I. **Member Requirements**

Per federal regulations, the IRB must be composed of the following:

- Have at least five members
- All members cannot be of the same profession
- All members cannot be of the same sex
- One member must be a non-affiliated member (not affiliated with the institutions served)
- One member must be a non-scientific member

IRB membership will include at least one member who is an expert in research involving vulnerable populations listed in IRB policy to include mentally disabled persons or persons with impaired decision-making capacity.

Senior level officials in Research Administration and GRU administration including, but not limited to, the President, Provost, all Associate Provosts, and Associate Vice-Presidents may not serve as voting members of the IRB.

II. **IRB Member Responsibilities**

The primary responsibility of the IRB member is to protect the rights and welfare of human research subjects. This obligation is maintained when the proposed research protocol is reviewed in compliance with applicable federal regulations, state and local laws and the interest of the local research community.

- Attend a majority of meetings (70%) and education sessions.
- Confirm or decline attendance to a meeting well in advance.
- Review all materials (IRB application, protocols, informed consent, questionnaires, recruitment documents, Investigator Brochures, etc.) on the meeting agenda.
- When assigned as a reviewer, post the review in eIRB (the electronic IRB system) by 9:00 a.m. the day of the IRB meeting.
- Review expedited actions/minutes linked to the agenda, and if issues or errors are found, resolve them with the IRB staff.
- Review monthly meeting minutes for accuracy and promptly notify the IRB Chair and/or staff of any corrections or additions.
- Discuss issues that are noted while reviewing the protocol.
- Recuse yourself from discussion and voting on any project where there is a potential conflict of interest.
- Maintain confidentiality for all discussions, reviews, and proprietary information you will encounter as an IRB member. All IRB members are
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required to sign a Confidentiality Statement upon appointment to a Committee.

- Allot time to read about updates and policies regarding human subjects protections, and avail yourself of education, IRB documents, and the experience of your colleagues

a. IRB Member Affiliation

1. An affiliated member is an employee or agent of the organization. Affiliated members include, but are not limited to, individuals who are: part-time employees; current students; members of any governing panel or board of the institution; paid or unpaid consultants; healthcare providers holding credentials to practice at the institution; and volunteers working at the institution on business unrelated to the IRB. An individual that has no affiliation with the organization registering the IRB, other than as an IRB member, is considered unaffiliated with the entity operating the IRB. Unaffiliated members may include people whose only association with the institution is that of a patient, subject, or former student at that institution. Paying unaffiliated members for their services would not make the member “otherwise affiliated” as stated in the regulations, or cause the member to have a conflicting interest.

   i. Affiliated members are selected from various colleges or departments as the need for expertise in a specific area presents itself. The IRB Chairperson, or the IRB Administrator, at the request of the IRB Chairperson, contacts the individual and the departmental chairperson to determine if an individual can serve.

   ii. For Charlie Norwood VA Medical Center members, the Medical Center Director selects and appoints members to the IRB. The IRB includes three Charlie Norwood VA Medical Center members as voting members and no votes are taken on protocols that involve the Charlie Norwood VA Medical Center unless at least one of these members is present. These individuals must be physicians according to VHA regulations. The IRB includes at least two VA full voting members. VA Members are appointed for three year terms and may be re-appointed to a new three year term without lapse in service at the end of each term.

III. IRB Member Appointment

The Institutional Official appoints the IRB members based upon the recommendation of the IRB Chairperson. Charlie Norwood VA Medical Center members are appointed by the Medical Center Director.
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Terms of service are one year (with the exception of members appointed by the CNVAMC) although a term may be less depending on the circumstances. These are reviewed on a case-by-case basis. There is no limit on the numbers of term that a member may serve.

A member may be terminated from service if the member requests termination, if the one-year term expires, or if a confirmed issue of non-compliance involves the member.

a. IRB Chair

The Institutional Official appoints the IRB Vice-Chairperson. There is no limit on the number of terms that the IRB Chair may serve.

The Chair is evaluated on a yearly basis by the Institutional Official, with input from the IRB Administrator. Several criteria are used in the evaluation process such as meeting attendance throughout their term, preparedness, interest and availability to continue in this role, leadership and management ability as well as staying abreast of current regulations, guidelines and national thought leaders.

b. IRB Vice Chairpersons

The Institutional Official appoints the IRB Vice-Chairpersons. There is no limit on the number of terms that the IRB Vice-Chairperson may serve. The Vice-Chairperson assumes the duties of the Chairperson during the absence of the Chairperson. The IRB Vice-Chairperson may approve research protocols if the protocol qualifies for exempt from full or expedited review. The IRB Chairperson and/or Vice-Chairpersons may not disapprove a protocol. All disapprovals, regardless of level of review, must be determined by the full committee.

The Vice-Chair is evaluated on a yearly basis by the IRB Chair, with input from the IRB Administrator. Several criteria are used in the evaluation process such as meeting attendance throughout their term, preparedness, interest and availability to continue in this role, leadership and management ability. Vice Chairpersons are expected to stay abreast of current regulations, guidelines and national thought leaders.

c. Alternate Members

Alternate members may be added to the Committee to serve in the absence of a regular member. Alternate members are selected with the expectation that they have similar expertise to the regular members. The alternate members are expected to fulfill all responsibilities of the regular member. Alternate members are evaluated in the same manner as full members. If an alternate member is to serve in the absence of a full member at the meeting, the regular member should notify the IRB Administrator of the change. Alternates and full members may attend the same meeting; however, only the
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full member will count towards the quorum and is the only one authorized to vote unless the full member is recused on a particular agenda item.

IV. IRB Member Education and Training

New members (full and alternate) are required to complete CITI (Collaborative Institutional Training Initiative) web-based training. Re-certification is required every three years of all IRB members.

Each new IRB member is required to complete an orientation session conducted by the Office of Human Research Protection. The orientation includes the following:

IRB history, IRB member information, IRB responsibilities, fiscal year meeting information, packet information, action items information, etc.

Each attendee is provided orientation information, IRB Policies and Procedures, IRB roster, IRB meeting dates and location directions, contact information, IRB Reviewer’s Checklist, and a copy of the Belmont Report.

Specific educational topics are presented to Committee members on an as needed basis such as when issues arise in the lay press, scientific journals and/or if a members requests the presentations.

At a minimum, formal one hour education is provided to the IRB on a quarterly basis. IRB members also receive email updates regarding IRB policy changes, educational offerings, etc...

V. IRB Member Evaluation

IRB members are evaluated on a yearly basis by the IRB Chair and IRB Administrator. Several criteria are used in the evaluation process such as meeting attendance over the term, preparedness, interest and availability to continue. IRB membership is also evaluated to ensure the composition of the IRB meets legal, regulatory and organizational requirements.

The dated and preferably signed CVs or résumés for IRB members and alternates are submitted at the time of initial appointment and then at each re-appointment for all members and alternates including the representatives from the Charlie Norwood VA Medical Center.

VI. IRB Members Stipends

IRB members receive a stipend based on the number of meetings attended. Stipends are disbursed in January and July.
VII. Conflict of Interest

Conflict of interest may be defined as: “A conflict between the private interests and official responsibilities of a person in a position of trust.” This definition is not limited to financial conflicts of interest.

Conflict of interest involves any situation in which it reasonably appears that a significant financial interest or other personal interest could compromise the integrity of work to be performed for GRU (for instance without limitation: in the design, conduct, or reporting of activities funded or proposed for funding by a sponsor; in the vendor selection process; in hiring or employment decisions; in research approval processes). A conflict of interest includes, without limitation, apparent or actual bias in the work to be performed for GRU, created by an individual’s personal relationships, or by an individual’s or family member’s significant financial interest or other interest in a company that does business with, competes or may compete with Georgia Regents University.

"Significant financial interest" means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interest); and intellectual property rights (e.g., patents, trademarks, copyrights and royalties from such rights). The term does not include:

- salary, royalties or other remuneration from GRU;
- income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities (in connection with approved outside professional activity);
- income from services on advisory committees or review panels for public or nonprofit entities (in connection with approved outside professional activity); or
- an equity interest that, when aggregated for the investigator and the investigator's spouse and dependent children, meets both of the following tests: [i] does not exceed $10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and (ii) does not represent more than a 5% ownership in any single entity; or
- other salary, royalties or other payments that, when aggregated for the investigator and the investigator's spouse and dependent children, are not expected to exceed $10,000 during the next twelve-month period.

EXCEPTION: When the proposed project involves human subjects and approval from the Institutional Review Board, the above monetary thresholds do not apply. In human subject research, the threshold for required conflicts of interest disclosure is any dollar or stock amount above zero.

The conflicts may also be research-related such as conflicts that arise out of an individual’s participation in the conduct or oversight of clinical research or non-research related if unrelated to clinical research.
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IRB members with a conflicting interest are:

- Excluded from the discussion except to provide information requested by the IRB.
- Required to leave the meeting room for discussion and vote and cannot simply abstain from voting
- Not counted towards the quorum.
- Documented in the minutes as being absent with an indication that a conflict of interest was the reason for the absence

If the investigator feels that a conflict of interest exists, the investigator may request in writing prior to the member assignment that an individual member not be assigned to review the protocol in question. The investigator must fully document the perceived conflict of interest. However, investigators may not select the IRB reviewers.

IRB members self-identify a conflict of interest for the review by the convened IRB. If the Conflict of Interest Panel has determined a conflict of interest, the individual is responsible for notifying the appropriate committees.

IRB members self-identify a conflict of interest for the research under expedited review. If the Conflict of Interest Panel has determined a conflict of interest, the individual is responsible for notifying the appropriate committees.

VIII. Consultants and Special Expertise

At times, additional or special expertise (either scientific, legal or scholarly) or a consultant will be required for the IRB to adequately review a protocol. The use of special expertise or a consultant is at the discretion of the IRB Chairperson or designee. If an IRB member feels additional expertise or consultant is needed for a protocol, they must contact the IRB Chair in advance of the meeting. Additional expertise or a consultant is sought from leaders in the field. The consultants’ review is presented to the fully convened IRB at the time the protocol is reviewed. The IRB Chair or designee may request the consultant’s attendance at the meeting to discuss their review.

The expert or consultant is not allowed to vote on the protocol.

If the consultant or individual with special expertise discloses a conflict of interest, they may only serve as the special expertise or consultant if the conflict of interest has been reported to the Conflict of Interest Panel and only if that Panel approves their service. The conflict of interest must be disclosed in writing to the convened IRB or the reviewer, as applicable.

The individual with special expertise or the consultant may provide information at the request of the IRB but they may not participate in the vote and must recuse themselves prior to that action if in attendance at the meeting.

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IX. IRB Roster Updates and Registration Updates with DHHS

IRB rosters are updated as membership changes.

The IRB Administrator is responsible for:

1. Reporting membership changes to the IRB Director and Institutional Official
2. Updating the internal IRB roster when membership changes occur.
3. Updating the IRB registration with DHHS
4. Maintaining all appointment, orientation, and training documents for each IRB member

X. IRB Meetings

The meeting schedule for each IRB is posted on the IRB websites. If a change in the meeting or application submission date is required, the IRB Administrator will notify the IRB members.

Attendance at a meeting for investigators or research team members is acceptable as a training and education opportunity. Guests such as students, new faculty members, staff or community members who wish to observe the IRB meeting in order to learn about research and who are not affiliated with a particular research protocol, or visitors from other Institutional Review Boards (IRB) may attend the IRB meeting if the following criteria are met:

- If the guests are required to attend by a faculty member as part of their curriculum, then the individual must contact the IRB Administrator at least one week before the scheduled meeting
- The Chairperson or designee, prior to the meeting, must approve each visitor’s request to attend.

Once the above criteria are met, and the Chairperson or designee approves the attendance of the individual, then the individual is responsible for approaching the IRB staff when they enter the meeting. Also, any individual may be asked to leave the meeting if the Chairperson or designee determines a sufficient need.

All visitors attending an IRB meeting must sign the Confidentiality Agreement upon entering the meeting.

a. Confidentiality of Discussions and Information Presented at the IRB Meeting

All information discussed in the IRB meetings is confidential. Official reports or letters to investigators regarding the status of the study must come through, or be approved by, the IRB Administrative Office and the IRB Chairperson or designee.

b. Voting Requirements

In compliance with federal regulations, no member of the research team may be present in the room for the discussion that follows the informational portion of the IRB
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review. The research team member may be asked a question to clarify an earlier response but cannot be in the room during the discussion and vote.

c. Reviewer System

i. For expedited actions, the reviewer is assigned by the IRB Chair or their designee. The reviewer is assigned based upon their area of expertise, years of service on the IRB, and availability to conduct the review.

ii. For submissions reviewed by the fully convened IRB, a primary reviewer system in which a primary and secondary reviewer are assigned to each submission that requires review by the fully convened IRB. The IRB Chair or their designee assigns the reviewer based upon their area of expertise, years of service on the IRB, and availability to conduct the review.

d. Quorum

Meetings begin when a quorum arrives and each required element is represented. A quorum is defined as a majority of the committee members and must include at least one non-scientific member. For VA related protocols, at least one of their appointees must be present and must be a physician for FDA regulated research. The IRB Chairperson or designee determines when quorum is met. A majority of the members present must approve a submission in order for it to be approved. Items can be discussed if quorum is not met; however, no votes may be taken. If quorum is lost during the meeting, not votes may be taken.

e. IRB Staff Attendance

The IRB Director and IRB Operations Manager attend the IRB meeting as their schedules permit. At least one of them will attend the meeting. The IRB Administrator attends the meeting. Their primary roles are to provide service to the IRB such as documentation of attendance and absences, conflicts of interests, votes (for, against and abstentions), guests, and regulatory compliance. They are also available to provide feedback on items that were noted during the administrative review.

The IRB Training Coordinator will attend on a scheduled bases to present the Education and Training topic 30 minutes before the meeting time. The Training Coordinator may also attend at least part of the meeting to determine any new or ongoing education and training needs that may be needed. If topics are introduced that require new or ongoing education and training needs then the IRB Director or Assistant Director is responsible for providing this information to the Clinical Trials Training Coordinator. IRB members or IRB staff may also request or recommend additional topics.

f. The IRB Regulatory Compliance Manager and a member of their staff will attend to present information regarding the audits conducted during the time period from the previous meeting to the current meeting. The Clinical Trials Auditor may also provide
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information from observing the informed consent process, when specifically authorized to do so by the IRB.

g. Communication

Members are notified of protocols, amendments and continuations that were approved via the expedited or exempt criteria by the electronic agenda and the electronic minutes of the full committee meeting. The meeting agenda is sent to the members, advisors and IRB staff via email prior to the meeting.

Members are notified regarding an upcoming meeting at least 7 days before the scheduled meeting. Members receive an email from the IRB Administrator, or their designee with instructions and the agenda attached. Members are also reminded to review the electronic agenda for submissions approved via the expedited procedure and reportable events.

Cancellation of meetings will be communicated to the IRB Members via email, phone calls, signs and personal messages. If there are agenda items listed for the meeting, the investigator will be notified of the rescheduling of their submission for another meeting.

After the meeting, the minutes are distributed via email. For those members who do not have an email address or may experience outages, the minutes may be sent via Federal Express or hand-delivered as necessary. Hard copies of the minutes are available if needed.

XI. Minutes Documentation

The IRB Chair, Minutes Writer and IRB Administrator compiles information during the meeting for inclusion in the minutes. The IRB Administrator tracks member attendance via a sign-in sheet all members must sign when entering the meeting. The IRB Administrator also tracks members who are out during discussion and vote of a submission. Late arrivals or early departures of IRB members are managed by the IRB Chair and IRB Administrator. The agenda lists all protocols to be reviewed as well as any absences or attendance needs of the committee members. The order of the agenda items may be shifted as needed to ensure that the primary reviewers are present. The minutes and the attendance sheet document the management of this issue.

a. IRB meeting minutes document the following:

- Education and training topic for the meeting
- Guests who attended the meeting
- Attendance at the meeting
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- Attendance of members or alternate member who participate through videoconference or teleconference, and documentation that those members received all pertinent material before the meeting and were able to actively and equally participate in all discussions
- Reminders about confidentiality of the IRB meetings
- Information only items
- Absence of an IRB member
- An alternate member serving instead of the regular member
- Any suspension and terminations by the IRB Chairperson
- Serious and continuing non-compliance and the management plan of those incidents, as appropriate
- Votes for each protocol as numbers for, against, or abstaining.
- Actions taken by the IRB
- Separate deliberations for each action
- The basis for requiring changes in research if applicable
- The basis for disapproving research if applicable
- A written summary of the discussion of controverted issues and their resolution
- Justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent document
- Rationale for significant and non-significant risk device determinations, for FDA regulated research
- The names of IRB members, consultants or special expertise that left the meeting because of a conflicting interest, along with the fact that a conflicting interest was the reason for the absence.

The IRB Clinical Compliance Coordinator and/or another IRB staff member will conduct an audit of the minutes before they are presented to the IRB Chair or designee. The Chair or designee reviews the minutes before they are distributed and approved. The minutes are not final until approved by the convened IRB. If minutes have to be altered or revised, the convened committee must approve the alterations or revisions. If the IRB database creates minor errors that require minor edits, this information does not require approval by the fully convened IRB.

Minutes are distributed via email to members, advisors, IRB staff, the institutional officials for GRU, as well as key stakeholders within the human research protection program. The Charlie
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Norwood VA Medical Center is notified of the minutes via the Administrative Officer (AO) for the Research and Development Office. The CNVAMC Chief of Staff is also copied on the distribution list. In an effort to increase efficiency, the AO is also provided a Word version of the minutes to assist in the preparation of documents for the R&D Committee meeting. The IRB Administrative Staff strives to make the minutes available for review within three weeks of the meeting. The minutes are not final until approved by the convened IRB.

It is the responsibility of the IRB Administrator to retain the original meeting minutes and support documentation.

XI  IRB Actions

Protocols may be approved, have deferred approval, tabled or disapproved. It is important that the various factors be balanced with regard to providing appropriate subject protections without unnecessarily delaying the project. The IRB Administrator notifies the researcher and research team of the IRB Chair/Designee/Fully Convened IRB’s determination regarding a submission with a deadline for researcher response.

The pathway followed is a judgment call by the primary reviewers and the full committee. It is based upon whether adequate information was provided by the principal investigator to the Committee to permit full evaluation of the protocol with regard to human subjects’ protection issues. There may be issues that will improve the overall submission but do not directly impact on the ability of the Committee to evaluate the study. Therefore, the following guidance is provided, recognizing that these decisions are based upon the judgment of the committee and cover a wide spectrum.

a. Approval

Protocols that receive full approval do not require any additional changes. Approval is granted when the protocol meets the following criteria in addition to any institutional requirements:

1. Risks to subjects and others were evaluated.
2. Risks have been minimized.
3. Anticipated benefits were evaluated.
4. Determination was made that risks to subjects or other are reasonable in relation to expected benefits.
5. Determine was made that the level for continuing review based on the level of risk is appropriate.
6. Evaluation of the adequate management of information as relevant to the protection of subjects occurred
7. Evaluation of whether the risk level assigned to the protocol would require observation of the informed consent process and if so, delegate this observation to IRB staff occurred.

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Officials of GRU, Georgia Regents Medical Center, and the Charlie Norwood VA Medical Center are prohibited from approving research that has not been approved by the IRB. Any undue influence felt by a reviewer, or IRB staff member must be reported to the IRB Director. Upon notification, the IRB Director will initiate an investigation promptly. The findings of the investigation will be reported to the institutional officials and recommendations for further actions will be made.

b. Deferred Approval

Most protocols fall into this category. The approval is deferred pending a satisfactory response from the principal investigator (PI) to the IRB’s requests for changes or clarifications (i.e., stipulations) to address deficiencies found in the protocol submission packet. The changes or clarifications requests most frequently pertain to components of the Description of Research Proposal (DRP), Informed Consent Document (ICD), Children’s Assent Document (CAD), IRB forms, and Regulatory Issues.

i. Minor Revisions

Minor revisions involve clarifications of procedures or situations that do not involve subject safety. These revisions can permit approval following review of the responses by the Chairperson or designee.

ii. Major Revisions

Major revisions involve significant issues relating to subject safety or study design. The responses from the Principal Investigator (PI) are sent to primary reviewers who bring the responses to the next Committee meeting for discussion. Risk-benefit determination cannot be made as these become major revisions that require committee re-review at the next convened meeting.

c. Tabled

Submissions are tabled for one or more of the following reasons:

- The assigned reviewers are not present and/or did not provide their comments regarding the submission
- A reviewer with a specific area of expertise required by the study is not in attendance at the meeting
- The submission is inadequate and must be rewritten before it may be reviewed by the fully convened IRB.
XII. IRB Record Storage

In accordance with 45 CFR 46.115(b); 38 CFR 16.11.115(B); 21 CFR 56.115(B); VHA Handbook 1200.5(7) and applicable state and local laws, all Georgia Regents University (GRU) Institutional Review Board (IRB) records must be retained and be accessible for inspection and copying by authorized representatives of appropriate federal agencies [Food and Drug Administration (FDA), Office of Human Research Protection (OHRP), Office of Research Oversight (ORO)], the Principal Investigator (PI) and his/her designees, and other administrative or department officials.

HHS regulations at 45 CFR 46.115(b) require that IRB records be retained for at least 3 years, and records relating to research which is conducted be retained for at least 3 years after completion of the research.

Protocol records are stored in the electronic IRB system. There are some records kept on site for active studies that were originally approved in the former paper system.

i. Inactive protocols from the paper system

All research protocol files that are no longer active such as those protocols whose approval expired, or was cancelled without subject enrollment, or were terminated (within the past year) are maintained in a locked storage space in the IRB suite and as space permits. All files that are no longer active (with expiration dates greater than one year ago) are maintained at a local secure data storage facility with limited access.

XIII. Quality Assurance/Quality Improvement

The GRU Compliance Coordinators (Auditors) conduct an internal audit of each IRB file in preparation for site audits. For more information on the GRU IRB auditing program, please view their web site. These findings are communicated to the GRU IRB Office Assistant Director who assigns these to the appropriate staff member for correction. Education and training or re-training may be necessary and is implemented.

The IRB Office Compliance Coordinators conduct quality assurance on every new study protocol approved by the IRB. Findings of the quality assurance are communicated to the IRB Administrator.