STERLING IRB Review Processes
VA Portland Health Care System Supplemental SOP

Purpose:

The purpose of this Standard Operating Procedure (SOP) is to document the process for communication between the VA Portland Health Care System and the Sterling IRB.

Background:

VA Portland Health Care System has received approval from the Veterans Health Administration (VHA) Office of Research and Development (ORD) to enter into an agreement with Sterling to serve as an IRB of record for funded or industry sponsored cooperative research studies or ORD approved expanded access programs. The reliance agreement content was approved at the national level by the Office of Research Oversight (ORO), ORD, and Sterling so no local changes are required. A Master Services Agreement is in place between the Office of Research and Development (ORD), and Sterling which includes VA specific requirements for IRB review.

This SOP is supplemental to the IRB SOP (formerly the IRB P&P), the VA medical facility IRB SOPs stored on the VAPORHCS Research & Development website, which is located at: https://www.portland.va.gov/research/documents/irb/irb-sop.doc, and is consistent with the Sterling's Investigator's Handbook located at: https://Sterlingirb.com/investigator-handbook/. The handbook should be disseminated and reviewed by all applicable research and study staff.

Sterling utilizes a secure web-based portal to facilitate research study submissions, regulatory compliance, and e-processing and tracking of research studies. The electronic platform is called SILVERLINK (https://Sterlingirb.my.irbmanager.com/) and allows real-time communication among sponsors, research sites, institutional representatives, and Sterling staff and IRB members. All parts of the IRB process from initial submission to study close-out/termination are supported by SILVERLINK. Note: Please contact the SILVERLINK Help Desk at 1-888-636-1062 or email support@Sterlingirb.com with any questions.

Institutional Official Responsibilities:

(1) The VA Portland Health Care System Institutional Official (IO) signs the Sterling IRB Reliance Agreement and Division of Responsibilities. This agreement replaces the VA Memorandum of Understanding (MOU) for IRB services (VHA Directive 1058.03). The agreement is updated as required by the Sterling IRB, and copies of the initial agreement and each update are sent to ORD and ORO when fully executed. ORO does not require updates to the agreement for changes of Institutional Official.
(2) A VA research staff member must be appointed as a liaison to ORD and the Sterling IRB. Any liaison change must be reported to ORD.
(3) Formally reports unanticipated problems, serious and/or continuing non-compliance, and suspension or termination of study activities originating at VA

Portland Health Care System as required by VA policy to ORO and external federal agencies or oversight bodies.

(4) Ensures that the Federalwide Assurance (FWA) and VA Addendum to the FWA are kept current as required by VHA Directive 1058.03.

Research & Development Committee (R&DC) Responsibilities:

(1) The convened R&DC and sub-committees may review the protocol prior to the Sterling IRB review and then the R&DC through designated review may grant final approval.
(2) Ensures that the investigator and study personnel have the resources, experience and training needed to conduct the research, all members of the research team have been credentialed, privileged, have an approved Scope of Practice if applicable, and have completed all training required by VA and Sterling in the protection of human subjects.
(3) Ensures that the Sterling IRB is provided with current state law requirements.
(4) Determine if non-Veterans should be enrolled in a specific study at VA Portland Health Care System if the VA Investigator requests non-Veteran enrollment in the study.
(5) Ensures Information Systems Security Officer (ISSO) and Privacy Officer (PO) preliminary reviews are provided to the IRB for review during the approval process and that all required final reviews are complete with all stipulations resolved before R&D Committee final approval is given and before the study is initiated.
(6) Ensures the VA Portland Health Care System conflict of interest policy will be followed, and relevant determinations and/or management plans will be forwarded to Sterling IRB per Sterling SOPs as described in the Sterling IRB Handbook.
(7) Ensures reviews by all applicable R&DC subcommittees are complete before the study is approved.
(8) Ensures that the study may not begin at VA Portland Health Care System until the R&D Committee approves the research study and the ACOS/R notifies the Principal Investigator in writing that he/she is authorized to initiate the study.
(9) Oversees the local regulatory aspects of the research and reviews protocol non-compliance reports.
(10) Reviews all determinations by the Sterling IRB of any reported incidents or unanticipated problems and/or serious or continuing noncompliance for acceptance or further action. Ensures any remediation is completed.
(11) Notify the IRB when a regulatory deficiency has been cited by an RCO or other regulatory audit that occurred during the time that the IRB was responsible for study oversight.
(12) Provide a mechanism to receive and address concerns from local study participants and others about the conduct of the research.
(13) Is authorized to observe any aspect of the research process including observing the informed consent process. The Sterling IRB retains the authority to direct this to be done when necessary, by VA Portland Health Care System.
(14) Conducts an annual review of the Sterling IRB and submits to the VA Facility Medical Center Director as required by ORD policy in VHA Directive 1200.01. This

review includes but is not limited to evaluation of the number of projects handled by the committee, communication between entities, changes in this reliance agreement, change in processes, and challenges. Sterling IRB has agreed to provide an annual summary to assist in R&DC review. The IRB's current membership roster is available in SilverLink and the Sterling IRB website, www.sterlingirb.com.

(15) Ensures formal notification in a timely manner to the Sterling IRB whenever there is a proposed change in Principal Investigator.

VA R&D Service/Office Responsibilities:

(1) Verifies that the following forms and agreements are signed and executed by the VA Portland Health Care System prior to use of the Sterling IRB and maintained in a current status:
   a. This local Sterling IRB SOP with review by the R&D Committee per local policy.
   b. The Institutional Reliance Agreement, signed by the Facility Director and Sterling IRB

(2) Correspondence from the Sterling IRB will be available to the Local Site Investigator through the SILVERLINK portal as indicated above, for inclusion in the Study Regulatory Binder.

(3) As needed, the R&DC coordinator or other facility personnel may apply for an account with the Sterling IRB (SILVERLINK) https://sterlingirb.my.irbmanager.com/ and have access to the files and correspondence to the investigator. Otherwise, the local investigator may download documents from the Sterling IRB web portal and provide copies of the documents to the R&DC coordinator who will, as appropriate, triage documents to oversight committees and oversight officials for action and maintain project files.

(4) Provides tracking for protocols and correspondence.

(5) Manage evaluation of financial conflict of interest.

(6) Ensures a process is in place to allow ISSO and PO access to study materials for project review prior to study submission and to facilitate communication between the ISSO, PO and PI so that preliminary stipulations can be addressed by the PI prior to submitting to Sterling IRB.

(7) The VA Endorsement Letter will serve as the site-specific IRB submission cover page. It must be signed by the ACOS/R&D, the AO/R&D or a designee other than the PI confirming that once all required approvals are in place the project may be conducted at the facility, the VA nor the NPC is contracting directly for the IRB review and that the PO and ISSO preliminary reviews have been completed. PIs may not sign the endorsement letter.

(8) In the event of a change in the lead local site PI, ensures coordination with the departing Local Site Investigator, the sponsor and the IRB. Coordinates with the new PI a transfer of the approved study, after the R&D office confirms that the proposed new PI has the appropriate credentials to proceed as PI and the new PI

has been approved by the Sponsor and the IRB. The IRB does not review or approve changes of sub-PIs.

(9) Ensures notification of the Research Compliance Officer (RCO) of the signed reliance agreement and this supplemental SOP including IRB specific reporting mechanisms.

(10) Promptly updates SOPs for changes in the IRB requirements and inform the research community affected (e.g., investigators, study coordinators, investigational pharmacist) as applicable for changes affecting their roles and responsibilities.

(11) Maintains current FWA and access to IRB Rosters. The IRB's current membership roster is available in SilverLink and the Sterling IRB website, www.sterlingirb.com

VA Privacy and Information System Security Officers Responsibilities:

(1) The VA Portland Health Care System PO and ISSO will review studies overseen by Sterling IRB. Preliminary PO and ISSO review must occur prior to submission to Sterling IRB.

(2) The PO will review the HIPAA authorization to ensure it contains all required elements and is consistent with all privacy requirements. The PO reviews the HIPAA authorization, informed consent document, and protocol for consistency.

(3) ISSO and PO preliminary reviews and recommendations must be included in the application information sent to Sterling IRB. All ISSO and PO identified concerns must be resolved prior to study initiation.

(4) Sterling IRB is not storing VA data on their platform; VA is transmitting a copy of VA data for the purpose of IRB review. As part of the ORD approval process for nationwide use of Sterling IRB, VACO ISSO reviewed the methods and systems over which a copy of VA data is securely transmitted to the IRB.

Research Compliance Officers (RCO) Responsibilities:

Complete informed consent audits and study regulatory audits as required in the RCO Audit Plan. RCOs will have access to the research subjects' records and/or case files for oversight and monitoring activities. All reports of apparent serious non-compliance, apparent continuing noncompliance, or apparent serious unanticipated problems resulting from an RCO audit will be reported to the local facility officials per VHA Directive 1058.01 policy and to the Sterling IRB. RCO audit findings that are reportable to the Sterling IRB will be submitted to the Sterling IRB within 5 business days in accordance with VHA Directive 1058.01. RCO audit reports with no findings or no immediate findings for studies overseen by the Sterling IRB will be submitted to the R&D Committee and to the Sterling IRB in a study specific batched annual report which may include any IC and HRPP audit reports. The RCO must ensure that the reports are uploaded within the required timeframe by those who have access to the system. RCOs are not required to audit Expanded Access Programs.

Local Principal Investigator (PI) Responsibilities:

(1) Ensure that study staff have been appropriately credentialed and privileged as applicable and have completed all required VA training in the protection of human subjects.
(2) All Investigators must submit an OGE 450-Alt-VA Form for review through the normal VA Portland Health Care System procedures. Information regarding the review and any relevant determinations or management plans must be shared with the Sterling IRB during the application process. The OGE 450-Alt-VA Forms are not sent to the Sterling IRB. The VAPORHCS Conflict of Interest In Research policy is available at: https://www.portland.va.gov/Research/piservices/rd_forms.asp.
(3) Ensure ISSO and PO preliminary reviews are conducted and provided to Sterling IRB for review prior to IRB approval. To limit multiple IRB submissions, any ISSO or PO requirements should be addressed by the PI prior to initial IRB submission. Final ISSO and PO reviews must be complete prior to initiating the study.
(4) Ensures the study is not initiated prior to receiving written ACOS implementation approval.
(5) Develop a recruitment plan. If potential subjects are to be identified from CPRS or any facility list of patients, a HIPAA authorization waiver must be requested and approved by the Sterling IRB prior to viewing records.
(6) Ensure non-Veterans are not enrolled without study specific approval by the R&D Committee.
(7) Ensure all study staff changes are made in IRBManager (IRBM). The IRB does not require review or approval of changes of local sub-investigators.
(8) Ensure VA required elements are in the informed consent including any language required by VHA Directive 1200.05 for Certificates of Confidentiality if applicable. If the HIPAA authorization is embedded in the consent document, ensure all required VA elements are included. Use the approved informed consent document for use at VA as approved by the IRB.
(9) If the HIPAA authorization is not embedded in the consent document, ensure required VA form 10-0493 is used. The form 10-0493 must be included in the Sterling IRB application packet and reviewed by the VA facility privacy officer prior to study approval by the R&D Committee. Ensure the approved form is used. Ensure the HIPAA authorization includes the VA-required elements if the authorization is combined with the written informed consent document.
(10) Write progress notes as appropriate.
(11) Maintain compliance with state, local, or institutional requirements related to the protection of human subjects.
(12) Comply with all Sterling IRB and VA Portland Health Care System requirements related to the protection of human subjects and adhere to responsibilities detailed in VHA Directive 1200.05 investigator section.
(13) Investigate and notify the Sterling IRB and R&DC of any study-specific incidence, experience or outcome that appears to rise to the level of an unanticipated event per Sterling IRB requirements and VHA requirements in VHA Directive 1058.01

respectively. The IRB requires that sponsors and/or investigators/sites (as appropriate) submit in writing any unanticipated problems (UAPs) involving risks to subjects or others, including adverse events that should be considered UAPs as described in Sterling IRB Handbook. Notification to the IRB of a UAP must occur within 5 business days from the time of identification. Deaths and life threatening events must be reported immediately per the Sterling IRB SOPs.. Refer to VHA Directive 1058.01 and the Sterling IRB Handbook and reporting summary sheet entitled "Events Reportable to the IRB" available on its website at http://www.sterlingirb.com

Investigate and notify the Sterling IRB and R&DC of any serious or continuing non-compliance, termination or suspension of research, privacy or information security incidents per local and VHA policies. Investigators are required to follow stricter reporting requirements per VHA Directive 1058.01 for information security incidents.

Sponsors, investigators and/or research staff must notify the IRB in writing of any instance of noncompliance with the regulations, VHA Directive 1058.01, and/or determinations and requirements of the IRB. This notification must be as soon as possible but no later than 5 business days from the time of discovery of the event.

(14) Propose/prepare a management/remediation plan to the R&DC and Sterling IRB for local potential unanticipated problems and possible serious or continuing noncompliance.
(15) Notify the Sterling IRB if a subject becomes incarcerated during participation in a study.
(16) Notify the Sterling IRB if a female subject becomes pregnant during her participation in a study.
(17) Maintain a regulatory file for the study under Sterling IRB purview as per local institution and sponsor policy.
(18) The PI will forward documents/communication to the research office per local policy.
(19) Upload copies of documentation going to and from the Sterling IRB into IRBM (e.g., amendments, notifications, continuing reviews, etc.).
(20) Notify the Sterling IRB and research office in the event of a proposed change in PI or a planned leave of absence.
(21) Acts as the point of contact for the Sterling IRB should they have any questions about the research proposed or being conducted at VA Portland Health Care System.
(22) Ensures the IRB required study site closure report is submitted to Sterling.