

1 SCOPE AND APPLICABILITY

- 1.1 The scope and purpose of this standard operating procedure (SOP) is to describe the policies and procedures the VA Central IRB will use in communicating the results of project reviews and actions taken to investigators, study teams, and local participating sites. It also details the policies and procedures for how the local participating sites, investigators, and study teams should respond to the VA Central IRB concerning communications requiring an action and/or response on their part.
- 1.2 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. This SOP includes initial review of new project applications, requests for continuing review, and requests for amendments to approved projects. This SOP does not apply to communications concerning adverse event and unanticipated problem reporting, protocol deviations, noncompliance reports, complaints, routine compliance audits, data monitoring reports, or reports of other oversight activities. Those are addressed in the applicable SOPs pertaining to those topics.
- 1.3 It is the policy of the VA Central IRB to foster open, frequent, and effective communications with investigators, study teams, 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 email is encouraged. Investigators must provide their VA email addresses to facilitate the communication process. Encryption must be used when the content of the email contains sensitive and/or confidential information.
- 1.4 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 appropriate steps in the review process, whether by email 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 via unencrypted email. Study teams are highly encouraged not to send any documentation to the VA Central IRB that contains PHI unless absolutely necessary and then this must be sent via an approved, secure method, such as encrypted email. If documents that need to be forwarded to the VA Central IRB contain identifying information, the study team should redact all such information prior to transmission unless otherwise instructed.
- 1.5 VA Central IRB administrative staff will communicate Reviewer comments requiring a response to study teams via email to facilitate prompt communication. (See VA Central IRB SOP 110.) Staff may also convey determinations made by the convened IRB to local study teams via email or phone but this preliminary 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 VA Central IRB Co-Chair. If the communication is by phone, the VA Central IRB Manager will follow up with an encrypted email referencing the conversation. If the action pertains to an amendment, no action may be initiated except to eliminate immediate hazards to participants, until the official written notice from the VA Central IRB is received.

1.6 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. 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.

1.7 The VA Central IRB also maintains the following to encourage timely and open communication between the VA Central IRB, the local sites, and study teams:

- VA Central IRB public website (www.research.va.gov/vacentralirb)
- VA Central IRB toll free number (877-254-3130)
- VA Central IRB general email address (vacentralirb@va.gov)
- VA Central IRB Liaison Folder on secure SharePoint site

2 DEFINITIONS

2.1 Cooperative Studies Program Coordinating Center (CSPCC). One of five centers established by the CSP to ensure that large clinical trials are scientifically sound, cost effective, and run efficiently and in accordance with all established regulations. These include Hines, Palo Alto, Perry Point, West Haven, and Boston. A sixth center is the Clinical Research Pharmacy located in Albuquerque, which provides input into the study design if the study involves drugs or medical devices and it is responsible for all drug-related activities, such as developing the drug handling protocol, negotiating with pharmaceutical companies, and packaging, distributing, and accounting for study drugs.

2.2 Institutional Official (IO). The IO is the individual legally authorized as Signatory Official to commit an institution to an Assurance. The IO is responsible for ensuring that the institution's HRPP functions effectively and that the institution provides the resources and support necessary to comply with all requirements applicable to research involving human subjects. The IO serves as the official representative of the institution to external agencies and oversight bodies and provides all written communication with external departments, agencies, and oversight bodies. (VHA Handbook 1200.05) A Senior Executive within the Office of the Principal Deputy Under Secretary for Health serves as the IO for the VHA Central Office HRPP and VA Facility Directors serve as the IO for local VA facilities.

2.3 Local Site Investigator (LSI). The Site Investigator or LSI is an investigator at a site participating in a multi-site research project. The LSI oversees scientific, technical, and day-to-day management of the research at the local site. The PI of a multi-site study can also be an LSI at their site or the site can have a different LSI for the same study.

2.4 Local Site Liaison. The Local Site Liaison is appointed by the local Medical Center Director to serve as the local facility's main point of contact with the VA Central IRB. This individual usually works in the facility Research Office and is responsible for ensuring timely and accurate communications between the VA Central IRB and local site research officials to include the Medical Center Director, ACOS/R&D, and the local R&D Committee as applicable.

2.5 Memorandum of Understanding (MOU). A written agreement between two VA facilities or between a VA facility and a non-VA Institution documenting their relationship and defining their respective roles and responsibilities within that relationship (VHA Handbook 1058.03, paragraph 4n).

2.6 Principal Investigator (PI). A PI is a qualified individual who directs a research project or research program. The PI oversees the scientific, technical, and day-to-day management of the research. In the event of an investigation conducted by a team of individuals, the PI is the responsible leader of the research team (VHA Handbook 1200.05).

3 RESPONSIBILITY

3.1 The IOs of the local participating sites are responsible for the following:

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

3.1.2 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.

3.1.3 Signing the 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 and incorporated into local facility SOPs.

3.2 Local Site Liaisons and designees are responsible for carrying out their appointed duties in accordance with the approved MOU. An Information Sheet for VA Central IRB Local Site Liaisons has been developed which details what is expected of the Local Site Liaison, what the Local Site Liaison can expect from the VA Central IRB, and how to navigate the SharePoint site. This handout can be found at Attachment 1.

3.3 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 in accordance with VA policy and VA Central IRB SOPs. In addition, per the approved MOU, RCOs are responsible for performing for cause audits at the request of the VA Central IRB and for providing the results to the IRB in a timely manner. An Information Sheet has also been developed for RCOs and can be found at Attachment 2.

3.4 Investigators are responsible for responding to requests and determinations of the VA Central IRB within the requested time frames specified. 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.

3.5 The VA Central IRB Administration Office is responsible for the following:

- 3.5.1 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, the electronic file on the VA Central IRB shared drive, and the secure VA Central IRB SharePoint site as applicable.
- 3.5.2 Keeping all applicable project tracking logs or databases up to date as communications are sent and received.
- 3.5.3 Promptly answering all email and telephone inquiries from investigators, local participating facilities, human research participants, and the general public.
- 3.5.4 Ensuring both the PRIDE toll free number and the VA Central IRB email box are checked at least once each work day and all inquiries responded to or forwarded to the applicable individual for response.
- 3.5.5. Making available copies of a newly approved PI/SC New Project Application available on Share Point for each participating site during the local comment period, as well the VA Central IRB approval letter.
- 3.5.6 Making copies of approved sets of VA Central IRB meeting minutes available to the site R&D Committees by uploading approved copies of the minutes to the VA Central IRB Liaison folder and ensuring all Local Site Liaisons are notified when an upload has occurred.

3.6 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 prior to the final 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.

4 PROCEDURE

4.1 Appointment of Local Site Officials. Upon receiving the signed copy of the MOU from the VHA Central Office Human Protections Administrator (HPA) 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:

- 4.1.1 The VA Central IRB SharePoint Administrator 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.
- 4.1.2 The VA Central IRB Administrator emails a copy of the signed MOU and a letter template to the IOs. The IO can use the template to appoint the Local Site Liaison and the Local Site Designee, as well as to provide comments to the VA Central IRB on newly approved projects. The same person can be appointed to do both functions or two different individuals can be appointed. One Alternate Site Liaison may also be appointed for large sites. A sample appointment template can be found at Attachment 3.

- 4.1.3 The local site IO or designee authorized to act on behalf of the facility may respond with the appointments via email. 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.
- 4.1.4 Upon receipt of the appointments, the VA Central IRB SharePoint Administrator updates the PRIDE Access database with the names of the appointees and sends the newly appointed Local Site Liaison the Information Sheet for Local Site Liaisons. Appointments remain in effect until a replacement appointment is named and written documentation received from the local VA facility.
- 4.1.5 Once a year the VA Central IRB Administration Office will send out a request for verification and update of local site officials to include the IO, R&D Committee Chair and Coordinator, local IRB Committee Chair and Coordinator, ACOS/R&D, Administrative Officer, Local Site Liaison, RCO, Local Site Designee, and local Non-Profit Corporation (NPC) IO and other contacts. Local sites will be requested to promptly respond to this update request so the VA Central IRB can ensure that required communications to the site are appropriately routed in a timely manner.
- 4.2 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 within 10 working days of the meeting in the following manner depending upon the type of review and determination made:
 - 4.2.1 If the new project application was deferred for major modifications, a written communication indicating the basis for this action and required modifications to secure approval is drafted by the assigned VA Central IRB Manager, reviewed/edited by the VA Central IRB Administrator, and then sent to a VA Central IRB Co-Chair for review, revision if applicable, and signature. The signed communication is then sent to the PI/SC, the National Study Coordinator, and to the Coordinating Center if applicable. The letter will also include the mechanism for the investigator to appeal the decision. This communication will not be forwarded to the local participating sites or LSIs at this time.
 - 4.2.2 If the new project application was approved contingent upon required minor modifications, the following actions are taken by the VA Central IRB administrative staff and Co-Chair:
 - 4.2.2.1 A written letter is prepared by the VA Central IRB Manager for the project detailing the specific determinations of the VA Central IRB and a detailed description of required modifications and the basis for making them, if applicable. The letter will also include the approval of any waiver requests, specify the period of approval, and include approval for the use of any vulnerable or other special populations like employees, pregnant women, etc.
 - 4.2.2.2 The draft of the letter is reviewed by the VA Central IRB Administrator, changes made as needed, and it is released for forwarding by the VA Central IRB Manager to the applicable VA Central IRB Co-Chair for signature.

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

4.2.2.4 Upon receipt of the signed letter, the VA Central IRB Manager uploads a copy to the VA Central IRB shared drive, and sends a signed copy with any applicable attachments, to the PI/SC and to the Coordinating Center if applicable. This can be sent via email or loaded on the SharePoint site and an email sent with the link to the SharePoint site.

4.2.3 If a PI/SC New Project Application was disapproved, the written communication will be drafted and processed per paragraph 4.2.1. The investigator will be given 60 days to appeal the disapproval decision in writing to the VA Central IRB. If the PI chooses to appeal, this must be forwarded to the VA Central IRB in a memorandum addressing each one of the disapproval reasons detailed in the letter. A copy will also be forwarded to the Coordinating Center and/or sponsor as applicable. A sample letter can be found at Attachment 7.

4.3 Communicating Results of Final Approval of PI/SC New Project Applications. Once a Reviewer indicates that all modifications have been adequately addressed for studies that were reviewed at the convened IRB or that all remarks and questions have been adequately responded to and any requested revisions made for new studies undergoing expedited review, the Reviewer will recommend approval of the study by completing or amending the applicable checklist or by sending an email with the approval recommendation to the assigned VA Central IRB Manager. The following actions will then take place.

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

4.3.1.1 This letter will include all the determinations made by the VA Central IRB or VA Central IRB Reviewer in accordance with the approval criteria to include the risk level of the study, the approval period and if the study was approved via expedited review, the applicable expedited review categories under which the study was reviewed. The letter will also include the following if applicable:

- Approval of any waiver requests to include both HIPAA waivers and waivers of informed consent or documentation of informed consent
- Approval for the use of any vulnerable populations such as pregnant women or participants with impaired decision-making capacity
- Approval for the use of non-Veterans as study participants
- Approval for the use of VA employees or students as study participants
- Approval for the use of participant SSNs
- 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, as an enclosure or attachment
- For FDA-regulated studies one or more of the following must be indicated: the IND number, validation that the study is exempt from IDE or IND regulations, or that a significant risk or non-significant risk determination was made.

4.3.1.2 The letter will also inform the study team that Local Site Investigator Applications can now be submitted and that the approved study documents are being provided to the local site designees in order for them to provide comments back to the IRB if they wish. Instructions for reporting reportable events will also be included in the letter as well as a reminder that all studies must still be approved in accordance with local site R&D Committee procedures before work on the project can begin.

4.3.1.3 The VA Central IRB Administrator reviews the draft letter and makes any necessary changes. The letter is forwarded by the VA Central IRB Manager to the VA Central IRB Co-Chair via email or uploaded to the Co-Chair folder on SharePoint and a task is assigned to the Co-Chair for review and signature.

4.3.2 The Presiding VA Central IRB Co-Chair for that study reviews the letter for accuracy and completeness, makes any necessary changes to the letter, signs it, and then forwards it back to the VA Central IRB Manager. Letters may be signed electronically if such capability is available.

4.3.3 The VA Central IRB Manager uploads the approved PI/SC Application documents, that are stamped or otherwise marked with the approval date, to the SharePoint site including the approved informed consent form(s) if applicable. The study manager makes it available to the PI/SC by emailing the link to the PI/SCs VA email address. The PI Local Site Liaison will also be included on the email, as will the National Study Coordinator and Coordinating Site personnel if applicable. SharePoint links cannot be sent to an investigator's or any other study team member's university email or other non-VA email address.

4.4 Local Site Comment Review Period. Upon approval of a new PI/SC Application, each local participating site named in the application will have the opportunity to provide comments to the VA Central IRB regarding their site's potential participation and to let the IRB know if they have any problems or concerns based on the approved study documents. The local site comment period will be conducted as follows:

4.4.1 A copy of the approved PI/SC New Project Application with associated documents and the determination letter addressed to the PI/SC is 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 4). The local site designees may provide comments on these documents and return them to the VA Central IRB. Local sites designees are asked to respond within 15 days of receiving the request for comment. These copies are loaded onto the SharePoint site and the local site designees, along with the local site liaisons, are sent a link informing them the documents are ready for review

4.4.2 Local sites can submit the completed VA Central IRB Forms 141 via email or upload the completed form to the VA Central IRB SharePoint site. Local sites should either submit comments or indicate they have no further comment. After the 15-day period is up, Local Site Investigator Applications will begin to be processed and approved. No reminders to the sites to submit comments will be sent. If comments are received after the end of the 15-day comment period, they will still be processed for review.

4.4.3 Any comments received that cannot be answered by the VA Central IRB Manager are sent to the Primary Reviewer for the study. The Primary Reviewer will review the comments and indicate one of the following: 1) No action needs to be taken and/or comments provided back to the site without any study actions taken, 2) The comment should be addressed by the LSI during the submission and review of the LSI Application, 3) the comment should be forwarded to the PI for a response or to consider as a suggestion, or 4) a request to amend the study should be sent to the PI. If the Reviewer indicates that a request to amend the study should be sent to the PI, the VA Central IRB Co-Chair will be informed. If the request involves a major change on a study reviewed by the VA Central IRB, it will be scheduled for review by the convened IRB prior to being forwarded to the PI. If the VA Central IRB Co-Chair and/or the convened IRB agree an amendment is required a letter will be signed by one of the Co-Chairs relaying the request to the PI. All other comments can be sent to the PI and/or LSIs via email.

4.4.4 The VA Central IRB Manager will ensure that each local site designee receives a response to any questions or concerns that were raised on the VA Central IRB Form 141 after the review by the VA Central IRB review is complete. The Manager will also update the VA Central IRB tracking database indicating the response status of each site. All correspondence concerning the comments and responses during the local site comment period will be kept on file in the project folder and/or on the VA Central IRB shared drive as applicable.

4.5 Communicating the Results of the Review of Local Site Investigator Applications: All Local Site Applications are reviewed via expedited review procedures unless deferred by the Primary Reviewer to a convened IRB meeting for review. The VA Central IRB Reviewer signs the approval on the VA Central IRB Form 111b, Reviewer Checklist for Local Site Applications, unless the Reviewer defers the review to a convened IRB meeting. The following actions take place after the Reviewer has made a determination:

4.5.1 If the LSI Application is approved, a letter is generated by the VA Central IRB Manager through the VA Central IRB tracking system indicating the date of approval, the continuing review approval expiration date, and listing the approved documents. This letter does not have to be signed by the Reviewer. The Reviewer checklist with the Reviewer's approval indicated or an email with the Reviewer's approval stated will be filed with the approval letter.

4.5.2 If the LSI Application is reviewed at a convened IRB, the VA Central IRB Manager forwards the letter to the VA Central IRB Co-Chair via encrypted email or via the SharePoint site for review and signature. The Co-Chair reviews the letter for accuracy and completeness, makes any necessary changes, signs the letter and returns it to the VA Central IRB Manager. If the LSI Application is disapproved, the letter will contain the basis for disapproval and the mechanism for the investigator to appeal. The disapproval notice will be forwarded to the investigator via encrypted email or posted to SharePoint and a link sent via unencrypted email.

4.5.3 For approved LSI Applications, the VA Central IRB Manager prepares a copy of the approved LSI Application and associated documents for distribution as follows:

- 4.5.3.1 Copies of the approved documents are 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.
 - 4.5.3.2 Other site specific documents are also uploaded as required per study design and choice of site in using any optional documents, such as various recruitment materials.
 - 4.5.3.3 Links to the approved documents are provided to all study and site personnel to include the LSI, PI/SC, the LSI and PI/SC Study Coordinators, the Coordinating Center if applicable, and the applicable Local Site Liaison, via email after upload of all documents is completed.
- 4.7 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:
- 4.7.1 For PI/SC Continuing Review Applications reviewed by the convened IRB, the following procedures will be followed:
 - 4.7.1.1 If the PI/SC Application is deferred for major modifications, the VA Central IRB Manager 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. Once modifications are received they will need to be reviewed by the convened IRB.
 - 4.7.1.2 If minor modifications are required for approval these will be communicated to the PI/SC in a formal written memorandum which is drafted and processed as above. The letter will also indicate the date the modifications must be received in order to be processed and the modifications reviewed and approved to avoid a lapse in the current approval of the project. Once the modifications have been received, the response can be reviewed via expedited review procedures per paragraph 4.7.4.
 - 4.7.1.3 If no modifications are required, the draft does not need to be reviewed by the VA Central IRB Administrator and can be sent directly to one of the Co-Chairs for signature.
 - 4.7.2 If the PI/SC Continuing Review Application is approved using expedited review procedures, the Reviewer will indicate approval on the VA Central IRB Form 114a, Reviewer Checklist for Continuing Reviewer (PI/SC Applications), the VA Central IRB Manager generates the PI/SC continuing review approval letter through the VA Central IRB tracking system indicating the date of approval, the continuing review approval expiration date, and listing the approved documents. This letter does not have to be signed by the Reviewer. The Reviewer checklist with the Reviewer's approval indicated or an email with the Reviewer's approval stated will be filed with the approval letter.

- 4.7.3 If an amendment was submitted and reviewed in conjunction with the Request for Continuing Review Report, the amendment will be separated from the continuing review application and processed separately from the continuing review application unless it pertains directly to the continuing review approval, i.e. an amendment is required to change something in order for continuing review to be granted.
- 4.7.4 All LSI Applications for continuing review are reviewed via expedited procedures unless deferred by the Primary Reviewer to a convened meeting of the IRB for review. No LSI Application can be given final approval prior to final approval of the PI/SC Application. If there are no modifications or if any changes or clarifications requested by the IRB have been made and the Reviewer has signed off on the approval on the checklist for a specific site, the VA Central IRB Manager generates the continuing review approval letter for each specific site through the VA Central IRB Access tracking system. The approval letter will contain the date of approval, the new continuing review approval expiration date, which will be the same date as the approved PI/SC Application, and a list of documents reviewed.
- 4.7.5 Once the approval letters are signed by the VA Central IRB Co-Chair or generated through the tracking system for expedited approvals, a copy of the approved PI/SC Application and associated documents, as well as the specific Local Site Investigator Application and associated documents if applicable, are made available to the PI/SC, applicable LSIs, PI/SC Study Coordinator and applicable LSI Coordinator, the Coordinating Center if applicable, and the applicable local VA Central IRB Site Liaisons via SharePoint. An email notification of the approval is sent with the applicable links.
- 4.7.6 Communicating lapses of approval is addressed in VA Central IRB SOP 112, Continuing Review and Approval Requirements.
- 4.8 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:
- 4.8.1 For PI and LSI amendments reviewed at the convened IRB, the letter relaying the determination by the VA Central IRB will be processed as per paragraph 4.7.1. or, if reviewed via expedited review procedures, the letter will be processed as per paragraph 4.7.2 except the letters will not include any reference to an approval lapse date.
- 4.8.2. Once approved, the approval letter and all associated documents approved with the amendment will be loaded to the VA Central IRB SharePoint site and links provided as indicated below:
- 4.8.2.1 For approved PI amendments, the PI, the PI National Study Coordinator, the Coordinating Center if applicable, all LSIs and LSI Coordinators, and all affected Local Site Liaisons will receive the email notification with link.
- 4.8.2.2 If the approved PI amendment involved changes in the informed consent document or any other model documents that are part of the approved study documents, each site

must update their site specific documents by uploading them to the SharePoint site. A separate amendment request (VA Central IRB Form 116) from each site does not have to be submitted as the local changes will be considered required site updates to the already approved Model document. If the changes involved the informed consent document, it is stamped with the current approval date of the PI/SC Model informed consent and the date of the LSI verification of the required change. Verified documents will be uploaded to SharePoint and email links sent to all applicable PI study and LSI study personnel and the Local Site Liaison.

4.8.2.3 The VA Central IRB Manager tracks the receipt of required updated documents. If the required documents are not received within 30 days of sending out the PI amendment approval, the noncompliance 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.

4.8.3 If an amendment request pertains to a specific local site, the email link to SharePoint will be sent 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.

4.9 Other Administrative Policies and Procedures Affecting Local Sites.

4.9.1 The VA Central IRB puts an approval date “stamp” only 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.

4.9.2 Letters for many types of communications with investigators and local sites are kept on the VA Central IRB shared drive and are available to VA Central IRB Managers to use as templates when drafting letters relaying the determinations of the VA Central IRB. Each letter must be customized per the applicable study and site and carefully reviewed to ensure it contains all applicable required elements for the action reviewed as well as the correct study and site identifying information. When a letter is issued that contains an error, such as a wrong investigator or site name, study teams and sites should immediately bring it to the attention of the VA Central IRB Manager for the study and a corrected letter will be issued.

4.9.3 All letters for study actions reviewed via expedited review procedures will be generated through the VA Central IRB Access tracking system, which has built-in templates. Each letter must still be carefully reviewed by the VA Central IRB Manager prior to release to ensure all information is complete and accurate. These letters will not be signed by the Reviewer. Supporting documentation with Reviewer approval will be kept by the VA Central IRB Administration Office on the VA Central IRB shared drive, and in the applicable project folder for FDA-regulated studies. If there is an error identified in the letter after its release, study teams should still notify the applicable VA Central IRB Manager and a corrected letter can be issued.

4.9.4 The VA Central IRB Table of Reporting Requirements (Attachment 5) lists the reporting timeframes and forms to be used for the type of reported event. The table is referenced in the final approval letters for PI/SC Applications, 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. It is meant to serve as a tool for both study teams and sites to determine what is reportable to the VA Central IRB and when.

5 DOCUMENTATION REQUIREMENTS

5.1 Copies of all official project related correspondence relaying decisions of the VA Central IRB, as well as Reviewer comments and study team responses, will be kept on file on the VA Central IRB shared drive and, for FDA-regulated studies, in paper as well. The SharePoint site is mainly used to distribute documents and may not contain all documents required for a study team regulatory binder and should not be used as such.

5.2 Copies of Local Site Liaison and Designee appointment letters will be used to update the VA Central IRB tracking database and kept on file with the current site MOU.

6 REFERENCES

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

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

6.3 VHA Handbook 1058.03, Assurance of Protection from Human Subjects in Research

6.4 21 CFR 56, U.S. Food and Drug Administration, Institutional Review Board



VA Central IRB Communications with Investigators, Other Study Team Members, and Local Participating Sites

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Page 13 of 13

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

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

5 Attachments

1. Information for VA Central IRB Local Site Liaisons
2. Information for Research Compliance Officers
3. Sample Local IO Local Site Liaison and Designee Appointment Letter
4. VA Central IRB Form 141, Potential Local Participating Site Comments to VA Central IRB Review of New PI/SC Project Application
5. Table of Reporting Requirements to the VA Central IRB for Principal Investigators/Study Chairs, Local Site Investigators, and Local VA Facility Research Compliance Officers