

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 administrative staff and VA Central IRB members follow when processing and reviewing submitted requests to amend, modify, or update projects that have already been approved by the VA Central IRB or have received an exemption from review.
- 1.2 This SOP applies to all research involving human participants that was submitted by VA investigators for review by the VA Central IRB, was approved or received an exemption from review, and remains active and open. It pertains to all Principal Investigators, Local Site Investigators, and their study coordinators participating in such research, as well as to VA Central IRB members, and to the VA Central IRB administrative support staff.
- 1.3 It is the policy of the VA Central IRB that amendments or modifications in research projects may not be initiated without prior review and approval by the VA Central IRB, except where necessary to eliminate apparent immediate hazard to human participants.
- 1.4 Requests to amend, modify, or update an approved project may be submitted to the VA Central IRB at any time during the current approval period. Amendments should only be submitted in conjunction with a continuing review report if the amendment is addressing a deficiency found during preparation of the report and which have a bearing on the continuing review approval. Otherwise, all amendments submitted with a continuing review application will be separated from the continuing review and processed separately.
- 1.5 The date when the current IRB approval period for a project expires is not changed based on the approval date of an amendment.
- 1.6 Amendments or modifications in projects determined to be exempt from IRB review by the VA Central IRB must also be submitted to the VA Central IRB, if the amendment or modification has the potential to change the exempt status.

2 DEFINITIONS

- 2.1 **Expedited Review.** In contrast to a convened IRB review process, the expedited review process consists of a review carried out by the IRB Chair or by one or more experienced voting members of the IRB designated by the IRB Chair in accordance with 38 CFR 16.110(b). (VHA Handbook 1200.05).
- 2.2 **Investigator.** An investigator is any individual who conducts research involving human subjects, including, but not limited to: the Principal Investigator (PI), Co-PI, co-investigator, and Local Site Investigator (LSI). The investigator must uphold professional and ethical standards and practices, adhere to all applicable Federal requirements, and comply with applicable local policies and procedures. (VHA Handbook 1200.05)
- 2.3 **Minimal Risk.** The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (38 CFR 16.102(i))

3 RESPONSIBILITY

- 3.1 Principal Investigators and Local Site Investigators are responsible for ensuring that all proposed changes to an approved project are submitted for review in accordance with this SOP prior to initiating any such changes. The only exception is if the change is necessary to eliminate any apparent hazard to human participants. If this is the case, the VA Central IRB should immediately be informed via telephone or e-mail and an amendment requesting the change be submitted within 5 work days. The VA Central IRB staff will consult with VA Central IRB Co-Chair to determine if a protocol deviation or SAE/UAP report should also be submitted.
- 3.2 The VA Central IRB is responsible for reviewing all requests to amend or modify an approved project in a timely manner via the expedited review process or by the convened IRB; making appropriate approval determinations; and communicating the results of the determinations to the investigators and local participating sites in writing.
- 3.3 The VA Central IRB Administrator is responsible for assisting investigators with meeting VA Central IRB amendment application requirements, maintaining the VA Central IRB website, and for ensuring all policies, procedures, and forms pertaining to the research project amendment or modification process are kept current and up-to-date. The VA Central IRB Administrator also tracks the timeliness of amendment processing and ensures all amendments approved under the expedited review process are reported at the next convened meeting of the VA Central IRB.
- 3.4 The VA Central IRB Managers are responsible for receiving and reviewing all requests for amendment, modification, or update of their assigned studies as follows:
- 3.4.1 VA Central IRB Managers will enter all amendment requests into the VA Central IRB tracking system immediately upon receipt and then process the request for review, to include sending comments from reviewers, and reviewing and processing the study team responses. The VA Central IRB Managers prepare and send out the amendment approval letters after receiving approval from the IRB Member Reviewer and ensure appropriate upload of all documents to the applicable SharePoint folder. The VA Central IRB Managers also send out e-mail notifications of the approval to all applicable parties, to include the applicable VA Central IRB site liaisons.
- 3.4.2 VA Central IRB Managers also assess requests for administrative updates and if a change is determined to be an update, process the change and ensure it is both posted to SharePoint and filed in the applicable project folder

4 PROCEDURE

- 4.1 Who Can Submit an Amendment or Modification Request: Both the PI/SC (Co-PI/SCs) and the LSI (Co-LSIs) can submit an amendment or modification requests as detailed below.
- 4.1.1 The PI/SC submits an amendment request when there is a change in how the overall project will be conducted. This can include, but is not limited to, the following:
- Change in project design or procedures;

**Requests to Amend, Modify, or
Update an Approved Project**

Document No.: VA-CIRB-SOP-113

Supersedes Previous
version: 6/24/2014Effective Date:
6/29/2016

Page 3 of 7

- Change in participant population and enrollment target numbers, to include addition of a new site or deletion of a current site;
- Change in risk/benefit analysis;
- Changes in recruitment strategy and/or participant payment procedures;
- Changes in informed consent procedures or documents;
- Changes in data collection and storage procedures, to include data banking;
- Change in PI/SC, Co-PI/SCs, anyone serving in an investigator role, or anyone mentioned by name in the protocol, informed consent, recruitment materials, or other study documents in which current point of contact information is essential; and
- Change in other study team members when required by the VA Central IRB or the local Research and Development Committees.

4.1.2 The LSI submits a request for amendment or modification for the local participating site when there is a site specific change. These can include, but are not limited to, the following:

- Change in LSI or Co-LSIs,
- Change in local study team members when serving in an investigator role or when mentioned by name in the informed consent or other study documents where current point of contact information is essential, or when required by local R&D policies or by the VA Central IRB.
- Changes in local site approved recruitment material specific to that site,
- Changes in the local site approved informed consent document specific to that site,
- Changes in resources available at the site to support the project,
- Changes in state laws or local requirements,
- Changes in data collection and storage procedures, to include tissue banking specific to that site; or
- Changes in the local site VA Form 10-1092, Investigational Drug Record.

4.1.3 Changes in other key study staff not mentioned in paragraphs 4.1.1 and 4.1.2 must be reported at the time of continuing review on the VA Central IRB continuing review application requests for PI/SCs and LSIs.

4.1.4 Changes in items such as phone or room numbers, correction of typographical errors, formatting issues, or other minor changes that do not change any of the approved content, are processed as updates and not amendments. The national or local study coordinators just need to submit the updated documents with an explanation via e-mail of what needs to be updated and why. These will be processed as administrative updates and not as amendments requiring review by a voting member of the VA Central IRB.

4.2 Completion and Submission of an Amendment Request: When an PI/SC or LSI requests an amendment or modification in an approved project, VA Central IRB Form 116 (Attachment 1), Request to Amend or Modify an Approved Project, must be submitted.

4.2.1 The amendment or modification request must include the following information:

- Type of amendment or modification (PI/SC or LSI),

Document No.: VA-CIRB-SOP-113

Supersedes Previous version: 6/24/2014

Effective Date:
6/29/2016

Page 4 of 7

- Description of the amendment or modification,
- Reason or rationale,
- The anticipated impact on risk-benefit ratio for participants,
- Whether or not modifications in the informed consent form are needed, and
- Whether it is appropriate to inform participants who have already consented to participate in the project of the changes and/or whether a re-consenting process is requested.

4.2.2 PI/SC amendments to a specific study will be assigned a number in chronological order for each amendment received. Each site amendment will also be assigned a number in chronological order.

4.2.3 The PI/SC or LSI will upload a signed electronic copy of the VA Central IRB Form 116 and all associated documents to the VA Central IRB secure SharePoint site. It can also be sent by encrypted e-mail. If the amendment or modification requires review by the convened VA Central IRB, the documents must be submitted no later than ten working days prior to a scheduled meeting. If the amendment or modification and associated documents are submitted later than this, the review may still occur at the intended meeting if the members have sufficient time to receive and review all the documentation. This will be left to the discretion of the VA Central IRB Administrator, assigned VA Central IRB Reviewer and the VA Central IRB Co-Chairs.

4.3 Completion and Submission of Associated Documentation: In addition to completing the VA Central IRB Form 116, the PI/SC or LSI submits the following associated documents if applicable for the type of change being requested. When making a change to any document, the study team must submit a copy with the changes highlighted (or a MS tracked changes file) and a clean copy for the official project file.

4.3.1 To add a new participating site or replace a site that was previously identified as a potential participating site, the PI/SC submits a VA Central IRB Form 116 while the new site(s) submits a VA Central IRB Form 104, Local Site Application. The site must have an active MOU on file with the VA Central Office HRPP in order for the site application to be reviewed by the VA Central IRB. If no MOU is on file, the VA Central IRB administrative staff will contact the site to assist them in processing the MOU. All revised documents must have a version number or version identifier and a date. A VA Central IRB Form 116 does not have to be submitted by the PI if the site was already listed on the approved VA Central IRB Form 108 and the number of sites approved is not being exceeded.

4.3.2 If there is a change in PI/SC, a VA Central IRB Form 134a, Change in Principal Investigator/Study Chair (Attachment 2) must be submitted in lieu of the VA Central IRB Form 116, with a current curriculum vitae or biosketch, a VA Central IRB Form 102, Local ACOS/R&D Review Supplement, and a COI determination from the PI/SC site or a current OGE Form 450-VA Alternative, Research Financial Conflict of Interest. Copies of all modified forms or other documentation in which the PI/SC is named must also be submitted.

- 4.3.3 If the proposed amendment or modification involves the informed consent or conveying new information, the PI/SC or LSI must indicate whether participants who have already consented to participate need to be re-consented and/or informed.
- 4.3.3.1 Modifications in the informed consent form must be submitted to the VA Central IRB for review as follows:
- A copy of the new, revised consent form with the changes highlighted, preferably through the use of the Word track change function; and
 - A copy of the new, revised consent form with the changes not highlighted to be used by the VA Central IRB to stamp the new approval date upon completion of the review.
- 4.3.3.2 If the PI/SC or LSI does not plan to re-consent participants already enrolled in the project but will inform them of the changes, a copy of the proposed letter sent to participants informing them of the changes must be submitted to the VA Central IRB for review and approval.
- 4.3.4 If there is a change in LSI, a VA Central IRB Form 134b, Change in or Addition of Local Site Investigator (Attachment 3), must be submitted by the new LSI and sent in by the PI/SC study team to include a current curriculum vitae or biosketch, a VA Central IRB Form 102, Local ACOS/R&D Review Supplement, and a COI determination from the LSI site or a current OGE Form 450-VA Alternative, Research Financial Conflict of Interest. Copies of all modified forms or other documentation in which the LSI is named must also be submitted.
- 4.3.5 If there is an approved change to the PI/SC Application that requires changes also be made in approved local site documents for all participating sites, each site only needs to submit the modified documents and they will be processed as administrative documents
- 4.3.5.1 The VA Central IRB Manager will verify that the required changes were made and file the materials in the study folder and upload verified copies onto the VA Central IRB SharePoint site as a verified update. Each update will be assigned a number in chronological order (for both PI and LSI updates) and the file name will contain this number and date, i.e., Update 01 062416. A notice that the changes were received, verified, and uploaded will be sent to the LSI study team, the PI/SC study team, and the VA Central IRB Local Site Liaison. If the changes involved the informed consent document, the informed consent document will be updated with the current PI/SC amendment date approval and the LSI Verification date of the updated materials.
- 4.3.5.2 The VA Central IRB Manager will follow-up with each site to ensure all documents are received within 10 work days of notification of the required changes. If documents are not received within 30 calendar days of notification, the issue will be referred to the VA Central IRB Administrator who will consult with a Co-Chair concerning possible non-compliance in accordance with VA Central IRB SOP 118, Serious and Continuing Noncompliance.

Document No.: VA-CIRB-SOP-113

Supersedes Previous version: 6/24/2014

Effective Date:
6/29/2016

Page 6 of 7

4.3.6 If there is a change that requires review at a local site by a Biosafety or Radiation Safety Committee, a copy of the applicable committee approval document must be submitted with the VA Central IRB Form 116.

4.4 **Exempt Projects:** Even though the VA Central IRB approved an exemption from review for a project, any changes made in the project that affect the design and conduct of the project must be reported to the VA Central IRB for review to determine that the project continues to be exempt.

4.4.1 Completion of a VA Central IRB Form 116, Request to Amend or Modify an Approved Study is not required. The PI/SC or LSI submits a cover Memorandum to the VA Central IRB indicating that changes are being made in the study and attaches a revised copy of the original VA Central IRB Form 105, Request for Exemption of Research, with the changes highlighted. A clean copy must also be submitted for the official project file. A revision number and date of revision must be indicated on the bottom of the form. Any revised documents must be included.

4.4.2 If the PI/SC or LSI determines that the project will probably no longer be exempt from IRB review due to the change or modification, or if the VA Central IRB determines this after the requested change is reviewed, a VA Central IRB Form 108 and any associated documentation must be submitted. A copy of the original exemption request and the changes to the grant application must also be submitted. This will be reviewed as a new project submission.

5 DOCUMENTATION REQUIREMENTS

- 5.1 All amendment requests and revised documents are filed in the applicable project folders on the VA Central IRB shared drive while paper copies of FDA-approved studies are maintained in the VA Central IRB paper-based study files.
- 5.2 Copies of approved documents in electronic format are also maintained on the VA Central IRB SharePoint site.

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 VHA Handbook 1200.01, The Research and Development (R&D) Committee Handbook
- 6.4 45 CFR 46, Department of Health and Human Services, Protection of Human Subjects, Subparts B through D
- 6.5 21 CFR 56, U.S. Food and Drug Administration, Institutional Review Boards
- 6.6 21 CFR 50, U.S. Food and Drug Administration, Protection of Human Subjects



Requests to Amend, Modify, or Update an Approved Project

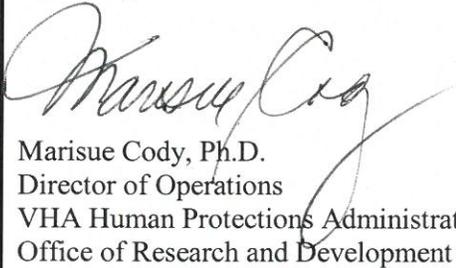
Document No.: VA-CIRB-SOP-113

Supersedes Previous version: 6/24/2014

Effective Date:
6/29/2016

Page 7 of 7

As the responsible authority delegated by the VHA Central Office Institutional Official for administrative oversight of the VA Central IRB, I have reviewed and approved the contents of this VA Central IRB Standard Operating Procedure.



Marisue Cody, Ph.D.
Director of Operations
VHA Human Protections Administrator
Office of Research and Development

3 Attachments

1. VA Central IRB Form 116, Request to Amend or Modify an Approved Project
2. VA Central IRB Form 134a, Change in Principal Investigator/Study Chair
3. VA Central IRB Form 134b, Change in or Addition of Local Site Investigator

Request to Amend or Modify an Approved Project



This form is used by an investigator to submit amendments or modifications in approved projects to the VA Central IRB for review and approval prior to implementing the changes, except where necessary to eliminate apparent immediate hazard to human participants.

I. Project and Investigator Information *Check Amendment Type:* PI LSI

| | |
|--|-----------------------------|
| Title of Project: | |
| VA Central IRB Study Number: | PI or LSI Amendment Number: |
| Name of PI/SC or LSI: | Email: |
| VA Facility Location: (City and State) | Telephone: |

II. Type of Amendment or Modification Request

Please check each type of change submitted with this amendment. Attach two copies of each revised document and ensure each document has a new version number and current date. One copy must show all changes highlighted/tracked and the other copy must be a clean copy with all revisions included. Note: A revised VA Central IRB Form 108 or 104 should not be submitted.

| Change Requested | Documents Required |
|---|--|
| <input type="checkbox"/> Study design or procedure | Submit revised protocol, updating current version number (<i>not</i> VA Central IRB Form 108). If change involves Biosafety or Radiation Safety, a copy of the approval letter must be included. |
| <input type="checkbox"/> Change in study team members who serve in the role of "investigator" and/or who obtain informed consent and/or are named in study documents provided to participants | Documentation required will depend on the new study team member's role in the study. Changes in other study team members must be reported at continuing review. Also, reference and complete Section V of this form. <i>Note: For changes in PI/SC or LSI, or Co-PI/SC or Co-LSIs, use VA Central IRB Form 134a or 134b as applicable in lieu of this form.</i> |
| <input type="checkbox"/> Increase or decrease in enrollment goals and/or changes in inclusion/exclusion criteria | Submit revised protocol with rationale for change. Submit just this amendment form for increases or decreases in specific site enrollment goals without further change in overall study goals. |
| <input type="checkbox"/> Recruitment methods or materials or participant payment | Submit revised recruitment materials with updated version dates. If there is a change in the recruitment process, submit revised protocol. If there is a change in participant payment, submit revised protocol and informed consent document if applicable. |
| <input type="checkbox"/> Vulnerable population safeguards | Submit a new or revised VA Central IRB Forms 110a, 110b, or 110c as applicable with updated version dates. Submit a revised protocol if there is a change in the use of a Vulnerable Population, such as the addition of a new vulnerable group. |
| <input type="checkbox"/> Informed consent document or process | Submit updated version of informed consent document (2 copies; one with revisions highlighted, to include revision date.) If there is a change in the process, submit revised protocol. Also reference and complete Section VI of this form. |
| <input type="checkbox"/> Informed consent waiver or alteration process | Submit a new or revised VA Central IRB Form 112a or 112b as applicable. Submit revised protocol if there is a change in process. |
| <input type="checkbox"/> HIPAA Waiver | Submit a new or revised VA Central IRB Form 103. Submit revised protocol if there is a change in process or procedures. |

| | |
|---|---|
| <input type="checkbox"/> HIPAA Authorization or procedure | Submit revised HIPAA Authorization. Also submit revised protocol if there is a change in procedure in obtaining the HIPAA authorization. |
| <input type="checkbox"/> Questionnaires and/or surveys | Submit revised questionnaires and/or surveys with revision dates. Submit a revised protocol as well if there is a change in how these are administered or if there is a new procedure. |
| <input type="checkbox"/> Investigator's Brochure | Submit brochure with changes. Submit revised protocol if there are any changes in risks, inclusion/exclusion criteria, or procedures for administration or use of the product. |
| <input type="checkbox"/> Increased Number of Sites | Submit revised protocol and VA IRB Form 104. <i>Note: A VA Central IRB Form 116 is not required for submitting VA Central IRB Forms 104 for sites already designated in the protocol or for replacement sites. When a site is dropped or closed, submit VA Central IRB Form 117b.</i> |
| <input type="checkbox"/> Other | Specify forms or documents being submitted if not checked above: <i>Specify:</i> |

Note: All revised documents submitted must have a current date and/ or have an updated version number and date as applicable. This includes revised forms.

III. Description and Rationale

Please provide a brief description and rationale for each type of change requested. Additional rows may be added as necessary.

| Description of Change or Modification | Rationale for Change or Modification <i>Note: a rationale <u>must</u> be provided for each change.</i> |
|---------------------------------------|--|
| | |
| | |

IV. Impact on Participants

Please answer the following questions.

1. Will the above changes have any impact on the research participants? Yes No

If no, skip to Section V. If yes, please complete the following:

2. Describe the impact the proposed amendment or modification will have on participants: *Note: If there are **multiple changes**, describe the impact of **each** specific change.)*

V. Changes in Personnel N/A

If the requested modifications do not involve any changes in personnel check the N/A block above and proceed to Section IV.

For changes in study team personnel, please complete the below tables and questions:

| Project Team Member | Degrees | VA Employee Status (WOC, IPA, #8 ^{ths} etc.) | Project Role | Obtaining Informed Consent? Yes/No | Access to Identifiable Participant Data? Yes/No | Date of Latest VA Human Subjects Protection Training |
|---------------------|---------|---|--------------|------------------------------------|---|--|
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

For those new team members who have a role of “investigator”, submit both a CV and a COI determination from your local site or a COI form signed by the study team members. Also attach any other study materials that will need to be changed if the individual is referenced by name.

List personnel who have departed.

| Name | Project Role | Date Departed |
|------|--------------|---------------|
| | | |
| | | |

Is an approved Scope of Practice on file for all new study team members for whom it is required?

Yes No.

. If no, indicate why and, if applicable, the status of this being accomplished:

VI. Informed Consent Changes N/A

If the requested modifications do not involve any changes in the informed consent documents or the informed consent process check the N/A block above and proceed to Section VII.

For changes requested in the informed consent process and/or informed consent documents, please complete the below items

1. Will you keep enrolling participants while these changes are being considered?

Yes No

b. Will the updated consent document contain new information which may affect current participants willingness to continue to participate?

Yes No

If yes, what is your plan for informing the participants of the changes? *(Please check one)*

- Participants will be re-consented *(Check one and describe re-consenting process below)*
- Immediately (Due to substantive change in risk)
- Next Study visit
- Other *(Describe below)*

Participants will be informed via letter *(Attached proposed letter to participants and describe how the letter will be sent to participants below)*

Other *(Please describe below)*

If any of the above three boxes have been checked, provide requested description below:

VII. Investigator Risk Assessment

The Principal Investigator/Study Chair or Local Site Investigator must check the applicable block and sign/date the amendment request below.

| | |
|--------------------------|---|
| <input type="checkbox"/> | There is no change in risks to participants enrolled or to be enrolled in the project. |
| <input type="checkbox"/> | There is an increase in risks to participants enrolled or to be enrolled in the project. Reasons and rationale are detailed in Section III. |
| <input type="checkbox"/> | There is a decrease in risks to participants enrolled or to be enrolled in the project. Reasons and rationale are detailed in Section III. |

I certify that all changes to be made in this approved project have been reported on this form and the attached documents. I attest that the project continues to be scientifically and ethically sound. I and my study team will continue to meet the ethical standards for research involving human participants and will comply with all VA Central IRB requirements for approval of this amendment.

Signature of LSI or PI/SC or Co-LSI or Co-PI/SC

Date

Submission Instructions

The VA Central IRB currently uses a secure SharePoint site for submission of project documents by project team members. Since this is a limited access site, if you do not already have access and need to submit an amendment, please contact the PRIDE Technical Support Specialist at 202-443-5653 or the VA Central IRB Administrator at 202-443-5649 to obtain access and further instructions.

For PI/SC Study Teams: Submit VA Central IRB 116 along with supporting documents. For PI/SC amendments requiring changes in associated Local Site documents, ensure that these are changed as required upon approval of the PI/SC amendment and uploaded to the VA Central IRB SharePoint site. PI/SC study teams should determine if they want to review all local site amendments prior to submission to the VA Central IRB or let the LSI sites submit these directly. This decision should be communicated to the Local Site Investigators and to the VA Central IRB. See below for further information about changes.

For Local Site Investigators: When submitting an LSI amendment, an update in response to an approved PI/SC amendment, or an administrative update, please ensure that the PI/SC receives a copy. The PI/SC study team will upload the document or authorize your site to upload the document. Do not revise and submit VA Central IRB Form 104. Please see below concerning how local site amendments and administrative updates should be submitted. See below for further information about changes.

Changes required as a result of an approved PI/SC amendment

- *If an approved PI/SC amendment affects documents that must be changed at the local site, submission of a VA Central IRB Form 116 is not required if only local contact information is being changed and no other change from the approved PI/SC amendment is being requested. The VA Central IRB Administration Office will verify the changes have been made upon receipt of the local documents, post them to SharePoint as a verified update, and send a verification memorandum to the study team with a link to the verified documents.*
- *If the changes involved revisions in the local informed consent document, the local informed consent form will be stamped with the PI/SC amendment approval date, as well as the local informed consent document verification date. These will not be processed as amendments requiring a review and determination by a voting member of the VA Central IRB. If the local site requested additional changes other than what was approved in the PI/SC amendment, a VA Central IRB Form 116 will need to be submitted by the local site in addition to the documents requiring verification based on the PI/SC approved amendment.*

Administrative Changes

- *If an administrative change is required in PI/SC and/or local site documents, i.e., changes in phone numbers, room numbers, etc. that does not change any procedure or any aspect of the approved PI/SC or LSI Application, both a clean and tracked changes version of the documents may be submitted to the VA Central IRB Manager for the study, along with a memorandum or e-mail detailing the changes. The VA Central IRB Manager will perform verification, add the changed documents to the approved study package on SharePoint and notify the study team that this has been done. These will not be processed as amendments requiring a review and determination of a voting member of the VA Central IRB.*

Local Site-Specific Changes

- *Submit a VA Central IRB Form 116 along with associated documents to the PI/SC study team if required. The PI/SC study team will upload or authorize the local study team to upload the documents to the VA Central IRB SharePoint site. Do not submit a revised VA Central IRB Form 104.*

For any other questions, please contact the VA Central IRB staff by e-mail at va.central.irb@va.gov or at the following toll-free number: 877-254-3130.

Change in or Addition of Principal Investigator /Study Chair (PI/SC)



VA Institutional Review Board for Multisite Studies

Use this form to request a change in or the of a Principal Investigator/Study Chair (PI/SC) who will be responsible for overseeing the overall conduct of a multisite research project for a study that approved by the VA Central IRB. This form is not to be used when there is a change in the Local Site Investigator at a participating site (see VA Central IRB Form 134b.)

Section 1: Site and Study Information

VA Facility Location:

VA Central IRB Study Number:

Title of Project:

Current PI/SC or Co-PI/SC Name:

PI/SC Application Amendment #:

Check the Applicable Box: Change PI/SC Addition of Co-PI/SC

Section 2: New Principal Investigator/Study (PI/SC) Chair General Information

New PI/SC) Name:

Academic Degrees:

Board Certifications:

Employment Status: (Check all that apply)

- VA Employee (Indicate VA percentage of time in 8ths _____)
- VA WOC/IPA
- Other (Specify) _____

VA Facility Location of new PI/Co-PI:

Is this the same facility as the previous PI/Co-PI or from a site already approved to participate in this study?

Yes No *If no, see question 5 in this section.*

Contact Information:

Phone:

VA E-mail:

Please note: The VA Central IRB can only send official study correspondence to the LSI's VA e-mail address and access to the VA SharePoint site is only granted through VA e-mail addresses.

- 1. Describe your qualifications to oversee the research detailed in this project and attach a copy of your CV or bio-sketch (Merit Review or NIH format). Be specific in regards to your research experience.**

Note: If you do not have any prior research experience, please indicate what provisions are being made to provide oversight or mentoring.

2. Indicate the date of your latest VA Human Subjects Protection Training:

Note: Completion date of training must be current within 3 years of submission date.

3. Indicate below how many of the following you currently supervise as a PI, Study Chair, or LSI (excluding this current application):

Open Research Projects Project Team Members
 Participating Sites Approximate Number of Active Project Participants

4. Has your participation in this project been reviewed by your local Conflict of Interest Committee or in accordance with your local conflict of interest policies and procedures? (Check only one box below)

- Yes. The determination of my local Conflict of Interest Committee or other local Conflict of Interest official review is attached.
- Review is pending. A determination will be forwarded upon completion of review. I understand no final decision regarding approval of this change can be made by the VA Central IRB until the local Conflict of Interest Committee or other local Conflict of Interest official determinations have been received and reviewed.
- There is no mechanism at our local site for doing the COI review. A copy of a completed OGE Form 450-VA Alternative, Research Financial Conflict of Interest, is enclosed.

5. Is a separate Local Site Investigator Application going to be submitted from the new PI/SC or Co-PI/SC site? A separate Local Site Investigator Application will need to be submitted if potential participants in the study will be recruited at the site and/or participating in the study using site resources. Please contact the VA Central IRB Administration Office if you have further questions concerning whether a separate Local Site Investigator Application is needed.

- N/A. PI/SC or Co-PI/SC is from same site as previous PI/SC or Co-PI/SC. Skip to section 3.
- Yes. List personnel below from this site only that will be assisting the Co- PI/SC in managing the overall study. Information on other study team members from this site who will be involved in local site issues only can be listed on the Local Site Investigator Application.
- No. Complete the below information for all personnel participating in the study at the site.
 - a. List project team members in the table below who will be involved in directing and/or conducting the overall project at this site. Submit conflict of interest determinations and attach biosketches or CVs of all study team members who function in an investigator role.

| Project Team Member | VA Status, i.e., # of 8ths or a WOC/ IPA | Degrees | Project Role | Access to Identifiable data? Yes/No | Obtaining Informed Consent? Yes/No | Date of Latest VA Human Subjects Protection Training |
|---------------------|--|---------|--------------|-------------------------------------|------------------------------------|--|
| | | | | | | |
| | | | | | | |
| | | | | | | |

Note: Additional project members may be added by inserting more rows in the table. If some project members are unknown at this time, they can be added at a later date through submission of an amendment.

b. Are there any applicable state and local laws at this site that differ from VA and other federal requirements concerning the conduct of human research (e.g., who may serve as a legally authorized representative?)

Yes No

If yes, please describe:

Section 3: New PI/SC or Co-PI/SC Statement

1. As a new PI/SC or a Co-PI/SC for this project, I acknowledge the following:

- I have the primary and ultimate responsibility for protecting the rights and welfare of research participants. I understand the ethical principles of human participant protection and Good Clinical Practice and I have the competencies and necessary resources to oversee the conduct of the research as currently outlined in the approved protocol.
- All new project team members will be trained on applicable project procedures and on all VA and other requirements pertaining to human participant protections as befits their roles, scope of practice, and responsibilities prior to participating in the project. I and my study team will conduct and oversee this project in accordance with all ethical standards required by the VA for the conduct of human subjects research.

2. I have read, understand, and accept the investigator responsibilities as outlined in VHA Handbook 1200.05 and that these include but are not limited to the following:

- Conducting the research in accordance with the VA Central IRB-approved project and all applicable VA and other requirements, including, but not limited to, human research requirements as described in VHA Handbook 1200.05, 38 CFR Part 16, FDA requirements, VA Central IRB requirements, and local policy and procedures, and maintaining all written documentation indicating compliance.
- Submitting all amendments to the project or changes in the informed consent to the VA Central IRB for review and approval prior to initiation, except when necessary to eliminate immediate hazard to the participants. Any changes implemented as a result of an immediate hazard will be promptly reported to the VA Central IRB as a project deviation and an amendment submitted if determined necessary.
- Promptly reporting to the VA Central IRB any reportable activity as defined by VA and other requirements and by VA Central IRB policies and procedures, to include interim results if available.
- Conducting project monitoring and data safety monitoring activities (if applicable) as appropriate for the IRB-approved project.
- Providing continuing review and closure reports to the VA Central IRB in a timely manner and in accordance with the VA Central IRB policies and procedures, to include reports of any unanticipated problems involving risks to subject or others and/or serious and continuing noncompliance.
- Following applicable requirements (e.g., information security) relevant to the conduct of the VA Central IRB-approved project and the maintenance of research records in accordance with the VA Records Control Schedule.
- Ensuring research does not start until final approval has been received from the VA Central IRB, other VA and federal requirements, and this facility's local Research and Development Office in accordance with local policies.

- Maintaining all study records in accordance with the VA Records Control Schedule.

PI/SC or Co-PI/SC Signature

Date

Checklist for submission

1. Please check to ensure all these mandatory documents are included in this package:

- Change in Principal Investigator/Study Chair (PI/SC) (VA Central IRB Form 134a)
- PI/SC or Co-PI/SC Biosketch (Merit Review or NIH Format)
- PI/SC or Co-PI/SC Conflict of Interest Determination or OGE Form 450-VA Alternative, Research Financial Conflict of Interest Determination.
- Local ACOS/R&D Review Supplement (VA Central IRB Form 102)

2. Include these documents if applicable to the study. There should be no changes in these documents other than the name and contact information of the new Principal Investigator/Study Chair. If other changes are required, a VA Central IRB Form 116, Request to Amend or Modify an Approved Project, should also be submitted. Please use the Microsoft Word track changes function to indicate modifications. Submit both tracked and untracked versions of the documents if such changes were made.

- VA Research Model Consent Form with Updated Version number/dates
- Revised Protocol with Updated Version number
- VA Investigational Drug Information Record (VA Form 10-9012) with Updated Version number/dates
- Model HIPAA Authorization form with Updated Version number/dates
- Model Recruitment Materials with Updated Version number/dates
- Model Participant Study Instructions with Updated Version number/dates
- Model Versions of Questionnaires or Surveys with Updated Version number/dates
- Model Scripts with Updated Version number/dates

List below any other documentation included in this application:

2. Review your application and obtain the signature of local ACOS/R&D on VA Central IRB Form 102, Local ACOS/R&D Review Supplement.

For any other questions, please contact the VA Central IRB staff by e-mail at va.central.irb@va.gov or at the following toll-free number: 877-254-3130.

Change in or Addition of Local Site Investigator (LSI)



Use this form to request a change in or the addition of a Local Site Investigator (LSI) who will be responsible for overseeing the conduct of a research project at a local participating site that was approved by the VA Central IRB. Use VA Central IRB Form 134a when there is a change in the overall Principal Investigator/Study Chair (PI/SC) or Co-PI/SC for a multi-site study.

Section 1: Site and Study Information

VA Facility Location:

VA Central IRB Study Number:

Title of Project:

Current Local Site Investigator Name:

Local Site Investigator Application Amendment #:

Check the Applicable Box: Change in LSI Addition of Co-LSI

Section 2: New Local Site Investigator General Information

New Local Site Investigator (LSI) Name:

Academic Degrees:

Board Certifications:

Employment Status: (Check all that apply)

VA Employee (Indicate VA percentage of time in 8ths _____)

VA WOC/IPA

Other (Specify) _____

Contact Information:

Phone:

VA E-mail:

Please note: The VA Central IRB can only send official study correspondence to the LSI's VA e-mail address and access to the VA SharePoint site is only granted through VA e-mail addresses.

1. Describe your qualifications to do the research detailed in this project and attach a copy of your CV or bio-sketch (Merit Review or NIH format). Be specific in regards to your research experience.

Note: If you do not have any prior research experience, please indicate what provisions are being made to provide oversight or mentoring.

2. Indicate the date of your latest VA Human Subjects Protection Training:

Note: Completion date of training must be current within 3 years of submission date.

3. Indicate below how many of the following you currently supervise as a PI, Study Chair, or LSI (excluding this current application):

_____ Open Research Projects
_____ Participating Sites

_____ Project Team Members
_____ Approximate Number of Active Project Participants

4. Has your participation in this project been reviewed by your local Conflict of Interest Committee or in accordance with your local conflict of interest policies and procedures?
(Check only one box below)

- Yes. The determination of my local Conflict of Interest Committee or other local Conflict of Interest official review is attached.
- Review is pending. A determination will be forwarded upon completion of review. I understand no final decision regarding approval of this change can be made by the VA Central IRB until the local Conflict of Interest Committee or other local Conflict of Interest official determinations have been received and reviewed.
- There is no mechanism at our local site for doing the COI review. A copy of a completed OCE 450 – VA Alternative, Revised Financial Conflict of Interest, form is enclosed.

Section 3: New Local Site Investigator Statement

1. As a new Local Site Investigator for this project, I attest to the following:

- I have reviewed the currently approved Project File, to include both the PI/SC and LSI approved applications and any associated amendments. I have not made any changes other than my name and contact information in all associated documents. If any other changes need to be made, I will submit a VA Central IRB Form 116, Request to Amend or Modify an Approved Project.
- I have adequate local resources and time to complete this project.
- All members of the local project team will continue to be trained on applicable project procedures, to include informed consent procedures if applicable, and on all VA and other requirements pertaining to human participant protections as befits their roles and responsibilities detailed in their scope of practice, prior to participating in the project.
- If applicable, the project team continues to have access to a population that will allow recruitment of the required number of participants.
- Our local VA facility continues to have adequate resources to support the conduct of this project, including medical and psychological resources that participants might require as a consequence of their participation in the project.

2. I have read, understand, and accept the investigator responsibilities as outlined in VHA Handbook 1200.05 as they pertain to the conduct of this study at this site and that these include but are not limited to the following:

- Conducting the project according to all applicable requirements, including but not limited to VHA Handbook 1200.05, 38 CFR 16, FDA requirements, VA Central IRB requirements, and local policy and procedures.
- Maintaining all research records in accordance with the VA Records Control Schedule.
- Not making any changes to the protocol, informed consent document or process, or any other associated documents without prior VA Central IRB approval, except to eliminate immediate hazards to participants.

- Promptly reporting to the VA Central IRB any new conflict of interest and any reportable activities as defined by VHA Handbook 1058.01.
- Cooperating with the Principal Investigator/Study Chair in the submission of all continuing review reports in a timely manner to avoid any lapses in VA Central IRB approval.
- Following applicable requirements VA privacy and information security policies relevant to the conduct of the VA Central IRB-approved project
- Ensuring the research does not start or any changes are implemented, except as described above, until notice of approval has been received from the VA Central IRB, this facility's local Research and Development Office in accordance with local policies, and for .

New Local Site Investigator Signature

Date

Checklist for Submission

1. Check to ensure all these mandatory documents are included in this package:

- Change in or Addition of Local Site Investigator (VA Central IRB Form 134b)
- Local Site Investigator Bio-sketch (Merit Review or NIH Format)
- Local Conflict of Interest Determination or ORD required Conflict of Interest Form (OGE Form 450)
- Local ACOS/R&D Review Supplement (VA Central IRB Form 102)

2. Include these documents if applicable to the study. There should be no changes in these documents other than the name and contact information of the new Local Site Investigator. If other changes are required, a VA Central IRB Form 116, Request to Amend or Modify an Approved Project, should also be submitted. Please use the Microsoft Word track changes function to indicate modifications. Submit both tracked and untracked versions of the documents if such changes were made.

- VA Research Consent Form with Updated Version number/dates
- VA Investigational Drug Information Record (VA Form 10-9012) with Updated Version number/dates
- Local HIPAA Authorization form with Updated Version number/dates
- Local Recruitment Materials with Updated Version number/dates
- Local Participant Study Instructions with Updated Version number/dates
- Local Versions of Questionnaires or Surveys with Updated Version number/dates
- Local Scripts with Updated Version number/dates

List below any other documentation included in this application:

3. Review your entire application prior to submission and obtain the signature of local ACOS/R&D on VA Central IRB form 102, Local ACOS//R&D Review Supplement.

4. Contact your PI/SC Study Team or the VA Central IRB Manager for the study for submission instructions.

For any other questions, please contact the VA Central IRB staff by e-mail at va.central.irb@va.gov or at the following toll-free number: 877-254-3130.