

TITLE: VA Central IRB Communications with Investigators and Local Participating Sites

1.0 PURPOSE

This Standard Operating Procedure (SOP) sets forth the policies and procedures the VA Central IRB will use in communicating the results of project reviews to investigators and local participating sites. It also details the policies and procedures for how the local participating sites and investigators should respond to the VA Central IRB concerning communications requiring an action and/or response on their part.

2.0 REVISION HISTORY

Date of Initial Approval	July 2, 2008
Revision Dates	November 2, 2009 March 24, 2010 September 13, 2010 February 14, 2011 August 9, 2011

3.0 SCOPE

3.1 This SOP applies to all research that is submitted to the VA Central IRB for review. It includes initial review of new project applications, requests for continuing review, and requests for amendments. This SOP does not apply to communications concerning adverse event and unanticipated problem reporting, project deviations, project noncompliance, complaints, routine compliance audits, data monitoring reports, or reports of other oversight activities. Those are addressed in the applicable SOPs pertaining to those topics.

3.2. This SOP applies to all VA Central IRB administrative staff, Principal Investigators/Study Chairs (PI/SCs) and their study teams, Local Site Investigators (LSIs) and their study teams, as well as local site Institutional Officials (IOs) and their designated responders and liaisons.

4.0 POLICY

4.1 It is the policy of the VA Central IRB to foster open, frequent, and effective communications with both investigators and local participating sites. The VA Central IRB administrative staff ensures that communications by the VA Central IRB are timely, accurate, and complete. In order to promote timely notification, the use of e-mail is encouraged. Investigators must provide their VA e-mail addresses to facilitate the communication process. For all e-mail related to the contents of a protocol or in regard to monitoring and oversight actions, the e-mail must be sent encrypted. For general e-mail pertaining to project

submission and processing logistics and policies and procedures, e-mail without encryption may be used.

4.2 It is the policy of the VA Central IRB that written communication concerning a study determination or action by the VA Central IRB is forwarded to the PI/SC, the LSIs, and to the local participating sites designees at each appropriate step in the review process, whether by e-mail, fax, encrypted e-mail, or uploaded to the VA Central IRB secure SharePoint Site. If the written communications are disseminated via the secure SharePoint site, specific access instructions with the appropriate links will be forwarded to investigators and authorized site personnel.

4.3 VA Central IRB administrative staff may communicate preliminary results of reviews by the VA Central IRB to a study team via encrypted mail or by phone to facilitate prompt communication. However, the communication should contain only the approval determination, i.e., approval contingent upon required minor modifications, and should state that other details will be provided in a written communication pending verification and signature from the Co-Chair, or other voting member of the VA Central IRB if applicable. If the communication is by phone, the VA Central IRB Coordinator will follow-up with an encrypted e-mail referencing the conversation. If the action pertains to an amendment, no action may be initiated except to eliminate immediate hazards to participants, until an approval letter is signed by one of the VA Central IRB Co-Chairs.

4.4 For Cooperative Studies Program (CSP) studies and for other studies that use a Coordinating Center, all written communications addressed to the PI/SCs and LSIs are also sent to the applicable Coordinating Center. Coordinating Center staff members do not receive written communications from the VA Central IRB to the local participating site liaisons or designees. For the purposes of this SOP, when referring to written communications sent to the PI/SCs and the LSIs, it is inferred that the documents are also sent to the applicable Coordinating Center.

4.5 The VA Central IRB encourages questions about the VA Central IRB review process from investigators, local participating sites, human research participants, the community of Veterans, and the public.

4.5.1 The VA Central IRB staff is available to investigators and sites via telephone and e-mail during normal duty hours (approximately 7:30 a.m. to 4:30 p.m. Eastern.) and will answer questions and/or respond to inquiries as soon as possible. Site personnel or investigators can also schedule in-person meetings with VA Central IRB staff if they are in Washington, DC, or are planning a visit, or they can request teleconferences, and/or webinars depending upon the topic to be discussed.

4.5.2 The VA Central IRB also maintains methods of communication open to not only investigators and local participating sites, but to the public as

well. These are the Program for Research Integrity Development and Education (PRIDE) toll free phone line at 877-254-3130 and the VA Central IRB general e-mail address at vacentralirb@va.gov. These are monitored on a daily basis and inquiries forwarded to the appropriate personnel for a timely response.

5.0 DEFINITIONS

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

6.0 RESPONSIBILITIES

6.1 The Institutional Officials (IOs) of the local participating sites are responsible for the following:

6.1.1. Appointing Local Site Liaisons at the local participating facility to serve as the main point of contact for the VA Central IRB.

6.1.2 Appointing the Local Site Designees who review the determinations of the VA Central IRB regarding its review of new project applications, provide comments, and submit a final local site participation decision regarding a specific study.

6.1.3 Signing the Memorandum of Understanding (MOU) between the local VA facility and the VHA Central Office regarding the use of the VA Central IRB as one of the local facility's IRBs of Record and for ensuring the provisions of the MOU are carried out by local VA facility staff.

6.2 Local Site Liaisons are responsible for carrying out their appointed duties in accordance with the approved MOU, to include ensuring that the local facility R&D Office maintains a complete copy of the current, approved project, and facilitating communications between the local site and the VA Central IRB regarding VA Central IRB decisions, local designee reviews, local R&D decisions, or any other actions regarding VA Central IRB-approved projects.

6.3 Local Site Designees are responsible for responding to the determinations of the VA Central IRB on new project applications within the required time frames and for submitting the final local site participation decision.

6.4 Research Compliance Officers (RCOs) and other Individuals at local participating sites who perform routine compliance monitoring of VA Central IRB-approved projects are responsible for reporting the results of their monitoring activities on those projects to the VA Central IRB.

6.5 Investigators are responsible for responding to the determinations of the VA Central IRB within the requested time frame specified in the determination letter, usually 30 calendar days, and for providing a complete and thorough

response. Investigators are also responsible for maintaining open and frequent communication with their local site Research and Development (R&D) offices and with the VA Central IRB to facilitate understanding, ensure the project is being conducted as approved by the VA Central IRB, and to protect the rights and welfare of the participants involved.

6.6 The VA Central IRB Coordinators and the VA Central IRB Administrator are responsible for the following:

6.6.1 Preparing and/or reviewing all written communication to both the local participating site and the investigators concerning actions taken by the VA Central IRB and for ensuring all documents pertaining to project actions are appropriately filed in the project folder and in the electronic file on the VA Central IRB shared drive and the secure VA Central IRB SharePoint site.

6.6.2 Keeping all applicable project tracking logs up to date as written communications are sent and received.

6.6.3 Promptly answering all e-mail and telephone inquiries from investigators, local participating facilities, human research participants, and the general public and for ensuring that all communications regarding the conduct of specific projects are filed in the applicable project folders and the VA Central IRB shared drive electronic folder.

6.6.4 Ensuring both the PRIDE toll free number and the VA Central IRB e-mail box are checked at least once each work day and all inquiries responded to or forwarded to the applicable individual for response.

6.6.5 Posting copies of the current approved project application package to the VA Central IRB secure SharePoint site for each participating site, as well as applicable copies of VA Central IRB meeting minutes in which an action was taken on a study that a site is participating in.

6.7 The VA Central IRB Co-Chairs are responsible for reviewing and approving the minutes or other written documentation prepared by the VA Central IRB staff regarding determinations made by the VA Central IRB during the convened VA Central IRB meeting, or during the expedited review process as applicable, prior to the results being released to the investigator and/or the local participating sites. The VA Central IRB Co-Chairs may make changes, additions, or deletions to the communications as needed.

7.0 PROCEDURES

7.1 Appointment of Local Site Officials. Upon receiving the signed copy of the MOU from the Director, PRIDE, and receiving notice that the VA Central IRB has been added as an IRB of record to a local VA facility's Federalwide Assurance (FWA), the following actions are taken:

7.1.1 The VA Central IRB Meeting Coordinator updates the PRIDE Access database of VA facilities indicating an MOU is in effect. The list of sites with active MOUs is also updated on the VA Central IRB website.

7.1.2 A copy of the signed MOU is sent via Express mail or by e-mail to the IO of the local VA facility with a cover letter signed by the Director, PRIDE, asking that a local official or a combination of local officials be appointed to serve as the Local Site Liaison (see Paragraph 6.2) and the Local Site Designee(s) (see Paragraph 6.3). The Local Site Liaison and the Local Site Designee(s) will:

- Respond to the initial review determination of the VA Central IRB for new projects
- Respond to the final review determination of the VA Central IRB and either agree to participate or decline to participate in the new project
- Serve as the local site liaison between the local site, the investigators and the VA Central IRB

7.1.3 The local site IO or designee authorized to act on behalf of the facility, may respond with the appointments via e-mail or a written memorandum sent via Express mail or by fax. VA Central IRB administrative staff will follow-up with the local facility if the appointment designations have not been received within 30 days after sending out the signed MOU. The VA Central IRB Meeting Coordinator continues to follow-up in 30-day intervals until the appointment designations are received.

7.1.4 Upon receipt of the appointments, the VA Central IRB Meeting Coordinator updates the PRIDE Access database with the names of the appointees. Local Site Liaisons are sent an information letter and a handout regarding their duties and responsibilities (Attachment 1) and will be invited to participate in any ongoing webinars that are available for local sites or one can be arranged per their request. Appointments remain in effect until a replacement appointment is named and written documentation received from the local VA facility.

7.2 Communicating the Results of Initial PI/SC New Project Application Reviews. The VA Central IRB communicates the results of the VA Central IRB review of new project applications to the PI/SC and the local participating VA sites within approximately 10 working days of an action being taken in the following manner:

7.2.1 If the new project application was tabled or deferred, a written communication indicating the basis for this action and required modifications to secure approval is sent to the PI/SC and Coordinating Center as applicable. The letter will also include the mechanism for the investigator to appeal the decision. The investigator will be asked to provide a response within 30 days of receipt of the communication or to provide a status update if a response cannot be

forwarded with the 30 days. The VA Central IRB Coordinator will continue to follow-up at 30 day intervals regarding the status of the study until a re-submission is received or the study is withdrawn. This communication will not be forwarded to the local participating sites or LSIs at this time.

7.2.2 If the new project application was approved contingent upon required minor modifications or approved contingent upon receipt of local participating site comments, the following actions are taken by the VA Central IRB administrative staff and Co-Chair:

7.2.2.1 A written letter is prepared by the VA Central IRB Coordinator for the project detailing the specific determinations of the VA Central IRB regarding the risk level, IRB approval criteria, the approval of any waiver requests, the approval period if reviewed at a convened meeting, any other determinations that were made, i.e., whether medical records will need to be flagged or issues concerning the use of a vulnerable population, and a detailed description of required modifications and the basis for making them, if applicable.

7.2.2.2 The draft of the letter is reviewed by the VA Central IRB Administrator, changes made as needed, and then forwarded by the VA Central IRB Coordinator to the applicable VA Central IRB Co-Chair for signature, along with any other documentation that needs to be signed, i.e., waiver requests or VA Form 10-9012s.

7.2.2.3 The VA Central IRB Co-Chair reviews the letter for completeness and accuracy, makes any necessary changes in the letter, and then signs the letter and returns it to the VA Central IRB Coordinator.

7.2.2.4 Upon receipt of the signed letter, the VA Central IRB Coordinator makes applicable copies for the file, scans and uploads a copy to the VA Central IRB shared drive, and sends a signed copy with any applicable attachments such as a marked up informed consent document indicating required modifications, to the PI/SC. This can be sent via encrypted e-mail or loaded on the SharePoint site.

7.2.2.5 Copies of the entire PI/SC New Project Application package and the VA Central IRB determination letter addressed to the PI/SC is also made available to each identified participating local site, along with VA Central IRB Form 141, Potential Local Participating Site Comments to VA Central IRB Review of New PI/SC New Project Application (Attachment 2), for the local site designee in regard to providing local site comments pertaining to the VA Central IRB review. Local sites are asked to respond within 30 days of receiving the request for comment. These copies are loaded onto the SharePoint site and the local site designees are sent a link informing them the documents are ready for review.

7.2.3 If a PI/SC New Project Application was disapproved, the investigator will be informed that he/she has 60 days to appeal the disapproval decision in writing to the VA Central IRB and that this must be done in a Memorandum addressing each one of the disapproval reasons detailed in the disapproval letter.

7.3 Receipt, Processing, and Review of Local Site Comments. Local sites can submit the completed VA Central IRB Forms 141 via encrypted e-mail, fax, Express mail, or upload the completed form to the VA Central IRB secure SharePoint site.

7.3.1 The VA Central IRB Coordinator follows-up seven days after sending out the request to each local site, if they have not already received a response, to determine if the individual designated by the IO has received the request for review.

7.3.2 Local sites must either submit comments or indicate they have no further comment. Seven days before the end of the 30-day comment period, if no comments have been received, the VA Central IRB Coordinator sends a reminder notice by e-mail. If comments are sent after the end of the 30-day comment period, they will be forwarded to the VA Central IRB Administrator for review and a determination concerning further processing and review.

7.3.3 The VA Central IRB Coordinator ensures the Local Site Tracking logs are kept up-to-date regarding the status of each site.

7.3.4 Upon receipt and review of all the local site comments that were received by the required deadline date, the convened Central IRB or, in the event of an expedited review, the Expedited Reviewer and VA Central IRB Co-Chair, will determine if any further modifications in the PI/SC New Project Application need to be made in accordance with those applicable SOPs (109 and 110).

7.4 Communicating Results of Final Approval of PI/SC New Project Applications. Upon receipt and verification of any required modifications, or if no further modifications were required as a result of the local site review, the following actions will be taken:

7.4.1 The VA Central IRB Coordinator prepares a draft approval letter for the signature of the Co-Chair.

7.4.1.1 This letter will include all the determinations made by the VA Central IRB in accordance with the approval criteria, risk level, any other determinations or restrictions made by the VA Central IRB, the approval of any waiver requests, and specify the period of approval. The approval letter also includes a list of all major documents approved as part of the approved PI/SC New Project Application, to include the date of each document, and revision numbers if applicable. This can be done in the body of the letter or as part of an

attachment depending on the study and the volume of documents. These documents include the VA Central IRB Form 108, the protocol, the informed consent document, and the HIPAA Authorization if applicable.

7.4.1.2 The VA Central IRB Administrator reviews the draft letter, makes any necessary changes, and the letter is then forwarded by the VA Central IRB Coordinator to the VA Central IRB Co-Chair via encrypted e-mail or uploaded to the Co-Chair folder on SharePoint.

7.4.2 The Presiding VA Central IRB Co-Chair for that study reviews the letter for accuracy and completeness and verifies, if applicable, that all required modifications were made in a satisfactory manner. The Co-Chair makes any necessary changes to the letter, signs it, and then forwards it back to the VA Central IRB Coordinator.

7.4.3 The VA Central IRB Coordinator then prepares a copy of the approved PI/SC package, to include the approved informed consent form, if applicable, that is stamped or otherwise marked with the VA Central IRB approval date, and makes it available to the PI/SC by uploading it into SharePoint and e-mailing the link to the PI/SCs VA e-mail address. SharePoint links cannot be sent to an investigator's university e-mail address. The approved package is also made available to the local VA Central IRB liaisons of the PI/SC and Co-PI/SCs sites as applicable, as well as the Coordinating Center site, if different.

7.5 Communicating the Results of the Review of Local Site Investigator Applications: Upon review of a LSI Application, the results of the review are communicated as detailed below. Copies of all VA Central IRB determination letters are also made available to the PI/SC on the VA Central IRB SharePoint site.

7.5.1 If the LSI Application was tabled or deferred, a letter is drafted by the VA Central IRB Coordinator indicating the basis for the deferral or tabled action, the modifications required to secure approval, and the mechanism for the investigator to appeal. If the LSI Application was approved contingent upon minor modifications, a letter is drafted detailing the required modifications. If the LSI Application was approved, a final approval letter is drafted indicating the approval date and approval period, which is the same as for the PI/SC Application, along with any site-specific comments or restrictions.

7.5.2. The VA Central IRB Coordinator forwards the letter to the VA Central IRB Co-Chair via encrypted e-mail or via the SharePoint site. The VA Central IRB Co-Chair reviews the letter for accuracy and completeness and verifies that any modifications that were required, if applicable, have been made in a satisfactory manner. The VA Central IRB Co-Chair makes any necessary changes, signs the letter and returns it to the VA Central IRB Coordinator.

7.5.3 The VA Central IRB Coordinator then prepares a copy of both the approved LSI and the PI/SC Application packages for distribution as follows:

7.5.3.1 A copy of both approved packages is sent to the LSI or uploaded to the site folder on the VA Central IRB SharePoint site, to include a copy of the approved informed consent document if applicable, that is stamped or otherwise marked with the VA Central IRB approval date.

7.5.3.2 A copy of the approved LSI Application package, to include a copy of the approved informed consent document if applicable, that is stamped or otherwise marked with the VA Central IRB approval date, is sent to the PI/SC or made available via SharePoint.

7.5.3.3 Copies of both the approved PI/SC and specific LSI Application package is made available via SharePoint to each applicable participating site.

7.6 Local Site Participation Decisions and Communication with Local Site Liaisons. Each site participating in the study is required to make a participation decision upon receipt of the approved PI/SC New Project Application and the approved Local Site Investigator Application as applicable.

7.6.1 A cover letter is included in the approved application package that is loaded on the secure SharePoint site addressed to the IO designee responsible for making the local site final participation decision for each site explaining the requirement for the site to complete the VA Central IRB Form 130a, Local Site Participation Decision Memorandum (Attachment 3).

7.6.1.1 If a project has no participating sites other than the PI/SC site and/or the involvement of other sites is only due to the involvement of a Co-PI for which a VA Central IRB Form 108a was submitted, a VA Central IRB Form 130b, PI/SC Site Participation Memorandum (Attachment 4) is sent to the applicable sites in lieu of the VA Central IRB 130a. A cover letter is drafted by the VA Central IRB Coordinator to accompany the Participation Decision Memorandum along with a copy of the approved PI/SC Application Package.

7.6.1.2 If the site is engaged only through the involvement of a Coordinating Center for which a VA Central IRB Form 108b was submitted, the involved sites will receive a VA Central IRB Form 130c (Attachment 5), Coordinating Site Local Site Participation Decision Memorandum. A cover letter is drafted by the VA Central IRB Coordinator to accompany the Participation Decision Memorandum along with a copy of the approved PI/SC Application Package.

7.6.2 Each site has 10 working days to submit the applicable VA Central IRB Form 130 to the VA Central IRB Coordinator. If the form is not received by the 10th work day, the VA Central IRB Coordinator will follow-up on a

weekly basis with the local site designee until the form is received. Upon receipt of the VA Central IRB Form 130, the following actions are taken:

7.6.2.1 If the site chooses not to participate, the VA Central IRB Administrator and Co-Chair are informed and will attempt to resolve any issues or concerns. If the situation cannot be resolved, the PI/SC is informed and sent a copy of the VA Central IRB Form 130. The local site is then dropped from the study.

7.6.2.2 If the site chooses to participate, a copy of the applicable VA Central IRB minutes and a copy of the complete, approved PI Application, and the LSI Application for that site if applicable, are made available on SharePoint to the local site liaison.

7.6.3 The Local Site Liaison is responsible for ensuring that a copy of the local R&D approval of the project is forwarded to the VA Central IRB Coordinator. If the local R&D approval is not received after 30 days from when the Participation Decision Memorandum was received, the VA Central IRB Coordinator will follow-up with the site liaison and will continue to follow-up at 30 intervals until the local R&D approval notice is received.

7.7 Communicating the Results of Continuing Reviews. The VA Central IRB communicates the results of continuing reviews to PI/SCs, LSIs, and local participating sites in the following manner:

7.7.1 If the PI/SC Application is deferred for major modifications, the VA Central IRB Coordinator will draft a letter containing the basis for the deferral action and detailing the modifications required for approval. The letter will also contain the deadline for re-submission that will allow the VA Central IRB to review the study again prior to any lapse in approval. This draft will be reviewed by the VA Central IRB Administrator and any necessary changes made prior to the letter being forwarded to the VA Central IRB Co-Chair for review and signature.

7.7.2 If minor modifications are required for approval these will be communicated to the PI/SC in a formal written memorandum. The letter is then reviewed and signed by the VA Central IRB Co-Chair. The letter will also indicate the date the modifications must be received in order to avoid a lapse in the current approval of the project.

7.7.3 If there are no modifications or if any required modifications have been made and submitted, the VA Central IRB Coordinator prepares the continuing review approval letter for the PI/SC Application for review, verification of any required modifications if applicable, and signature of the Co-Chair. If an amendment was submitted in conjunction with the Request for Continuing Review Report, the approval of the amendment will be incorporated into the letter for the continuing review approval if feasible. Otherwise, a separate letter will be

issued, i.e., the amendment required additional modifications separate from the continuing review approval or the amendment was disapproved, tabled, or deferred. The new approval letter contains the VA Central IRB determinations based on the IRB approval criteria, confirms the current risk level, and indicates the new approval period expiration date. The letter is reviewed by the VA Central IRB Administrator prior to forwarding to the Co-Chair for signature.

7.7.4 For Local Site Investigator Applications, if there are no modifications or if any required modifications have been made and submitted, the VA Central IRB Coordinator prepares the continuing review approval letter for each specific site for review, verification of any required modifications if applicable, and signature of the VA Central IRB Co-Chair. If an amendment was submitted with the Request for Continuing Review Report, the approval of the amendment will be incorporated into the continuing review approval letter if feasible. The letter contains the determinations made by the Expedited Reviewer and Co-Chair based on the IRB approval criteria and indicates the new approval period expiration date.

7.7.5 Upon signature of the final continuing review approval of the PI/SC Application by the Co-Chair, the following actions take place:

7.7.5.1 For projects that involve only the review of the PI/SC Continuing Review Application, a copy of the approved application package will be made available on SharePoint and an e-mail message with the link sent to PI/SC and any Co-PI/SCs, the designated local site liaison for the PI/SC site, the designated liaison for the site of any Co-PI/SC listed, and to each of the participating Coordinating Centers if applicable.

7.7.5.2 For projects that also involve Local Site Investigator Applications, a copy of the approved PI/SC Application package and the specific Local Site Investigator Application package, is made available to the applicable LSIs and local VA Central IRB liaisons via SharePoint. The PI/SC, and Coordinating Center as applicable, also have access and are notified of the upload to SharePoint of each of the approved LSI Applications.

7.7.6 If modifications are requested, these must be submitted and reviewed and approved prior to the expiration of the current approval period. Communicating lapses of approval is addressed in VA Central IRB SOP 112, Continuing Review and Approval Requirements.

7.8 Communicating the Results of Requests to Amend an Approved Project. The VA Central IRB communicates the results of the review of requests to amend an approved project in the following manner:

7.8.1 If the PI/SC submitted the request for amendment and it pertains to the entire project, the results of the VA Central IRB review are communicated to the PI/SC in a written memorandum via upload to SharePoint

or encrypted e-mail. The approved amendment application package, to include the approval memorandum, is also made available to the LSIs and local VA Central IRB liaisons via SharePoint and they are notified of the link via encrypted e-mail.

7.8.1.1 If the amendment involved changes in the informed consent document that must be made by the local participating sites or if any other changes must be made by the local site, the VA Central IRB administrative staff follow-up with each local site until the revised consent or any other documents that needed to be changed by the local site due to the approved amendment are received by the VA Central IRB.

7.8.1.2 A separate amendment request (VA Central IRB Form 116) from each site does not have to be submitted. However, upon receipt of revised informed consent documents based on the approved PI/SC amendment, the VA Central IRB Coordinator assigns each local site submission an amendment number and processes them for approval of the Co-Chair or Expedited Reviewer as applicable. If the changes involved the informed consent document, the document is stamped with the current approval date and a copy sent to the sites, along with the approval letter.

7.8.2 The VA Central IRB Coordinator follows-up approximately every two weeks until the required documents are received. If the required documents are not received within 60 days of notification of the requirement, the non-compliance of the particular local site is forwarded to the VA Central IRB for potential review under VA Central IRB SOP 118, Serious and Continuing Noncompliance.

7.8.3 If the amendment request from a PI/SC pertains only to the PI Application and/or does not affect the local participating sites, the local sites are sent a copy of the final approval memorandum and any revised documents with no further action required on the part of the local sites.

7.8.4 If an amendment request pertains to a specific local site, the results of the review will be drafted in a memorandum by the VA Central IRB Coordinator and reviewed and approved by one of the VA Central IRB Co-Chairs. The memorandum and any associated documentation will then be forwarded to the LSI with copies to the PI/SC, the applicable VA Central IRB Local Site Liaison, and for CSP Studies or other studies utilizing Coordinating Centers, to the applicable Coordinating Center.

7.9 Version Dates and Approval Dates for Local Materials.
b before approval by the VA Central IRB.

7.9.2 The VA Central IRB only puts an approval date "stamp" on the informed consent form version approved per VA requirements. However, per local policy requirements in regard to the displaying of recruitment materials in

the local facility, the VA Central IRB can also put an approval date on approved local recruitment materials if local policy will not allow the materials to be displayed or distributed otherwise.

7.10 Sample Letters. Sample letters for some types of communications with investigators and local sites are kept on the VA Central IRB shared drive. These are samples only and can be used as the basis for the VA Central IRB Coordinators to draft each letter. Each letter must be customized per the applicable study and carefully reviewed to ensure it contains all applicable required elements for the action reviewed.

7.10 Table of Reporting Requirements (Attachment 6). This table contains a list of reporting requirements to the VA Central IRB and is referenced in the final approval letters for PI/SC Applications, the final approval letters for all Local Site Investigator Applications, and continuing review approval letters for both PI/SC and Local Site Investigator Applications. It is also available on the VA Central IRB website. The table also contains required reporting timeframes and the forms to be used for the type of reporting event.

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 from Human Subjects in Research

8.4 VHA Handbook 1605.01, Privacy and Release of Information

8.5 21 CFR 56, U.S. Food and Drug Administration, Institutional Review Board

8.6 45 CFR 164.508, HIPAA Privacy Rule

6 Attachments

1. Responsibilities of the Local Site Liaison Handout
2. VA Central IRB Form 141, Potential Local Participating Site Comments to VA Central IRB Review of New PI/SC New Project Application
3. VA Central IRB Form 130a, Local Site Participation Decision Memorandum
4. VA Central IRB Form 130b, PI/SC Site Participation Decision Memorandum
5. VA Central IRB Form 130c, Coordinating Center Local Site Participation Decision Memorandum
6. Table of Reporting Requirements

August 9, 2011

VA Central IRB SOP 111

I have reviewed and I approve the contents of this SOP.


K. Lynn Cates, MD
Director, PRIDE

Date: 8/10/11

Information for VA Central IRB Local Site Liaisons



In accordance with the Memorandum of Understanding your facility has with the Veterans Health Administration Central Office Human Research Protections Program (VHACO HRPP) for the VA Central IRB to serve as one of your IRBs of record, a Local Site Liaison must be appointed to assist the VA Central IRB in facilitating its oversight, compliance, and monitoring functions as they pertain to VA Central IRB-Approved studies. Section 1 of this handout details the responsibilities of the local VA Central IRB site liaison, Section 2 details what the liaison can expect from the VA Central IRB, and Section 3 discusses communications between the VA Central IRB Liaison and the VA Central IRB through the use of the VA Central IRB secure SharePoint system.

Section 1: VA Central IRB Local Site Liaison Responsibilities

Some of these responsibilities may be shared with other local site personnel but the VA Central IRB Liaison will serve as the main point of contact for the VA Central IRB.

- Facilitating communication with the VA Central IRB as needed and ensuring copies of all approved study documents that are loaded onto the VA Central IRB SharePoint site are downloaded for the site Research Office files as applicable; this also includes VA Central IRB reviews of serious adverse events, unanticipated problems involving risks to subjects or others, complaints, protocol deviations or other reports of non-compliance, such as VA Central IRB responses to RCO regulatory or informed consent audit reports.
- Assisting other designated site personnel in performing initial and final review functions as appointed per the MOU and relaying the results to the VA Central IRB.
- Providing results of initial local site review and approval in accordance with local R&D policies on new project applications or other types of reviews, i.e., Biosafety and/or Radiation Subcommittees, performed on a VA Central IRB-approved projects.
- Ensuring results of audits by local facility staff or outside agencies are provided in a timely manner on projects overseen by the VA Central IRB.
- Making necessary records available to the VA Central IRB as required to facilitate its oversight, compliance, and monitoring functions.
- Ensuring the VA Central IRB is immediately informed of actions taken by your site involving restriction, suspension, or termination of research privileges involving the Local Site Investigator or the research team members associated with a VA Central IRB-approved project.
- Providing feedback to the VA Central IRB on its operations and ensuring the VA Central IRB is included as part of the local site annual HRPP review.
- Ensuring the VA Central IRB is informed when personnel designated to perform functions per the MOU change. This is extremely important in order to ensure that the appropriate individuals receive e-mail notifications when documents are uploaded to the VA Central IRB SharePoint site and for VA Central IRB staff to be able to maintain up-to-date access controls for the site. *(Note: The Local Site Medical Center Director must appoint local designees in writing. This*

documentation can be forwarded to the VA Central IRB via e-mail.)

- Ensuring complaints and other events requiring reporting per VHA Handbook 1058.01 and the VA Central IRB Table of Reporting Requirements, which can be found on the VA Central IRB website, have been or are promptly reported to the VA Central IRB by responsible personnel in the required timeframes.

The VA Central IRB Local Site Liaison serves as the main Point of Contact for the VA Central IRB concerning local site issues.

Section 2: What Local Site Liaisons Can Expect from the VA Central IRB and its Administrative Staff

The VA Central IRB Administrator and/or the assigned VA Central IRB Coordinators for respective studies will ensure the following:

- Timely notification to the Local Site Liaison and other applicable site personnel when documents that are ready to be reviewed have been uploaded onto the VA Central IRB SharePoint site, such as requests for comment on initial VA Central IRB review of PI/SC Applications, requests for local site participation decisions, or other requests for information or notices of VA Central IRB actions.
- Granting access to the VA Central IRB secure SharePoint site to authorized site personnel and uploading copies of the following documents as they are processed, with appropriate notification to the local site liaison and other applicable site personnel concerning availability of the documents for review:
 - The approved PI/SC Application and Local Site Investigator Application packages as applicable, to include approved, stamped informed consent forms
 - Approved amendments to the Principal Investigator Application
 - Approved amendments to your Local Site Investigator's Application
 - Continuing review approvals and study closures applicable to the Local Site Investigator's involvement in the project
 - Notices of suspension, termination, or findings of serious and continuing noncompliance impacting the Local Site Investigator's involvement in the project. *(These may also be sent by encrypted e-mail.)*
 - VA Central IRB actions taken in response to reviewed reports, i.e., serious adverse event reports, DSMB reports, pertaining to the local site's participation in studies overseen by the VA Central IRB.
- Making VA Central IRB records available as needed to local site officials for compliance monitoring or other oversight obligations.
- Responding to any audit reports or other findings involving the operations of the VA Central IRB and the studies it oversees in a timely manner
- Providing input or information as requested to a local site request for information concerning the annual review of its HRPP or its accreditation/re-accreditation process.

Section 3: Use of the VA Central IRB SharePoint Site to Facilitate Communications and Disseminate Documents

- Each VA Central IRB Local Site Liaison will be granted access to the following folders on the VA Central IRB SharePoint Site. Notices will be sent via e-mail by VA Central IRB staff to VA Central IRB Liaisons, study team members, and others as applicable, when new documents are added:
 - VA Central IRB Local Site Liaison Folder
 - Study folders for which your local site is or has been designated as a potential participating site.
- The VA Central IRB Liaison folder consists of the following subfolders:
 - VA Central IRB minutes – Contains copies of approved meeting minutes of the VA Central IRB; within this subfolder meeting minutes are grouped by year and are searchable; recommend searches be conducted by VA Central IRB study number since all actions usually reference this number.
 - Current VA Central IRB Membership Roster
 - Current VHA Central Office HRPP Evaluation – this is provided to assist local sites in their annual HRPP evaluation, which must include the VA Central IRB.
- Within the study folder, the VA Central IRB Liaison will have access to the following subfolders, as will all local study team members:
 - PI/SC Project Documents – contains copies of the approved application package, to include the protocol and informed consent forms, as well as approved amendments and continuing review documents
 - LSI Project Documents – each VA Central IRB Liaison and each local study team will only have access to their own site folder. This folder will include the approved LSI Application, as well as approved LSI amendments and continuing review applications.
 - VA Central IRB Notifications – This folder is used by the VA Central IRB to post new notifications to study teams and VA Central IRB Local Site Liaisons, such as notifications when a continuing review is due or a response to a reported protocol deviation or SAE report. It is a temporary folder and documents usually only remain in this folder for 90 days or less depending upon the action. Site specific notifications will have a site folder with site name as a subfolder.
 - VA Central IRB Submission – This folder can be used by the VA Central IRB Liaison or the site study team to post newly submitted documents or responses to other documentation. A site specific subfolder should be created when uploading documents and a separate e-mail message sent to the VA Central IRB Coordinator of the study when uploading items to this folder to facilitate timely notification.
- The VA Central IRB staff highly encourages all VA Central IRB Liaisons to put an alert on the VA Central IRB Liaison folder, as well as your Local Site folder and the PI/SC folder within the main study folder; the system will e-mail you when new documents have been uploaded or you can request a summary notification of all actions to be sent at one time each day.

If you have any questions or concerns regarding your liaison duties and responsibilities, the functions and process of the VA Central IRB, or the procedures for accessing and using SharePoint, please contact the VA Central IRB at 1-877-254-3130.

Potential Local Participating Site Comments to VA Central IRB Review of New PI/SC New Project Application



This checklist is used by the designated local site representative to provide comments to the VA Central IRB regarding the VA Central IRB initial review of a New PI/SC Project Application.

1. Project and Reviewer Information *(To be completed by VA Central IRB Coordinator)*

VA Central IRB Number:		Due Back to VA Central IRB:	
Title of Project:			
Principal Investigators:			
Potential Local Participating Site:			
Site Reviewer:			

2. Site Response *(To Be Completed by Site Reviewer)*

<p>After reviewing the PI/SC New Project application and other applicable documents for the above referenced study, check one of these options:</p> <p><i>Note: The Site Reviewer must be the individual designated by the local Medical Center Director to perform such reviews.</i></p>	<p><input type="checkbox"/> I have no further comments <i>Please sign and date this form below and return it to the VA Central IRB via encrypted e-mail or load onto the secure SharePoint server by the due date.</i></p> <p><input type="checkbox"/> Yes, I have comments for consideration. <i>Please annotate comments on the attached site comment worksheet. Then sign and date this form and return it to the VA Central IRB by the due date.</i></p> <p>_____</p> <p>Signature/Name of Site Reviewer Date</p>
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3. Potential Local Participating Site Comments**VA Central IRB Review**

<i>(To Be Completed by Site Reviewer)</i>	<i>(To Be Completed by VA Central IRB Reviewer)</i>
VA Central IRB Form 108:	Response:
Protocol:	Response:
Informed Consent and HIPAA Issues:	Response:
Recruitment Procedures / Materials:	Response:
Other Comments:	Response:

Boxes may be expanded as necessary to accommodate comments.

Local Site Participation Decision Memorandum



This form is to be used by designated local site officials to indicate on behalf of a local site whether the site agrees to participate or declines to participate in a project approved by the VA Central IRB in which their site is listed as a potential participating site.

Instructions:

- In accordance with the Memorandum of Understanding (MOU) your site has with the VHA Central Office to use the VA Central IRB as one of your IRBs of Record for the review of selected VA Office of Research and Development projects, the site may elect to either participate or to decline to participate in a project after reviewing the final approval determination of the VA Central IRB for a particular project.
- The final approval determination of the VA Central IRB for the project named on this VA Central IRB Form 130a is being provided in accordance with this provision of the MOU. In addition, a copy of the approved PI/SC New Project Application and your approved Local Site Investigator Application are included in the materials you received with this form. Please review these documents and indicate the participation decision of your facility on the VA Central IRB Form 130a.
- The Local Site Participation Decision document must be returned to the VA Central IRB Administrative Office within **10 working days** of your receipt of this document. You may return this Participation Decision form to the VA Central IRB via one of the following methods:
 - **Fax the form to the following number: 202-495-6155.**
 - **Scan the signed form and send via encrypted e-mail to the designated VA Central IRB Coordinator for this project or upload the signed form to your local site folder for this study on the VA Central IRB SharePoint site.**
- If your site decides to participate, please assist your Local Site Investigator in following local procedures for obtaining approval at your site in accordance with your local R&D policies and VHA Handbook 1200.01. A copy of the VA Central IRB meeting minutes at which this project was approved, or at which the expedited approval was reviewed, will be uploaded to the VA Central IRB SharePoint site and your local site liaison will be notified when they are available.
- If you have any questions concerning the provision of the site decision, the final determination of the VA Central IRB concerning this project, or the provisions of the Memorandum of Understanding, please contact the designated VA Central IRB Coordinator or call the **VA Central IRB toll-free number at 1-877-254-3130.**

Local Site Participation Decision Memorandum



Project Identification *(To be completed by the VA Central IRB administrative staff)*

Title of Project:

Principal Investigator:

Local Site:

Local Site Investigator:

Date Forwarded to Site:

VA Central IRB Coordinator:

LOCAL SITE PARTICIPATION DECISION

Please check one of the below boxes:

<input type="checkbox"/>	Our site will participate in the above named project. The project will be reviewed in accordance with our local facility R&D policies and a copy of our local R&D approval letter forwarded to the VA Central IRB Administrative Office when available.
<input type="checkbox"/>	Our site will participate in the above named project. The project has already been reviewed in accordance with our local facility R&D policies and a copy of the approval letter is attached.
<input type="checkbox"/>	Our site declines to participate in the above named project. The reasons for this declination are indicated below. We will inform our Local Site Investigator of this decision. <i>Please indicate reasons:</i>

Note: The IRB meeting minutes at which this project was approved, or at which the expedited approval was reviewed, will be uploaded to the VA Central IRB SharePoint site for this project and your local site liaison will be informed that the minutes are available for review upon review at a subsequent meeting of the VA Central IRB and approval and signature by one of the Co-Chairs.

Signature

VA Central IRB Form 130a

Date

Page 2 of 2
Local Site Participation Decision Memorandum
Updated: August 8, 2011

PI/SC Site Participation Decision Memorandum

(No Separate Local Site Investigator Application)



This form is to be used by designated local site officials when the PI/SC is from their site and a separate Local Site Investigator Application is not being submitted, to indicate on behalf of the local site whether the site agrees to participate or declines to participate in a project approved by the VA Central IRB.

Instructions:

- In accordance with the Memorandum of Understanding (MOU) your site has with the VHA Central Office to use the VA Central IRB as one of your IRBs of Record for the review of selected VA Office of Research and Development projects, the site may elect to either participate or to decline to participate in a project after reviewing the final approval determination of the VA Central IRB for a particular project.
- The final approval determination of the VA Central IRB for the project named on this VA Central IRB Form 130b is being provided in accordance with this provision of the MOU. In addition, a copy of the approved PI/SC New Project Application is included in the materials you received with this form. Please review this application and indicate the participation decision of your facility on this VA Central IRB Form 130b.
- The Local Site Participation Decision document must be returned to the VA Central IRB Administrative Office within **10 working days** of your receipt of this document.
- You may return this Participation Decision form to the VA Central IRB via one of the following methods:
 - **Fax the form to the following number: 202-495-6155**
 - **Scan the signed form and send via encrypted e-mail to the designated VA Central IRB Coordinator for this project**
 - **Upload the signed form to your local site folder for this study on the VA Central IRB SharePoint site.**
- If your site decides to participate, the project must also be approved at your site in accordance with your local R&D policies and VHA Handbook 1200.01. A copy of the VA Central IRB meeting minutes at which this project was approved, or at which the expedited approval was reviewed, will be uploaded to the VA Central IRB SharePoint Site and your local site liaison will notified when they are available.
- If you have any questions concerning the provision of the site decision, the final determination of the VA Central IRB concerning this project, or the provisions of the Memorandum of Understanding, please contact the designated VA Central IRB Coordinator or call the **VA Central IRB toll-free number at 1-877-254-3130.**

PI/SC Site Participation Decision Memorandum

(No Separate Local Site Investigator Application)



Project Identification <i>(To be completed by the VA Central IRB administrative staff)</i>
Title of Project:
Principal Investigator/Study Chair (PI/SC):
PI/SC Site:
Date Forwarded to Site:
VA Central IRB Coordinator:

PI/SC SITE PARTICIPATION DECISION

Please check one of the below boxes:

<input type="checkbox"/>	Our site will participate in the above named project. The project will be reviewed in accordance with our local facility R&D policies and a copy of our local R&D approval letter forwarded to the VA Central IRB Administrative Office when available.
<input type="checkbox"/>	Our site will participate in the above named project. The project has already been reviewed in accordance with our local facility R&D policies and a copy of the approval letter is attached.
<input type="checkbox"/>	Our site declines to participate in the above named project. The reasons for this declination are indicated below. We will inform the Principal Investigator for this study of this decision. <i>Please indicate reasons:</i>

Note: The IRB meeting minutes at which this project was approved, or at which the expedited approval was reviewed, will be uploaded to the VA Central IRB SharePoint site for this project and your local site liaison will be informed that the minutes are available for review upon review at a subsequent meeting of the VA Central IRB and approval and signature by one of the Co-Chairs.

Signature

Date

Coordinating Center Local Site Participation Decision

(No Separate Local Site Investigator Application or PI/SC Application was submitted from site)



VA Institutional Review Board for Multisite Studies

This form is to be used by designated local site officials to indicate on behalf of the local site whether the site agrees to participate or declines to participate in a project approved by the VA Central IRB. This form is only used when no Principal Investigator/Study Chair or Local Site Investigator Application was submitted from their site and the only involvement in the study by site personnel is through their role in the Coordinating Center's operations.

Instructions:

- In accordance with the Memorandum of Understanding (MOU) your site has with the VHA Central Office to use the VA Central IRB as one of your IRBs of Record for the review of selected VA Office of Research and Development projects, the site may elect to either participate or to decline to participate in a project after reviewing the final approval determination of the VA Central IRB for a particular project.
- The final approval determination of the VA Central IRB for the project named on this VA Central IRB Form 130c is being provided in accordance with this provision of the MOU. In addition, a copy of the approved PI/SC New Project Application is included in the materials you received with this form. Please review this application and indicate the participation decision of your facility on this VA Central IRB Form 130c.
- We request that this document be returned to the VA Central IRB Administrative Office within **10 working days** of your receipt of this document.
- You may return this Participation Decision form to the VA Central IRB via one of the following methods:
 - **Fax the form to the following number: 202-495-155**
 - **Scan the signed form and send via encrypted e-mail to the designated VA Central IRB Coordinator for this project**
 - **Upload the signed form to your local site folder for this study on the VA Central IRB SharePoint site.**
- If your site decides to participate, the project must also be approved at your site in accordance with your local R&D policies and VHA Handbook 1200.01. A copy of the VA Central IRB meeting minutes at which this project was approved, or at which the expedited approval was reviewed, will be uploaded to the VA Central IRB SharePoint Site and your local site liaison will be notified when they are available.
- If you have any questions concerning the provision of the site decision, the final determination of the VA Central IRB concerning this project, or the provisions of the Memorandum of Understanding, please contact the designated VA Central IRB Coordinator or call the **VA Central IRB toll-free number at 1-877-254-3130**.

Coordinating Center Local Site Participation Decision

(No Separate Local Site Investigator Application or PI/SC Application was submitted from site)



VA Institutional Review Board for Multisite Studies

Project Identification (To be completed by the VA Central IRB administrative staff)

Title of Project:

Principal Investigator/Study Chair (PI/SC):

Site Coordinating Center is Located:

Date Forwarded to Site:

VA Central IRB Coordinator:

COORDINATING CENTER LOCAL SITE PARTICIPATION DECISION

Please check one of the below boxes:

<input type="checkbox"/>	Our site will participate in the above named project. The project will be reviewed in accordance with our local facility R&D policies and a copy of our local R&D approval letter forwarded to the VA Central IRB Administrative Office when available.
<input type="checkbox"/>	Our site will participate in the above named project. The project has already been reviewed in accordance with our local facility R&D policies and a copy of the approval letter is attached.
<input type="checkbox"/>	Our site declines to participate in the above named project. The reasons for this declination are indicated below. We will inform the Coordinating Center of this decision. <i>Please indicate reasons:</i>

Note: If either one of the boxes above are checked, a copy of the VA Central IRB meeting minutes at which this project was approved, or at which the expedited approval was reviewed, will be uploaded to the VA Central IRB SharePoint site for this project and your local site liaison will be informed that the minutes are available for review.

Signature

VA Central IRB Form 130c

Date

Table of Reporting Requirements to the VA Central IRB for Principal Investigator/Study Chair, Local Site Investigators, and Local VA Facility Research Compliance Officers



The following represents the types of events and information requiring prompt reporting to the VA Central IRB. Guidance on submission of other types of information commonly submitted to the VA Central IRB is also included.

Type of Report	Description	Form	Time Frame
All Unanticipated (Unexpected) Local Serious Adverse Events	Serious adverse events are adverse events in human research that result in: <ul style="list-style-type: none"> • Death • A life-threatening experience • Hospitalization (for a research participant not already hospitalized) • Prolongation of Hospitalization (for a research participant already hospitalized) • Persistent or significant disability or incapacity • Congenital anomaly or birth defect, or • The need for medical, surgical, behavioral, social, or other intervention to prevent any of the above. 	VA Central IRB Form 119: Report of Serious Adverse Events and Unanticipated Problems Involving Risks to Participants or Others	No later than 5 business days after being made aware of the occurrence
Unanticipated Problems Involving Risks to Participants or Others	Serious problems or events in research, which in the opinion of the reporting individual are: <ul style="list-style-type: none"> • not expected in terms of nature, severity, or frequency of occurrence, as documented in the research protocol or other materials approved or received by the IRB <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> • Places participants or others at a substantial greater risk of harm or discomfort related to the research than was previously known or recognized. 	VA Central IRB Form 119: Report of Serious Adverse Events and Unanticipated Problems Involving Risks to Participants or Others	No later than 5 business days after being made aware of the occurrence
Noncompliance: Protocol Deviations and Protocol Violations	A deviation from the VA Central IRB-approved protocol or determinations of the VA Central IRB is noncompliance. The words protocol deviation and protocol violation are synonymous. Protocol deviations or protocol violations that must be reported no later than 5 business days after being made aware of the occurrence are those that are likely to substantially adversely affect any of the following: <ul style="list-style-type: none"> • the rights, safety, or welfare of the research participant • the participant's willingness to continue participation; or • the integrity of the research data, including VA information security requirements 	VA Central IRB Form 129: Report of Protocol Deviations or Violations	5 business days after being made aware of the occurrence
<p style="color: red;">NOTE: Do not use VA Central IRB Form 129 to report a protocol deviation or violation that occurred without VA Central IRB approval in order to eliminate apparent immediate hazard to the research participant. Report the protocol deviation or violation to the VA Central IRB by using VA Central IRB Form 119: Report of Serious Adverse Events and Unanticipated Problems Involving Risks to Subjects or Others</p>			

Table of Reporting Requirements (cont.)

Type of Report	Description	Form	Time Frame
Modifications or Amendments	Amendments or modifications to approved projects must be submitted to the VA Central IRB for review and approval prior to implementation, except when necessary to eliminate apparent immediate hazard to human participants. Examples of modifications or amendments include protocol amendments, investigator's brochures, informed consent form changes, and addition of recruitment materials.	VA Central IRB Form 116: Request to Amend or Modify an Approved Project	Variable depending upon the modification or amendment
Change in Principal Investigator/Study Chair (PI/SC)	A change in the Principal Investigator/Study Chair for a VA Central IRB-approved project must be submitted to the VA Central IRB.	VA Central IRB Form 116: Request to Amend or Modify an Approved Project, biosketch, and local COI determination.	Prior to initiating change
Change in Local Site Investigator (LSI)	Changes in local site investigators for a research project conducted at multiple sites with a PI/SC currently approved by the VA Central IRB must be submitted to the VA Central IRB.	VA Central IRB Form 134: Change in Local Site Investigator Application	Prior to initiating change
Addition of Local Site Investigator	Addition of local site investigators and sites must be approved by the VA Central IRB prior to initiating the research project at the site.	VA Central IRB Form 104: Local Site Investigator Application	Prior to initiation addition
Changes in Study Team Members or Study Personnel	VA Central IRB approval is not required for changes in study personnel (other than the PI/SC or LSI) unless that individual is specifically named in the protocol. If the individual is named in the protocol, VA Central IRB approval of an amended protocol is required. Otherwise, changes in study personnel can be reported as a notification to the VA Central IRB at continuing review.	If named in protocol, use VA Central IRB Form 116: Request to Amend or Modify an Approved Project	Prior to initiation addition if individual is named in the VA Central IRB-approved protocol
Complaints	Complaints received about a study approved by the VA Central IRB must be reported to the VA Central IRB. Complaints will be summarized in the continuing review application sent to the VA Central IRB. However, complaints indicating that a research subject's rights, safety or welfare may have been or were at risk of being substantially adversely affected (e.g., complaint about being inappropriately consented) must be reported within 5 business days after the individual making the report is aware of the complaint.	No VA Central IRB Form required	5 business days after being made aware of the complaint
Suspension, Admin Hold, or Termination of Research	A change in status of research activities of a VA Central IRB-approved project, such as a suspension (e.g., administrative hold) of subjects who can be entered into a study or termination initiated by a sponsor, PI/SC, or LSI, must be reported to the VA Central IRB.	No VA Central IRB Form required.	5 business days after being notified

Table of Reporting Requirements (cont.)

Type of Report	Description	Form	Time Frame
Incarceration of the Participant	Incarceration of participants must be reported to the VA Central IRB. Research participants who are placed on probation or required to wear monitoring device are generally not considered to be prisoners.	No VA Central IRB Form required	5 business days after being made aware of the incarceration of the participant
New Information that Indicates a Change to the Risks or Potential Benefits of the Project	New information that indicates a change to the risks or potential benefits of the project must be reported to the VA Central IRB.	No VA Central IRB Form required	5 business days after being made aware of the new information
Miscellaneous	Project specific materials, such as VA Form 10-9012: Investigational Drug Information Record, must be submitted to the VA Central IRB. If you are unsure whether a document requires submission or reporting, please contact the VA Central IRB the PRIDE toll free number 877-354-3130 or vacentralirb@va.gov	No VA Central IRB Form required	Variable depending upon the material

Local Site Investigators (LSIs) should not report serious adverse events or unanticipated problems involving risks to participants or others if the reportable problem or event did not occur locally.

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

Table of Reporting Requirements (cont.)

For Local VA Facility Research Compliance Officers

Type of Report	Description	Form	Time Frame
Informed Consent, Regulatory Audit, or other Audit Activity	If an informed consent audit, regulatory audit, or other type of audit activity is conducted by the RCO of a VA Central IRB-approved protocol, the VA Central IRB must receive a copy of the findings. The VA Central IRB must be notified within 5 business days by the RCO if the RCO identifies apparent serious or continuing noncompliance as a result of the audit activity. Otherwise, the audit activity can be submitted with the continuing review application materials for the VA Central IRB-approved protocol.	No VA Central IRB Form required	Submit by encrypted email to Annette.Anderson3@va.gov within 5 business days if the audit activity involves identification of apparent serious or continuing noncompliance.