI(s), the local site liaisons, and the sponsor if VA Central IRB approval of a project lapses.

4 PROCEDURE

4.1 Notification of Continuing Review Requirements.

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

4.1.1.1 The VA Central IRB administrative staff sends an electronic notice to the PI/SC with attached continuing review forms and instructions how to load 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 those studies utilizing one.

4.1.1.2 The initial notification consists at a minimum of:

- Name of Study and PI/SC,
- 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 (usually at least two months prior to the expiration date);
• VA Central IRB Form 115b, Application for Continuing Review: Local Site Investigators (Attachment 1), if applicable; and
• VA Central IRB Form 115a, Application for Continuing Review: Principal Investigator/Study Chair (Attachment 2).
• OGE Form 450 Alternative-VA, Research Financial Conflict of Interest Statement

4.1.1.3 A follow-up reminder notice is sent to the PI/SC by the Continuing Review Manager via email if a continuing review request or closure report is not received within 30 days of the expiration date and then weekly follow-up notices will be sent until the report is received.

4.1.2 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 115b, 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 Form 115b to the PI/SC, while still allowing sufficient time for the PI/SC to review the submitted applications and prepare and submit the PI/SC Application to the VA Central IRB by the established deadline.

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

4.2.1 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, as well as copies of the VA Central IRB determination or acknowledgement letter for those reports already reviewed since the last continuing review, and
• Updated OGE Forms 450 for all study team members serving in an investigator role, or a memorandum from the designated FCOI official at that site that a COI review has been performed for specified investigators and the results of the review.

4.2.2 If an LSI application is approved by the VA Central IRB after the date set by the PI for submission of the LSI applications to the PI for inclusion in the PI/SC overall submission, then the LSI must submit (through the PI/SC) a memorandum that nothing has changed in the approved LSI application since the VA Central IRB approval, or if there has been a change, the
LSI must state what the change is and indicate when the amendment will be submitted if applicable. If there has been a change in personnel that does not require submission of an amendment, this can be stated in the memorandum.

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

4.3.1 Additional documents 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,
- 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, as well as copies of the VA Central IRB determination or acknowledgement letter for those reports already reviewed since the last continuing review; and
- OGE Forms 450 for all study team members serving in an investigator role or a memorandum from the designated FCOI official at that site that a COI review has been performed for specified investigators and the results of the review.

4.3.2 If the PI/SC has not received a particular LSI Application by the deadline date, the PI/SC should not hold-up 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.

4.4. Administrative Screening. VA Central IRB Continuing Review staff will perform an administrative screening of the continuing review applications upon receipt that will include the following:

- That all sites that have been approved and not yet closed have submitted a completed and signed VA Central IRB Form 115b or a closure report (see paragraph 4.8.3).
- That all required documents and any additional documents have been submitted as indicated on the VA Central IRB Forms 115a and 115bs.
- If additional personnel have been added since last continuing review that training is current and any serving in an investigator role have been previously added per an IRB-approved amendment.
- Verifying that there are no identified conflicts of interest for all study personnel serving in an investigator role or if there are identified conflicts, that these are sent to the applicable OGE office or that an OGE memorandum concerning the conflict has been submitted.
• That the protocol abstract has been updated since the last continuing review or initial approval
• That the amendment summary table matches the record of amendment approvals on file for both the PI and LSI Applications
• That all applicable sections on the VA Central IRB Forms 115a and 115b have been completed.
• That any submitted RCO audits have been noted and none involve apparent serious noncompliance that has not already been reviewed by the VA Central IRB. If an audit report that has not yet been reviewed by the VA Central IRB does identify apparent serious noncompliance it must be immediately forwarded to the VA Central IRB Administrator.

4.4.1 If any information is incomplete, missing, or requires correction, the PI study team is contacted via e-mail and asked to submit the required information as soon as possible. A record of the contact is kept in the continuing review file on the VA Central IRB shared drive.

4.4.2 If the study requires review at a convened meeting, the Continuing Review Manager adds the review to the agenda of an upcoming meeting at least one meeting prior to the expiration date or preferably two meetings prior to the expiration date if possible. 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-Chairs to determine if an unscheduled meeting should be called to review the action.

4.4.3 The Continuing Review staff 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, 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.

4.4.4 The Continuing Review staff 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.

4.5. 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.

4.5.1 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”, establishes the date by which the expiration period will be calculated for the approval period specified by the VA Central IRB.
4.5.2 For new projects undergoing expedited review, the date the Co-Chair approves the PI/SC New Project Application after any required modifications (if any) were made, is the date by which the expiration date will be calculated for the approval period.

4.5.3 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:

4.5.3.1 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.”

4.5.3.2 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 VA Central IRB Primary Reviewer.

4.5.3.3 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. This includes studies reviewed via expedited procedures and by the convened IRB.

4.5.4 When the IRB approves the research with conditions at the time of continuing review before the expiration date of the preceding approval period, IRB approval does not lapse even if the investigator needs additional time to satisfy some or all of the conditions. The IRB will establish a date by which the investigator must respond to the conditions and will then determine if the conditions are met or other action needs to be taken. If the investigator does not respond in a timely manner, the IRB may take additional action, such as suspension of enrollment and/or study activities.

4.6 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 personal identifiable information. No enrollment of participants can occur.

4.6.1 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.

4.6.2 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.

4.6.3 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).

4.6.4 The VA Central IRB will notify the PI/SC, the sponsor funding the project, affected participating sites, and affected LSIs of lapses of study approval. (See Attachment 3, Sample Notification Letter for Lapse in Project Approval.) 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 email with a read receipt requested and all notification documents will also be uploaded to the VA Central IRB SharePoint study site.

4.6.5 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 or site will be considered noncompliant and the Board will proceed in accordance with VA Central IRB SOP Serious and Continuing Noncompliance and consider the study or site for termination. If study or site termination is not in the best interest of participants, the study may be continued until the participants have safely completed the study or can be withdrawn but no new enrollment can take place.

4.6.5.1 If the PI/SC wants to re-open a study that lapsed and it has been over 30 days since the lapse occurred, 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.

4.6.5.2 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.

4.6.6 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 4.6.1 through 4.6.4 must still take place. The VA Central IRB will review the submitted materials as soon as practicable.

4.7 Project Closure. Upon completion or termination of an approved project, the principal investigator must submit a VA Central IRB Form 117a, Project Closure Report (Attachment 4), to the VA Central IRB. This should be done when the study is completed and not when the next continuing review report is due.

4.7.1 The Project Closure Report is forwarded to the Primary Reviewer for review. If the Primary Reviewer has any questions concerning the report, these will be forwarded to the PI/SC for a response.
4.7.2 Once the response is received, reviewed by the Primary Reviewer and there are no more questions, the VA Central IRB Manager 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 Manager updates the tracking system 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.

4.7.3 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 (Attachment 5). The VA Central IRB Form 117b is reviewed by the Primary Reviewer. If there are no further questions, the VA Central IRB administrative staff sends the LSI and the PI/SC an acknowledgement and concurrence memorandum indicating that the VA Central IRB considers the study at that site to be closed. The VA Central IRB Manager updates the tracking system 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.

4.8 Tracking of Continuing Review Actions and Expiration Dates. All actions pertaining to the continuing review process will be tracked in the VA Central IRB Access-based tracking system.

4.8.1 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 Manager for the study will enter the date of the IRB approval expiration into the VA Central IRB continuing review tracking system to include whether the next review will be at the convened IRB or by expedited review and if expedited, what categories may apply.

4.8.2 The VA Central IRB Continuing Review Manager and staff will ensure that the receipt of continuing review reports is entered into the Access tracking system in a timely manner, as well as all other tracking actions concerning the Reviewers and the study team.

4.8.3 Upon continued approval of a study and its associated sites, the VA Central IRB Continuing Review staff is responsible for updating the Access tracking system with the new approval expiration date and ensuring that all expedited approval actions are reported accurately to the next convened IRB meeting.

5 DOCUMENTATION REQUIREMENTS
5.1 Continuing review approvals, disapprovals and other determinations are documented on the applicable VA Central IRB forms or letters and archived in accordance with VA Central IRB SOPs and VHA and federal requirements.

5.2 Records on closed studies will be stored in separate folders on the shared drive and SharePoint system apart from the active files. Paper files will be maintained in separate storage from the active files and kept in accordance with the VA Records Control system until destruction is authorized.

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

6.2 VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research
6.3 21 CFR 56, U.S. Food and Drug Administration, Institutional Review Boards


6.5 FDA Information Sheet, Guidance for Institutional Review Boards and Clinical Investigators, 2012 Update, Continuing Review After Study Approval

Attachments:

1. VA Central IRB Form 115b, Application for Continuing Review: Local Site Investigators
2. VA Central IRB Form 115a, Application for Continuing Review: Principal Investigator/Study Chair
3. Sample Notification Letter for Lapse in Project Approval
4. VA Central IRB Form 117a, Project Closure Report
5. VA Central IRB Form 117b, Local Site Project Participation Closure Report
Application for Continuing Review: Local Site Investigators

This form is to be used to request continuing approval from the VA Central IRB for local site participation in an approved VA Central IRB Study. To request study closure at a local site, do not use this form and instead use VA Central IRB Form 117b, Local Site Closure Report.

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 as part of the PI/SC Continuing Review submission for the entire study in sufficient time for the review to take place before the current IRB approval period expires.

- The LSI must also submit the following documents, as applicable, with the Continuing Review application:

  - Currently signed and dated OGE Forms 450 Alternative-VA, Research Financial Conflict of Interest Statement for all study personnel serving in an Investigator role (Electronic completion with digital signature is acceptable) OR a memorandum from local site FCOI Officer indicating a review was performed by the site.
  - Copy of the VA Central IRB currently approved informed consent document - must include current VA Central IRB approval date. A PDF is acceptable.
  - Copy of VA Central IRB Determination or Acknowledgement from review of Informed Consent, Regulatory Audit(s, or any other reports from oversight agencies conducted by RCO or equivalent since last Continuing Review application. If audit was not previously submitted and reviewed by the VA Central IRB, please submit the audit with this continuing review report.

- Submit this entire application and associated documents to the PI/SC in electronic form according to the PI/SC study team instructions. Each section must contain a response. File names should be kept short, but should include the VA Central IRB study number and type of document. (e.g., 09-01 consent, 09-01 115b LSI CR).

- Amendments should not be submitted with this continuing review application unless the amendment has a direct bearing on the review and approval of this application. Otherwise, submit all amendments separately and notify the applicable VA Central IRB Manager of their submission.

- Please contact the assigned VA Central IRB Manager or staff members listed in your initial notifications if you have any further questions or call the VA Central IRB Toll-free line at 1-877-254-3130

Please remove/delete this instruction page prior to submitting your completed file to the Study PI/SC
## I. Project and Investigator Identification

1. **Title of Project**

2. **VA Central IRB Study Number**

3. **Local Site Investigator (LSI)**
   - If more than two Co-LSIs, add additional rows.
   - LSI Name: [Value]
   - Phone: [Value]
   - VA E-mail: [Value]
   - Co-LSI Name: [Value]
   - Phone: [Value]

4. **Local VA Facility**
   - Name: [Value]
   - Location (City): [Value]

5. **Local Study Coordinators:**
   - If more than two Project Coordinators, add additional rows
   - Name: [Value]
   - Phone: [Value]
   - E-mail: [Value]
   - Name: [Value]
   - Phone: [Value]
   - E-mail: [Value]

## II. Project Team Members

Please list all local site project team members currently working on this project and those being added with this report. Additional rows may be inserted into the table as needed.

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<th>Name</th>
<th>Project Role</th>
<th>Obtaining informed consent? Y/N</th>
<th>Date of Current Human Subjects Protection Training</th>
<th>Staff added and approved by the IRB since last continuing review</th>
<th>Staff being added with this Continuing Review report</th>
<th>Check if Scope of Practice on file at local site (Per VHA Directive 1200-01)</th>
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Please list all local personnel who have left the project since the last continuing review. Additional rows may be added as needed.

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III. Current Project Status at Site

The Local Site Investigator must check one of the following to indicate the current status of the study at the site:

- [ ] 1. Site has no interaction with participants (i.e.; chart review, data analysis only study)
- [ ] 2. Not yet open to enrollment
- [ ] 3. Open to enrollment; no participants yet enrolled.
- [ ] 4. Active and open to enrollment; participants undergoing interventions per approved project.
- [ ] 5. Closed to enrollment; participants continue undergoing interventions per approved project. **Date Closed to Enrollment:**
- [ ] 6. Closed to enrollment; participants are in follow-up only (e.g. survival) **Date Participant Intervention Ended:**
- [ ] 7. No further patient interventions or follow-up; ongoing data analysis of private identifiable information only. **Date Follow-up Ended:**

IV. Participant Enrollment Summary

*For those projects that utilize records or specimens (versus human participants), document the number of records or specimens that have been reviewed or collected when the application asks for the number of subjects.*

1. Total *Number of Participants Approved for this Project per Local Site Investigator Application*

<table>
<thead>
<tr>
<th>Since Last VA Central IRB Approval</th>
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<td><strong>Note:</strong> For first time Continuing Review application, please complete only the “Since Original VA Central IRB Approval” Column. All others complete both columns.</td>
<td></td>
</tr>
</tbody>
</table>

2. 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
   - identifiable data on human subjects under a waiver of informed consent

**This includes screen failures after consent and participants who have withdrawn or were withdrawn by the study team.**
3. Number of Participants Enrolled Who Failed Screening
   - Project does not have screening procedures after consent.

4. Number of Participants Randomized **AFTER** Consent and Screening.
   - Project does not randomize after consent.

6. Number of Participants Withdrawn
   **For the withdrawals, indicate reasons and totals:**

## V. Participant Recruitment Issues and Complaints

*For the below questions, please include only site-specific issues. Issues affecting the overall study will be reported on the PI/SC Application.*

1. Have there been any difficulties in the recruitment of participants since the last Continuing Review application that may impact the projected completion date for the study at this site?
   - [ ] No.
   - [ ] Yes. Please explain the recruitment difficulties that were or are currently being experienced:

2. Have there been any complaints from participants or others since the last Continuing Review application?
   - [ ] No.
   - [ ] Yes. Please describe the complaint, indicate its status, and explain why it was not reported to the VA Central IRB.

## VI. Participant Enrollment by Gender, Race, and Ethnic Group

*Check if data not collected*

Enter the cumulative enrollment for your local site. *For those projects that utilize records or specimens (versus human participants), document the number of records or specimens that have been reviewed or collected.*

<table>
<thead>
<tr>
<th></th>
<th>American Indian or Alaskan Native</th>
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<th>Black or African American</th>
<th>Native Hawaiian or other Pacific Islander</th>
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</tr>
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</table>

*TOTAL

*Provide rationale if figures do not add up:
### VII. Ongoing Monitoring

**Please answer the following questions concerning adverse events, unanticipated problems, and complaints that occurred since initial site approval or since last continuing review approval for the site.**

1. Since the **last** Continuing Review, have there been any adverse events or protocol deviations/violations occurring at your local site that **did not** require immediate reporting and have NOT previously been reported to the VA Central IRB?

   - [ ] No.
   - [ ] Yes. Give overall total and summarize types of events that occurred below or attach a separate summary report or table.

2. Since the last Continuing Review application, has the profile of adverse events (in terms of frequency, severity or specificity) occurring at the site changed from previous experience or protocol expectations?

   - [ ] No.
   - [ ] Yes. Explain:

3. Since the last Continuing Review application, has any new information affected the reasonableness of risk associated with the research in relation to the anticipated benefit, and/or affected the willingness of the participants to enroll, or to continue in the research?

   - [ ] No
   - [ ] Yes. Explain:

4. Has an informed consent audit been completed by the local RCO since the last Continuing Review?

   - [ ] N/A (Waiver of informed consent or Waiver of Documentation)
   - [ ] No
   - [ ] Yes. Indicate date of audit:

      Has this report already been reviewed by the VA Central IRB?

      - [ ] Yes. Submit the VA Central IRB determination or correspondence letter
      - [ ] No. Submit a copy of the audit with the Continuing Review report

5. Since the last Continuing Review application, has your local RCO performed a Regulatory audit at your site?

   - [ ] No.
   - [ ] Yes. Indicate date of audit:

      Has this report already been reviewed by the VA Central IRB?

      - [ ] Yes. Submit the VA Central IRB determination or correspondence letter.
      - [ ] No. Submit a copy of the audit with the Continuing Review report.

6. Have any audits been conducted by any other entities NOT previously reported to the VA Central IRB?

   - [ ] No. Attach a copy of the IRB determination letter.
   - [ ] Yes. Attach a copy of the audit.

**Note:** If any RCO report not previously reported indicates “apparent serious noncompliance” submit immediately; do not wait to include with this report.
VIII. Documentation Verification Checks and Additional Information

1. Since the last Continuing Review, has your local site submitted any local amendments and received approval from the VA Central IRB?

☐ No  ☐ Yes. If yes, please complete the table below and submit the VA Central IRB approval letter only:

<table>
<thead>
<tr>
<th>Amendment Number</th>
<th>Date of IRB Approval</th>
<th>Amendment Main Content</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. What is the version number and/or date of your latest IRB-approved protocol?

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

IX. Local Investigator Certification/Affirmation

The Local Site Investigator must read the below and sign and date the form.

1. I have completed this Continuing Review application and included all applicable supplemental documents. All unidentified unanticipated internal or local unanticipated serious adverse events have been reported as required and applicable.

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.

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 or the applicable OGE forms 450 are included in this submission.

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.

5. 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.
6. 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.

Local Site Investigator Signature __________________________ Date

X. Contents of Application Package

Please check all documents included in this package:

- VA Central IRB Form 115b, Application for Continuing Review: Local Site Investigator
- Statement from site COI Administrator/Committee that all COI forms reviewed OR OGE Forms 450 electronically completed with digital signature for all study staff serving in an investigator role. ***If not electronically completed must be currently signed and dated.
- Current VA Central IRB-approved (with approval dates) Informed Consent Document(s). A PDF is fine.
- Current HIPAA authorization(s)
- Copy of Informed Consent Audit(s) or Regulatory Audit(s) Conducted at LSI VA Facility or any other report from an oversight agency not previously reviewed by the VA Central IRB
- Copy of VA Central IRB audit determination letters or Correspondence from previously submitted and reviewed audits if not immediately reportable.
- Summary of adverse events and protocol deviations not previously reported to or reviewed by the IRB.

Please indicate below any other documents included with this Continuing Review application.
- Other:
- Other:
- Other:
Application for Continuing Review: Local Site Investigators

This form is to be used to request continuing approval from the VA Central IRB for local site participation in an approved VA Central IRB Study. To request study closure at a local site, do not use this form and instead use VA Central IRB Form 117b, Local Site Closure Report.

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 as part of the PI/SC Continuing Review submission for the entire study in sufficient time for the review to take place before the current IRB approval period expires.**

- The LSI must also submit the following documents, as applicable, with the Continuing Review application:
  - Currently signed and dated OGE Forms 450 Alternative-VA, Research Financial Conflict of Interest Statement for all study personnel serving in an Investigator role (Electronic completion with digital signature is acceptable) OR a memorandum from local site FCOI Officer indicating a review was performed by the site.
  - Copy of the VA Central IRB currently approved informed consent document - must include current VA Central IRB approval date. A PDF is acceptable.
  - Copy of VA Central IRB Determination or Acknowledgement from review of Informed Consent, Regulatory Audit(s, or any other reports from oversight agencies conducted by RCO or equivalent since last Continuing Review application. If audit was not previously submitted and reviewed by the VA Central IRB, please submit the audit with this continuing review report.

- Submit this entire application and associated documents to the PI/SC in electronic form according to the PI/SC study team instructions. Each section must contain a response. File names should be kept short, but should include the VA Central IRB study number and type of document. (e.g., 09-01 consent, 09-01 115b LSI CR).

- Amendments should not be submitted with this continuing review application unless the amendment has a direct bearing on the review and approval of this application. Otherwise, submit all amendments separately and notify the applicable VA Central IRB Manager of their submission.

- Please contact the assigned VA Central IRB Manager or staff members listed in your initial notifications if you have any further questions or call the VA Central IRB Toll-free line at 1-877-254-3130

Please remove/delete this instruction page prior to submitting your completed file to the Study PI/SC
# Application for Continuing Review: Local Site Investigators

**I. Project and Investigator Identification**

1. **Title of Project**

2. **VA Central IRB Study Number**

3. **Local Site Investigator (LSI)**
   - **If more than two Co-LSIs, add additional rows.**
   - LSI Name: [ ]
   - VA E-mail: [ ]
   - Phone: [ ]
   - Co-LSI Name: [ ]
   - VA E-mail: [ ]
   - Phone: [ ]

4. **Local VA Facility**
   - Name: [ ]
   - Location (City): [ ]

5. **Local Study Coordinators:**
   - **If more than two Project Coordinators, add additional rows**
   - Name: [ ]
   - E-mail: [ ]
   - Phone: [ ]
   - Name: [ ]
   - E-mail: [ ]
   - Phone: [ ]

**II. Project Team Members**

*Please list all local site project team members currently working on this project and those being added with this report. Additional rows may be inserted into the table as needed.*

<table>
<thead>
<tr>
<th>Name</th>
<th>Project Role</th>
<th>Obtaining informed consent? Y/N</th>
<th>Date of Current Human Subjects Protection Training</th>
<th>Staff added and approved by the IRB since last continuing review</th>
<th>Staff being added with this Continuing Review report</th>
<th>Check if Scope of Practice on file at local site (Per VHA Directive 1200-01)</th>
</tr>
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**III. Current Project Status at Site**

*The Local Site Investigator must check one of the following to indicate the current status of the study at the site:*

1. Site has no interaction with participants (i.e.; chart review, data analysis only study)
2. Not yet open to enrollment
3. Open to enrollment; no participants yet enrolled.
4. Active and open to enrollment; participants undergoing interventions per approved project.
5. Closed to enrollment; participants continue undergoing interventions per approved project.  
   **Date Closed to Enrollment:**
6. Closed to enrollment; participants are in follow-up only (e.g. survival)  
   **Date Participant Intervention Ended:**
7. No further patient interventions or follow-up; ongoing data analysis of private identifiable information only.  
   **Date Follow-up Ended:**

**IV. Participant Enrollment Summary**

*For those projects that utilize records or specimens (versus human participants), document the number of records or specimens that have been reviewed or collected when the application asks for the number of subjects.*

1. **Total *Number of Participants Approved for this Project per Local Site Investigator Application**

   **Note:** For first time Continuing Review application, please complete only the “Since Original VA Central IRB Approval” Column. All others complete both columns.

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2. **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;  
   - identifiable data on human subjects under a waiver of informed consent  

   **This includes screen failures after consent and participants who have withdrawn or were withdrawn by the study team.**
3. Number of Participants Enrolled Who Failed Screening
   - Project does not have screening procedures after consent.

4. Number of Participants Randomized **AFTER** Consent and Screening.
   - Project does not randomize after consent.

6. Number of Participants Withdrawn
   - For the withdrawals, indicate reasons and totals:

### V. Participant Recruitment Issues and Complaints

*For the below questions, please include only site-specific issues. Issues affecting the overall study will be reported on the PI/SC Application.*

1. Have there been any difficulties in the recruitment of participants since the last Continuing Review application that may impact the projected completion date for the study at this site?
   - No.
   - Yes. Please explain the recruitment difficulties that were or are currently being experienced:

2. Have there been any complaints from participants or others since the last Continuing Review application?
   - No.
   - Yes. Please describe the complaint, indicate its status, and explain why it was not reported to the VA Central IRB.

### VI. Participant Enrollment by Gender, Race, and Ethnic Group

*Provide rationale when totals do not add up.*

<table>
<thead>
<tr>
<th>Gender</th>
<th>American Indian or Alaskan Native</th>
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*Provide rationale if figures do not add up:
**VII. Ongoing Monitoring**

*Please answer the following questions concerning adverse events, unanticipated problems, and complaints that occurred since initial site approval or since last continuing review approval for the site.*

1. Since the last Continuing Review, have there been any adverse events or protocol deviations/violations occurring at your local site that did not require immediate reporting and have NOT previously been reported to the VA Central IRB?

   - [ ] No.
   - [ ] Yes. Give overall total and summarize types of events that occurred below or attach a separate summary report or table.

2. Since the last Continuing Review application, has the profile of adverse events (in terms of frequency, severity or specificity) occurring at the site changed from previous experience or protocol expectations?

   - [ ] No.
   - [ ] Yes. Explain:

3. Since the last Continuing Review application, has any new information affected the reasonableness of risk associated with the research in relation to the anticipated benefit, and/or affected the willingness of the participants to enroll, or to continue in the research?

   - [ ] No
   - [ ] Yes. Explain:

4. Has an informed consent audit been completed by the local RCO since the last Continuing Review?

   - [ ] N/A (Waiver of informed consent or Waiver of Documentation)
   - [ ] No
   - [ ] Yes. Indicate date of audit:

   Has this report already been reviewed by the VA Central IRB?

   - [ ] Yes. Submit the VA Central IRB determination or correspondence letter
   - [ ] No. Submit a copy of the audit with the Continuing Review report

5. Since the last Continuing Review application, has your local RCO performed a Regulatory audit at your site?

   - [ ] No.
   - [ ] Yes. Indicate date of audit:

   Has this report already been reviewed by the VA Central IRB?

   - [ ] Yes. Submit the VA Central IRB determination or correspondence letter.
   - [ ] No. Submit a copy of the audit with the Continuing Review report.

6. Have any audits been conducted by any other entities NOT previously reported to the VA Central IRB?

   - [ ] No. Attach a copy of the IRB determination letter.
   - [ ] Yes. Attach a copy of the audit.

*Note: If any RCO report not previously reported indicates “apparent serious noncompliance” submit immediately; do not wait to include with this report.*
VIII. Documentation Verification Checks and Additional Information

1. Since the last Continuing Review, has your local site submitted any local amendments and received approval from the VA Central IRB?

   - No
   - Yes. If yes, please complete the table below and submit the VA Central IRB approval letter only:

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2. What is the version number and/or date of your latest IRB-approved protocol?

3. Please provide any additional information specific to your local site’s participation not addressed in the above sections and/or supplementing the Continuing Review application (e.g., presentations or publications).

IX. Local Investigator Certification/Assurance

The Local Site Investigator must read the below and sign and date the form.

1. I have completed this Continuing Review application and included all applicable supplemental documents. All unidentified unanticipated internal or local unanticipated serious adverse events have been reported as required and applicable.

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.

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 or the applicable OGE forms 450 are included in this submission.

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.

5. 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.
6. 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.

<table>
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<th>Local Site Investigator Signature</th>
<th>Date</th>
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</table>

### X. Contents of Application Package

Please check all documents included in this package:

- [ ] VA Central IRB Form 115b, Application for Continuing Review: Local Site Investigator
- [ ] Statement from site COI Administrator/Committee that all COI forms reviewed OR OGE Forms 450 electronically completed with digital signature for all study staff serving in an investigator role. ***If not electronically completed must be currently signed and dated.
- [ ] Current VA Central IRB-approved (with approval dates) Informed Consent Document(s). A PDF is fine.
- [ ] Current HIPAA authorization(s)
- [ ] Copy of Informed Consent Audit(s) or Regulatory Audit(s) Conducted at LSI VA Facility or any other report from an oversight agency **not previously reviewed** by the VA Central IRB
- [ ] Copy of VA Central IRB audit determination letters or Correspondence from previously submitted and reviewed audits if not immediately reportable.
- [ ] Summary of adverse events and protocol deviations not previously reported to or reviewed by the IRB.

Please indicate below any other documents included with this Continuing Review application.

- [ ] Other:
- [ ] Other:
- [ ] Other:
From: VA Central IRB

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

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 approval has lapsed. Please forward a sample copy of this notice 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 form 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)
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. After 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

<table>
<thead>
<tr>
<th>Title of Project</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal Investigator/Study Chair (PI/SC)</td>
<td></td>
</tr>
<tr>
<td>VA Central IRB Project #</td>
<td></td>
</tr>
<tr>
<td>PI Contact Information</td>
<td>Phone: E-mail: Assigned VAMC:</td>
</tr>
<tr>
<td>Date of Closure</td>
<td></td>
</tr>
</tbody>
</table>

Reason for Closure (Check one)

- Project Completed
- Project Not Started or was Cancelled
- VA Central IRB Approval Lapsed over 30 days
- Study Inactive
- Project Transferred to another site
- Other (specify): _______________

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

<table>
<thead>
<tr>
<th>Participant/Subject Data Element (Please complete all applicable fields)</th>
<th>Number of Participants/Subjects</th>
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<tbody>
<tr>
<td>Since Last Continuing Review</td>
<td></td>
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<tr>
<td>Total Enrolled</td>
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</tr>
<tr>
<td>Total Withdrawn/Dropped Out</td>
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</table>

The below information must be completed if the data was collected. Check this box if the data was not collected ☐

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<td>Total African-American</td>
<td>Total Caucasian</td>
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<tr>
<td>Total Asian/Pacific Islander</td>
<td>Total American Indian/Alaska Native</td>
</tr>
<tr>
<td>Total Hispanic Origin</td>
<td>Total Other</td>
</tr>
</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>Reason for Withdrawal/Drop Out</th>
<th>Number Withdrawn or Dropped</th>
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For Entire Study

<table>
<thead>
<tr>
<th></th>
<th>Number of Participants</th>
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<tbody>
<tr>
<td>Total Accrual Goal</td>
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<tr>
<td>Total Enrolled</td>
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<tr>
<td>Total Withdrawn/Dropped Out</td>
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</tbody>
</table>

The below information must be completed if the data was collected.
Check this box if the data was not collected

<p>| | |</p>
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<tbody>
<tr>
<td>Total Males</td>
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<tr>
<td>Total Females</td>
<td></td>
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<tr>
<td>Total African-American</td>
<td></td>
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<tr>
<td>Total Caucasian</td>
<td></td>
</tr>
<tr>
<td>Total Asian/Pacific Islander</td>
<td></td>
</tr>
<tr>
<td>Total American Indian/Alaska Native</td>
<td></td>
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<tr>
<td>Total Hispanic</td>
<td></td>
</tr>
</tbody>
</table>

III. Adverse Events, Unanticipated Problems, Complaints, and Audits

Please complete each of the following questions pertaining to the conduct of this study at your site.

1. Have there been any adverse events, unanticipated problems, or complaints originating at your site or for the overall study 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 or unanticipated problems that were related or probably related to the research were immediately reported and all others summarized at the last continuing review.
   - Yes. Immediately report events that were serious, unanticipated, and related or probably related to the VA Central IRB. Do not wait to submit with this report. For events not immediately reportable, provide the overall total and a summary of the types of events that occurred as an attachment to this report.

2. Have there been any audits of this study at your site since the last continuing review, to include audits conducted by your local RCO? Note: If local policy requires that the RCO conduct a closure audit, “Yes” should be checked below and a copy attached.

   - Yes. Attach a copy of the report. If report was already forwarded to the VA Central IRB, indicate date forwarded: ______________ .
   - No. Complete the below information:
     - Date of last RCO Informed Consent Audit: _____________
     - Date of last RCO Regulatory Audit: _____________
Not Applicable. Please check as many boxes below as applicable to the study.

- Study has approved informed consent and/or documentation of informed consent waivers.
- Study was under three years in length.
- Local policy does not require a closure audit to be performed by RCO.

**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. 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, 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, explain.

4. Were there any unexpected safety developments?
   □ Yes  □ No  □ Not applicable
   If yes, 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, 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 study
   participants?
   □ 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.

<table>
<thead>
<tr>
<th>Box</th>
<th>Certification Statement</th>
</tr>
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<tbody>
<tr>
<td>1.</td>
<td>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.</td>
</tr>
<tr>
<td>2.</td>
<td>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.</td>
</tr>
<tr>
<td>3.</td>
<td>Additional private identifiable information or identifiable specimens from or about the participants are not being obtained.</td>
</tr>
<tr>
<td>4.</td>
<td>The analysis of all study data that includes identifiable private information or identifiable specimens is complete.</td>
</tr>
<tr>
<td>5.</td>
<td>Any remaining data analysis or manuscript preparation only involves de-identified data analysis as described above and in the approved protocol.</td>
</tr>
<tr>
<td>6.</td>
<td>If any follow-up procedures are being done they are for clinical purposes only.</td>
</tr>
<tr>
<td>7.</td>
<td>No further contact with enrolled subjects is necessary, except as described in the informed consent for re-contact for additional studies.</td>
</tr>
<tr>
<td>8.</td>
<td>If specimens and/or data are maintained in a repository, the repository has been approved in accordance with VHA handbook 1200.12 and the repository overseen by a VA facility's IRB of record.</td>
</tr>
<tr>
<td>9.</td>
<td>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.</td>
</tr>
<tr>
<td>10.</td>
<td>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.</td>
</tr>
<tr>
<td>11.</td>
<td>The study sponsor has provided permission to close the study.</td>
</tr>
<tr>
<td>12.</td>
<td>No participants were enrolled and/or no private identifiable data or identifiable specimens were collected or generated.</td>
</tr>
<tr>
<td>13.</td>
<td>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.</td>
</tr>
<tr>
<td>14.</td>
<td>The study sponsor has provided permission to close the study.</td>
</tr>
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</table>

Signature of Principal Investigator or Study 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.

After 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 by any of the site study team members 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 at the site or by any of the site study team members.

I. Project Identification

<table>
<thead>
<tr>
<th>Title of Project</th>
<th>Local Site Investigator (LSI)</th>
<th>VA Central IRB Project #</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

<table>
<thead>
<tr>
<th>LSI Contact Information</th>
<th>Phone:</th>
<th>E-mail:</th>
<th>Assigned VAMC:</th>
</tr>
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<tbody>
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<table>
<thead>
<tr>
<th>Date of Closure</th>
<th>Reason for Closure (Check one)</th>
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<tbody>
<tr>
<td></td>
<td>Project Completed</td>
</tr>
<tr>
<td></td>
<td>Study Inactive</td>
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</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Participant/Subject Data Element (Please complete all applicable fields)</th>
<th>Number of Participants/Subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Since Last Continuing Review</td>
<td></td>
</tr>
<tr>
<td>Total Enrolled</td>
<td></td>
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<tr>
<td>Total Withdrawn/Dropped Out</td>
<td></td>
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</tbody>
</table>

The following must be completed if the data was collected:

|                            |                                |
| Total Males                |                                |
| Total Females              |                                |
| 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.

<table>
<thead>
<tr>
<th>Reason for Withdrawal/Drop Out</th>
<th>Number Withdrawn or Dropped</th>
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</table>

III. Adverse Events, Unanticipated Problems, Complaints, and Audits

Please complete each of the following questions pertaining to the conduct of this study at your site.

1. Have there been any adverse events or unanticipated problems 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 or unanticipated problems that were related or probably related to the research were immediately reported and all others summarized at the last continuing review.
   - [ ] Yes. Immediately report events that were serious, unanticipated, and related or probably related to the VA Central IRB. Do not wait to submit with this report. For events not immediately reportable, provide the overall total and a summary of the types of events that occurred as an attachment to this report.

2. Have there been any audits of this study at your site since the last continuing review, to include audits conducted by your local RCO? Note: If local policy requires that the RCO conduct a closure audit, “Yes” should be checked below and a copy attached.
   - [ ] Yes. Attach a copy of the report. If the report was already forwarded to the VA Central IRB, indicate the date forwarded: ___________________.
   - [ ] No. If no, please complete the below information:
     - Date of last RCO Informed Consent Audit: ____________
     - Date of last RCO Regulatory Audit: ____________
   - [ ] Not Applicable. Please check as many boxes below as applicable to the study.
     - [ ] Study has approved informed consent and/or documentation of informed consent waivers.
     - [ ] Study was under three years in length.
     - [ ] Local policy does not require a closure audit to be performed by RCO.
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 site or in conjunction with the PI/SC study team?  □ Yes    □ No

   If yes, answer the following additional questions:

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

☐ Yes  ☐ No  ☐ Not applicable

If yes, please explain.

4. 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.

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

☐ Yes  ☐ No

If yes, please explain.

6. 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 study participants?

☐ Yes  ☐ No

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

7. 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.*

<table>
<thead>
<tr>
<th>Box</th>
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<tbody>
<tr>
<td>☐</td>
<td>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 the collection of long-term follow-up data, at this site and the project is permanently closed to enrollment at this site.</td>
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_________________________  _______________________
Signed                    Date