VA Northeast Ohio Healthcare System (VANEOHS)
Medical Research Service
Standard Operating Policy/Procedure (SOP)

Effective Date: 06/04/2020
SOP Title: Use of Western Institutional Review Board (WIRB) – Copernicus Group (WCG)
SOP Number: HSP-030
Version: 01

Purpose:

The purpose of this Standard Operating Procedure (SOP) is to document the process for communication between the VA Northeast Ohio Healthcare System (VANEOHS) and the Western Institutional Review Board (WIRB)-Copernicus Group (WCG).

Background:

VANEOHS has received approval from the Veterans Health Administration (VHA) Office of Research and Development (ORD) to enter into an agreement with WIRB-WCG 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 WIRB-WCG so no local changes are required. A Master Services Agreement is in place between the Office of Research and Development (ORD), and WIRB-WCG which includes VA specific requirements for IRB review.

This SOP is supplemental to the VA medical facility IRB and Human Research Protection Program (HRPP) SOPs located at https://www.clevelandvaresearch.org/research-sops and is consistent with the WIRB-WCG Standard Operating Procedures (SOPs), located at: https://www.wirb.com/Pages/DownloadForms.aspx

The WIRB-WCG "Guide for Researchers" is located at the end of this SOP. Any changes to the policies and procedures are communicated via the WIRB-WCG website. WIRB-WCG utilizes a client web portal to facilitate research study submissions, regulatory compliance, and e-processing and tracking of research studies. Connexus, WIRBs client portal enables secure submission and tracking of research. All parts of the IRB process from initial submission to study close-out/termination are supported by the Connexus web portal. Applications and study forms are located at: https://www.wirb.com/Pages/DownloadForms.aspx

Note: Please contact WIRB at 800-562-4789 or email at clientservices@wirb.com with any questions.

Institutional Official Responsibilities:

(1) The VANEOHS Institutional Official (IO) signs the WIRB-WCG Reliance Agreement and Division of Responsibilities. This agreement replaces the VA Memorandum of Understanding (MOU) for IRB services (VHA Handbook 1058.03). The agreement

is updated as required by WIRB-WCG, 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) Appoints the Local VA Facility Liaison to serve as the administrative liaison between the VANEOHS and the IRB as required by WIRB-WCG. The name of the liaison will be reported to ORD and designated on WIRB-WCG form HRP 290. Any liaison change must be reported to WIRB-WCG and ORD.

(3) Formally reports unanticipated problems, serious and/or continuing non-compliance, and suspension or termination of study activities originating at VANEOHS as required by VA policy to ORO and external federal agencies or oversight bodies.

(4) Updates and signs the Federal-wide Assurance (FWA) and VA Addendum to the FWA.

Research & Development Committee (R&DC) Responsibilities:

(1) The convened R&DC and sub-committees may review the protocol prior to the WIRB-WCG 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 training required by VA and WIRB-WCG in the protection of human subjects.

(3) Ensures that the WIRB-WCG IRB is provided with current state law requirements.

(4) Determine if non-Veterans should be enrolled in a study at VANEOHS if the VA Investigator requests non-Veteran enrollment into the study.

(5) Ensures Information Systems Security Officer (ISSO) and Privacy Officer (PO) review is complete before R&D Committee final approval is given and before the study is initiated.

(6) Ensures the VANEOHS conflict of interest policy will be followed, and relevant determinations and/or management plans will be forwarded to the WIRB-WCG per WIRB-WCG SOPs.

(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 VANEOHS 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 WIRB-WCG 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 on 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 WIRB-WCG IRB retains the authority to direct this to be done when necessary by VANEOHS
(14) Conducts an annual review of the WIRB-WCG 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 MOUs or other agreements, change in processes, and challenges. WIRB-WCG has agreed to provide an annual summary to assist in R&DC review.
(15) Ensures formal notification in a timely manner to the IRB whenever there is a proposed change in Principal Investigator. WIRB-WCG requires sponsor approval of PI change prior to IRB review.

VA R&D Service/Office:

(1) Verifies that the following forms and agreements are signed and executed by the VANEOHS prior to use of the WIRB-WCG IRB and maintained in a current status:
   a. This WIRB-WCG IRB SOP with review by the R&D Committee per local policy.
   b. The Reliance Agreement signed by the Facility Director and WIRB-WCG.
(2) Correspondence from the WIRB-WCG IRB will be sent to the Local Site Investigator, for inclusion in the Study Regulatory Binder.
(3) Upon request WIRB-WCG will provide the VA with the expedited review eligibility category for any IRB expedited review action.
(4) As needed, the VA Facility Liaison or other facility personnel may apply for a Connexus account with the WIRB-WCG IRB and have access to the files and correspondence to the investigator. The local investigator may download documents from the WIRB-WCG 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.
(5) In the event of a change in the 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.
(6) Manage evaluation of financial conflict of interest.
(7) Provides tracking for protocols and correspondence.
(8) Ensures notification of the Research Compliance Officer (RCO) of the signed reliance agreement and this supplemental SOP including IRB specific reporting mechanisms.
(9) Promptly updates SOPs for changes in the IRB requirements and informs the VA research community (e.g., investigators, study coordinators, investigational pharmacist) as applicable for changes affecting their roles and responsibilities.

(10) Maintains current FWA and access to WIRB-WCG IRB rosters. WIRB-WCG provides current IRB rosters to clients with IRB approval letters (Certificates of Action).
(11) Receives IRB minutes related to VA research. Minutes are provided to VA medical facilities upon request.

VA Privacy and Information System Security Officers:

(1) The VANEOHS PO and Systems ISSO will review studies overseen by WIRB-WCG 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) WIRB-WCG 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 WIRB-WCG 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. All reports of apparent serious non-compliance, apparent continuing noncompliance, or apparent serious unanticipated problems resulting from an RCO audit will be processed within the facility as specified by VHA Handbook 1058.01. RCOs will have access to the research subjects' records and/or case files for oversight and monitoring activities. RCO audit reports including but not limited to audits with no findings or no immediate findings for studies overseen by the WIRB-WCG IRB will be submitted to the R&D Committee. RCO audit findings that are reportable to the WIRB-WCG IRB will be submitted to the WIRB-WCG IRB within 5 business days in accordance with the WIRB-WCG IRB and VHA Handbook 1058.01. 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 VANEOHS procedures. Information regarding the review and any relevant determinations or management plans must be shared with WIRB-WCG during the application process via WIRB IRB Form HRP-290. Detailed information regarding submission and review of OGE 450-AltVA Form can be found in Medical Center Policy (MCP) 151-014 Research Service Financial Conflict of Interest Policy. This MCP be found on the VANEOHS Sharepoint site https://dvagov.sharepoint.com/sites/Cleveland/mcp/SitePages/Home.aspx

(3) Ensure ISSO and PO reviews are complete prior to initiating the study.
(4) Ensures the study is not initiated prior to receiving written ACOS/R 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 prior to viewing records.
(6) Ensure non-Veterans are not enrolled without approval by the R&D Committee.
(7) Ensure all study staff changes are reported to the Research & Development Committee Coordinator. The PI must keep an up to date study staff list in their regulatory documents.
(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 WIRB-WCG 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 WIRB-WCG IRB and VANEOHS 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 WIRB-WCG IRB and R&DC of any study-specific incidence, experience or outcome that appears to rise to the level of an unanticipated event per WIRB-WCG IRB requirements and VHA requirements in 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 WIRB-WCG IRB SOP. Notification to the IRB of a UAP must occur promptly but no later than 5 business days from the time of identification.

Investigate and notify the WIRB-WCG IRB and R&DC of any and/or 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 Handbook 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, this Handbook, 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 the event identification.

(14) Responsible for proposing/preparing a management/remediation plan to the R&DC and WIRB-WCG IRB for local potential unanticipated problems and possible serious or continuing noncompliance.
(15) Notify the WIRB-WCG IRB if a subject becomes incarcerated during participation in a study.
(16) Notify the WIRB-WCG IRB if a female subject becomes pregnant during her participation in a study.
(17) Maintain a regulatory file for the study under WIRB-WCG IRB purview as per local institution and sponsor policy.
(18) The PI will forward documents/communication to the research office per local policy.
(19) Submit copies, via email, of documentation going to and from the Advarra IRB to the VANEOHS R&D Coordinator.
(20) Notify the WIRB-WCG IRB and research office in the event of a proposed change in PI or a planned leave of absence. WIRB-WCG expects the PI to initiate the process for change of PI and requires the sponsor to approve and the institution to approve prior to submission to the IRB.
(21) Acts as the point of contact for the WIRB-WCG IRB should they have any questions about the research proposed or being conducted at VANEOHS, not on behalf of the institution.
(22) With reasonable advanced notice the PI will meet with WIRB-WCG representatives when requested.

Review date for this SOP is June 3, 2023.