

TITLE: Application Requirements for New Projects Funded or Sponsored by the Office of Research and Development (ORD) Services

1.0 PURPOSE

This Standard Operating Procedure describes the application requirements that must be met by Principal Investigators (PIs) or Study Chairs (SCs) and Local Site Investigators (LSIs) for submitting new projects involving multi-site human participant research to the VA Central IRB for review. It also describes the policies and procedures the VA Central IRB administrative staff members follow when conducting administrative reviews of new project applications and scheduling projects for review by the VA Central IRB.

2.0 REVISION HISTORY

Date of Initial Approval	April 16, 2009
Revision Dates	April 16, 2009 September 23, 2009 March 17, 2010 September 13, 2010 August 11, 2011

3.0 SCOPE

3.1 This SOP applies to new ORD multi-site projects designated by one of the ORD services for review by the VA Central IRB. The ORD services designating the projects for review by the VA Central IRB are:

- Clinical Science Research and Development (CSR&D), to include the Cooperative Studies Program (CSP); currently all new CSP studies are submitted to the VA Central IRB.
- Health Services Research and Development (HSR&D), to include the Quality Enhancement Research Initiative (QUERI)
- Rehabilitation Research and Development Service (RR&D)

3.2 This SOP does not pertain to requests for exemption, which are covered in VA Central IRB SOP 107, Requests for Exemption Review and Determination.

4.0 POLICY

4.1 The VA Central IRB only accepts new multi-site projects for review that have been referred to it by one of the ORD funding services listed in paragraph 3.1. These projects have gone through a scientific merit review as part of the funding process. A single site pilot project that has the potential to expand to a multi-site project will also be accepted for review.

4.2 It is the policy of the VA Central IRB that a project is not scheduled for initial review by the VA Central IRB until all application requirements as detailed in this SOP are met. New project applications and associated documents must contain a sufficient description of the proposed research for the VA Central IRB to make an informed determination regarding all required regulatory approval criteria, as well as VA and VA Central IRB requirements.

5.0 DEFINITIONS

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

6.0 RESPONSIBILITIES

6.1 Principal Investigator /Study Chair (PI/SC) – The PI/SC is responsible for the overall conduct of the project and for ensuring implementation of the project is in compliance with VA and all other requirements for the conduct of human research in accordance with paragraph 9 of VHA Handbook 1200.05. The PI/SC and the PI/SC's National Study Coordinator serve as the main points of contact on the study team for the VA Central IRB regarding the project. For the purposes of this SOP, the PI/SC is responsible for the following:

6.1.1 The PI/SC, or designee, submits all required documentation regarding the project to the VA Central IRB, to include all requirements as specified in VHA Handbook 1200.05, paragraph 10. This documentation includes but is not limited to the VA Central IRB Form 108, Principal Investigator/Study Chair New Project Application (Attachment 1) and all associated attachments to include the protocol and the informed consent document and HIPAA authorization if applicable.

6.1.2 For some projects, there may be one or more Co-PI/SCs designated. For these projects, one of the Co-PI/SCs must complete the VA Form 108 and the other Co-PI/SC(s) must complete a VA Form 108a (Attachment 2), Co-PI New Project Supplement, and submit this form with the VA Central IRB Form 108 as part of the complete application package.

6.1.3 A PI/SC may also serve as the LSI for his or her home site. In this case, the PI/SC also prepares the VA Central IRB Form 104, Local Site Investigator Application (Attachment 3), to include all associated attachments, for the specific site.

6.1.4 The PI/SC recruits the LSIs for each of the other participating sites as applicable. The PI/SC is responsible for reviewing all the LSI applications to ensure consistency with the PI/SC application and/or any modifications that are requested by the VA Central IRB. The PI/SC then submits the LSI applications to the VA Central IRB. The PI/SC is responsible for ensuring

that no research begins at any of the engaged sites in the study until all required approvals have been received.

6.2 Local Site Investigator (LSI) – The LSI must provide a rationale for any differences between the PI/SC and LSI application. The LSI is responsible for all aspects of the research project conducted at the local site in accordance with paragraph 9 of VHA Handbook 1200.05 and for ensuring compliance at that site with all VA and other requirements for the conduct of human research. For the purposes of this SOP, the LSI recruits the local site project team and prepares the LSI Application for the specific participating local site. The LSI is responsible for not beginning any research project at that site until all required approvals have been received.

6.3 Project Team Members – All project team members at each participating local site, including the PI/SC and LSIs, are responsible for following the project plan, identifying any conflicts of interest, maintaining research records in accordance with VHA Handbook 1200.05, paragraph 9i, and adhering to all VA and other requirements regarding the conduct of human research. They are also responsible for remaining current on all VA required training on the protection of human research participants, as well as VA data security and privacy requirements.

6.4 Associate Chief of Staff for Research and Development (ACOS/R&D) – For the purposes of this SOP, the ACOS/R&D is responsible for reviewing the PI/SC New Project Application or the LSI New Project Application as applicable, prior to submission to the VA Central IRB. The ACOS/R&D signs the applicable application certifying the following on behalf of the PI/SC site and/or the local participating site:

- The PI/SC, or LSI as applicable, and the rest of the project team have the experience and training needed to conduct the project.
- All the site project team members have been appropriately credentialed and privileged and they have all completed required VA training in the protection of human research participants and if applicable, Good Clinical Practices.
- The local facility has reviewed or is in the process of reviewing any potential conflicts of interest of local site project team members and the results of the review have been or will be forwarded to the VA Central IRB.
- The facility and the PI/SC and/or LSI as applicable have the resources to support the functions and operations of the project as detailed
- If there are any local context issues requiring review by the VA Central IRB that these have been identified in the application
- The project will not begin at the local participating facility until the PI/SC, or LSI as applicable, has received written approval to initiate the study in accordance with VHA Handbook 1200.01.

6.5 VA Central IRB – The VA Central IRB is responsible for fulfilling all responsibilities and performing all functions of an IRB of record as specified in VHA Handbook 1200.05 for all projects it receives for review. Once a project is approved, the VA Central IRB is responsible for overseeing the project and conducting continuing review as required.

6.6 VA Central IRB Coordinator – For the purposes of this SOP, the assigned VA Central IRB Coordinator is responsible for completing the following for all projects assigned:

- Entering the new project application into the VA Central IRB Project Tracking Logs
- Performing administrative review of submitted project applications to ensure they are complete
- Working with the PI/SC, LSIs, and local site points of contact to obtain any missing or incomplete documentation/information
- Completing VA Central IRB Form 109a, Site Tracking Log (Attachment 3), and using it to track all local site application submissions for a specific project
- Completing the VA Central IRB Form 109b, Administrative Checklist for PI/SC New Project Application (Attachment 4)
- Completing the VA Central IRB Form 109c, Administrative Checklist for Local Site Investigator Applications (Attachment 5)

6.7 VA Central IRB Administrator – For the purposes of this SOP, the VA Central IRB Administrator is responsible for the following:

- Coordinating application deadlines and VA Central IRB meeting dates with the VA Central IRB Co-Chairs, ensuring these are communicated to the project teams, and publishing them on the VA Central IRB website
- Working with the PI/SC and local site project teams to educate them on new project application requirements and procedures
- Ensuring that the participating local sites for a new project have entered into an MOU with the VHACO and listed the VA Central IRB as an IRB of record on their FWA
- Educating participating local sites on their responsibilities under the MOU through the use of webinars, informative website content, conference calls, and in-person seminars
- Assigning new projects upon receipt to a VA Central IRB Coordinator
- Assisting the VA Central IRB Coordinators in obtaining missing documentation and in communicating with the PI/SC, LSIs, and the local sites as needed
- Coordinating the workload to ensure that it is evenly distributed among the VA Central IRB Coordinators
- Ensuring all new projects submitted are entered into the applicable VA Central IRB Project Tracking Logs and that these are kept up-to-date

- Ensuring that projects are scheduled for review by the IRB in a timely manner while still allowing IRB members sufficient time to perform a thorough review

6.8 For all Office of Research and Development Cooperative Studies Program projects and for all other studies that use a Coordinating Center to assist in the management of the multi-site study, a VA Central IRB 108b, Coordinating Center PI/SC New Project Application Supplement (Attachment 6), must be completed and submitted with the PI/SC New Project Application. If the PI/SC is located at the same site as the Coordinating the ACOS/R&D does not need to sign the VA Central IRB 108b in addition to the VA Central IRB Form 108.

7.0 PROCEDURES

7.1 Projects to be Submitted to the VA Central IRB and Pre-Submission Requirements.

7.1.1 Currently, the Cooperative Studies Program Central Office has determined all new multi-site CSP studies will be submitted to the VA Central IRB for review. As of September 30, 2010, all other ORD service (HSR&D, QUERI, and RR&D) multi-site new projects that have not been previously reviewed by an IRB must also be submitted to the VA Central IRB for review. An investigator, whether the investigator is the PI/SC or an LSI, cannot choose to use another IRB for review of these projects.

7.1.2 Each ORD service, or in some instances the PI/SC, provides the following information to the VA Central IRB Administrator upon a project being approved for funding.

- Title of the project and assigned ORD service project number if applicable
- Name and contact information for the PI/SC
- The name and point of contact for the project manager or national coordinator
- A list of potential participating sites if available
- A copy of the scientific merit review results if applicable

7.1.3 The VA Central IRB Administrator reviews the list of potential participating sites to ensure that all identified sites have an active MOU on file and have listed the VA Central IRB on their local facility FWA.

7.1.3.1 The VA Central IRB Administrator contacts sites that have not listed the VA Central IRB as an IRB of record and assists them in submitting all required documentation in accordance with VA Central IRB SOP 101, VA Central IRB Authority, Responsibilities, and Activities.

7.1.3.2 For projects under the Cooperative Studies Program (CSP), the VA Central IRB Administrator checks and ensures the following:

7.1.3.2.1 That the local facility in which the CSP Coordinating Center (CSPCC) involved in the project is housed has a current MOU on file and that the VA Central IRB is listed as an IRB of record as required by VA Central IRB SOP 101, VA Central Institutional Review Board (IRB) Authorities, Responsibilities, and Activities.

7.1.3.2.2 If the PI/SC is located at a facility that is not otherwise a participating site, that the PI/SC's site has a current MOU on file and that the VA Central IRB is listed as an IRB of record for the facility.

7.1.3.3 If the PI/SC is still in the process of recruiting local sites, the PI/SC may forward the names of the potential sites and LSIs to the VA Central IRB Administrator as they become known. The VA Central IRB Administrator ensures that regular contact is kept with the PI/SC during an ongoing site recruitment process to facilitate communication with the potential sites as soon as possible.

7.1.4 The VA Central IRB Administrator contacts the PI/SCs and project manager/national coordinator of designated projects and informs them of the following:

- PI/SC New Project Application requirements to include:
 - Application deadlines
 - Development of model forms for use by local participating sites in developing their own local forms for participants
 - Submission procedures
- IRB review procedures

7.1.5 The VA Central IRB Administrator makes available to the PI/SC, LSIs, and other members of the project team as applicable to schedule an optional investigator webinar presented by the VA Central IRB using the VA Live Meeting functionality. This educational webinar reviews the VA Central IRB application process and the various application forms, as well as providing a forum for investigator questions to VA Central IRB staff. This is recommended when there are a large number of sites that will be participating.

7.2 Application Requirements for PI/SCs.

7.2.1 The PI/SC should thoroughly review all application instructions and complete all required forms in order to ensure timely processing of the project by the VA Central IRB. The PI/SC is encouraged to contact the VA Central IRB Administrative Office throughout the process of completing the VA Central IRB Form 108, PI/SC New Project Application, and any other required

forms, with questions or concerns. LSI Applications cannot be submitted until the main project application has been reviewed by the VA Central IRB.

7.2.2 Prior to submitting the application package to the VA Central IRB the PI/SC must ensure the following:

- The latest version of the grant application, or the protocol as applicable, and funding letter are attached to the application package
- That the documents checked on the front page of the VA Central IRB Form 108 are included as part of the package or are listed as "Pending" if they are not attached at the time of initial submission
- The VA Central IRB Protocol Supplement for Multi-site Studies (Attachment 8), describing how the PI/SC will manage the overall study and communicate with the participating sites must be included or submitted prior to final review and approval
- All informed consent forms, if applicable must be submitted in Microsoft Word format
- The signatures of the applicable Department Chief of the department the PI/SC is assigned, or the Chief of Staff if the PI/SC is a Department Chief, and the local ACOS/R&D are obtained certifying their review and concurrence with the contents of the package. If the ACOS/R&D is the PI/SC, the Chief of Staff signs in place of the ACOS/R&D.

7.2.3 The PI/SC must meet the above requirements and the following additional minimum application submission requirements in order for a project to be accepted for review by the VA Central IRB:

7.2.3.1 One signed copy of the application package must be submitted in electronic format via encrypted e-mail, encrypted CD/DVD, or uploaded onto the VA Central IRB SharePoint site. Other electronic methods of submission may be authorized on a case-by-case basis in consultation with the VA Central IRB Administrator based on local capabilities as long as all VA information security requirements are met. If a signed copy cannot be submitted electronically, the signature pages can be submitted via or express mail.

7.2.3.2 A PI/SC New Project Application package must be received by the VA Central IRB Administration Office no later 15 working days prior to a scheduled meeting of the VA Central IRB in order to be considered for review at that meeting. However, if the application is not complete or there are significant deficiencies, it will not be scheduled for review until these deficiencies are addressed. Exceptions to this policy can be made by a Co-Chair.

7.2.3.3 If a PI/SC wants to request that the project be reviewed utilizing expedited review procedures, the PI/SC can complete a VA Central IRB Form 126, Request for Expedited Review (Attachment 7), and attach it to the application package.

7.3 Application Requirements for Local Site Investigators.

7.3.1 The PI/SC project team will provide the LSIs at the potential participating sites with a copy of the PI/SC New Project Application package as reviewed and approved by the VA Central IRB and assist the LSIs in compiling and preparing the LSI Applications. Additionally, LSIs, and local study coordinators if applicable, will be given access to the VA Central IRB SharePoint PI/SC folder. The PI/SC study team will set internal project deadlines for submission of the LSI Applications to the PI/SC study team. All LSI Applications are submitted to the VA Central IRB through the PI/SC project team unless an exception is requested and approved by both the PI/SC study team and the VA Central IRB Administrator.

7.3.1.1 The LSI is expected to thoroughly review all application instructions and complete all required forms to ensure timely processing of their Local Investigator Site Application by the VA Central IRB. The LSI may also contact the VA Central IRB Administrative Office with questions or concerns throughout the application process.

7.3.1.2 Model forms may have been provided to the LSI by the PI/SC, including a model informed consent document. Other than changes in local site contact information, LSIs must ensure that any other changes made to the model forms are highlighted and justification for the changes provided. If changes to the model form are made, the LSI provides a copy of the form with the changes highlighted or shown in the track change function of Microsoft Word. A clean copy without highlights or tracked changes must also be included as part of the application package.

7.3.1.3 In addition to providing justification for any changes to the model forms provided by the PI/SC, the LSI must provide a rationale for any difference in the LSI Application and the information provided in the PI/SC Application and protocol.

7.3.1.4 Prior to submission of the VA Central IRB Form 104 application package to the PI/SC project team, the LSI ensures a review has been completed by the applicable Department Chief or the LSI's supervisor and the local facility ACOS/R&D and both their signatures obtained on the VA Central IRB 104.

7.3.2 The LSI submits a minimum of one signed electronic copy of the application package to the PI/SC study team. The PI/SC project team reviews the LSI Applications from the potential participating sites for consistency with the PI/SC Application and requests any changes as needed. The PI/SC then arranges for the submission of the LSI Applications to the VA Central IRB with the VA Central IRB Coordinator assigned to the project. The VA Central IRB Coordinator arranges for the PI/SC study team to upload the application to the VA Central IRB SharePoint site.

7.3.3 If an exception is granted by the PI/SC study team and the VA Central IRB Administrator, the LSI may submit the LSI Application directly to the VA Central IRB via the SharePoint site. Other methods of electronic submission may be authorized on a case-by-case basis in consultation with the VA Central IRB Administrator and the PI/SC project team based on local capabilities as long as all VA information security requirements are met.

7.3.4 If there are delays in the signing of the MOU, the update of the FWA for a local participating site, or in the submission of the LSI Application from a particular site, the VA Central IRB Coordinator consults with the PI/SC on a course of action. If desired, the PI/SC can add or drop a site from the project by informing the VA Central IRB in writing. If a site is added, the LSI Application for that site must be completed and submitted as described above.

7.4 Administrative Review by the VA Central IRB Administrative Office.

7.4.1 Upon receipt of the PI/SC application package, the VA Central IRB Administrator logs the receipt of the PI/SC New Project Application into the VA Central IRB Form 137, Master Study Status Log (Attachment 9). A VA Central IRB project tracking number is assigned based on the calendar year received and the next available number (e.g., 09-15). The VA Central IRB Administrator also assigns a VA Central IRB Coordinator to the project based on workload. The VA Central IRB Administrator then emails the PI/SC confirming receipt of the project package, relays the assigned tracking number, and gives contact information for the assigned VA Central IRB Coordinator.

7.4.1.1 The assigned VA Central IRB Coordinator will continue as the VA Central IRB Coordinator of the project through the submission and approval of the LSI Applications unless the workload or the departure of a Coordinator requires a change. The assigned VA Central IRB Coordinator will also continue to administratively monitor the study and serve as the main VA Central IRB point of contact for the study once it is approved.

7.4.1.2 The VA Central IRB Coordinator then prepares a VA Central IRB Form 109a, Site Tracking Log (Attachment 10). This form is used to track submission of the PI/SC Application and the Local Site Investigator Applications, as well as the MOU/FWA update status of the sites. In addition, this form is used to track the actions taken by both the VA Central IRB and the sites during the entire review and approval process for the project.

7.4.1.3 The VA Central IRB Coordinator then performs an administrative screening of the PI/SC Application Package using VA Central IRB Form 109b, Administrative Pre-Screening Checklist for PI/SC New Project Applications.

7.4.1.3.1 If required documents are missing or there are other administrative issues that need to be addressed, the VA Central IRB Coordinator contacts the PI/SC study team. The VA Central IRB Coordinator advises the PI/SC study team of the date by which missing documents are needed or any outstanding issues need to be resolved if the project is to be reviewed at the next regularly scheduled convened meeting of the VA Central IRB.

7.4.1.3.2 The VA Central IRB Coordinator follows-up with the investigator in writing no less than once per month until the documents are received or the project is withdrawn by the PI/SC.

7.4.1.4 The VA Central IRB Coordinator documents all contacts with the PI/SC study team concerning study related issues. Routine contacts concerning such issues as logistics for submitting documents, availability for teleconferences etc., need not be documented, as long as they do not pertain to actual protocol-related issues. Upon completion of the administrative review process, all project documents, including any revisions, modifications, other pertinent documents, or correspondence discussing project issues and their resolution are filed in the official project folder and uploaded to the VA Central IRB shared drive. Procedures pertaining to the creation of the official folder can be found in VA Central IRB SOP 116, Maintenance of VA Central IRB Files.

7.4.1.5 Upon completion of the administrative screening process, the VA Central IRB Coordinator signs the VA Central IRB Form 109b and files a copy of the completed checklist with the study file.

7.4.1.6 The VA Central IRB Coordinator then prepares the project for review by assigned VA Central IRB Reviewers in accordance with VA Central IRB SOP 108, VA Central IRB Meeting Preparation and Administration, or VA Central IRB SOP 110, Expedited Review Process, as applicable.

7.4.1.7 In the interest of time, the VA Central IRB Coordinator may forward the application package to the VA Central IRB Regulatory Reviewer and to the Privacy Officer Representative and Information Security Officer Representative prior to the completion of the administrative review in order to facilitate timely comments from those individuals.

7.4.2 Upon receipt of an LSI Application, the assigned VA Central IRB Coordinator updates the protocol tracking logs and assigns the application a VA Central IRB LSI Application number. This number will consist of the project number and a numeric value based on the order in which the LSI Applications are received, i.e., 07-15/1. A separate project folder is created for each participating site submitting an LSI Application.

7.4.2.1 The assigned VA Central IRB Coordinator prepares and completes a VA Central IRB Form 109c, Administrative Pre-Screening Checklist for Local Site Investigator Applications.

7.4.2.1.1 If required documents are missing or there are other administrative issues, the VA Central IRB Coordinator contacts the LSI, or works through the PI/SC study team as requested, to obtain the documentation or a resolution of any other issues. The VA Central IRB Coordinator advises the LSI and/or the PI/SC study team of the date the documents are needed and of the outstanding issues that need to be resolved if the project is to be reviewed at the next regularly scheduled convened VA Central IRB meeting.

7.4.2.1.2 The VA Central IRB Coordinator follows-up in writing no less than once per month until the documents are received, the outstanding issues resolved, or the site is dropped as a participating site in the project by the PI/SC.

7.4.2.1.3 The VA Central IRB Coordinator documents all contacts with the LSIs and keeps hard copies of all written correspondence, including e-mails, in the official folder by site. The only exception is for routine contacts concerning logistical issues that have no bearing on the protocol or protocol-related issues. Upon completion of the administrative review process all project documents, including any revisions submitted and any other pertinent documents discussing project issues and their resolution are filed in the official project folder per VA Central IRB SOP 116.

7.4.3 The assigned VA Central IRB Coordinator keeps the PI/SC study team, and LSI as applicable, updated on the status of the project and sends an update in writing as the project completes each step. The VA Central IRB Coordinator also updates the VA Central IRB Form 109a, Site Tracking Log as applicable.

7.4.4 All documents filed in the official project files, to include documents received from the project team, the completed pre-screening checklists, and any other correspondence pertinent to the content of the project, are also uploaded onto the VA Central IRB shared drive in accordance with VA Central IRB SOP 116.

7.4.5 All project documentation that is actively being worked on by VA Central IRB staff may be kept in the various office locations of the VA Central IRB administrative staff who are working on them. All project documentation will be secured under lock and key at the end of the work day.

7.5 VA Central IRB Website. The VA Central IRB Administrator provides content to the PRIDE website developers as it relates to the VA Central IRB new project application process. This content contains the latest information about

the VA Central IRB project application process and submission requirements including but not limited to the following:

- Information for Investigators and Local Participating Sites on VA Central IRB submission requirements and review processes
- Application deadlines and meeting dates
- VA Central IRB SOPs and electronic forms for download
- List of sites with approved and current MOUs already in place
- A "What's New" link to highlight new or revised items that have been added to the site
- Point of Contact Information

8.0 REFERENCES

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

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

8.3 VHA Handbook 1058.03, Assurance of Protection for Human Subjects in Research

8.4 VHA Handbook 1108.04, Investigational Drugs and Supplies

8.5 45 CFR 46, Department of Health and Human Services, Protection of Human Subjects, Subparts B through D

8.6 21 CFR 50, U.S. Food and Drug Administration, Protection of Human Subjects

8.7 21 CFR 312, U.S. Food and Drug Administration, Investigational New Drug Application

8.8 21 CFR 361, U.S. Food and Drug Administration, Prescription Drugs for Human Use Generally Recognized as Safe and Effective and not Misbranded: Drugs Used for Research

8.9 21 CFR 600, U.S. Food and Drug Administration, Biological Products: General

8.10 21 CFR 812, U.S. Food and Drug Administration, Investigational Device Exemptions

10 Attachments

1. VA Central IRB Form 108, Principal Investigator/Study Chair New Project Application

2. VA Central IRB Form 108a, Co-Principal Investigator/Study Chair New Project Application Supplement
3. VA Central IRB Form 104, Local Site Investigator Application
4. VA Central IRB Form 109b, Administrative Pre-Screening Checklist for PI/SC New Project Applications
5. VA Central IRB Form 109c, Administrative Pre-Screening Checklist for Local Site Investigator Applications
6. VA Central IRB Form 108b, Coordinating Center PI/SC New Project Application Supplement
7. VA Central IRB Form 126, Request for Expedited Review
8. Protocol Supplement for Multi-Site Studies
9. VA Central IRB Form 137, Master Study Status Log
10. VA Central IRB Form 109a, Local Participating Site Tracking Log

I have reviewed and approved the content of this SOP.



K. Lynn Cates, MD
Director, PRIDE

Date: 8/11/11

Principal Investigator/Study Chair New Project Application



Principal Investigator/Study Chair Name:

Project Title:

Check to indicate application status:

Initial Revised

Date:

Application Instructions

- The VA Central IRB reviews all ORD-funded VA research projects that have more than one VA site engaged in human subjects research, as well as single site pilot studies that, if successful, will eventually have multiple VA sites engaged in human subjects research. The VA Central IRB **does not** review projects that have only one site engaged in human subjects research. If you have any questions as to whether or not your project has more than one VA site engaged in human subjects research, please contact the VA Central IRB Administrator at 202-443-5649 **BEFORE** working on your application for the VA Central IRB.
- The Principal Investigator (PI)/Study Chair (SC) must use this form to submit new research project applications to the VA Central IRB. The PI/SC's Supervisor and ACOS/R&D or Chief of Staff of the PI/SC's site also must complete a portion of this form.
- Each section must contain a response. Please ensure all responses are consistent with the approved funded project and the informed consent and HIPAA Authorization if applicable. Other documents associated with this application as checked below should be submitted with the completed application. Documents can be submitted in PDF or Microsoft Word format with the exception of the informed consent document. This document must be submitted in Microsoft Word. Please ensure the file name includes the name of the document, last name of PI, and date (e.g., 108.PI name.date).

Contents of Application Package (Please check all documents included in this package)

***Indicates a mandatory document for all studies. All VA Central IRB forms indicated below can be found on the VA Central IRB website:**

- | | |
|--|--|
| <input type="checkbox"/> PI/SC New Project Application* | <input type="checkbox"/> HRC Minutes (For CSP studies only) |
| <input type="checkbox"/> Protocol and Protocol Supplement for Multi-Site Studies* | <input type="checkbox"/> Scientific Merit Review Letter or Minutes* |
| <input type="checkbox"/> Conflict of Interest Determination(s)* | <input type="checkbox"/> Vulnerable Population Supplement (VA Central IRB 110 Series) |
| <input type="checkbox"/> Study Team Biosketches (Merit Review/NIH format)* | <input type="checkbox"/> Investigator's Drug Brochure |
| <input type="checkbox"/> Co-PI/Sc New Project Application Supplement (VA Central IRB Form 108a) | <input type="checkbox"/> Investigator Device Information |
| <input type="checkbox"/> Model VA Research Informed Consent Form (VA Form 10-1086) | <input type="checkbox"/> Model Participant Instructions |
| <input type="checkbox"/> Request for Waiver or Alteration of Informed Consent (VA Central IRB Form 112a) | <input type="checkbox"/> Model Recruitment Materials |
| <input type="checkbox"/> Model Consent for Use of Picture and/or Voice (VA Form 10-3202) | <input type="checkbox"/> Model Questionnaires or Surveys |
| <input type="checkbox"/> Request for HIPAA Waiver of Individual Authorization (VA Central IRB Form 103) | <input type="checkbox"/> Model VA Investigational Drug Information (VA Form 10-9012) |
| <input type="checkbox"/> HIPAA Authorization | <input type="checkbox"/> Data Collection Forms/Tools/Case Report Forms/etc. |
| <input type="checkbox"/> Prior Study Informed Consent Form (If this is a follow-up study) | <input type="checkbox"/> Request for Expedited Review (VA Central IRB Form 126) |
| | <input type="checkbox"/> CSP Coordinating Center PI/SC New Project Application Supplement (VA Central IRB Form 108b) |

Please List any other documentation included in this package: (e.g., off-site waiver requests, tissue banking application/approval letter, Certificate of Confidentiality, Data Use Agreements, DMC charter, etc.)

Submission Instructions

1. Please review your entire application prior to submission and ensure the following:

- All three required signatures have been obtained, to include the required signatures if submitting a Co-PI/SC New Project Application Supplement. If submitting a revised application, only the signature of the PI/SC is required. Ensure you include the version number/date for all revisions.
- The attachments match with what you have indicated on the preceding page. If any of the attachments have been revised, include the version number and date of revision.
- Unnecessary page breaks have been removed and any formatting errors have been corrected
- All sections of the application have been completed or marked "Not Applicable."
- If this is a revised application, please include both a "**tracked changes**" and a "**clean**" copy of all revised documents and indicate revision dates on all documents revised.

Please note for CSP studies only: All new applications must either be submitted through the applicable CSP Coordinating Center or include a letter from the Coordinating Center attesting that the application is cleared for submission.

2. Please contact the VA Central IRB Administrator at Annette.Anderson3@va.gov or at va.central.irb@va.gov for instructions on how to upload the application and all associated documents to the VA Central IRB secure SharePoint site. You must have a valid VA e-mail address and be granted access before you can access the secure VA Central IRB SharePoint site.

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.

Please note: After the PI/SC New Project Application is approved, the PI/SC will be responsible for submitting all Local Site Investigator Applications (VA Central IRB Form 104) to the VA Central IRB. It is the PI/SC's responsibility to review all Local Site Investigator Applications to ensure consistency with the approved PI/SC New Project Application.

Project Title:

Section 1: Study General Information

Principal Investigator (PI)/Study Chair (SC) Name:		Academic Degrees:
Board Certifications:		
Is there a Co-PI or Co-Study Chair?		
<input type="checkbox"/> No.		
<input type="checkbox"/> Yes. Name:		Site:
<i>Note: If there is a Co-PI or Co-Study Chair, he or she must complete VA Central IRB Form 108a, Co-PI/SC New Project Application Supplement. This should be signed by the required officials at the Co-PI/SC's site and submitted as an attachment to this application.</i>		
Employment Status: (Check all that apply)		
<input type="checkbox"/> VA Employee (Indicate VA percentage of time in 8ths _____)		
<input type="checkbox"/> VA WOC (Without Compensation)		
<input type="checkbox"/> IPA (Intergovernmental Personnel Act)		
<input type="checkbox"/> Other (Specify) _____		
VA Facility Name:		
VA Station Number:	Phone:	
VA Facility Address:	Fax:	
	VA E-mail:	
Name of Project Coordinator:	Phone:	
FAX:	VA E-mail:	
1. Describe your qualifications to do the research detailed in this project and attach a copy of your biosketch (Merit Review or NIH Format):		
2. Indicate below how many of the following you currently oversee as a PI/SC:		
_____ Open Research Projects	_____ Project Team Members (<i>Project Coordinator, Statistician, etc.</i>)	
_____ Participating Sites	_____ Approximate Number of Active Project Participants	
3. Complete the following regarding human subject training and Conflict of Interest information:		
a. Date of VA Human Participant Protection/Good Clinical Practice Education: (<i>Must be within two years of project submission date</i>)		
b. Has your participation in this project been reviewed by your local Conflict of Interest or in accordance with your local conflict of interest policies and procedures?		
<input type="checkbox"/> Yes. The findings of my local Conflict of Interest Committee or other local Conflict of Interest review are attached.		
<input type="checkbox"/> Review is pending. Determination will be forwarded upon completion of review.		
<input type="checkbox"/> There is no mechanism at our site for doing COI review. Copies of completed disclosure forms for all applicable study team members are attached. <i>Note: Local VA facility forms may be used or, if no local form is available, contact the VA Central IRB Administrator.</i>		

4. Does this project involve a Coordinating Center? Yes No

If yes, please provide the name of the Coordinating Center and contact information below.

Name of Coordinating Center:

Contact Name (Program Manager or other POC):

Phone Number:

E-mail Address:

Note: A VA Central IRB Form 108b, Cooperative Studies Program (CSP) Coordinating Center PI/SC New Project Application must also be completed by Coordinating Center personnel and attached as a supplement to this application.

5. Is a separate Local Site Investigator Application going to be submitted from the 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.

Yes. List personnel below from this site only that will be assisting the 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. Please complete the below information.

a. Please list project team members in the table below who will be involved in directing and/or conducting the overall project at this site. Submit a Conflict of Interest determination for all study members that will participate with 5% or more effort. Attach biosketches or CVs of all study team members who function in a scientific or medical capacity.

Note: Do not list CSP Coordinating Center personnel. If any CSP Personnel are also investigators, these should be listed on the VA Central IRB Form 108b.

Project Team Member	VA Status, i.e., # of 8ths or WOC	Degrees	5% or More Effort? Yes/No	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 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:

c. If applicable per the study design, if the PI/SC is not a clinician, is there an appropriately credentialed and privileged clinician who has been designated as a member of the study team to make required decisions to help protect the health of the subject, review data on adverse events, and report new findings?

Yes No N/A

Section 2: Project Overview

Please Note: For VA Central IRB review, your protocol must contain all information described in Sections 2 through 11 of this Application. In most cases, the protocol submitted for Merit Review will require substantial modifications to meet this requirement.

1. **What type of protocol is this?** (Please check one)

CSP Clinical Science HSR&D Rehab VHA Central Office
 Other (Specify):

2. **Give a brief non-technical summary of the project in terms that would be understandable to non-medical personnel.** (Please limit to a maximum of 500 words as counted by your spell checker.)

3. **Is this a clinical trial?** Yes No

If yes, what type? (Check all that apply)

Phase I Phase II Phase III Phase IV

4. **What is the purpose of the project to include what is the relevance to Veterans?**

5. **What are the research questions or hypotheses?** (Please cite scientific or scholarly rationale.)

6. **What research methods will be used in the project?** (Check all that apply)

<input type="checkbox"/> Surveys/Questionnaires	<input type="checkbox"/> Interviews	<input type="checkbox"/> Audio Taping
<input type="checkbox"/> Behavioral Observations	<input type="checkbox"/> Chart Reviews	<input type="checkbox"/> Video Taping
<input type="checkbox"/> Focus Groups	<input type="checkbox"/> Randomization	<input type="checkbox"/> Double-Blind
<input type="checkbox"/> Control Group	<input type="checkbox"/> Placebo	<input type="checkbox"/> Withhold/Delay Treatment
<input type="checkbox"/> Specimen Collection	<input type="checkbox"/> Deception	<input type="checkbox"/> Other (Specify:)

7. **Describe the project design and procedures, to include methods of statistical analysis, sample size, and power analysis as applicable.**

8. **Does the project involve usual care?** Yes No

If yes, please answer the following additional questions:

a. Who will provide the usual care i.e., the study team or the participant's health care provider?

- b. Clearly differentiate what is usual care and what procedures and/or interventions are being performed solely for research purposes. Indicate if usual care is limited to one arm of the study or if it is being delivered to all participants:

Research procedures:

Usual Care:

9. What is the importance of the knowledge this project is likely to generate?

10. For intervention projects, are there procedures for the orderly withdrawal or termination of participation in the project by the participants?

Yes No Not Applicable

If yes, please briefly describe the procedures or, if not, explain why there is not need for established procedures. (If yes, these procedures also need to be described in the informed consent document.)

11. Does this project involve international research? Yes No

Section 3: Potential Risk/Benefit Analysis

1. What are the potential risks or harms for participants in this project? *Note: Clearly delineate between the risks of usual care and the risks of the research interventions.*

Note: Risks or harms can be physical, psychological, financial, social, or legal. They may involve breaches of confidentiality and privacy.

2. Please indicate the potential risk level of the project: (Minimal Risk is defined as "the probability or 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.")

Minimal Greater than Minimal

Note: The VA Central IRB will make the final determination regarding the risk level of the project.

4. What are the anticipated benefits, if any, to participants or to society from this project?

5. Please describe procedures or monitoring activities designed to minimize risk:

6. Will any of the following be administered to participants or will they be exposed?

Ionizing Radiation Yes No

Radioactive Materials Yes No

7. Check if your study is a prospective or retrospective study.

Prospective Retrospective

Please complete one of the two sections below depending upon the box checked.

If you checked prospective, please specify the details of the plan below. Depending on the study, some of the below items may be N/A:

- a. What safety information, including SAEs/UAPs, will be collected?
- b. How will the safety information be collected? *(e.g. case report forms, at study visits, by follow-up telephone calls with participants)*
- c. The frequency of data collection, to include when safety data collection starts:
- d. If not using a Data Monitoring Committee (DMC), indicate statistical tests to be used for analyzing the safety data to determine if harm is occurring: *Check if N/A*
- e. Specify conditions that would trigger an immediate suspension of the research:
Check if N/A
- f. Specify procedures to determine when and how to notify individual participants or their health care providers of findings that may affect the participant's health or welfare:

If you checked retrospective, please describe your data safety and monitoring plan to include, if applicable a discussion with the study subjects of possible study outcomes that may affect the subject's health or welfare and/or a procedure to determine when and how to notify an individual or their health care provider of findings that may affect the subject's health or welfare.

8. Will an independent Data Safety Monitoring Board (DSMB) or DMC monitor the project?

Yes No

If yes, please provide contact information for the DSMB or DMC or Coordinating Center Representative and attach a copy of the charter or provide a description of its responsibilities:

Name:

Phone Number:

Title:

E-mail:

Check if charter is attached or will be provided.

Description of Responsibilities include frequency of meetings:

9. How will you manage information from participating sites that might be relevant to participant protection and describe how that information will be conveyed to the VA Central IRB (i.e., reports of problems, interim results)?

The Protocol Supplement for Multi-Site studies must also be attached.

Note: The VA Central IRB uses a secure SharePoint site for the reporting of all SAEs, protocol deviations, and unanticipated problems involving risks to subjects or others. See VA Central IRB Table of Reporting Requirements available on the VA Central IRB website and include procedures below, and in protocol, as applicable.

Section 4: Human Participant Information

1. What is your planned total enrollment?

2. Please describe any inclusion or exclusion criteria and provide justification:

3. What populations will be targeted for recruitment as participants? Check all that apply.

Males	<input type="checkbox"/>
Females	<input type="checkbox"/>
Inpatients	<input type="checkbox"/>
Outpatients	<input type="checkbox"/>
VA Employees	<input type="checkbox"/>
Students	<input type="checkbox"/>
Non-English Speaking	<input type="checkbox"/>
Veteran Family members	<input type="checkbox"/>
Non-Veterans*	<input type="checkbox"/>
Other (Specify)	<input type="checkbox"/>

***If non-veterans is marked above, please indicate whether they are bonafide volunteers and explain why sufficient veterans are not available to participate in the project and present additional justification for the inclusion of non-veterans, i.e., the study requires the participation of VA employees who may not be Veterans, the participation of Veteran caregivers or family members etc.:**

4. Does this project target a specific race or ethnic group as participants? Yes No

If yes, check all that apply.

Race	
American Indian or Alaskan Native	<input type="checkbox"/>
Asian	<input type="checkbox"/>
Black or African American	<input type="checkbox"/>
Native Hawaiian or other Pacific Islander	<input type="checkbox"/>
White	<input type="checkbox"/>
Other	<input type="checkbox"/>

Ethnicity	
Hispanic or Latino	<input type="checkbox"/>
Not Hispanic or Latino	<input type="checkbox"/>
Other	<input type="checkbox"/>

Why was this group(s) chosen?

5. What are the age ranges of participants? If yes, check all that apply.

Children (Under 18) <i>Requires Waiver from CRADO</i>	<input type="checkbox"/>
Young Adults (18-21)	<input type="checkbox"/>
Adults (22-65)	<input type="checkbox"/>
Seniors (Over 65)	<input type="checkbox"/>

6. Are there specific reasons why certain populations (i.e., age or ethnic groups) are excluded as participants? Yes No

If yes, please specify reasons:

7. Does the project involve the enrollment of any of the following populations or categories of participants? *Note: These populations must be checked yes if they are not being excluded from the research.*

	Yes	No
a. Employees or students	<input type="checkbox"/>	<input type="checkbox"/>
b. *Individuals with impaired decision making capacity	<input type="checkbox"/>	<input type="checkbox"/>
c. *Pregnant women	<input type="checkbox"/>	<input type="checkbox"/>
d. Economically and/or educationally disadvantaged persons	<input type="checkbox"/>	<input type="checkbox"/>
e. *Prisoners	<input type="checkbox"/>	<input type="checkbox"/>
f. Illiterate, limited, or no English language proficiency	<input type="checkbox"/>	<input type="checkbox"/>
g. Terminally ill patients	<input type="checkbox"/>	<input type="checkbox"/>

8. If applicable, what is the justification for including any of the above populations or categories of participants in the project?

9. If the project involves enrolling any of the above populations or categories of participants, please describe any project-specific measures or special considerations, steps, or safeguards to ensure that these populations or special classes are adequately protected. (**Attach the applicable vulnerable population supplement, VA Central IRB Form 110 series, if enrolling pregnant women, prisoners, or participants with impaired decision-making capacity*)

Section 5: Informed Consent

1. Are you requesting a waiver or alteration of informed consent? *Check all that apply. If more than one box is checked, specify the applicable portion of the study to which the checked box applies.*

<input type="checkbox"/>	No
<input type="checkbox"/>	Yes, a waiver for the entire study. (VA Central IRB Form 112a is attached)
<input type="checkbox"/>	Yes, a waiver for recruitment purposes only. (VA Central IRB Form 112a is attached)
<input type="checkbox"/>	Yes, an alteration of the informed consent process. (VA Central IRB Form 112a is attached).

2. How will informed consent be sought and documented? *Check all that apply. If more than one box is checked, specify the applicable portion of the study to which the checked box applies.*

<input type="checkbox"/>	Informed Consent will not be sought.
<input type="checkbox"/>	Written informed consent from participants (VA Form 10-1086 is attached).
<input type="checkbox"/>	Written informed consent from participants' legally authorized representatives (LAR) as required by VA policy and/or applicable state laws (VA Form 10-1086 is attached).
<input type="checkbox"/>	Request Waiver of Documentation of Informed Consent (VA Central IRB Form 112b is attached).

3. Please describe the plan for training Local Site Investigators on informed consent procedures? Check if Not Applicable. This can only be checked if a waiver of informed consent for the entire study is being sought>

4. Is anyone on the PI/SC study team that is not going to be listed on a Local Site Application going to be involved in obtaining informed consent?

Yes No

If yes, please indicate who will be obtaining informed consent:

5. Does the project propose the use of assent for participants unable to give informed consent?

Yes No Not Applicable

If yes, please describe the process for obtaining assent:

6. How will the participant's privacy interests be protected? Note: Confidentiality of data will be addressed in Section 10.

7. How are participants to be protected against undue influence or coercion?

8. Indicate below what method was used to perform a readability evaluation of the written model informed consent form and the results.

Note: A model VA Form 10-3203, Consent for Use of Picture and/or Voice, must also be submitted when pictures of subjects are taken or a video or audio recording of a research subject is made and documentation of the research subject's participation is included in the research subject's VHA health record.

Section 6: HIPAA Authorization for Project Participants

1. Please check all of the following that apply if Protected Health Information (PHI) will be used. If more than one box is checked, specify the part or phase of the study to which the specific checked boxes apply:

<input type="checkbox"/>	PHI is not being used. HIPAA authorization is not required.
<input type="checkbox"/>	A project specific participant HIPAA Authorization form is attached.
<input type="checkbox"/>	A request for a HIPAA Waiver of Individual Authorization (VA Central IRB Form 103) is attached.
<input type="checkbox"/>	A request for a HIPAA Waiver of Individual Authorization (VA Central IRB Form 103) for recruitment purposes only is attached. If checked, please provide justification:

Please note: The VA Central IRB does not accept informed consent documents that include the HIPAA authorization as part of the informed consent. It must be separate.

2. Will you be requesting that participants authorize release of medical records or health information from non-VA sites? Yes No

If yes, attach a model authorization request.

Section 7: Participant Recruitment Information

1. Please detail your plan for the just, fair, and equitable recruitment and selection of subjects to include where recruitment will take place, methods used, and sequence of recruitment procedures.

Note: VA policy prohibits "cold calls" to potential VA research participants. Initial contact must be made in person or by letter prior to making any telephone contact unless there is written documentation that the subject is willing to be contacted by phone about the specific study or the specific kind of research. Telephone calls must begin by referring to previous contacts, and when applicable, the information provided in the informed consent form and is limited to those topics outlined in the VA Central IRB-approved study package. The initial telephone contact must also provide a telephone number or other means for the potential participant to use to verify the study constitutes VA research.

2. How will the recruitment strategies vary for participating sites?

3. Are any standard recruitment materials going to be made available to Local Participating Sites?

Yes No

4. If yes, please indicate the types of materials to be used below and attach copies:

<input type="checkbox"/>	No advertisements will be used.
<input type="checkbox"/>	Fliers
<input type="checkbox"/>	Newspaper
<input type="checkbox"/>	Letters
<input type="checkbox"/>	Websites
<input type="checkbox"/>	Television
<input type="checkbox"/>	Radio
<input type="checkbox"/>	Video (A script may be provided)
<input type="checkbox"/>	Audio (A script may be provided)
<input type="checkbox"/>	Other (Please specify, i.e., physician referrals)

Note: All recruitment materials must be reviewed and approved by the VA Central IRB prior to being used as part of any recruitment activities. All recruitment materials must include a statement that the study involves VA research and a telephone number or other means for the potential participant to use to verify that the study is VA research.

Section 8: Payment to Participants

Please note: The method and relative amounts) of payment must be the same at all participating sites whenever possible. Local Site Investigators must provide justification to the VA Central IRB for differences in method and/or relative amounts.

1. Please indicate the method of payment:

No Participant Payments	<input type="checkbox"/>
Travel and Parking	<input type="checkbox"/>
Cash or Check	<input type="checkbox"/> Amount per visit: Total amount:
Gift Cards	<input type="checkbox"/> Amount per visit: Total amount:
Other (<i>Specify, i.e., Meal vouchers:</i>)	<input type="checkbox"/> Specify:

2. Provide justification that the proposed payments are reasonable and commensurate with the expected contributions of the participant to the project:

3. If participants are to be paid, specify the following:

- a. Source of payment to include who is dispensing the payment:
- b. Payment schedule to include when payment will be rendered. If not pro-rating payments, indicate why.
- c. Will SSN be requested and/or used in making payment? Yes No

Section 9: Biological Specimens

1. If biological specimens will be used in this protocol, please list below the types of specimens. Not Applicable. Skip to Section 10.

2. Will biological specimens be collected for:

Research purposes only? Yes No
For clinical purposes and used in this study? Yes No

If the answer to both questions is yes, specify which of the specimens indicated in question 1 are collected for each purpose:

For research purposes:

For clinical purposes and used in this study:

3. Please respond to the following questions by checking the appropriate box:

	Yes	No	N/A
a. Does the project involve genetic testing?	<input type="checkbox"/>	<input type="checkbox"/>	
b. Will specimens be kept for future, unspecified use?	<input type="checkbox"/>	<input type="checkbox"/>	
c. Will samples be made anonymous to maintain confidentiality? <i>Note: Coding data is not considered making it anonymous.</i>	<input type="checkbox"/>	<input type="checkbox"/>	
d. Will specimens be destroyed after the project-specific use is completed?	<input type="checkbox"/>	<input type="checkbox"/>	
e. Will specimens be sold in the future?	<input type="checkbox"/>	<input type="checkbox"/>	
f. Will donors be paid for their specimens now or in the future?	<input type="checkbox"/>	<input type="checkbox"/>	
g. Will donors be informed of the results of the specimen testing?	<input type="checkbox"/>	<input type="checkbox"/>	
h. Are there any implications for family members based on specimen testing results? (If yes, they may be participants.)	<input type="checkbox"/>	<input type="checkbox"/>	
i. Will donors be informed of results obtained from their DNA?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. Will specimens be de-identified?

Yes No

If yes, please describe the procedures you will use, to include at what point in the process will the specimens be de-identified.

5. What measures will you take to minimize the potential for physical, psychological, financial, social, or legal harm from breaches of confidentiality and privacy resulting from unauthorized access to or loss of the specimens?

6. Will you bank collected tissue for future use?

Yes No **If yes, the following additional questions must be answered:**

a. Describe where the tissue will be banked. If this is a non-VA site, indicate if the mandatory approval from ORD has been sought. Attach a copy of the tissue banking application (VA Form 10-0436) if available.

b. Who is responsible for overseeing the operations of the tissue bank (i.e., local IRB)?

7. How will destruction of samples be substantiated?

Section 10: Privacy, Confidentiality, and Information Security in Research

1. What type of data will be received by the Principal Investigator/Study Chair?

Check all that apply.

- De-identified – Data does not contain any identifiers that could link the data to a specific participant. *(See VHA Handbook 1605.01, Appendix B, para 2b, for a list of identifiers that must be removed before data can be considered de-identified. Data must be de-identified in accordance with HIPAA and Common Rule criteria. Scrambling of names and social security numbers is not considered de-identified information.)*
- Identified – Data contains direct identifiers sufficient to identify participants as indicated in VHA Handbook 1605.01, Appendix B, para 2b.
- Coded – Data linked to a specific subject by a code rather than a direct identifier. While the data may contain some protected health information only someone possessing the code can link the data to a particular participant.

If you checked coded, please specify who will maintain the link or code and who will have access to the link or code:

2. Will Protected Health Information (PHI) be obtained during the course of this study?

- Yes No

If yes, answer the questions below:

a. Indicate how the PHI will be obtained by checking one or more of the boxes below:

- From existing sources such as medical records, clinical databases, or research records.

Specify each source and who maintains them:

- Directly from project participants.

Specify how the participants will be contacted and by whom:

b. Check any of the following HIPAA identifiers that may be collected and recorded during the course of the study.

<input type="checkbox"/> Names	<input type="checkbox"/> Social security numbers or scrambled SSNS	<input type="checkbox"/> Device identifiers and serial numbers
<input type="checkbox"/> E-mail addresses	<input type="checkbox"/> Medical record numbers	<input type="checkbox"/> URLs (Universal Resource Locator)
<input type="checkbox"/> All elements of dates (except year) and any age over 89 <i>Specify:</i>	<input type="checkbox"/> Health plan beneficiary numbers	<input type="checkbox"/> IP Addresses (Internet Protocol)
<input type="checkbox"/> Telephone numbers	<input type="checkbox"/> Account numbers	<input type="checkbox"/> Biometric Identifiers including finger and voice print
<input type="checkbox"/> Fax numbers	<input type="checkbox"/> Certificate or license numbers	<input type="checkbox"/> Full face photographic images and any comparable images
<input type="checkbox"/> All geographic subdivisions' smaller than a state <i>Specify:</i>	<input type="checkbox"/> Vehicle ID and serial numbers including license plate numbers	<input type="checkbox"/> Other unique identifying number, characteristic, or code <i>Specify:</i>

3. **If SSNs (full, scrambled, last 4) are being obtained, indicate why they are being obtained, in what form, and what security measures are in place to protect them.** *Note: Investigators can obtain and use real SSNs only when the use of the real SSNS is required to meet the specific aims of the research protocol or to enter information in the subject's health records. Study team members are prohibited from obtaining SSNs by phone.* Check if N/A

4. **Will a non-VA entity have access to VA sensitive data?** Yes No

If yes, please specify each entity and what their role is in the study:

Specify if there is or will be a Data Use Agreement (DUA) or in the case of a contractor, a Business Associate Agreement. Attach a copy if available.

5. **Who on the study team will have access to the data? (Specify approximate number of personnel and their job categories, i.e., Co-investigators, Nurse Coordinators, etc.)**

6. **Will specially obtained software be used?** Yes No

If yes, what software, the source of the software, whether a license will be required and who will fund the license, as well as any data that will be stored in temporary files on the computer's hard drive.

7. **Will any web-based applications be used?** Yes No

If yes, identify the application and its security features. Indicate how it will be used, i.e., for recruiting subjects, completing questionnaires, or processing data.

8. **How will electronic data, as well as paper records be secured? If data is being stored on a computer hard drive, indicated if it is encrypted per VA guidelines.**

9. **Will any mobile devices be used in the study?** Yes No

If yes, indicate that mobile devices will be encrypted and that the encryption is FIPS 140-2 validated.

10. **How will data be transmitted and/or shipped and how will it be protected during transmission or shipping?**

11. How will project research data be stored?

- a. Indicate precisely where data will be stored to include physical site, network location/server name, type of mobile storage device, building and room number etc.

Note: If data will reside on a non-VA server or non-VA equipment, please specify that the server is certified and accredited as required by the Federal Information Security Management Act of 2002 (FIMSA) and that you have obtained the required permissions for use of a non-VA server. See your Information Security Officer (ISO)

- b. If VA sensitive information is being stored outside the protected VA environment, the following questions must be answered: N/A
- (1) How is the data being protected?
- (2) Indicate what VA information will be returned to the VA, how the information will be returned, or what are the plans for its destruction at the alternate non-VA site.

12. How long will the research data be stored?

13. Describe how the data will be destroyed once the maximum retention period or the period specified above, if longer, is reached?

Note: Please include in your plan that the ISO and Privacy Officer will be notified within one hour of the improper use or disclosure, as well as any other local policies.

14. What is your plan for protecting project research data from improper use or disclosure? As part of your response to this question, indicated that removal of access to research study data will be accomplished for study personnel when they are no longer part of the research team.

15. Have you applied or do you plan to apply for a Certificate of Confidentiality?

- Yes No *If yes, you need to include this fact in the informed consent form.*

Note: A Certificate of Confidentiality helps investigators protect the privacy of human research participants enrolled in biomedical, behavioral, clinical and other forms of sensitive research. Certificates protect against compulsory legal demands, such as court orders and subpoenas, for identifying information or identifying characteristics of a research participant. For more information on Certificate of Confidentiality go to: <http://grants.nih.gov/grants/policy/coc/>.

16. Will data be disclosed outside of VHA?

- Yes No

If yes, describe to whom the data is to be disclosed, the justification for such disclosure, and the authority for the disclosure, i.e, HIPAA authorization or VA Form 10-5045, Request for and Authorization to Release Medical Records or Health Information.

17. Will data be banked for re-use in future studies?

Yes No

If yes, describe where the data will be banked and whether this is an existing repository with appropriate oversight mechanisms in accordance with VHA Handbook 1200.12 or indicate that approval will be sought from the local IRB where the repository will be housed or the creation and maintenance of the repository?

Section 11: FDA-Regulated and Other Products

1. Does the project require use of FDA-regulated drugs, biologics, or devices?

Yes No (Skip to Section 12)

2. Does the project involve an Investigational New Drug Application (IND) or Investigational New Device Exemption (IDE)?

Yes No

If yes, attach a copy of any applicable correspondence with the FDA and complete the following:

a. Indicate the name of the person or organization holding the IND or IDE:

b. Is there a plan for on-site data monitoring?

Yes No

If yes, specify who will conduct monitoring responsibilities and how often.

3. How will FDA-regulated products used in this study be dispensed and tracked to participating sites?

4. If using FDA-regulated drugs or biologics, please indicate use: Check here if N/A .

<input type="checkbox"/>	Investigational or Unapproved Drug(s) or Biologics (Attach a copy of the FDA's acknowledgement letter stating that FDA received the IND application.)
<input type="checkbox"/>	Approved Drug(s) or Biologics For Approved Uses
<input type="checkbox"/>	Approved Drug(s) or Biologics for Unapproved Uses (Use will be inconsistent with product labeling or involves a new use, labeling, advertising change, or a change in dose, dosage form, administration schedule, or recipient)

5. List all drugs, biologics, or supplements to be used below. Check here if N/A .

Generic Name	Trade Name	Manufacturer	Use Consistent with Product Labeling? Yes/No	IND Number if Applicable

Note: Add additional rows to table if necessary

- a. Is an Investigator's brochure included with the application materials?
 Yes No If no, please indicate why?
- b. For all approved drugs used for an unapproved use, describe the unapproved use. Check here if N/A .
- c. If an IND is not required, explain and/or provide sponsor or FDA documentation. Check here if N/A .

6. If using FDA-regulated devices, please indicate use: Check here if N/A .

<input type="checkbox"/>	Investigational or Unapproved Device(s)
<input type="checkbox"/>	Approved Device(s) for an Approved Use
<input type="checkbox"/>	Approved Device(s) for an Unapproved Use
<input type="checkbox"/>	Other Specify (e.g., humanitarian use device; 510k clearance)

7. List the FDA-regulated devices that will be used. Check here if N/A .

Name	Manufacturer	Use Consistent with Product Labeling? Yes, No, or N/A	Significant Risk (SR) or Nonsignificant Risk (NSR), Unknown, or N/A	IDE Number if Applicable

- a. Is manufacturer's device information included with the application materials?
 Yes No
- b. If this is a non-significant risk device study, is documentation attached with the application materials explaining the manufacturer's or a sponsor's determination why the device is not a Significant Risk (SR) device? (See 21 CFR 812)
 Yes No
- c. If applying for an IDE, is a copy of the dated IDE application letter to the FDA attached?
 Yes No N/A

Section 12: Local Site Investigator and Local Participating Site Information:

What is the total number of Local Participating Sites?

Please list below all Local Participating Sites and the Local Site Investigators, along with their contact information. If all local sites have not yet been identified, please so state and inform the VA Central IRB Administration Office as soon as they are identified.

Each Local Site Investigator must submit a separate Local Site Investigator Application (VA Central IRB Form 104) after approval of the PI/SC Application by the VA Central IRB.

As the Principal Investigator/Study Chair, it is your responsibility to ensure that the Local Site Investigators listed below are properly qualified to carry out all aspects of the research project that have been delegated to them. The Principal Investigator/Study Chair retains ultimate responsibility for the conduct of the project.

Note: Additional Local Participating Sites may be added in the future through submission of a project amendment and a Local Site Investigator Application to the VA Central IRB.

Local Site Investigator:	Local VA Facility:
Telephone: Email: Fax:	VA Facility Address: Line 1: Line 2: Line 3:

Copy and paste table as a "nested table" as many times as needed to list all Local Site Investigators.

Section 13: Principal Investigator/Study Chair Statement

1. As the Principal Investigator/Study Chair for this project, I acknowledge that I have the primary and ultimate responsibility for protecting the rights and welfare of research participants and that I understand the ethical principles of human participant protection and Good Clinical Practice. I have the competencies and the resources to conduct the research outlined in this application and I attest that the application is scientifically and ethically sound.

2. I also attest that all 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.

3. I have read, understand, and accept the investigator responsibilities as outlined in VHA Handbook 1200.05, paragraph 9 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.
- If applicable, providing ORD-approved "Volunteering in Research" brochure prior to obtaining informed consent and HIPAA authorization from participants, appropriately documenting the informed consent and authorization, and maintaining a master list of all participants and/or requesting waivers of these requirements with appropriate justification.
- 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.

Principal Investigator/Study Chair Signature

Date

**Section 14: Principal Investigator/Study Chair Supervisor
(Must be at least a Section or Department Chief)**

I have reviewed this application as completed by the PI/SC, who is under my supervision. I approve the conduct of the research by the PI/SC, to include the use of any time and resources within this department/section/Facility, as specified in this application.

Supervisor

Date

Printed Name

Department/Section/Facility

**Section 15: Associate Chief of Staff for Research and Development (ACOS/R&D) at
PI/SC Local Facility**

Note: If the ACOS/R&D is the PI/SC, the Facility's Chief of Staff must complete this Section.

As the Associate Chief of Staff for Research and Development or Chief of Staff at this VA medical facility, I have reviewed this project and the Principal Investigator/Study Chair's qualifications and I certify the following:

- The Principal Investigator/Study Chair and, if applicable, the rest of the project team from this facility have the experience and training needed to conduct this project. All members of the project team have been appropriately credentialed, privileged, have an approved scope of practice, and have completed all required VA training in the protection of human participants and Good Clinical Practice.
- This facility has reviewed or is in the process of reviewing any potential conflicts of interest the Principal Investigator/Study Chair and any of the project team members may have in accordance with our local policies and procedures. A summary of the determinations made and any management plans is either attached to this application or will be forwarded separately for review by the VA Central IRB.
- This facility, the Principal Investigator/Study Chair, and the local project team have the resources to support the functions and operations of the project as detailed.
- This project will not begin at this facility until the PI/SC has received written approval to initiate the study in accordance with VHA Handbook 1200.01.

Please check one of the boxes below:

This facility will also serve as a participating site for this project and will also be submitting a separate Local Site Investigator Application (VA Central IRB Form 104) upon approval of this Principal Investigator/Study Chair New Project Application (VA Central IRB Form 108).

Yes No

ACOS/R&D or Chief of Staff Signature

Date

ACOS/R&D or Chief of Staff Printed Name

Phone Number: _____

E-mail Address: _____

Co-Principal Investigator/Study Chair New Project Application Supplement



Co-Principal Investigator/Study Chair Name:

VA Facility Name:

Check to indicate application status:

Initial **Revised**
Version #:

Project Title:

Date:

Supplement Application and Submission Instructions

- The Co-Principal Investigator (PI)/Study Chair (SC) must use this form to submit as a supplement to the Principal Investigator/Study Chair New Project Application to the VA Central IRB. The Co-PI/SC's Supervisor and ACOS/R&D or Chief of Staff of the Co-PI/SC's site also must complete a portion of this form. When submitting a revised VA Central IRB Form 108, only the signature of the PI/SC who signed the original Form 108 is needed. This form does not need to be resubmitted. It is only re-submitted if something on this form changes. The Co-PI may sign amendment requests if the PI/SC who signed the 108 is not available. Ensure the version number and date are included for all revisions.
- Upon completion of this form, it should be appended to the VA Central IRB Form, PI/SC New Project Application and submitted with the rest of the application package.

Section 1: Co-PI/Study Chair General Information

Co- Principal Investigator (PI)/Study Chair (SC) Name:

Academic Degrees:

Board Certifications:

Employment Status: *(Check all that apply)*

- VA Employee (Indicate VA percentage of time in 8ths _____)
- VA WOC (Without Compensation)
- IPA (Intergovernmental Personnel Act)
- Other (Specify) _____

VA Facility Name:

VA Station Number:

Phone:

Fax:

VA Facility Address:

E-mail:

Name of Project Coordinator:

Phone:

FAX:

E-mail:

1. Describe your qualifications to do the research detailed in this project and attach a copy of your biosketch (Merit Review or NIH Format):

2. Indicate below how many of the following you currently oversee as a PI/SC or Co-PI/SC:

_____ Open Research Projects _____ Project Team Members (*Project Coordinator, Statistician, etc.*)
_____ Participating Sites _____ Approximate Number of Active Project Participants

3. Complete the following regarding your training and Conflict of Interest information:

- a. Date of VA Human Participant Protection/Good Clinical Practice Education:
- b. Has your participation in this project been reviewed by your local Conflict of Interest or in accordance with your local conflict of interest policies and procedures?
- Yes. The findings of my local Conflict of Interest Committee or other local Conflict of Interest review are attached.
- Review is pending. Determination will be forwarded upon completion of review. I understand no final decision regarding approval can be made by the VA Central IRB until the local Conflict of Interest determinations have been received and reviewed.

4. Is the Co-PI from the same site as the PI? Yes No

If yes, skip to Section 2.

If no, please complete the remainder of this section.

5. Is a separate Local Site Investigator Application going to be submitted from the 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.

- 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. Please complete the below information.
- 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 a Conflict of Interest determination for all study members that will participate with 5% or more effort. Attach biosketches or CVs of all study team members who function in a scientific or medical capacity.

Note: Do not list CSP Coordinating Center personnel. If any CSP Personnel are also investigators, these should be listed on the VA Central IRB Form 108b.

Project Team Member	VA Status, i.e., # of 8ths or WOC	Degrees	5% or More Effort? Yes/No	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 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 2: Co-Principal Investigator/Study Chair Statement

1. As a Co-Principal Investigator/Study Chair for this project, I acknowledge that I share primary and ultimate responsibility for protecting the rights and welfare of research participants with other Co-PI/SCs and that I understand the ethical principles of human participant protection and Good Clinical Practice. I have the competencies and resources adequate to conduct the research outlined in this application and I attest that the application is scientifically and ethically sound.

2. I attest that all 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.

3. I have read, understand, and accept the investigator responsibilities as outlined in VHA Handbook 1200.05, paragraph 9 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.
- If applicable, providing ORD-approved "Volunteering in Research" brochure prior to obtaining informed consent and HIPAA authorization from participants, appropriately documenting the informed consent and authorization, and maintaining a master list of all participants and/or requesting waivers of these requirements with appropriate justification.
- 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.

Co-Principal Investigator/Study Chair Signature

Date

Section 3: Co-Principal Investigator/Study Chair Supervisor (Must be at least a Section or Department Chief)

I have reviewed this application as completed by the Co-PI/SC, who is under my supervision. I approve the conduct of the research by the Co-PI/SC, to include the use of any time and resources within this department/section/Facility, as specified in this application.

Supervisor

Date

Printed Name

Department/Section/Facility

Section 4: Associate Chief of Staff for Research and Development (ACOS/R&D) at Co-PI/SC Local Facility

Note: If the ACOS/R&D is the Co-PI/SC, the Facility's Chief of Staff must complete this Section.

As the Associate Chief of Staff for Research and Development or Chief of Staff at (**Name of Local Facility**), I have reviewed this project and the Co-Principal Investigator/Study Chair's qualifications and I certify the following:

- The Co-Principal Investigator/Study Chair and, if applicable, the rest of the project team from this facility have the experience and training needed to conduct this project. All members of the project team have been appropriately credentialed, privileged, and have completed all required VA training in the protection of human participants and Good Clinical Practice.
- This facility has reviewed or is in the process of reviewing any potential conflicts of interest the Co-Principal Investigator/Study Chair and any of the project team members may have in accordance with our local policies and procedures. A summary of the determinations made and any management plans is either attached to this application or will be forwarded separately for review by the VA Central IRB.
- This facility, the Co-Principal Investigator/Study Chair, and the local project team have the resources to support the functions and operations of the project as detailed.

- This project will not begin at this facility until the Co-PI/SC has received written approval to initiate the study in accordance with VHA Handbook 1200.01.

Please check one of the boxes below:

This facility will also serve as a participating site for this project and will also be submitting a separate Local Site Investigator Application (VA Central IRB Form 104) upon approval of the Principal Investigator/Study Chair New Project Application (VA Central IRB Form 108).

Yes No

ACOS/R&D or Chief of Staff Signature

Date

ACOS/R&D or Chief of Staff Printed Name

Phone Number: _____

E-mail Address: _____

Local Site Investigator Application



VA Facility Name:

Please check to indicate application status:

Local Site Investigator Name:

Initial Revised
Version #:

Project Title:

Date Submitted:

Application Instructions

- The Local Site Investigator (LSI), the LSI's supervisor, and the ACOS/R&D, or Chief of Staff if the ACOS/R&D is the LSI, for a participating site must complete this form.
- Each section must contain a response. Please ensure all responses are consistent with the approved funded project, the Principal Investigator (PI)/Study Chair(SC) New Project Application, and model informed consent form (if applicable).
- Other documents associated with this application as checked below should also be submitted electronically. Documents can be submitted in PDF or Microsoft Word format with the exception of the informed consent document. This document must be submitted in Microsoft Word. Please ensure the file name includes the name of the document, site, and date (e.g., 104.site.date)

Contents of Application Package

The following documents are mandatory for all studies. Please check to indicate they are included:

- Local Site Investigator Application (VA Central IRB Form 104)
- Local Site Biosketches or CVs of Applicable Study Team Members (Merit Review or NIH Format)
- Local Study Team Conflict of Interest Determinations

Please include the below documents if applicable to the study. If the documents have been modified from the model documents provided by the PI/SC, other than inserting name of facility, local investigator names, and other contact information, 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 (VA Form 10-1086)
- Local HIPAA Authorization form
- Local Recruitment Materials
- Local Participant Study Instructions
- Local Versions of Questionnaires or Surveys
- Local Scripts
- VA Investigational Drug Information Record (VA Form 10-9012)
- Consent for Use of Picture and/or Voice (VA Form 10-3203) (*Only to be used if the form will be part of the participant's VA medical record.*)

Please list below any other documentation included in this application (e.g., results of review by other local committees.)

Submission Instructions

1. Please review your entire application prior to submission and ensure the following:

- All three required signatures have been obtained. For revisions, only the signature of the LSI is required. Ensure you include the version number and date for all revised documents.
- The attachments match with what you have indicated on the preceding page
- Unnecessary page breaks have been removed and any formatting errors have been corrected
- All sections of the application have been completed or marked "Not Applicable."
- If this is a revised application, please include both a "tracked changes" and a "clean" copy of all revised documents.

2. Please contact your PI/SC Study Team for submission instructions. All Local Site Applications are to be submitted to the PI/SC Study Team. They will then in turn forward all Local Site Investigator Applications to the VA Central IRB Administration Office.

3. Upon submission of your LSI Application, you will be given access to the VA Central IRB SharePoint site and will receive an e-mail with the link. You will then be able to use this link to access approved study documents and VA Central IRB correspondence. You must have a valid VA e-mail address in order to access the VA Central IRB SharePoint site.

Note: For CSP studies, all submissions must be submitted through or endorsed by the applicable CSP Coordinating Center.

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.

LOCAL SITE INVESTIGATOR APPLICATION

PROTOCOL TITLE:

Section 1: Local Site Investigator General Information

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 (Without Compensation)

IPA (Intergovernmental Personnel Act)

Other (Specify) _____

VA Facility Name:

VA Station Number:	Phone:
	Fax:
	VA E-mail:
VA Facility Address:	

1. Describe your qualifications to do the research detailed in this project and attach a copy of your biosketch (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

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

2. 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

3. Please list project team members in the table below who will be involved in directing and/or conducting the project at this site. Attach a biosketch or CV of team members who will function in a medical or scientific capacity and Conflict of Interest Determination for all team members who will be expending 5% or more effort on this project.

Project Team Member	Degrees	5% or More Effort? Yes/No	Project Role	Obtaining Informed Consent? Yes/No	Access to Identifiable Participant Data? 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.

4. Has your participation in this project and that of your project team been reviewed by your local Conflict of Interest Committee or in accordance with your local conflict of interest policies and procedures?

- Yes. The determinations of my local Conflict of Interest Committee or other local Conflict of Interest review are attached.
- Review is pending. Determinations will be forwarded upon completion of review. I understand no final decision regarding approval of this project can be made by the VA Central IRB until the local Conflict of Interest Committee determinations have been received and reviewed.
- There is no mechanism at our local site for doing the COI review. Copies of completed disclosure forms for all applicable study team members are attached. ***(Local VA facility forms can be used or, if there is no local form, contact the VA Central IRB Administrator)***

Section 2: Local Participating Site Overview

1. Where will the research project be conducted? (Check all that apply)

- VA Inpatient Setting
- VA Outpatient Clinic
- VA Clinician Office
- VA Laboratories
- Participant Homes
- Affiliate Location
- Other (Specify):

If research is conducted at affiliate location, please specify where and how much of the project will be conducted at that location. Check N/A if not applicable.

2. What resources are available at your facility to treat emergencies resulting from project-related procedures, as well as any non-emergency or psychological referrals that may be required? (Check all that apply)

- Basic Life Support (BLS) trained personnel
- Advanced Cardiac Life Support (ACLS) trained personnel and crash cart
- Emergency drugs and supplies to stabilize participant until emergency personnel arrive
- Emergency response team within facility
- 911 or other emergency response number
- Psychological counseling
- N/A
- Other Please explain:

If not all resources required to treat emergencies resulting from project-related procedures, as well as non-emergency or psychological referrals that may be required, are available at your facility, specify below your plan to handle emergencies requiring these resources.

3. If the project is not conducted at a medical facility, what medical facility and/or services will you use in an emergency? N/A

How much time does it take to get to the above-named medical facility from where the project is to be conducted?

4. Are there applicable state and local laws that differ from VA and other federal requirements concerning the conduct of research activities (e.g., who may serve as a legally authorized representative or additional requirements for the informed consent process)? (Check with your local Research Office and or see instructions for completing this form)

- No
 Yes; please explain:

5. Are there any cultural, ethnic, religious, or other special characteristics of the community, or local issues that the VA Central IRB needs to consider in its review of the project?

- No
 Yes; please explain:

6. Does this project require review by another local committee? (e.g., Recombinant DNA Advisory Committee, Scientific Review Subcommittee, Radiation Safety Committee, Biosafety Committee)

- No
 Yes. Please specify committees:

If yes, please check one of the following:

- Results of committees listed above are attached
 Other committee reviews are still pending and are expected to be complete by:
(Indicate date when results will be available)

Section 3: Local Site Potential Risk/Benefit Analysis

1. **Are there any additional risks to participants in this project at your site than what was described in the PI/SC Application?** *(Note: Risks or harms can be physical, psychological, financial, social, or legal. They may also involve breaches of confidentiality and privacy.)*

No
 Yes; please explain:

2. **Are there any differences in anticipated benefits to participants or society at your site from what was described in the PI/SC Application?**

No
 Yes; please explain:

3. **What is your plan for identifying any problems that arise during the conduct of this project at your site?** *(e.g., How will you identify adverse events?)*

4. **How will you convey information, such as serious adverse events, to the Principal Investigator/Study Chair and/or to the VA Central IRB?** *(e.g., encrypted e-mail, secure fax, use of SharePoint)*

Note: The VA Central IRB has a secure website link for the reporting of SAEs/UAPs and protocol deviations.

5. **If the VA Central IRB determined during its review of the PI/SC New Study Application that the medical record must be flagged, how this is done at your site?** N/A

Section 4: Local Site Human Participant Information

1. What is your planned enrollment at this site and what is your expected accrual rate (e.g., number per month)?

2. What populations at your site will be targeted for recruitment as participants? Check all that apply.

Males	<input type="checkbox"/>
Females	<input type="checkbox"/>
Inpatients	<input type="checkbox"/>
Outpatients	<input type="checkbox"/>
VA Employees	<input type="checkbox"/>
Students	<input type="checkbox"/>
Non-English Speaking	<input type="checkbox"/>
Veteran Family members	<input type="checkbox"/>
Non-Veterans*	<input type="checkbox"/>
Other (Specify)	<input type="checkbox"/>

*If non-veterans is marked above, is the justification for using the non-Veterans the same as Specified in the PI/SC Application? Yes No

If no, provide additional justification for the use of non-Veterans:

3. Will you target a specific race or ethnic group as participants? Yes No

If yes, check all that apply.

Race		Ethnicity	
American Indian or Alaskan Native	<input type="checkbox"/>	Hispanic or Latino	<input type="checkbox"/>
Asian	<input type="checkbox"/>	Not Hispanic or Latino	<input type="checkbox"/>
Black or African American	<input type="checkbox"/>		
Native Hawaiian or other Pacific Islander	<input type="checkbox"/>		
White	<input type="checkbox"/>		

If specific races or ethnic groups are marked above, is the justification for using them the same as specified in the PI/SC Application? Yes No

If no, provide additional justification for the use of these populations:

4. What are the age ranges of participants? Check all that apply.

Children	<input type="checkbox"/> *If checked, see below.
Young Adults (18-21)	<input type="checkbox"/>
Adults (22-65)	<input type="checkbox"/>
Seniors (Over 65)	<input type="checkbox"/>

Is this the same age range as specified in the PI/SC Application? Yes No

If no, provide the rationale for using participants in a different age range:

What is the legal age for an adult in your local jurisdiction: _____

Does your study include emancipated minors and if so, what is the definition of an emancipated minor in your local jurisdiction:

**Note: A waiver from the Chief Research and Development Officer (CRADO) is required for the use of children. (See VHA Handbook 1200.05)*

5. Do you plan to enroll any of the following populations or categories of participants at your site?

	Yes	No
a. Employees or students	<input type="checkbox"/>	<input type="checkbox"/>
b. Individuals with impaired decision making capability	<input type="checkbox"/>	<input type="checkbox"/>
c. Pregnant women	<input type="checkbox"/>	<input type="checkbox"/>
d. Economically and/or educationally disadvantaged persons	<input type="checkbox"/>	<input type="checkbox"/>
e. Patients for whom you currently provide medical care	<input type="checkbox"/>	<input type="checkbox"/>
f. Prisoners	<input type="checkbox"/>	<input type="checkbox"/>
g. Illiterate, limited, or no English language proficiency	<input type="checkbox"/>	<input type="checkbox"/>
h. Terminally ill patients	<input type="checkbox"/>	<input type="checkbox"/>

If you answer yes to any of the above populations or categories of participants, please describe any site-specific measures or special considerations, steps, or safeguards to ensure that these populations or special classes are adequately protected if different from those in the PI/SC Application or project. *Note: If you plan to enroll pregnant women, prisoners, or individuals with impaired decision making capacity at this site and the PI/SC has not submitted a VA Central IRB Form 110, Vulnerable Population Supplement, for that population as part of the PI/SC Application for the entire study, it must be completed and submitted with this application.*

Check if there is no difference from PI Application or Not Applicable.

Section 5: Local Site Informed Consent

1. Will you be obtaining informed consent at this site?

Yes No **If no, please skip to Section 6.**

2. Who will conduct the consent discussion with the local site participants? (Check all that apply)

- Local Site Investigator
- Local Sub/Co-investigator
- Local Research Project Team Member (Specify who: _____)
- Other: *Please explain:*

3. Where will the informed consent process at this site take place? (Check all that apply)

- N/A
- In a private room
- In a waiting room
- In an open ward
- In a group setting
- Over the phone
- Other: *Please explain:*

4. How will the participant's privacy interests be protected? Note: Confidentiality of data will be addressed in Section 10. Please address protecting privacy here.

5. How will you be sure there is sufficient opportunity or time for the participants to read the informed consent and consider whether or not to participate before signing? (Check all that apply)

- Participants will be allowed to take the unsigned consent form home for consideration prior to signing it.
- Participants will be allowed a waiting period of _____ (e.g., number of hour/days) to consider their decision.
- Other *Please explain:*

6. Are there any differences in the steps taken at your site to minimize the possibility of coercion or undue influence from those described in the PI/SC Application?

- No
- Yes; please explain:

7. Will you or a member of your research team be obtaining informed consent from someone other than the participant?

- No
- Yes

If yes, how will you determine which individuals meet the criteria for being a legally authorized representative (LAR) under VA requirements or applicable state laws?

- Request documentation of authorization.
- Obtain verbal confirmation from the LAR.
- Other *Please explain:*

What is the definition of a LAR for your local jurisdiction:

8. Will you or a member of your research team be obtaining assent from participants who are unable to give informed consent (e.g., participants with impaired decision making capacity)?

- N/A
- No
- Yes

If you will not be obtaining assent from participants who are unable to give informed consent, please explain why not?

9. If some or all participants at this site have impaired decision making ability, how will their capacity to consent be determined? Check here if N/A .

10. What is the language of the participants (or parents or LAR as applicable) you plan to enroll at this site?

- English
- Spanish. *Note:* If your VA Facility has a large Spanish-speaking population of Veterans, and you do not plan to recruit Spanish-speaking participants, please provide justification:

Other:

11. If you are enrolling non-English speaking participants (or obtaining consent from non-English speaking parents or LARs), what is your plan for conducting the consent discussion in the language understandable to the participant, and for ongoing communication with the participant throughout the project and in case of emergency if applicable:

- N/A
- At least one member of the project team is fluent in the language that will be used for communication, and that staff member(s) will be available during emergencies
- The project team has 24-hour access to a translation service with sufficient medical expertise to discuss the research in this project.
- Other *Please explain:*

12. Besides the Local Site Investigator and site-specific points of contact information, have you further modified the model informed consent document(s) provided by the Principal Investigator/Study Chair?

- Yes
- No

If yes, please provide justification for the changes:

Reminder: Please use the Microsoft Word track changes function to indicate modifications in the model informed consent document provided by the PI/SC. Submit BOTH tracked and untracked versions of the documents.

Section 6: Local Site HIPAA Authorizations

Have you made any modifications to the model HIPAA authorization documents provided by the Principal Investigator/Study Chair?

- Yes No N/A

If yes, please provide justification and provide copies of the modified documents:

Section 7: Local Site Participant Recruitment Information

1. Are there any differences in your local site recruitment strategy from that detailed in the PI/SC Application?

- Yes No

If yes, please indicate the differences and justify:

2. Who will be primarily responsible for recruiting potential participants at this site?

3. How will initial contact with the participant be made? (e.g. local clinics, physician referrals, letters to prospective participants – Note: VA policy prohibits “ cold calls” to potential VA research participants.)

4. Will you be using any of the following methods to recruit participants?

(Please check all that apply.)

- N/A
- Local database for which participants have given prior permission to be contacted for Research *Note: If this option is checked, the site will need to submit a local Request for Waiver of HIPAA authorization if this was not done by the PI/SC.*
- Personal contact with patients or students over whom you have direct/indirect oversight
- Provider Referrals

5. Please indicate below the following types of recruitment materials that will be used at this site?

<input type="checkbox"/>	No Advertisements will be used.
<input type="checkbox"/>	Fliers
<input type="checkbox"/>	Newspaper
<input type="checkbox"/>	Letters
<input type="checkbox"/>	Websites
<input type="checkbox"/>	Television
<input type="checkbox"/>	Radio
<input type="checkbox"/>	Video
<input type="checkbox"/>	Audio
<input type="checkbox"/>	Customer Surveys
<input type="checkbox"/>	Other (Please specify, i.e., Employee Newsletter)

Please note that drafts of advertisements and scripts of audio and video materials may be provided for review. However, final versions of all recruitment materials must be reviewed and approved by the VA Central IRB prior to being used as part of any recruitment activities.

If standard recruitment materials were provided by the Principal Investigator/Study Chair, have you made any changes to those materials other than local site name or Local Site Investigator contact information?

Yes No N/A

If yes, please explain:

Section 8: Local Site Payment to Participants

Check here if there is no payment to participants at this site: **Continue to Section 9.**

If payment is going to be provided to participants at this site, complete the below questions.

1. Does your payment plan (methods or relative amounts of payment) differ that than described in the PI/SC Application?

- No. Continue to Section 8.
- Yes. Complete the table below and answer the following questions:

No Participant Payments	<input type="checkbox"/>
Travel and Parking	<input type="checkbox"/>
Cash or Check	<input type="checkbox"/> Amount per visit: Total amount:
Gift Cards	<input type="checkbox"/> Amount per visit: Total amount:
Other (<i>Specify, i.e., Meal vouchers:</i>)	<input type="checkbox"/> Specify:

2. If participants are to be paid at this site differently from the PI/SC Application, specify the following:

- a. If payment amount differs, provide justification that the proposed payment are reasonable and commensurate with the participant's contribution to the project:
- b. Source of payment to include who is dispensing the payment:
- c. Payment schedule to include when payment will be rendered. If not pro-rating payments, indicate why.
- d. Will SSNs be requested and/or used in making payment? Yes No

Section 9: Local Site Biological Specimens

1. If biological specimens will be used or collected at this site, please list the types of specimens below:

Not Applicable. Skip to Section 10.

2. Will certain biological specimens be collected for research purposes only?

Yes
 No

Specify:

3. Will biological specimens collected for clinical purposes be used in this protocol?

Yes
 No

Specify:

4. Will specimens be de-identified?

Yes
 No

If yes, please indicate which specimens and describe below the procedures you will use if different from those described in the PI/SC Application.

N/A (Procedures are the same)

Specify:

5. Are there any differences in the measures you will take to minimize the potential for physical, psychological, financial, social, or legal harm from breaches in confidentiality and privacy resulting from participating in this aspect of the research project than those described in the PI/SC Application?

Yes
 No

6. Will you bank collected tissue at this site?

Yes No

If yes, will you bank it according to the approved PI/SC Application?

Yes No

If no, the following additional questions must be answered:

a. Describe any banking procedures which are different from the approved PI/SC Application.

- b. If the tissue bank is at a different location than indicated in the approved PI/SC Application describe where the tissue will be banked. If this is a non-VA site, indicate if the mandatory approval from ORD has been sought. Attach a copy of the tissue banking application (VA Form 10-0436) if available.
- c. Who is responsible for overseeing the operations of the tissue bank (i.e., local IRB)?

Section 10: Local Site Confidentiality of Data and Information Security

PLEASE NOTE: This section must be individualized for your local site. Do not cut and paste sections of the protocol to address the questions.

1. What type of data will be received by the Local Site Study Team?

Check all that apply.

- De-identified – Data does not contain any identifiers that could link the data to a specific participant. *(See VHA Handbook 1605.01, Appendix B, para 2b, for a list of identifiers that must be removed before data can be considered de-identified. Data must be de-identified in accordance with HIPAA and Common Rule criteria. Scrambling of names and social security numbers is not considered de-identified information.)*
- Identified – Data contains direct identifiers sufficient to identify participants as indicated in VHA Handbook 1605.01, Appendix B, para 2b.
- Coded – Data linked to a specific subject by a code rather than a direct identifier. While the data may contain some protected health information only someone possessing the code can link the data to a particular participant.

If you checked coded, please specify who will maintain the link or code and who will have access to the link or code:

2. Will Protected Health Information (PHI) be obtained at this site during the course of this study?

- Yes No

If yes, answer the questions below:

a. Indicate how the PHI will be obtained by checking one or more of the boxes below:

- From existing sources such as medical records, clinical databases, or research records.

Specify each source and who maintains them:

- Directly from project participants.

Specify how the participants will be contacted and by whom:

b. Check any of the following HIPAA identifiers that may be collected and recorded during the course of the study at this site:

<input type="checkbox"/> Names	<input type="checkbox"/> Social security numbers or scrambled SSNS	<input type="checkbox"/> Device identifiers and serial numbers
<input type="checkbox"/> E-mail addresses	<input type="checkbox"/> Medical record numbers	<input type="checkbox"/> URLs (Universal Resource Locator)
<input type="checkbox"/> All elements of dates (except year) and any age over 89 <i>Specify:</i>	<input type="checkbox"/> Health plan beneficiary numbers	<input type="checkbox"/> IP Addresses (Internet Protocol)
<input type="checkbox"/> Telephone numbers	<input type="checkbox"/> Account numbers	<input type="checkbox"/> Biometric Identifiers including finger and voice print
<input type="checkbox"/> Fax numbers	<input type="checkbox"/> Certificate or license numbers	<input type="checkbox"/> Full face photographic images and any comparable images
<input type="checkbox"/> All geographic subdivisions' smaller than a state <i>Specify:</i>	<input type="checkbox"/> Vehicle ID and serial numbers including license plate numbers	<input type="checkbox"/> Other unique identifying number, characteristic, or code <i>Specify:</i>

3. If SSNs (full, scrambled, last 4) are being obtained, indicate why they are being obtained, in what form, and what security measures are in place to protect them. *Note: Investigators can obtain and use real SSNs only when the use of the real SSNS is required to meet the specific aims of the research protocol or to enter information in the subject's health records. Study team members are prohibited from obtaining SSNs by phone.* Check if N/A

4. Will a non-VA entity have access to VA sensitive data other than that specified in the PI/SC Application? Yes No

If yes, please specify each entity and what their role is in the study:

Specify if there is or will be a Data Use Agreement (DUA) or in the case of a contractor, a Business Associate Agreement. Attach a copy if available.

5. Who on the local study team will have access to the data? (Specify approximate number of personnel and their job categories, i.e., Co-investigators, Nurse Coordinators, etc.)

6. Will specially obtained software be used other than that specified in the PI/SC Application? Yes No

If yes, what software, the source of the software, whether a license will be required and who will fund the license, as well as any data that will be stored in temporary files on the computer's hard drive.

7. Will any web-based applications be used other than specified in the PI/SC Application? Yes No

If yes, identify the application and its security features. Indicate how it will be used, i.e., for recruiting subjects, completing questionnaires, or processing data.

8. How will electronic data, as well as paper records be secured? If data is being stored on a computer hard drive, indicated if it is encrypted per VA guidelines.

9. Will any mobile devices be used in the study at this local site? Yes No

If yes, indicate that mobile devices will be encrypted and that the encryption is FIPS 140-2 validated.

10. How will data be transmitted and/or shipped and how will it be protected during transmission or shipping?

11. How will project research data be stored?

a. Indicate precisely where data will be stored to include physical site, network location/server name, type of mobile storage device, building and room number etc.

Note: If data will reside on a non-VA server or non-VA equipment, please specify that the server is certified and accredited as required by the Federal Information Security Management Act of 2002 (FISMA) and that you have obtained the required permissions for use of a non-VA server. See your Information Security Officer (ISO)

b. If VA sensitive information is being stored outside the protected VA environment, the following questions must be answered: N/A

(1) How is the data being protected?

(2) Indicate what VA information will be returned to the VA, how the information will be returned, or what are the plans for its destruction at the alternate non-VA site.

12. How long will the research data be stored?

13. Describe how the data will be destroyed once the maximum retention period or the period specified above, if longer, is reached?

Note: Please include in your plan that the ISO and Privacy Officer will be notified within one hour of the improper use or disclosure, as well as any other local policies.

14. What is your plan for protecting project research data from improper use or disclosure? As part of your response to this question, indicated that removal of access to research study data will be accomplished for study personnel when they are no longer part of the research team.

15. Will data be disclosed outside of VHA from this site?

- Yes No

If yes, describe to whom the data is to be disclosed, the justification for such disclosure, and the authority for the disclosure, i.e. HIPAA authorization or VA Form 10-5045, Request for and Authorization to Release Medical Records or Health Information.

16. Will data be banked for re-use in future studies differently than is described in the PI/SC Application?

- Yes No N/A

If yes, describe where the data will be banked and whether this is an existing repository with appropriate oversight mechanisms in accordance with VHA Handbook 1200.12 or indicate that approval will be sought from the local IRB where the repository will be housed or the creation and maintenance of the repository?

Section 11: FDA-Regulated and Other Products Used at Local Site

1. Does the project require use of FDA-regulated drugs, biologics, devices, or other products at this site? (Note: Include all drugs and devices required as part of the project or trial.)

- Yes No (Skip to Section 12)

2. What are the FDA-regulated drugs, biologics, devices, or other products such as supplements, that will be evaluated and/or dispensed at this site? List below.

If a device(s) is used, who will have control and manage the device(s)?

3. How will FDA-regulated and other products used in this protocol be dispensed and tracked to participants at this site?

4. If using drugs, has the Pharmacy been contacted and agreed with the plan?

- Yes
 No

If no, please indicate why:

Note: For investigational drugs, attach a completed and signed local VA Form 10-9012, Investigational Drug Information Record for each drug, to be approved by the VA Central IRB.

Section 12: Local Site Investigator Statement

- 1. I have reviewed the project application as submitted by the Principal Investigator/Study Chair and I have indicated on this application if I have made any changes in the model documents. I am providing a clean and track changes copy of any model documents I have changed.**
- 2. As the Local Site Investigator for this project, I attest to the following:**
 - I acknowledge that I have the primary and ultimate responsibility for protecting the rights and welfare of research participants at this site and that I understand the ethical principles of human participant protection and Good Clinical Practice. 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.
 - I have adequate local resources and time to complete this project.
 - All members of the local project team will be trained on applicable project procedures, to include informed consent procedures, and on all VA and other requirements pertaining to human participant protections as befits their roles and responsibilities as detailed in their scope of practice prior to participating in the project.
 - The project team has access to a population that will allow recruitment of the required number of participants.
 - Our local VA facility has 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.
- 3. I have read, understand, and accept the investigator responsibilities as outlined in VHA Handbook 1200.05, paragraph 9, 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, and maintaining all written documentation indicating compliance.
 - If applicable, providing ORD-approved brochure "Volunteering in Research" prior to obtaining informed consent and HIPAA authorization from participants, appropriately documenting the informed consent and authorization, and maintaining a master list of all participants.
 - Not make 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, the local Institutional Official, and Principal Investigator/Study Chair any new conflict of interest or reportable activity as defined by VA and other requirements, as well as 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.
 - Cooperating with the Principal Investigator/Study Chair in the submission of all continuing review reports and project and data safety monitoring efforts.
 - 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 the research does not start 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 the PI/SC.

Local Site Investigator Signature

Date

Local Site Investigator Printed Name

Section 13: Local Site Investigator's Supervisor (Must be at least a Section or Department Chief)

I have reviewed this application as completed by the Local Site Investigator, who is under my supervision. I approve the conduct of the research by the Local Site Investigator, to include the use of any time and resources within this Department/Section/Facility, as specified in this application.

Supervisor Signature

Date

Printed Name : _____

Department/Section/Facility: _____

Section 14: Review by Local Site Associate Chief of Staff for Research and Development (ACOS/R&D) at the Local Investigator's Site

Note: If the ACOS/R&D is the LSI, the Facility's Chief of Staff must complete this Section.

1. As the Associate Chief of Staff for Research and Development or Chief of Staff {Name of Local Facility}, I have reviewed this project, the local site project team qualifications, and site requirements. I have concluded that this facility is an acceptable site to conduct this project and I certify the following:

- The Local Site Investigator and the rest of the local site project team have the experience and training to conduct this research. All members of the project team have been appropriately credentialed, privileged, have an appropriate scope of practice, and have completed all required VA training in the protection of human participants and Good Clinical Practice.
- This facility has reviewed or is in the process of reviewing any potential conflicts of interest any of the project team members may have in accordance with our local policies and procedures. A summary of the determinations made and any management plans is either attached to this application or will be forwarded separately for review by the VA Central IRB.
- The local project team has access to a population that will allow recruitment of the required number of participants and the local project team has the time to complete the project.
- This project will not begin at this site until the LSI has received written approval to initiate the study in accordance with VHA Handbook 1200.01.
- This facility has adequate resources, including medical and psychological resources that participants might require as a consequence of their participation in the project, to support the functions of this site as detailed in the project.

2. I have considered whether or not there are state and local laws governing the proposed project. I have also considered whether there are any cultural, ethnic, religious, or special characteristics of the community, or other local issues that the VA Central IRB needs to consider in its review. I have the following comments regarding these local context issues: *(If none, so state)*

3. The Federalwide Assurance for our VA Facility is current and lists or will list the VA Central IRB as an IRB of Record for this facility. We have a current, approved Memorandum of Understanding (MOU) on file with the VHA Central Office Human Research Protections Program (HRPP) or will obtain one prior to this Local Site Investigator Application being considered by the VA Central IRB for approval.

ACOS/R&D or Chief of Staff Signature

Date

ACOS/R&D or Chief of Staff Printed Name

Phone Number: _____

E-mail Address: _ _____

Administrative Pre-Screening Checklist for PI/SC New Project Applications



This form is used by VA Central IRB Administrative staff to perform an initial pre-screen of a PI/SC New Project Application

Section 1: Principal Investigator/Study Chair (PI/SC) and Project General Information

VA Central IRB Project Number Assigned:	Date Received:
Title of Project:	
Name of Principal Investigator (PI):	PI Site:

1. Is the PI Site a VA employee? Yes No

2. Is there a Co-PI and is the Co-PI a VA Employee? Yes No
If yes, does the application contain a completed VA Central IRB Form 108a? Yes No

3. Has the PI (Co-PI) provided their VA e-mail addresses? Yes No

4. An LEIE was performed on PI/SC (and Co-PI/SC as applicable) on:
Results:

5. Have all documents listed on the front of the VA Central IRB Form 108 been received?
 Yes No

List any missing required documents in Section 4 of this form.

Section 2: Issues That Must Be Addressed

1. Has the PI/SC (Co-PI/SC as applicable) completed VA Human Participant Protection/Good Clinical Practice Education within two years of project submission:

- No. Evidence of training completion within one year must be received prior to final approval of the project by the VA Central IRB. *Add to Section 5, Issue Requiring Resolution*
- Yes.

2. Has the local site identified a Conflict of Interest concerning the PI/SC (Co-PI/SC) and/or study team?

- No. File Local Conflict of Interest findings in study file and include as part of agenda package.
- Yes. Include as part of agenda package and if a potential COI was ruled out, ensure applicable documentation from the VA facility's Office of Regional Counsel ruling out the COI is provided.
- Pending. Local Conflict of Interest findings must be received and reviewed by the Board prior to approval of project. *Add this to Section 4, Missing Documents.*

3. Does the project involve a Coordinating Center? No Yes

If yes, the following questions must be answered.

a. Does the Coordinating Center have an MOU/FWA on file?

- No. Immediately inform the VA Central IRB Administrator. Add to Section 5.
 Yes.

b. For CSP projects, was the project submitted through the Coordinating Center POC?

- N/A
 Yes
 No. If no, contact the POC for the Coordinating Center and obtain verification in writing that the study version submitted is the one approved by the Coordinating Center.

4. Does the project appear to involve more than minimal risk?

- No.
 Yes. If yes, is a data safety monitoring plan included as part of the application or is the plan adequately described within the VA Central IRB Form 108?
 No. Add to Section 4.
 Yes.

5. Does the project involve the use of a vulnerable population or a special class of participants?

- No.
 Yes. What vulnerable population is included? _____

A Vulnerable Population Supplement (VA Central IRB Form 110 series) must be included with application if project involves **prisoners, pregnant women, or participants with impaired decision making ability**. A Board member or an ad hoc advisor having experience with the vulnerable population must also be present at the meeting at which this project will be reviewed. Add to Section 4 if one of these populations is to be enrolled and the applicable supplement is not attached.

6. Does the project involve the use of non-Veterans? No Yes

If yes, does the VA Central IRB form 108 contain adequate justification for their use.

7. How is informed consent going to be addressed? (Check all that apply)

- A waiver or alteration is being requested for the project.
 A waiver or alteration is being requested for recruitment purposes only.
 Written informed consent will be obtained from participants.
 Written informed consent will be obtained from participants' Legally Authorized Representative (LAR).
 Assent will be obtained from participants with impaired decision making capability.
 A waiver of documentation of informed consent is being requested.

Have all required documents been submitted?

- No. List them in Section 4
 Yes.

8. Has a readability evaluation been performed by the principal investigator on the informed consent document?

- No. Perform one using Word tools and indicate outcome. Result _____
 Yes. Result _____ if results above 8th grade, list in Section 5.

9. Are recruitment materials going to be provided to potential participants?

- No.
- Yes. Ensure copies of all recruitment materials are included as part of this application. *List missing materials in section 4.*

10. Does the project involve the use of FDA-regulated drugs, biologics, or devices?

- No.
- Yes. If project involves drugs or devices for other than an approved use, ensure the investigator's drug brochure or manufacturer's device information is included in the application. *Any missing materials should be listed in Section 4.*

If yes, the following additional questions must be answered:

a. For investigational drugs, is a *Model VA Central IRB Form 10-9012* Investigational Drug Information Record included in the application?

- No. *List in Section 4.*
- Yes
- N/A

b. For investigational devices, has the investigator provided enough information about the device for the Board to make a SR/NSR determination?

- No. *List in Section 4.*
- Yes
- N/A

c. Has the IND or IDE been provided?

- No. *List in Section 4.*
- Yes
- N/A

If yes, validate and specify method and date of validation:

Method:
Date:

11. Is the application signed by the PI/SC, the PI/SC's supervisor, and the ACOS/R&D of the PI/SC Site?

- No. Immediately notify investigator of signature requirements. *Add to Section 5.*
- Yes.

12. If the investigator has identified potential participating sites, do all of them have an active MOU with the VHA Central Office HRPP including the PI and Co-PI sites?

- No. Inform the VA Central IRB Administrator. *Add to Section 5.*
- Yes.

Section 3: Informed Consent Administrative Review

Check here if N/A

Required Elements	YES	NO	N/A
All of these elements must be present. If one or more are not present, contact the investigator and ask that a revised document be submitted. Add to Section 5.			

1. Does the informed consent contain the name of the project?	<input type="checkbox"/>	<input type="checkbox"/>	
2. Does the model informed consent contain the name of the Principal Investigator or placeholder for the LSI?	<input type="checkbox"/>	<input type="checkbox"/>	
3. Is there a statement indicating that the project involves research?	<input type="checkbox"/>	<input type="checkbox"/>	
4. Is there an explanation of the purposes of the research?	<input type="checkbox"/>	<input type="checkbox"/>	
5. Is the duration of the participant's expected participation stated?	<input type="checkbox"/>	<input type="checkbox"/>	
6. Is there a detailed chronological description of the procedures to be followed?	<input type="checkbox"/>	<input type="checkbox"/>	
7. Are procedures that are being done solely for the purposes of the research identified as such?	<input type="checkbox"/>	<input type="checkbox"/>	
8. Are procedures which are experimental identified as such?	<input type="checkbox"/>	<input type="checkbox"/>	
9. Is the participant advised of any reasonably foreseeable risks or discomfort that may occur as a result of their participation?	<input type="checkbox"/>	<input type="checkbox"/>	
10. Is there a description of any potential benefits to the participant or to others that may reasonably be expected from the research?	<input type="checkbox"/>	<input type="checkbox"/>	
11. Are appropriate alternative treatments or procedures that may be advantageous to the participant disclosed?	<input type="checkbox"/>	<input type="checkbox"/>	
12. Is there a statement describing the extent to which the confidentiality of records identifying the participants will be maintained?	<input type="checkbox"/>	<input type="checkbox"/>	
13. For research involving more than minimal risk, is there a description of what compensation may be available if an injury occurs as a result of the research to include where further information may be obtained?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Are points of contact provided for the participant to contact for answers to questions about the research, research participant's rights, and in the event of a research-related injury to the participant?	<input type="checkbox"/>	<input type="checkbox"/>	
15. Is at least one of the points of contact someone other than the investigator or project team members whom the potential participant can contact to verify the validity of the project?	<input type="checkbox"/>	<input type="checkbox"/>	
16. Is there a statement that participation is voluntary and that refusal to participate or a decision to terminate their participation will involve no penalty or loss of benefits to which the participant is otherwise entitled?	<input type="checkbox"/>	<input type="checkbox"/>	
17. Is there a statement that a veteran participant will not be required to pay for care in a VA research project except for any applicable co-payments unrelated to the research project?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Additional Required Elements			
These elements are required if applicable to the project. If not present, contact the investigator immediately and ask for submission of a revision.	YES	NO	N/A
1. Is there a statement that the particular treatment or procedure may involve risks to the participants (or to the embryo or fetus if the participant becomes pregnant) which are currently unforeseeable?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Does the document include anticipated circumstances under which the participant's participation may be terminated by the investigator with the participant's consent?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Are there any additional costs to the participant that may result from participation in the research consistent with the federal laws concerning veteran's eligibility for medical care and treatment?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. Is there a statement concerning the consequences of a participant's decision to withdraw from the project and procedures for orderly termination of participation by the participant?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Is there a statement that significant new findings developed during the course of the project that may relate to the participant's willingness to continue participation will be provided to the participant?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Is the approximate number of participants that that will be involved in the project stated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Is there a statement regarding any payment the participant is to receive?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Is there a statement concerning any schedule of payments the participant is to receive?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Is there a statement that federal agencies such as the FDA, OHRP, and the GAO, may have access to the records?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. If an FDA-regulated test article is involved, is there a statement that the FDA may choose to inspect research records that include the participant's individual medical records?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Section 4: Missing Required Documents

Check one of the following:

- No required project documents were missing from the initial submission.
- Based on an administrative review of the project, the following required documents were not submitted as part of this application.

Document	Date PI Contacted	Form of Contact	Date Received

Add additional rows as needed

Section 5: Issues Requiring Resolution

Check one of the following:

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

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

Add additional rows as needed

Section 7: Assigned VA Central IRB Coordinator Recommendation

1. All documents and all administrative issues have been resolved for this PI/SC New Project Application and it is ready for review by the Board. The following type of review is appropriate with this project:

- Expedited Convened Board

2. The following documents have been prepared as applicable: **(Check all that apply)**
Note: Obtain names of assigned reviewers from VA Central IRB Administrator.

- Reviewer Checklist for Primary Reviewer Name: _____
- Reviewer Checklist for Secondary Reviewer Name: _____
- Reviewer Checklist for Informed Consent Reviewer Name: _____
- Expedited Review Eligibility Determination (VA Central IRB Form 121)
- ISO Certification
- Privacy Officer Certification
- Regulatory Advisor Certification
- The Local Site Tracking Log has been initiated for this study, the completion of the Admin review indicated and the documents made available to all other reviewers..

VA Central IRB Coordinator: _____ Date: _____

Administrative Checklist for Local Site Investigator Applications



Project Information

VA Central IRB Number	
Title of Project	
Principal Investigator	
Type of Review for LSI Applications Based on Review of PI/SC Application or Determination of the IRB	<input type="checkbox"/> Expedited <input type="checkbox"/> Convened

Checklist Items					
Mandatory Documents Received					
1. Local Site Investigator Application					
2. Electronic Submission of Package					
3. Study Team Biosketches					
4. Local COI Determinations					
Other Documents Received as Applicable					
1. VA Research Consent Form (VA Form 10-1086)					
2. Local HIPAA Authorization					
3. Local Recruitment Materials/Scripts					
4. Voice/Photo Consent (VA Form 10-3203)					
5. Investigational Drug Information Record (10-9012)					
6. Participant Instructions					
7. Questionnaires or Surveys					
8. Case Reports					
Other Documents Not Listed Documents:					

Checklist Items					
Issues to be Addressed for All Studies					
1. There is an active MOU and FWA is updated. If a CBOC is listed as a site, it is included on an FWA for which the VA Central IRB is listed as an IRB of Record.					
2. The LSI and all members of the local project team have completed VA Human Participant/Good Clinical Practice Education within two years of application submission.					
3. There are no COIs identified or a management plan has been identified for review.					
4. The LSI Application is signed by LSI, Supervisor, and ACOS/R&D of the site.					
9. No changes were made in the Informed Consent document except for site POC information.					
10. No changes were made to the HIPAA authorization except for site POC information.					
11. No changes were made to the recruitment materials except for site POC information.					
12. There are no modifications in any of the participant instructions, surveys, questionnaire, or scripts.					
13. There are no changes in the model photo/voice consent except for POC site information.					
14. There are no changes in the Investigative Drug Information Record except for POC site information.					

15. The site has not identified any other committee reports that need to be considered by the VA Central IRB in their review of the project such as Biosafety or Radiation Safety.					
Comments:					

Missing Required Documents

Check one of the following:

- No required project documents were missing from any of the submitted local site applications.
- Based on an administrative review of the project, the following required documents were not submitted as part of this application.

Site	Document	Name of Individual Contacted	Date Contacted	Form of Contact	Date Received

Add additional rows as needed

Section 5: Issues Requiring Resolution

Check one of the following:

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

Site	Issue	Name of Individual Contacted	Date Contacted	Form of Contact	Date Resolved	Resolution

Add additional rows as needed

Coordinating Center PI/SC New Project Application Supplement



Principal Investigator/Study Chair Name:

Coordinating Center Name:

Project Title:

Date:

Supplement Application and Submission Instructions

- This form must be completed by the applicable Center Director for all studies submitted to the VA Central IRB if a Coordinating Center is engaged in the research study. This form must be submitted to the VA Central IRB as a supplement to the PI/SC New Project Application (VA Central IRB Form 108).
- A separate form must be completed for each engaged Coordinating Center. Do not complete this form for research activities conducted by the CSP Clinical Research Pharmacy Coordinating Center located in Albuquerque, New Mexico, that are part of their routine research support activities.
- After applicable signatures are obtained, this form should be included as part of the PI/SC Application with the box on the front page of the VA Central IRB Form 108 next to the name of this form checked off indicating the PI/SC Application package contains this document.

Section 1: CSP Center Information

Project Manager Name at Coordinating Center:	
VA Station Number:	Phone:
VA Facility Address:	Fax:
	VA E-mail:
1. Is the Coordinating Center Project Manger going to serve as the primary Point of Contact for VA Central IRB communication regarding this study? <input type="checkbox"/> Yes <input type="checkbox"/> No. If no, please indicate below who is the main point of contact. Name: _____ Phone: _____ FAX: _____ VA E-mail: _____	
2. Are any of the Coordinating Center personnel serving as investigators on this study? <input type="checkbox"/> Yes <input type="checkbox"/> No	

If yes, please indicate the individual's name and capacity served below and include a copy of the individual's CV with this supplement.

Project Team Member	Degrees	5% or More Effort? Yes/No	Project Role	Access to Identifiable Participant Data? Yes/No	Date of most recent GCP Training

Note: Additional project members may be added by inserting more rows in the table. If some project members are unknown at this time, indicate this by inserting "TBD" in the project team member column.

If no, specify below the role of the Coordinating Center in this project: A summary can be provided with references made to more detailed portions of the VA Central IRB Form 108 or the protocol document.

3. Will a Local Site Investigator Application also be submitted from this site?

A separate Local Site Investigator Application must be submitted in addition to this supplement if the site is engaged in the research beyond the activities conducted or overseen by the Coordinating Center.

Yes No

Section 3: Center Director

As the Center Director, I have reviewed this supplement and certify the following:

- o All personnel in this Coordinating Center who will be involved in this project have been appropriately credentialed, privileged, and have completed and are up-to-date on all required VA training the protection of human participants and in Good Clinical Practices
- o The Coordinating Center will follow VA Central IRB SOPS in requesting changes in approved studies, the submission of continuing review requests, and in reporting problems

Please check one of the boxes below:

This VA facility will also serve as a participating site for this project in addition to Coordinating Center functions. This VA facility is located at the same site as the PI/SC or Co-PI/SCs of this study or a Local Site Investigator.

Yes No

Center Director

Date

Printed Name

Phone and VA E-mail Address

Section 4: Associate Chief of Staff for Research and Development (ACOS/R&D) or Chief of Staff at Local Facility CSP Center

(Signature of this supplement by the ACOS/R&D is only required if the PI/SC is not located at the same facility as the Coordinating Center.)

As the Associate Chief of Staff for Research and Development or Chief of Staff at this facility, I have this supplement and certify the following:

- The members of the CSP Coordinating Center have been appropriately credentialed, privileged, and have completed all required VA training in the protection of human participants and Good Clinical Practice.
- This facility has reviewed or is in the process of reviewing any potential conflicts of interest the any of the listed CSP project team members may have in accordance with our local policies and procedures. A summary of the determinations made and any management plans is either attached to this application or will be forwarded separately for review by the VA Central IRB.
- This facility will adhere to the Memorandum of Understanding signed with the VHA Central Office regarding the use of the VA Central IRB.
- This project will not begin at this facility until written approval has been received from both the VA Central IRB and from this facility in accordance with our local Research and Development (R&D) Committee policies.

ACOS/R&D or Chief of Staff Signature

Date

ACOS/R&D or Chief of Staff Printed Name

Phone Number: _____

VA E-mail Address: _____

Request for Expedited Review of New Project



This form is used by the Principal Investigator to request an expedited review by the VA Central IRB of a new project.

Section 1: Project and Principal Investigator Information

Title of Project:	
Name of Principal Investigator (PI):	
PI Phone Number:	PI E-Mail Address:
Name of PI Facility:	
Mailing Address:	

Section II: Evaluation of Risk

All three boxes must be checked in order to proceed to Section III and request an expedited review.

If all three boxes are not checked, the project does not qualify for expedited review and this form does not need to be submitted with the PI New Project Application.

- The project presents no more than minimal risk to participants.

A project is minimal risk if 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)).

- The identification of participants or their responses will not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- The project is not classified.

Section III: Expedited Review Category

Please check one or more of the following categories to indicate the category under which this project qualifies for expedited review.

If the project does not fit into one of the below categories, it does not qualify for expedited review.

- Category 1:** Clinical studies of drugs and medical devices only when one of the following conditions is met.
 - 1a:** An investigational device exemption application (21 CFR Part 812) is not required.
 - 1b:** The medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- Category 2:** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - 2a:** From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week.
 - 2b:** From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
- Category 3:** Prospective collection of biological specimens for research purposes by noninvasive means.
- Category 4:** Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing.
- Category 5:** Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). This category also includes research involving materials that were previously collected for either non-research or research purposes, provided that any materials collected for research were not collected for the currently proposed research.
- Category 6:** Collection from voice, video, digital or image recordings made for research purposes.
- Category 7:** Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Please provide a short justification for the assignment of the above category:

Section IV: Investigator Signature

I am requesting that this project be reviewed under the expedited review process. I believe this project meets the qualification for the designated expedited review category or categories indicated above.

Principal Investigator's Signature

Date

Local Participating Site Tracking Log

Study: _____ Type Review: _____
 Category (If Expedited): _____

PI Application

Site	VA Central IRB Num	PI/Co-PI/CC	MOU/ FWA	PI APP Recv'd	Admin Review	IRB Review Comments	Reg Review	Privacy Review	ISO Review	Comments to PI	PI Resp Rec'd	Convened Review or Sent to Rev	Board Dec Ltr

LSI Applications *Local R&D Approval from PI site must be received before final VA Central IRB approval of any LSI Applications can be granted)*

Site	Local Site Trkg Num	LSI	MOU/ FWA	LSI APP Recv'd	Admin Review	Reviewer Comments	Sent to LSI	LSI Res Recvd	Board or Fw to Rev	Board Dec Ltr	LSI Resp Rec'd	Board Dec Ltr	Reported Board

30-Day Comments

Site	Comments Received	Review by Board or Reviewer	Response Sent

Rows are added as needed and columns expanded as form is being filled out.
 Panes can be frozen as appropriate for ease in viewing on screen,

