**Western Institutional Review Board (WIRB)-Copernicus Group (WCG)**

**IRB REVIEW PROCESS**

 **Atlanta VA Health Care System SUPPLEMENTAL SOP**

**Purpose:**

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

**Background:**

The Atlanta VA Health Care System 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 the IRB of record. 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 HRPP SOPs stored on Atlanta VA Health Care System Research website located at: https://www.atlanta.va.gov/services/research/Conducting\_Human\_Research.asp and is consistent with the WIRB-WCG Standard Operating Procedures (SOPs), located at:

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| <https://www.wirb.com/Pages/DownloadForms.aspx> |

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 Atlanta VA Health Care System 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 ORO when fully executed. ORO does not require updates to the agreement for changes of Institutional Official.
2. Appoints the Local VA Facility Liaison required by WIRB-WCG. The liaison will be designated in this SOP and on WIRB-WCG form HRP 290. In addition, the name of the liaison and changes of liaison will be reported to ORD as required by ORD. Formally reports unanticipated problems, serious and/or continuing non-compliance, and suspension or termination of study activities originating at Atlanta VA Health Care System as required by VA policy to ORO and external federal agencies or oversight bodies.
3. 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 and good clinical practice. Ensure VA required elements are in the informed consent including any language required by VHA Directive 1200.05 for Certificates of Confidentiality if applicable.
3. Oversees the local regulatory aspects of the research and reviews protocol non-compliance reports.
4. Ensures protocol is compliant with state, local and Atlanta VA Health Care System requirements related to the protection of human subjects. Ensures that the WIRB-WCG IRB is provided with current state law requirements.
5. Ensures the Atlanta VA Health Care System 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.
6. 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.
7. 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 Atlanta VA Health Care System.
8. Ensures Information Systems Security Officer (ISSO) and Privacy Officer (PO) review is complete before the study is initiated.
9. Ensures reviews by all R&DC subcommittees are complete before the study is approved.
10. Ensures that the study may not begin at Atlanta VA 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.
11. 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.
12. Provide a mechanism to receive and address concerns from local study participants and others about the conduct of the research.
13. Ensures formal notification in a timely manner to the IRB whenever there is a proposed change in Principal Investigator.
14. Notify the IRB when a regulatory deficiency has been cited on an audit that occurred during the time that the IRB was responsible for study oversight.
15. Determine if non-Veterans should be enrolled in a study at their facility.

**VA R&D Service/Office:**

1. Verifies that the following forms and agreements are signed and executed by the Atlanta VA Health Care System prior to use of the WIRB-WCG IRB and maintained in a current status:
	1. This WIRB-WCG IRB SOP with review by the R&D Committee per local policy.
	2. 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 as indicated above, for inclusion in the Study Regulatory Binder.
3. As needed, the R&DC coordinator 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 deliver 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.

1. In the event of a change in the PI, ensures coordination with the departing Local Site Investigator, the sponsor and the IRB. The Research office will coordinate 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. The Research office helps track and coordinate amendment to the R&D Committee.
2. Manage evaluation of financial conflict of interest.
3. Provides tracking for protocols and correspondence.
4. Promptly updates SOPs for changes in the IRB requirements and informs the research community affected.
5. Maintains current FWA and access to IRB rosters. WIRB-WCG provides current IRB rosters to clients with IRB approval letters (Certificates of Action).
6. Receives IRB minutes related to VA research. Minutes are provided to VA medical facilities upon request.
7. Acts as the point of contact for the WIRB-WCG IRB should they have any questions about the research proposed or being conducted at Atlanta VA Health Care System.

**VA Privacy and Information System Security Officers:**

1. The Atlanta VA Health Care System PO and Systems ISSO will review studies overseen by WIRB-WCG IRB.
2. The PO will review the HIPAA authorization and other documents as appropriate to ensure the study is consistent with all privacy requirements per the VHA Research Protocol Privacy Review Checklist (form 10-250).

**Research Compliance Officers (RCO) Responsibilities:**

1. Complete informed consent audits and study regulatory audits as required in the RCO Audit Plan.
2. RCO audit reports including but not limited to 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. 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.

**Local Principal Investigator (PI) Responsibilities:**

1. Develop a recruitment plan. If potential subjects are to be identified from CPRS, request a waiver of HIPAA authorization to view records.
2. 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.
3. Ensure all study staff changes are made in accordance with the AVAHCS staff change SOP and tracked via RCMS.
4. Submit a completed/signed Conflict of Interest Disclosure for investigators.
5. Ensure non-Veterans are not enrolled without approval by the R&D Committee.
6. Write progress notes as appropriate (note requirements if under a certificate of confidentiality).
7. Investigate and notify the WIRB-WCG IRB and 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.
	1. 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. If the WIRB-WCG IRB makes a determination of UAP the determination will be reported to R&D Committee and the RCO.
	2. Investigate and notify the WIRB-WCG IRB and 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.
	3. 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. If the WIRB-WCG IRB makes a determination of Serious or Continuing Noncompliance the determination will be reported to R&D Committee and the RCO.
8. 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.
9. Ensure ISSO and PO review is complete prior to initiating the study.
10. Ensure VA required elements are in the informed consent including any language required by VHA Directive 1200.05 for Certificates of Confidentiality if applicable. Use the approved informed consent form for use at VA as approved by the IRB. If the HIPAA authorization is not embedded in the consent form, ensure required VA form 10-0493 is used.
11. Maintain a regulatory file for the study under WIRB-WCG IRB purview as per local institution and sponsor policy.
12. Submit the AVAHCS Research Office to be maintained in the study file.
13. Notify the WIRB-WCG IRB if a subject becomes incarcerated during participation in a study.
14. Notify the WIRB-WCG IRB if a female subject becomes pregnant during her participation in a study.
15. Maintain compliance with state, local, or institutional requirements related to the protection of human subjects.
16. Comply with all WIRB-WCG IRB and Atlanta VA Health Care System requirements related to the protection of human subjects and adhere to responsibilities detailed in VHA Directive 1200.05 investigator section.
17. Notify the WIRB-WCG IRB and research office in the event of a proposed change in PI or a planned leave of absence. The Research Office will confirm that the new PI is credentialed and qualified to oversee the research study prior to notification to WIRB-WCG.
18. Acts as the point of contact for the WIRB-WCG IRB should they have any questions about the research proposed or being conducted at Atlanta VA Health Care System.
19. With reasonable advanced notice the PI will meet with WIRB-WCG representatives when requested.
20. The PI will forward documents/communication to the research office per local policy.