Georgia Regents University Human Research Protections Program (HRPP) Overview

Purpose and Applicability

Georgia Regents University (GRU) established the Human Research Protection Program (HRPP) to monitor, evaluate, and continually improve the protection of human research participants; dedicate resources sufficient to do so; exercise oversight of research protection; educate investigators and research staff about their ethical responsibility to protect research participants; and when appropriate provide a mechanism to intervene in research and respond to the concerns of research participants. This program applies to all research approved by a GRU IRB, to include Georgia Regents University, GR Medical Center, other GRU facilities, and GRU-IRB approved studies conducted at the Charlie Norwood VA Medical Center. GRU has designated the GRU IRB Office and Institutional Official to provide oversight for the HRPP.

All human research conducted in our research community must comply with the policies and procedures outlined in the IRB policies and all applicable institutional policies. Human research must receive the designated Institutional Review Boards (IRBs) approval prior to initiation of the research.

The GRU IRB Office web site contains the policies, procedures guidance for the Institutional Review Boards (IRBs) and the members of our research community involved in the conduct of human research. The GRU research community includes GRU, GR Medical Center, other GRU facilities and the Charlie Norwood VA Medical Center. Members of this research community are the faculty, staff and students of each institution.

Ethical Principles

The GRU (HRPP) fosters a research environment that promotes the respect for the rights and welfare of individuals recruited for, or participating in, research conducted by or under the auspices of the institution. In the review and conduct of research, GRU’s IRBs are guided by the ethical principles regarding all non-exempt research involving humans as set forth in the report of the National Commission for the Protection of Human Participants of Biomedical and Behavioral Research titled: Ethical Principles and Guidelines for the Protection of Human Participants of Research, often referred to as the Belmont Report, (National Commissions for the Protection of Human Participants of Biomedical and Behavioral Research, April 1979):

• Respect for persons is applied by obtaining informed consent or granting a waiver of the consent process or documentation of consent, consideration of privacy, confidentiality, and additional protections for vulnerable populations.
• Beneficence is applied so that possible benefits are maximized and possible risks are minimized to the persons involved.
• Justice is evidenced in the equitable selection of participants.

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Additionally, to honor its commitment to the Charlie Norwood VA Medical Center (VAMC), the institution abides by the Department of Veterans Affairs policies for human research protection, including the regulations at 38 CFR 16, and the Veterans Health Administration (VHA) Handbook 1200.5.

The actions of GRU will also conform to all other applicable federal, state, and local laws and regulations. All institutional and non-institutional performance sites for this institution, domestic or foreign, will be obligated by this institution to conform to ethical principles which are at least equivalent to those of this institution, as cited in the previous paragraph or as may be determined by the Department of Health and Human Services (DHHS) Secretary.

Engagement in Research
The institutions are engaged in research when the planned project meets the DHHS definition or the FDA definition of human participants’ research.

Federal wide Assurance
GRU, GR Medical Center and GRU Research Institute hold a federal wide assurance (FWA) from the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP). This FWA is an agreement between DHHS and the institution(s) to review and approve federally funded research involving human participants in accordance with the ethical principles outlined in the Belmont Report and the DHHS regulations 45 CFR Part 46.

Applicable Regulations
The Georgia Regents University HRPP is established pursuant to and in accordance with the laws, regulations and principles listed below regarding the protection of human research participants. GRU will adhere to these laws, regulations and principles with regard to Research conducted by or under its auspices:

- The Department of Health and Human Services (HHS) policy and regulations at 45 CFR Part 46 Subparts A, B, C and D also known as the Federal Policy for the Protection of Human Participants or the “Common Rule” (collectively referred to in this document as the “HHS Regulations,” found at http://www.hhs.gov/ohrp/policy/common.html

- Food and Drug Administration (FDA) regulations at 21 CFR Parts 50, 54, 56, 312, 314, 600 601 812 and 814 51 and 56 (collectively referred to in this document as the “FDA Regulations,” found at http://www.cfsan.fda.gov/~dms/reg-2.html

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• International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines, as adopted by FDA.

Organizational Leadership, Authority, Structure and Function of the Human Research Protection Program
The GRU IRB Office, in collaboration with the Institutional Official (IO), and applicable GRU Research Administration Leadership provides oversight of the human research protection program for the following entities:

Georgia Regents University
The Institutional Official (I.O.) is responsible for carrying out the institution’s human research protections program. The I.O. has assigned the role of the Human Protections Administrator (HPA) to the IRB Office Director. The HPA is the primary contact person for human subject protection issues, including the investigation and reporting of non-compliance matters, and plays a key role in ensuring that the institution fulfills its responsibilities under the FWA. The HRPP is a cooperative effort of four other major shareholders; the institution’s administration, the IRBs, the administrative units within Research Administration (RA) [e.g. IRB Office, Division of Sponsored Programs Administration, etc.] and investigators, including faculty, staff or students.

Georgia Regents Medical Center (“GRMC”)
GR Medical Center is a non-profit corporation that operates the hospitals and clinics of Georgia Regents University (“GRU”). GR Medical Center is a “cooperative organization.” GR Medical Center exists to support the clinical, educational and research activities at GRU. The GRMC hospitals and clinics consist of the

“GR Medical Center Hospitals and Clinics,” the main adult hospital and outpatient clinics, to include the GR Cancer Center, and the “Children’s Hospital of Georgia.” GR Medical Center also operates some separate facilities in Augusta and beyond

Georgia Regents Research Institute
Georgia Regents Research Institute (GRRI) is a separate, non-profit research corporation established for GRU research studies. The Institute is a separate 501 (c) (3) corporation in the State of Georgia. Per industry standard, the proper party for research study agreements at our institution is GRRI (State law prohibits GRU, a public institution, from entering into agreements with terms longer than one year, and imposes other restrictions that make MCGRI an essential party to our study contracts.) GRRI subcontracts with GRU, which employs the research staff, for performance of the work in each study.

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GRRI has assigned the primary duties related to the human research protection program to the GRU IRB.

**Georgia Regents Medical Associates (GRMA)**

GRMA is an unincorporated association, and it is a "cooperative organization," which means that it has been approved by the Board of Regents of the University System of Georgia as an affiliated but separate entity that helps to further the purposes of the Board of Regents of the University System of Georgia. There are affiliation agreements between GRMA and GRU, and GRMA and GRMC. Membership in GRMA is limited to GRU faculty physicians and oral surgeons. GRMA bills and collects the professional fees from its members’ practice. They are also authorized to “conduct and manage” the practice, which means that GRMA contracts with managed care companies to establish billing rates for GRMA members, and operates a small number of clinics where GRMA members practice. GRMA does not establish the working hours or conditions for its members, and they do not supervise or control the clinical judgment of its members. GRMA members primarily practice at the facilities operated by GRMC. GRMA only maintains the medical and other records for the small number of clinics that it operates. GRMA does have non-physician employees, including administrative and clinical staff. GRMA has assigned the primary duties related to the human research protection program to the GRU OHRP.

**Charlie Norwood VA Medical Center**

The Charlie Norwood VA Medical Center has a separate FWA (FWA#00002534) that designates the GRU IRBs as their IRB of record. Accordingly, the GRU IRBs meet the requirements of the Veterans Affairs (VA) regulations for human participants research at 38 CFR 16, 17, the Veterans Health Affairs (VHA) handbook, and guidance, memorandums, and policies related to human participants research. Research involving human participants conducted at the Charlie Norwood VA Medical Center, by Charlie Norwood VA Medical Center personnel, or by GRU personnel in conjunction with the Charlie Norwood VA Medical Center may be reviewed only by the GRU IRBs.

The IRB Office Director serves as the liaison between GRU and the CNVAMC. The IRB Office Director or their designee may attend R&D Committee meetings. The OHRP Director participates in discussion and review of Charlie Norwood VA Medical Center policy and procedures as it relates to human participants protection and ensures that GRU IRB records are in order for any audits or reviews conducted by agencies inspecting the Charlie Norwood VA Medical Center human subject protection program.

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GRU's IRBs review human participants research conducted at the Charlie Norwood VA Medical Center (CNVAMC) under a Memorandum of Understanding (MOU). The CNVAMC HPA is the primary contact for human subject protection issues, including the investigation and reporting of non-compliance matters, and plays a key role in ensuring that the institution fulfills its responsibilities under the FWA.

A Memorandum of Understanding (MOU) serves as the IRB Authorization Agreement (IAA) that outlines the responsibilities of both GRU and the Charlie Norwood VA Medical Center as related to the protection of human participants and IRB review of research conducted at the Charlie Norwood VA Medical Center. The policies and procedures governing human participants’ research at Charlie Norwood VA Medical Center are detailed on the GRU web site for CNVAMC.

Augusta Biomedical Research Corporation
Augusta Biomedical Research Corporation (ABRC) was established by the Charlie Norwood VA Medical Center in 1989 pursuant to sections 7361 through 7368 of Title 38 U.S.C. ABRC provides a mechanism for the administration of private and public grants to support the research and education missions of the Charlie Norwood VA Medical Center. Augusta Biomedical Research Corporation is a state chartered corporation/charitable organization and is a 501(c)(3) federal tax-exempt organization. The sole purpose of ABRC is to advance the research and education missions of the Department of Veterans Affairs (DVA), and specifically the Charlie Norwood VA Medical Center, through the support of research-related and education.

Institutional Review Boards
GRU maintains three internal IRBs in compliance with state and federal regulations:

- Institutional Review Board A (Biomedical)
- Institutional Review Board B (Social/Behavioral and Educational)
- Institutional Review Board C (Oncology-focused)

The IRBs are responsible for review of research applications, before the research-related activities begin, to protect the rights and welfare of human subjects, and to ensure their safety. The internal IRBs also review protocols conducted at the Charlie Norwood Veterans Affairs Medical Center under a memorandum of understanding.

GRU may grant authority to the internal IRBs listed above to: Approve, require modifications to secure approval, and disapprove all human subjects research activities overseen and conducted at GRU, GR Medical Center, GR Medical Associates

- Suspend or terminate approval of human subjects research
- Observe, or have a third party, observe the consent process and the conduct of the research

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All human subjects research conducted at GRU, GR Medical Center, and GR Medical Associates must be approved by an institutionally designated IRB before the research may begin. Any faculty member, student, or staff member who proposes to engage in research involving the use of human subjects must have the research reviewed and approved by the IRB before any research-related activities may begin.

Records of review decisions on the use of human subjects and of informed consent will developed and maintained by the GRU IRBs in compliance with state and federal regulations. The IRBs are administratively and financially supported by the GRU Office of Human Research Protection and report to the Institutional Official designated in the GRU federal wide assurance.

**External IRBs**

GRU has agreements with the external IRBs listed below to allow IRB review of specific human subjects’ research. However, to maintain the highest standards of human research oversight, only a GRU-approved external IRB may be utilized by a GRU investigator per the list below. The following external IRBs are available for use according to the criteria listed below:

- Western Institutional Review Board (WIRB®)
  - Externally-sponsored clinical trials, which have undergone FDA review
- Chesapeake Research Review, Inc. (CRRI)
  - Externally-sponsored clinical trials
- National Cancer Institute Central IRB
  - Cooperative Clinical Oncology Group Protocols
- University of Georgia
  - Review is based upon a Memorandum of Understanding which outlines IRB of record based on Principal Investigator primary appointment and location of the research.
- Other GRU Approved IRB- requests reviewed on a case by case basis

Investigators are responsible for notifying the GRU IRB Office of their submission to the external IRB. The GRU IRB Office provides an internal release before any research activities may occur, per the GRU IRB Policy: “Investigator Responsibilities for Using a GRU-External IRB”.

**GRU IRB Office**

**The mission and goals of the IRB Office are:**

- to ensure the research goals of the enterprise are met ensuring compliance and protection of human subjects involved in research

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- to serve as the central contact for facilitating the goals of the Enterprise Human Research Protection Program (HRPP)

The IRB Office provides:

- Administrative support for the internal IRBs and a liaison for the external IRBs
- Monitoring and oversight for all IRB approved studies
- Education and training for human research investigators, staff, and IRB members

Jurisdiction of the IRB Office
The GRU IRB Office has jurisdiction over all GRU human subject research regardless of funding status and source and has been granted the authority by the institution and the institutional review boards to observe the consent process and the conduct of the research:

- At this institution
- By or under the direction of any employee or agent of this institution (including students) in connection with his or her institutional responsibilities
- By or under the direction of any employee or agent of this institution using any property or facility of this institution,
- Or involving the use of this institution’s nonpublic information to identify or contact human participants.

Auditing and Compliance Program
GRU established a Human Research Protection Program (HRPP) and included an Auditing and Compliance (A&C) Program that is overseen by the IRB Director and IRB Regulatory Compliance Manager. The goal of the A&C program is to assure ongoing compliance with the requirements of the institution’s Human Participants Protection Program and to provide education, guidance and auditing/monitoring services in order to promote an environment of continuous quality improvement so that human participants’ research at GRU is conducted according to the highest ethical standards.

Resources for the Human Research Protection Program
The Institutional Official is directly responsible for providing resources to support the HRPP. Resources include, but are not limited to, providing for educational programs (initial and continuing) for IRB members, IRB Office Staff, and investigators; space for IRB meetings; sufficient personnel to support the research protocol review process; sufficient equipment to aid the functions of the IRB Office, internal IRBs and external IRBs in the research protocol review process (computers, an information system, etc.); required record keeping (space and materials); and direct financial support (salaries, supplies, etc...). These resources are evaluated at the time of increased growth of the human research program and annually per the State of Georgia budget reparation process.

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IRB Office Staffing
The IRB Office Director is a member of the staff of the Division of Clinical and Translational Sciences and has day-to-day responsibilities for the operation of the HRPP. Additionally, the IRB Office is staffed by individuals such as the Regulatory Compliance Manager, IRB Operations Manager, Nurse Compliance Coordinator, Compliance Coordinator, Trainer, 4 IRB Administrators, IRB Office Specialist, and IRB Office Associate. The duties and responsibilities for all staff are found in their respective job descriptions, and their performance is evaluated on an annual basis.

IRB Office Space
The IRB Office currently occupies 1782.4 square feet on the second floor of Pavilion III in suite CJ-2103.

What is Research?
The GRU IRBs utilize the following definitions/descriptions for research:

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. 45CFR46.102(d)

A systematic investigation is an activity that involves a prospective research plan, which incorporates data, both quantitative and qualitative, and data analysis to answer a research question.

Investigations designed to contribute to generalizable knowledge would include one or more but not limited to, the following, concepts

- The knowledge contributes to a theoretical framework of an established body of knowledge.
- The primary beneficiaries of the research are other researchers, scholars and practitioners in the field of study.
- Publication, presentation or other distribution of the results is intended to inform the field of study.
- The results are expected to be generalized to a larger population beyond the site of data collection.
- The results are intended to be replicated in other settings.
The Food and Drug Administration (FDA) defines a clinical investigation as:
“...any experiment that involves a test article and one or more human participants, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that must meet the provisions of part 58, regarding nonclinical laboratory studies. The terms research, clinical research, clinical study, study, and clinical investigation are deemed to be synonymous for purposes of this part.”

Human Subject
Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP) defines a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains:
(1) data through intervention or interaction with the individual or
(2) identifiable private information 45 CFR 46.102(f)

For medical device studies involving in vitro diagnostics and unidentified tissue specimens, the FDA defines the unidentified tissue specimens as human participants.

Intervention is defined as physical procedures by which data are gathered and manipulations of the research subject or the environment of the research subject for research purposes.

Interaction is defined as communication or interpersonal contact between investigator and research subject.

Food and Drug Administration (FDA) definition of a human subject: 21 CFR 56.102(e) defines human subject as an individual who is, or becomes, a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient.

21 CFR 56.812 (p) defines a human subject as an individual who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control. A subject may be in normal health or may have a medical condition or disease.
The terms research subject and research participant may be used interchangeably.

**Human Derived Material**

The GRU IRBs define human derived material as follows, but not limited to:

- Medical records, electronic or hard copy
- Data storage (i.e., database, spreadsheet, or other document or electronic type)
- Data obtained from questionnaires, surveys, interviews, etc.
- Fetal material including the placenta, amniotic fluid, fetal membranes, and umbilical cord
- Placenta removed at delivery
- Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor
- Pathological specimens
- Diagnostic specimens (blood, sputum, urine, hair and nail clippings) collected
- Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction or permanent teeth if routine patient care indicates a need for extraction
- Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric acid solution to the tongue
- Supra- and sub gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques
- Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings
- Sputum collected after saline mist nebulization
- Excreta and external secretions (including sweat)
- Primary cell lines (or those not generally available through commercial sources)

Note: There are also cultural or ethnic groups whose beliefs are such that they may object to the use of any samples of human tissue for research. One must be aware of these boundaries and respect them in the research design and conduct.


The HRPP and IRB policies will be revised as needed to ensure they remain current and reflect current practice. When the need for revision(s) is identified the individual or department will need to email the applicable Research Administration leadership, to include the Institutional Official (IO), requesting the
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change. The I.O., IRB and/or other key stakeholders will evaluate the internal form regarding the change(s) being implemented.

The GRU HRPP policies and procedures are based, in part, on the relevant federal regulations and guidance, state and local laws, relevant GRU policies and procedures and generally accepted standards within the human subject protections field. Final policy drafts are presented to the I.O., IRB Office Director, and IRB Leadership Committee (Consisting of all internal IRB Chairs, Vice Chairs, IRB Administrators, I.O. and other key stakeholders) for review and implementation.

Measurement and Improvement of the Human Research Protection Program
The institution monitors and measures the effectiveness of the human research protection program by conducting an annual review of the HRPP. This review is conducted annually in conjunction with fiscal year budget evaluation and preparation period. The objectives of this review are to assess the HRPP to determine:

- if adequate resources are allocated to ensure compliance with organizational policies and procedures, applicable laws, regulations, codes, and guidance
- if the organization is efficiently and effectively meeting the goals of the HRPP

If it is noted during the review that improvements are needed, the Institutional Official in collaboration with the IRB Director prepares a plan of improvement to be implemented. After implementation, these changes are monitored and measured to determine the effectiveness of improvements. If additional changes are required, these are identified and reviewed.

Human Research Protection Program Educational Requirements Initial Requirements
The GRU HRPP includes on-going educational requirements for the entire research community. The HRPP education program consists of an initial mandatory training session for all individuals who are involved in the conduct, review, or oversight of human subject research. No individual identified as key research personnel on a project will be allowed to participate in research activities involving human participants until the initial training requirement is met. The initial training requirement is fulfilled by completing the on-line Collaborative Initial Training Initiative (CITI) course.

What Human Research Protection Education Is Required For GRU Research Team Members?
All research team members at GRU, GR Medical Center and GR Medical Associates must complete the required education program, Collaborative Institutional Training Initiative (CITI), prior to IRB submission or the GRU IRB Office release for the external IRBs. Protocols may be reviewed but will not be approved until all research team members have completed the required training.

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HIPAA Requirements
If the research involves the use of protected health information (PHI) from GRU or GR Medical Center, the researcher and all persons involved in the conduct of the research must also complete the GRU HIPAA research training course. Educational offerings from other institutions will be evaluated by the Enterprise Privacy Officer on a case-by-case basis for equivalency to GRU standards.

HIPAA Compliance and HIPAA Education Program
The Health Insurance Portability and Accountability Act (HIPAA) [45 CFR 160, 164] outlines a set of regulations that govern privacy, security, and electronic transactions standards for health care information. Congress requires that all “covered entities” comply with each set of HIPAA standards. GRU, GR Medical Center, and GR Medical Associates and have been classified a “Hybrid Entity” under HIPAA. A “Hybrid Entity” is defined as a covered entity that is made up of health care and non-health care components, but whose covered functions are not its primary function. Non-health care examples of the institution include the many educational programs as well as the non-human research programs. HIPAA only applies to the covered functions within the Hybrid Entity. In addition to the penalties outlined in the HIPAA regulations, GRU and GR Medical Center employees who fail to comply with HIPAA are subject to sanctions from the institution that could include dismissal. Human participants research activities that use or disclose health-related information that is Protected Health Information (PHI) may be subject to the HIPAA Privacy Rule requirements [45 CFR 160, 45 CFR 164]. At GRU, health-related information is considered to be PHI if any of the following apply:

- The researcher obtains it directly from a healthcare provider, a health plan, a healthcare clearinghouse or an employer (other than records relating solely to employment status)
- The records were created by any of the entities noted above and the researcher obtains the records from an intermediate source which is NOT a school record or employment record related solely to employment status
- The researcher obtains it directly from the subject in the course of providing treatment/health care to the subject.

The Privacy Rule requires that each institution "train all members of its workforce on the policies and procedures with respect to protected health information required by this subpart, as necessary and appropriate for the members of the workforce to carry out their function within the covered entity." This education requirement applies to investigators and research staff (research coordinators, research assistants and other key research personnel) who (a) are conducting human participants research, (b) are conducting research that involves protected health information, and (c) are also within the covered entity. In order to be compliant with the HIPAA educational requirements, researchers must complete the GRU HIPAA Training Course.
Research Team Members
Research team members are all persons who will have a significant role in the design or conduct of the research. Research Team members are individuals or personnel approved by the IRB to have contact with human participants or their identifiable information. This approval can occur at initial submission or by submitting a personnel change (or protocol revision if the PI is being changed) to add the individual to the protocol.

There are multiple roles that may be assigned to an individual during the life cycle of a research protocol. Most of these roles may be easily defined as:
- Principal Investigator (PI) or Project Director (PD),
- Sub-Investigator (Sub I),
- Faculty Sponsor (FS),
- Study Coordinator (SC),

There are other roles that may not be as easily defined. Each role is required to protect the rights and welfare of human participants and/or human derived materials and identifiable information. These protections may be tangible protections such as locks on doors to prevent unauthorized physical access or they may be as intangible as maintaining the highest level of confidentiality.

For more information regarding the roles of each the research team members, please refer to the IRB policies.

Continuing Education
All investigators and key research personnel involved in human subject research are also encouraged to seek continuing education in human subject protections. Educational opportunities may be found by attending approved educational offerings on campus or approved conferences or educational courses dealing with human participants’ research within GRU or outside of the institution. There is only one continuing education course that is a requirement mandated by the IRB Office and the institution for human subject researchers, and that is the completion of the CITI (Collaborative Institutional Training Initiative) “recertification” every three years.

IRB Member Education
New IRB members attend initial and follow-up orientation sessions to learn about their roles and responsibilities as an IRB member. IRB members also receive periodic training during the fully convened IRB meetings.

Required Education for Researchers at the Charlie Norwood VA Medical Center
All research team members at the Charlie Norwood VA Medical Center must complete the required education program, Collaborative Institutional Training Initiative (CITI), prior to IRB approval. Protocols may be reviewed but will not be approved until all research team members have completed the

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required training. The CITI program requires a time investment so plan ahead. Recertification is required per VA requirements.

**Required Education for Research Team Members that are not affiliated with GRU, GR Medical Associates, or the Charlie Norwood VA Medical Center**

Non-affiliated research team members are required to complete the Collaborative Institutional Training Initiative (CITI) training of their institution, if applicable, or of GRU.

**Institutional Responsibilities and Policies Regarding Conflict of Interest**

The institution has policies and procedures that require the reporting of Conflicts of Interests (COI) and Conflicts of Commitments for all employees. The GRU, GR Medical Center, and GR Medical Associates Conflict of Interest Policy is available on the Office of Legal Affairs website. The Medical College of Georgia has a separate COI policy.

**Research Conducted with Other Institutions or Performance Sites**

The relationship and duties for each site should be documented in a Memorandum of Understanding (MOU) or other written agreement. The IRB of record may require a copy of the IRB approval letter from that institution or other performance site. The IRB may serve as the IRB of record with a properly executed IRB Authorization Agreement. The IRB Office staff will route these agreements for the approval of the FWA institutional official.