Grady Research Oversight Committee (ROC)*

OVERVIEW AND GUIDELINES

I. PROTOCOL SUBMISSIONS TO THE ROC

A. A complete research protocol must be submitted and approved by the Grady Research Oversight Committee before research can begin in the Grady Health System.

B. The protocol submission should include the standard information required by the affiliated Institution's (IRB)

C. The protocol submitted to the Grady ROC must contain the following:

1. **Study Protocol**. This is the standard information provided to the IRB
2. **Summary statement**. A summary of the purpose of the study and the hypothesis. Note that the IRB "lay summary statement" is sufficient for this purpose.
3. **Budget statement**. A description explaining the payment of direct costs for Grady personnel, medications or other Grady resources involved in the research. If no costs will be incurred by Grady, please describe how this is possible in the cover letter.
4. Copy of **IRB approved informed consents**. The consent form should note that Grady is a site for the research and should also mention "The Grady Health System" in the standard disclaimer statement (compensation section of consent).
5. Copy of **IRB approval letter**.
6. **Grady Research Application form**. A statement of the coordination process with the Grady services involved in the research proposed, (e.g., nursing, lab, radiology, pharmacy, social work, etc.

   * Please note: A full-time Investigational Drug service is **NOT** available at Grady. Pharmacy services request for research conducted at the Grady sight are limited, due to manpower constraints. For studies that require the storing, dispensing and distributing, etc. of drugs, you must contact Philip Powers, PharmD, the Investigational Drug Coordinator at 404-616-9701.Pharmacy services are not guaranteed for any project.
7. The ROC application must be signed by the Principal Investigator and by the investigator's Chief of Service at Grady indicating their awareness of the study.

D. Mail protocols to Cassandra Crane, Grady Health System, Box #26290 or deliver to her at Main Grady, 6Th Floor, Room 6C-617 (located in the Health Outcomes Center).

II. RESPONSIBILITIES

A. All research must have prior IRB approval from an affiliated institution before submitting to the ROC.

B. The ROC is the ONLY research governing body at Grady from which a researcher can receive formal approval for their studies.

C. All projects must be approved by the ROC before patient enrollment or data collection can begin.

D. Projects will require annual review and/or renewal by the ROC (see section III).

E. Responsibility of the Researcher

1. A member of the researcher team submitting a proposal to the ROC must be a member of the Grady clinical staff and have appropriate patient care privileges.
2. The researcher must comply with all the requirements of the IRB of the affiliated institution.
3. The researcher must provide the required information to the Grady ROC listed in section I above.
4. The researcher must discuss the project and coordinate with the appropriate Grady services.

5. The researcher must ensure that Grady is adequately reimbursed for direct expenses related to the research.
6. The researcher must ensure that the patient's rights and confidentiality are respected.
7. The researcher must not begin patient enrollment or data collection until there is appropriate IRB and ROC approval of a project.
8. The researcher should notify the ROC if an approved project is has been terminated or has discontinued.
9. To the extent possible, all abstracts, papers, presentations, etc. will acknowledge that Grady was a site where the research was performed.
10. The researcher should submit a copy of all publications, abstracts, and presentations resulting from the study at such time they become available, to the Chief of the Medical Staff's office by interoffice mail to Box 26298.

F. Responsibilities of the ROC

1. The ROC Coordinator will try to make sure all documents required are included in the submission packet prior to submitting to the ROC.
2. After receiving the complete packet, the ROC committee will review it at their next monthly meeting, which is usually the 1st Monday of every month (except holidays, in which case meetings are rescheduled at a later date the same month).
3. If the Committee has questions or concerns, the researcher will receive written notification requesting additional information and/or clarification. If the PI does not respond or fails to make the requested changes in a timely manner, the project will remain in a *PENDING status* and research may **not** begin until it has been *APPROVED.*
4. Since the informed consent form used is the one approved by the Affiliated Institution's IRB, the ROC will only suggest changes to the consent form when absolutely necessary.
5. The ROC tracks all studies currently conducted on the Grady Campus.

III. PROJECT CONTINUATION:

This portion of the policy applies to research projects that will continue beyond one year from the date of the current ROC approval.

1. If the project is ongoing, the researcher must notify the ROC annually in order to continue the research at Grady.
2. Prior to the ROC expiration date noted on the approval letter, the researcher must submit a request to renew the study by completing the ROC application and submitting all required documents requested for renewal (see ROC application for more information).

IV. IV. PROJECT MODIFICATION:

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1. If there are any modifications to the research study, they must be approved by the Affiliated Institution's IRB before submitting them to the ROC.
2. After receiving IRB approval, the researcher must submit a modification request for the study by completing the ROC application and submitting all documents that have been modified (see ROC application for more information).