Human Subjects Research at the Charlie Norwood Veterans Affairs Medical Center

I. Purpose

This policy and procedure describes the provision of services by Georgia Regents University IRBs to the Charlie Norwood Veterans Affairs Medical Center as established through the CNVAMC/GRU Memorandum of Understanding that outlines the responsibilities of the CNVAMC and Georgia Regents University through GRUs IRB. The GRU Biomedical and Oncology IRBs are designated as the IRBs of record for the CNVAMC pursuant to the entities respective FWAs.

Protocols reviewed by the GRU IRB on behalf of the CNVAMC receive the same IRB review, both initial and continuing, as those conducted on behalf of GRU investigators GRU; provided, however, that GRU shall assure that CNVAMC research or other VA-supported research shall not be assigned to a commercial IRB for review. The GRU IRB does and shall continue to meet all Department of Veterans Affairs requirements for an affiliate human studies subcommittee of the CNVAMC Research and Development Committee (hereafter referred to as “CNVAMC R&D”).

II. Responsibilities

The CNVAMC R&D Committee reviews CNVAMC protocols. Review of the CNVAMC protocol by the R&D is in addition to, and not in lieu of, GRU IRB review and approval.

The CNVAMC is responsible for ensuring compliance with the GRU IRBs’ determinations and with the terms of its own FWA. Specifically, the CNVAMC R&D is responsible for reviewing and approving all GRU IRB determinations for CNVAMC Research. However, the CNVAMC R&D may not overrule the negative decisions made by the GRU IRBs. The CNVAMC shall initiate a quality assurance program for Human Subjects Research protection in conjunction with the GRU IRB to evaluate programs on an on-going basis. Findings and follow-up from any review will be reported to the respective GRU IRB.

The GRU IRBs agree to apply and adhere to all applicable VA regulations, including 38 CFR Part 16 and VHA Handbook 1200.05, in reviewing all CNVAMC funded and non-funded Human Subjects Research.

The CNVAMC shall provide at least two (2) IRB voting members to each GRU IRB that reviews CNVAMC research protocols. CNVAMC IRB members are appointed by the Director of the CNVMAC. All members representing the CNVAMC must have at least 5/8ths compensated appointment with the CNVAMC. Members must further have an interest in CNVAMC research.
and must demonstrate competence in human subjects research protection by meeting all CNVAMC and GRU IRB member educational requirements.

At least one voting CNVAMC appointed member must be present at any GRU IRB meeting in order for the GRU IRB to vote concerning a CNVAMC research protocol; provided, however, that this member does not have any conflict of interest regarding any CNVAMC research protocol on which the GRU IRB is voting. The vote on CNVAMC research protocols must be tabled at any GRU IRB meeting at which the foregoing prerequisite is not satisfied.

Per the requirement set forth in the VA regulations, the GRU IRB will forward to the CNVAMC Research Office complete non-redacted draft of the GRU IRB meeting minutes within three weeks of the meeting. Copies of the final approved signed GRU IRB meeting minutes will be maintained by both the GRU IRB and the CNVAMC Research Office. For VA research in which the approval of research is contingent on specific minor conditions as laid out by the Chair or their designee, the approval will be documented in the agenda or minutes of the first IRB meeting that takes place after the date of approval.

III. IRB Review Process

CNVAMC investigators and staff must familiarize themselves with all applicable institutional policies and procedures (both CNVAMC and GRU IRB)

CNVAMC investigators and staff must complete all required human subjects research training required by the IRB and the VA.

Protocol Submissions and Approvals:

The investigator must obtain IRB approval of new protocols, exempt protocols, amendments, and continuing review prior to submitting to the CNVAMC R&D for review and approval. Investigators must follow VA and IRB policies and procedures for this. This includes:

Human Subjects Research Determination

The investigator is responsible for submitting research proposals to the GRU IRB for a determination as to whether the proposal meets the criteria for human subjects research. The determination may only be made by the IRB.
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New Protocols

1. If the research protocol will be conducted at GRU and the CNVAMC, investigators must submit a separate protocol for the VA site, to specifically address all applicable VA requirements.

2. Investigators are responsible for obtaining approval from the CNVAMC Privacy Officer (PO) and Information Security Officer (ISO) via the Privacy and Security checklist, which the PO and ISO will forward to the IRB. **Please note, the IRB cannot accept the protocol without the completed, signed checklist.**

   Investigators are responsible for obtaining “departmental approval” in eIRB from the CNVAMC Research Administration Office. In order to ensure this occurs, the investigator must indicate CNVAMC as an affiliated site in the eIRB system. Once the study is submitted, the CNVAMC Research Office will be automatically notified, via email, of the requirement to review and sign-off on the protocol.

3. The “departmental approval” issued by the CNVAMC Research Office must include an attached copy of the CNVAMC ICD review, signed by the CNVAMC Research Office designee.

4. The protocol application must indicate:
   a. The CNVAMC will be a performance site engaged in human subjects research
   b. Information to be used on the CNVAMC Informed Consent Document (VA Form 10-1086) with the appropriate subject injury language, and CNVAMC contact information (name and number).
   c. The HIPAA Authorization and Revocations forms
   d. For studies involving the use of investigational drugs, supplying the IND number and documentation of IND status.
   e. Request for waiver of the consent process, waiver of documentation of consent, and/or waiver of HIPAA Authorization with the applicable justifications, which the IRB will review.

IRB Review

The GRU IRB determines the appropriate review type for CNVAMC research protocols in accordance with their policies and procedures. The IRB Chair, designee, or fully convened IRB will conduct all reviews of CNVAMC human subjects research. CNVAMC research protocols requiring expedited review or an exemption determination shall be reviewed by the IRB Chair or experienced IRB voting member designated by the Chair, in accordance with 38 CFR

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16.110(b) and reported in the minutes of the next convened IRB meeting. When reviewing the CNVAMC research protocols that require full IRB review, the IRB that is reviewing and voting on these protocols shall do so only if at least one CNVAMC IRB voting member representative is present at the convened IRB meeting at which time the review takes place. For FDA regulated research, a licensed physician must be included in the IRB quorum.

The VA Research Administrative Office review of the informed consent document will include documentation of inclusion of all required VHA elements. This checklist will be attached with the Research Administrative Office department approval. The IRB will review the consent document for consistency with the protocol, application, and HIPAA Authorization and Revocation forms, if applicable.

The IRB is also responsible ensuring the consent form includes all applicable elements and appropriate signature blocks in accordance with and to the extent required by 38 CFR 16.117 and VHA Handbook 1200.05.

For CNVAMC research, the IRB will prohibit entering non-veterans into CNVAMC research unless there are insufficient veterans available to complete the research.

Communication Regarding Submission Status

Following review of a CNVAMC research protocol, the GRU IRB will provide the R&D with a copy of the correspondence sent to the PI setting forth whether the protocol has been granted approval, deferred approval with stipulations, tabled, or disapproved, and the reasons therefore. Any concerns or criteria for approval of the CNVAMC research protocol may also be communicated to the R&D via the CNVAMC representative sitting on the IRB that reviewed the protocol at issue.

The GRU IRB must review and approve all waivers of HIPAA Authorization for CNVAMC protocols and otherwise provide review for CNVAMC in accordance with HIPAA regulations. VA HIPAA Authorizations are approved by the CNVAMC. The VA & VA Privacy Officer are authorized to change the HIPAA template, not the IRB.

The GRU IRB approval letter will contain a statement that, prior to initiation of VA research, CNVAMC R&D approval is required. The IRB will ensure the meeting minutes, reviewer checklists, and/or correspondence document VA-specific requirements, as applicable.

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The IRB Chair will report any determination of serious or continuing noncompliance to the CNVAMC Research Compliance Officer who will notify, as needed, the CNVAMC Institutional Official listed on the Memorandum of Understanding.

The PI is responsible for responding to any items or concerns regarding the CNVAMC research protocol being reviewed directly to the IRB. In order to proceed with the CNVAMC research protocol, the PI must have the final approval of both the GRU IRB and CNVAMC R&D. In the event the R&D overrides an approval by the GRU IRB, the PI must not start any part of the CNVAMC research protocol unless and until all concerns have been addressed and each committee grants its final approval. The R&D may not approve a CNVAMC research protocol that has been disapproved by the GRU IRB.

Continuing Review

The CNVAMC Research Administration Office maintains information on the approval periods of all CNVAMC-associated projects with information obtained from GRU approval letters and from the GRU eIRB database. The GRU IRB sends PIs expiration notices for their CNVAMC protocol, but PIs are ultimately responsible for monitoring the approval periods of their CNVAMC protocol and submitting the continuing review request to the IRB by the deadline. The CNVAMC Administrative sends the PI notices for annual continuation reports and the PI is responsible for submitting the report by the established deadline so that it can be reviewed and approved by the R&D Committee prior the the expiration date.

For CNVAMC research that lapsed approval due to failure to gain continuing review, the investigator is required to immediately submit to the IRB a list of subjects for whom suspension of the research would cause harm, and for the IRB chair, with appropriate consultation with the VA Chief of Staff, to determine which subjects could continue in the research because it is in their best interest. Lapses in gaining continuing review must be reported to the sponsoring agency and/or private sponsor, by the investigator. The CNVAMC and IRB are responsible for reporting the lapse to ORD, ORO, and other federal agencies, as appropriate.

Protocol Revisions/Amendments

Any protocol revision or amendment of a CNVAMC protocol must be approved the IRB and R&D in that order. If the amendment addresses an issue related to biosafety or radiation safety, then the change must be reviewed and approved by the appropriate VA regulatory committee.

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before IRB approval can be granted. Investigators must submit protocol revisions/amendments to the GRU IRB directly for review and approval.

**Reportable Events**

Investigators are responsible for submitting all reportable events and unanticipated problems involving risks to subjects or others in accordance with the IRB Policies and Procedures. The IRB is responsible for notifying the VA Research Administrative Office when a reportable event is submitted on a CNVAMC protocol. Investigators are responsible for providing copies of these reports to the CNVAMC Research Administration Office.

**IV. Emergency Use of a Test Article**

Please refer to the IRB policy regarding Emergency Use of a Test Article for specific details regarding this process. The investigator must follow the procedures listed in the above-referenced policy. Informed consent must be obtained. The investigator must notify the CNVAMC R&D when an emergency use has occurred. Data may not be collected for research purposes. The investigator must obtain IRB approval for any subsequent use of the test article.

*The VA does not allow planned emergency research under any circumstances.*

**V. Conflict of Interest**

The investigator and research staff must follow the IRB policies and procedures regarding conflict of interest. The IRB has final authority for COI determinations and for approvals of COI management plans. VA representatives on the IRB must comply with the GRU IRB policies for committee members.