**Advarra, Inc. IRB REVIEW PROCESS**

**ATLANTA VA HEALTH CARE SYSTEM (AVAHCS) 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 Advarra IRB.

**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 Advarra, Inc. to serve as the IRB of record and has signed a reliance agreement with Advarra. The reliance agreement content was approved at the national level by the Office of Research Oversight (ORO), ORD, and Advarra, Inc. No local changes are required.

This SOP is 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 Advarra IRB Standard Operating Procedures (SOPs), located at:

[https://www.cirbi.net/CIRBI/sd/Rooms/DisplayPages/LayoutInitial?Container=com.webridge.entity.Entity[OID[AC482809EC03C442A46F2C8EEC4D75D3](https://www.cirbi.net/CIRBI/sd/Rooms/DisplayPages/LayoutInitial?Container=com.webridge.entity.Entity%5bOID%5bAC482809EC03C442A46F2C8EEC4D75D3). The Advarra IRB Handbook for Investigators, Sponsors, and Sponsors’ Representatives is located at the end of this SOP. Any changes to the Handbook are communicated via the IRB’s cloud based Advarra Center for IRB Intelligence CIRBI Platform (www.cirbi.net) and will be posted in the Reference Materials section of CIRBI for immediate access.

Advarra utilizes a cloud-based electronic platform to facilitate research study submissions, regulatory compliance, and e-processing and tracking of research studies. The electronic platform is called the Advarra CIRBI Platform and allows real-time communication among sponsors, research sites, institutional representatives, and Advarra staff and IRB members. All parts of the IRB process from initial submission to study close-out/termination are supported by CIRBI. Note: Please contact the CIRBI Help Desk at 1-866-99CIRBI (1-866-992-4724) or email CIRBI@advarra.com with any questions.

**Institutional Official Responsibilities:**

1. The Atlanta VA Health Care System Institutional Official (IO) signs the Advarra, Inc. IRB 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 the Advarra IRB, 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, in writing, the Signatory Institution Primary Contact(s) required by the Advarra IRB.
3. Formally reports unanticipated problems, serious and/or continuing non-compliance, and suspension or termination of study activities originating at the Atlanta VA Health Care System 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 Advarra 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 project, all members of the project team have been credentialed, privileged, have an approved Scope of Practice if applicable, and have completed all required VA training in the protection of human subjects and good clinical practice.
3. Oversees the local regulatory aspects of the research and reviews protocol non-compliance reports.
4. Ensures protocol is compliant with state, local and the Atlanta VA Health Care System requirements related to the protection of human subjects. Ensures that the Advarra 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 Advarra per Advarra SOPs.
6. Reviews all determinations by Advarra 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 Advarra IRB retains the authority to direct this to be done when necessary by the 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 the 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 Advarra 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. Advarra 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. Provide updates 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 Advarra IRB and maintained in a current status:
	1. This Advarra IRB SOP, reviewed by the R&D Committee.
	2. The Reliance Agreement, signed by the Facility Director and Advarra, Inc.
2. Correspondence from the Advarra 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 an account with the Advarra IRB (CIRBI) <http://www.cirbi.net> and have access to the files and correspondence to

the investigator. Otherwise, the local investigator should download documents from the Advarra 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, the departing Local Site Investigator notifies the R&D office and 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.
2. Manage evaluation of financial conflict of interest.
3. Provide tracking for protocols and correspondence.
4. Promptly update SOPs for changes in the IRB requirements and inform the research community affected.
5. Maintain current FWA and access to IRB Rosters.

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

1. The Atlanta VA Health Care System PO and Systems ISSO will review studies overseen by Advarra 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.

**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 with no findings or no immediate findings for studies overseen by the Advarra IRB will be submitted to the R&D Committee. RCO audit findings that are reportable to the Advarra IRB will be submitted to the Advarra IRB within 10 business days in accordance with Advarra IRB policy and coordinated with ORO.

**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 (see above note).
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 per the AVAHCS staff change SOP and tracked via RCMS.
4. Submit a completed/signed Conflict of Interest Disclosure for investigators. Financial Conflict of Interest Form Templates are emailed to Principal Investigator and all Co-Investigators via local database. Emails include instructions to complete and sign form electronically, and email directly to local Technology Transfer Specialist/COI Administrator. After review, COI Administrator updates the completion date in the database if no conflicts are found or emails form to OGC for review if conflicts are present.
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 Advarra IRB and R&DC of any study-specific incidence, experience or outcome that appears to rise to the level of an unanticipated event per Advarra 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 Advarra IRB SOP. Notification to the IRB of a UAP must occur promptly but no later than 2 weeks (10 business days) from the time of identification.

Investigate and notify the Advarra 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 2 weeks (10 business days) from the time of the event.

1. Responsible for proposing/preparing a management/remediation plan to the R&DC and Advarra IRB for local potential unanticipated problems and possible serious or continuing noncompliance.
2. Ensure ISSO and PO review is complete prior to initiating the study.
3. 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. Ensure the HIPAA authorization includes the VA-required elements.
4. Maintain a regulatory file for the study under Advarra IRB purview as per local institution and sponsor policy.
5. Upload copies of documentation going to and from the Advarra IRB into the AVAHCS Electronic Request to Review Research Proposals (eRRRP) as appropriate.
6. Notify the Advarra IRB if a subject becomes incarcerated during participation in a study.
7. Notify the Advarra IRB if a female subject becomes pregnant during her participation in a study.
8. Maintain compliance with state, local, or institutional requirements related to the protection of human subjects.
9. Comply with all Advarra 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.
10. Notify the Advarra IRB and research office in the event of a proposed change in PI or a planned leave of absence.
11. Acts as the point of contact for the Advarra IRB should they have any questions about the research proposed or being conducted at the Atlanta VA Health Care System.
12. The PI will forward documents/communication to the HPA in the research office per local policy.