Subject: Use of Western Institutional Review Board (WIRB)-Copernicus Group (WCG) as IRB of Record

Purpose:

The purpose of this Standard Operating Procedure (SOP) is to document the process for communication between the Minneapolis VA Health Care System (MVAHCS) and the Western Institutional Review Board (WIRB)-Copernicus Group (WCG).

Background:

MVAHCS 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 MVAHCS HRPP SOPs and Research Service SOPs stored on R:\All_Staff\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 MVAHCS Institutional Official (IO) signs the WIRB-WCG Institutional Authorization 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 MVAHCS 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. The IRB Administrator or IRB Coordinator is appointed to fulfill this role.

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

(4) Maintains the currency of the Federal-wide Assurance (FWA) and VA Addendum to the FWA.

Research & Development Committee (RDC) Responsibilities:

(1) The convened RDC and sub-committees may review the protocol prior to the WIRB IRB review and then the RDC 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 WIRB in the protection of human subjects.

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

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

(5) Ensures Information Systems Security Officer (ISSO) and Privacy Officer (PO) review is provided to the WIRB and all issues are resolved before R&D Committee final approval is given and before the study is initiated. The site liaison will ensure PO/ISSO review is accomplished prior to the MVAHCS investigator's submission of the study application to WIRB. Corrections will be made to applicable documents per PO/ISSO stipulations prior to the submission to WIRB. If changes cannot be accomplished prior to WIRB submission (e.g., questions are raised regarding the protocol document), those questions will be forwarded to WIRB for consideration to be addressed prior to the RDC's receipt of the study for consideration.

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

(7) Ensures reviews by all applicable RDC subcommittees are complete before the study is approved.

(8) Ensures that the study may not begin at MVAHCS 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 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) Notifies WIRB when a regulatory deficiency has been cited on a Research Compliance Officer (RCO) or other regulatory audit that occurred during the time that WIRB was responsible for study oversight.

(12) Provides 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 IRB retains the authority to direct this to be done when necessary by MVAHCS.

(14) Conducts an annual review of the WIRB 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 IRB has agreed to provide an annual summary to assist in R&DC review.

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

VA Research Service/Office:

(1) Verifies that the following forms and agreements are signed and executed by the MVAHCS prior to use of the WIRB IRB and maintained in a current status:
   a) This WIRB IRB SOP.
   b) The Institutional Authorization Agreement, signed by the Facility Director and WIRB-WCG.

(2) Correspondence from the WIRB IRB will be sent to the Local Site Investigator as indicated above, for inclusion in the Study Regulatory Binder.

(3) As needed, the RDC coordinator or other facility personnel may apply for an account with the WIRB IRB (using IRBNet) and have access to the files and correspondence to the investigator. Otherwise, the local investigator may download documents from the WIRB IRB web portal (IRBNet) and provide copies of the documents to the RDC coordinator and/or Local Site Liaison who will, as appropriate, triage documents to oversight committees and oversight officials for action and maintain project files.

(4) 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 Research 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.

(5) Manages evaluation of financial conflict of interest.

(6) Provides tracking for protocols and correspondence.

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

(8) 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.

(9) Maintains current FWA and access to IRB Rosters.

(10) Requests IRB minutes related to VA research if indicated by the RDC. (Minutes are provided to VA medical facilities upon request.)

VA Privacy and Information System Security Officers:

(1) The MVAHCS PO and ISSO will review studies overseen by WIRB 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. Initial reviews are provided to the IRB for their deliberations.

(3) WIRB 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 WIRB 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:

(1) Completes informed consent audits and study regulatory audits as required in the RCO Audit Plan.
(2) 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.
(3) RCOs will have access to the research subjects' records and/or case files for oversight and monitoring activities.
(4) RCO audit reports including but not limited to with no findings or no immediate findings for studies overseen by the WIRB IRB will be submitted to the R&D Committee.
(5) RCO audit findings that are reportable to the WIRB IRB will be submitted to the WIRB IRB within 5 business days in accordance with IRB policy. The RCO must ensure that the reports are uploaded within the required timeframe by those who have access to the system.
(6) 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 MVAHCS procedures. Information regarding the review and any relevant determinations or management plans must be shared with the WIRB IRB during the application process. The PI will submit completed Research Financial Conflict of Interest Statements (COI forms) for the PI and all Co-Investigators/Sub-Investigators in the electronic protocol management system.
(3) Ensures MVAHCS ISSO and PO reviews are provided to the IRB and issues, if any, are resolved prior to initiating the study.
(4) Ensures the study is not initiated prior to receiving written ACOS implementation approval.
(5) Develops 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 made in the electronic protocol management system (iRIS or VAIRRS/IRBNet, as applicable).
(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, ensures required VA form 10-0493 is used. The form 10-0493 must be included in the WIRB IRB application packet and reviewed by the VA facility Privacy Officer prior to study approval by the R&D Committee. Ensures the approved form is used. When using a combined form, ensures the VA-required elements of the HIPAA authorization are present if the authorization is combined with the written informed consent document.
(10) Writes progress notes as appropriate.
(11) Maintains compliance with state, local, or institutional requirements related to the protection of human subjects.

(12) Complies with all WIRB IRB and MVAHCS requirements related to the protection of human subjects and adhere to responsibilities detailed in VHA Directive 1200.05 investigator section. Investigates and notifies the WIRB IRB and RDC of any study-specific incidents, experiences or outcomes that appear to rise to the level of an unanticipated event per WIRB IRB requirements and VHA requirements in VHA Handbook 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 the WIRB IRB SOP. Notification to the IRB of a UAP must occur promptly but no later than (5) business days from the time of identification.
(13) Investigates and notifies WIRB IRB and RDC of any serious and/or continuing non-compliance, termination or suspension of research, or 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, 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 the event.
(14) Is responsible for proposing/preparing a management/remediation plan to the RDC and WIRB IRB for local potential unanticipated problems and possible serious and/or continuing noncompliance.
(15) Notifies the WIRB IRB if a subject becomes incarcerated during participation in a study.
(16) Notifies the WIRB IRB if a female subject becomes pregnant during her participation in a study.
(17) Maintains a regulatory file for the study under WIRB IRB purview as per local institution and sponsor policy.
(18) Forwards documents/communication to the research office per local policy.
(19) Uploads copies of documentation going to and from the WIRB IRB into the electronic protocol management system (iRIS or VAIRRS/IRBNet, as applicable).
(20) Notifies the WIRB 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 WIRB IRB should they have any questions about the research proposed or being conducted at MVAHCS.

PROCEDURES:

To Initiate a New Study

(1) Prior to WIRB IRB review, the MVAHCS PO and ISSO must conduct their review. Any comments/stipulations must either be addressed prior to the investigator's submission to WIRB, or the comments must be submitted to WIRB with the application materials.
(2) Investigator prepares the IRB application in IRBNet.
(3) The ACOS/R/designee verifies PO and ISSO review has been accomplished, and verifies that neither the VA nor the VA NPC is contracting directly for IRB review services for the project.
(1) The investigator submits the required documentation, including PO and ISSO comments and local considerations as applicable, to WIRB IRB for review.
(2) Investigator receives the WIRB approval documentation and the approved informed consent document, HIPAA Authorization form, and Waiver of HIPAA Authorization (all as applicable).

(3) After WIRB IRB approval is obtained, Investigator submits an abbreviated application in the MVAHCS electronic protocol management system. This application contains the elements required for SRS review.
In addition to the questions in the abbreviated application, the following documents will be submitted:
    a) HIPAA Authorization form approved by WIRB IRB (for records, not review/approval)
    b) Informed consent document approved by WIRB IRB (for records, not review/approval)
    c) Protocol approved by WIRB IRB (for records, not review/approval)
    d) WIRB IRB's initial approval letter of the MVAHCS Investigator, including the specific approval of the above documents, as applicable.
    e) Research Financial Conflict of Interest Statements for each Investigator on the MVAHCS study team for local review

(4) The MVAHCS designated liaison with WIRB IRB will ensure the submission receives MVAHCS PO and ISSO review. Any concerns/stipulations of the PO/ISSO will be addressed.

(5) The MVAHCS designated liaison with WIRB IRB will ensure the review by an MVAHCS IRB voting member of the Research Financial Conflict of Interest Statement(s) (COIs).

(6) The Investigator receives documentation of the review/approval by the Subcommittee on Research Safety (SRS).

(7) The submission will be noted in the MVAHCS protocol tracking system with WIRB IRB as the IRB of record.

(8) The WIRB IRB and SRS approvals will be forwarded to RDC in the electronic protocol management system.

(9) Following approval by the RDC, the Associate Chief of Staff/Research (ACOS/R) will issue a document authorizing the initiation of the research and then the MVAHCS PI may initiate the study.

Study Procedures/ Amendments/ Continuing Review

(1) For studies under a Certificate of Confidentiality, an electronic health record (her) progress note entry should indicate only that an individual has been enrolled in a research study, any details that would affect the subject's clinical care, and the name and contact information for the MVAHCS Investigator conducting the study. Subjects' informed consent and HIPAA authorization documents are not to be included in the health record and should be kept with the study files.

(2) Study team submits proposed staff changes by submitting an updated contact form in IRBNet.
    a) The addition of personnel must also be requested in the MVAHCS electronic protocol management system. If adding an Investigator, a Research Financial Conflict of Interest Statement (COI) must be included in the submission.

(3) Human subject protocols that require a modification/amendment must be submitted as outlined by the WIRB IRB SOP. After WIRB IRB approval, the amendment/modification will be communicated to the MVAHCS liaison by WIRB IRB. All documents associated with the modification (e.g., protocol, consent form, WIRB IRB approval memo) will be forwarded to the liaison.

(4) Any revisions affecting the following require submission of a modification/amendment via the MVAHCS electronic protocol management system for local review by the PO/ISSO:
    a) Data use/storage in VA
    b) Who has access to data inside and/or outside VHA
    c) Data sources (e.g., audio, video, paper surveys, web-based surveys)
    d) Process of transmitting/sending/sharing data inside and/or outside MVAHCS (e.g., a new URL)
    e) Research Financial Conflict of Interest Statement changes for existing study personnel
(5) Upon receiving WIRB IRB Continuing Review approvals (i.e., the IRB approval memo), Investigator will forward them to the liaison.

Reporting

(1) Reporting will be in compliance with VHA Handbook 1058.01
(2) *Serious Adverse Events* (meeting the criteria of a physical or psychological event that results in: Death or life-threatening experience, or Hospital admission or prolongation of hospitalization, or Persistent or significant disability or incapacity, or Intervention to prevent such an outcome) which the MVAHCS Investigator determines are **Unexpected**, and there is a reasonable possibility the event is **Related** to the research, are to be reported to the WIRB IRB within 5 business days.
(3) *Local Unanticipated Problems* (a project-related event that is likely to substantially adversely affect the safety, rights, or welfare of human research subjects, or compliance with the protocol, VA policy, or federal regulations, or information security or integrity of the research data) which the MVAHCS Investigator determines are **Unexpected**, and there is a reasonable possibility the event is **Related** to the research, and subjects or others are at **Greater risk of harm** than was previously known due to the incident, must be reported by the MVAHCS Investigator to the WIRB IRB within 5 business days of becoming aware.
(4) *Privacy breaches or information security events* must be reported to the MVAHCS Privacy Officer (PO) and/or Information Systems Security Officer (ISSO) within 1 hour of discovery.
(5) Local apparent serious or continuing noncompliance must be reported promptly to the WIRB IRB. This may include complaints from subjects or others, protocol deviations (as defined in the WIRB IRB SOPs) and audit findings.
(6) Suspension or termination by the MVAHCS Signatory Official will be reported to the WIRB IRB promptly.

Study Closure

Studies will be closed with the WIRB IRB using the procedures outlined in the WIRB IRB SOPs. In addition, the study will be closed at MVAHCS by the study staff/PI submitting a closure request in the electronic protocol management system.

References:

WIRB SOPs
MVAHCS HRPP SOPs

MVAHCS Reporting SOP
MVAHCS R&D Committee SOP
VHA Handbook 1058.01
VHA Handbook 1200.05