



**Research Oversight Committee (ROC)**

Grady Health System (GHS)  
80 Jesse Hill Jr. Drive SE, P.O. Box 26290  
Atlanta, GA 30303  
(Located on 6C- Center for Clinical Performance Improvement)

Office 404-616-7757  
Fax 404-616-0747  
Email: [research@gmh.edu](mailto:research@gmh.edu)

**Guidelines:** (see page 3)

**A. Submission Category:** (Please check all that apply).

- New Protocol: (Study never approved by ROC. Include all documents listed in Section B., as appropriate)
  
- Renewal: (Study has previously been approved by ROC. Include the IRB Renewal Approval letter, the new IRB “Stamped-Approved” Informed Consent and HIPAA Authorization, Lay Summary, IRB Submission Form and any documents that have changed and have been IRB Approved).
  - Please check here if the research protocol is closed to enrollment, all patient visits are complete, including patient follow-up visits, and the IRB and ROC expiration dates will occur during this time. By checking this box, you are indicating that the approved research protocol is in “**Data Analysis**” phase and no study-related patient care or visits are occurring.
  
  - Please check here if the research protocol is a chart review, survey or questionnaire.
  
- Modification: (Include the Approved IRB “Request for Modification” form, all the documents that have been revised and “Stamped-Approved” by the IRB and a Lay Summary.)  
Check all that apply:  
 Informed Consent     Protocol     Personnel     Other \_\_\_\_\_

**B. Documents Required:** (Check all documents that are included with this application for submission)

- ROC Application form (signed by the appropriate Grady Chief of Service)
- Financial Clearance Letter (see section I of this application)
- IRB Approval Letter *or* IRB Modification Approval Form
- IRB Submission Form / Application (New, Renewal or Modification)
- IRB Approved Informed Consent
- IRB Approved HIPAA Authorization
- IRB Approved Research Protocol
- Lay Summary
- Data Collection Forms (surveys, questionnaires, telephone scripts, data collection)
- Advertisements (flyers, brochures, handouts, etc.)

**C. Study Information:**

IRB # \_\_\_\_\_ IRB Expiration Date: \_\_\_\_\_

Obtained IRB Approval From:  Emory     Morehouse     Other: \_\_\_\_\_

Short Title of Study: \_\_\_\_\_  
\_\_\_\_\_

**D. Principal Investigator:** (Person noted as Principal Investigator in the IRB approval notice.)

PI's Name (Degree): \_\_\_\_\_  Emory     Morehouse     Other: \_\_\_\_\_

Department & Division \_\_\_\_\_

Grady Based Investigator Overseeing Study: \_\_\_\_\_

E. **Contact Information:** (Person to be notified for any questions, concerns, and approval status).

Contact Person: \_\_\_\_\_ Phone: \_\_\_\_\_

Email: \_\_\_\_\_ Pager #/Cell # \_\_\_\_\_ Fax: \_\_\_\_\_

## **ROC APPLICATION**

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F. **Locations of Patient Interaction/Enrollment:** (i.e. Medical Clinic I, OBGYN, IDP, Pharmacy, etc.)

\_\_\_\_\_

G. **Funding:**

Funded  Yes  No  Pending Sponsor (if applicable) \_\_\_\_\_

H. **Services:**

Will services at GHS be utilized which are not considered part of routine medical care?  No  Yes

Check appropriate boxes below.

Cath Lab

Medical Records

Non-Invasive Cardiology

CT Scan

MRI

Nursing/Patient Care Services

General Radiology

Pharmacy

Nuclear Medicine

Laboratory

Ultrasound

Other special Services or Equipment: (please specify) \_\_\_\_\_

I. **Financial Clearance Letter:**

All studies conducted within the Grady Health System must receive financial clearance by the Office of Grant Administration within the Finance Department. "Financial Clearance" includes costs of the research procedures required, as well as ancillary (Lab, Pharmacy, Radiology) fees, personnel costs, startup fees, overhead, etc. Contact David Noble at **404.616.1828** or **grants@gmh.edu** to initiate the Pre-Award application process. This mechanism also applies to studies with non-billable services, such as those involving patient registries and retrospective data review.

J. **Requirements for Consent Form:**

a. **GHS Disclaimer:** This statement must be included in the Compensation Section of the consent form and should read as follows.

"We will give you emergency care if you are injured by this research. However, **Grady Health System** (you may also include any other institutions that are participating in the study) has not set aside funds to pay for this care or to compensate you if a mishap occurs. If you believe you have been injured by this research, you should contact Dr. \_\_\_\_\_ (Phone \_\_\_\_\_)".

b. **Patient Rights:** This statement must be included in the Contact Persons Section of the consent and should read as follows:

"If you are a patient receiving care from the Grady Health System, and you have a question about your rights, you may contact Dr. Curtis Lewis, Senior Vice President for Medical Affairs at (404) 616-4261".

K. **Data Collection Form:**

a. Will a data collection form be used in this study? Yes  No

b. If so, will this form remain permanently in the patient's GMH medical record? Yes  No

\*\*\*\* If you selected "Yes" to this question, the Grady Forms Committee must approve this form. For more information, please contact Director of Health Information Management at 404-616-4277.

L. **EPIC Access**

- a. Will EPIC access be needed for this study? Yes  No
- b. If “Yes”, please print names of study team members legibly in the spaces provided. **Please provide evidence of CITI training and ensure study personnel are indicated on IRB Approval letter or associated IRB application.**

1. \_\_\_\_\_ 2. \_\_\_\_\_  
 3. \_\_\_\_\_ 4. \_\_\_\_\_

M. **Signatures:** The following signatures are required before submitting this packet to the ROC. See Page 3 for the listing of Grady Chief of Services.

<b>Signature of Principal Investigator</b>	<b>Print Name</b>	<b>Date</b>
<b>Signature of Grady Chief of Service</b>	<b>Print Name</b>	<b>Date</b>

**General Guidelines:**

- **Research at GHS:** A complete research study must be submitted to the ROC and receive ROC approval before you can begin research, (i.e. patient enrollment or data collection, etc.) in the Grady Health System.
- **Application: Complete pages 1 and 2 of the ROC Application Form** and include only one (1) copy of the documents required. The ROC Application must be completed with each (New, Renewal or Modification) submission.
- **IRB Approval:** You must obtain IRB approval for your study **before** submitting it to the ROC for approval.
- **Submission Deadline:** All submissions must be submitted by the **last Monday** of every month in order to be processed for the next committee review, which takes place on the **first Monday** of every month. Deliver, Mail, or email submission documents to the ROC at the address listed on Page 1 of this application.
- **Notification of Approval:** You will be notified by email, regarding the status of your study usually within **5-7 business days** after the ROC meeting.
- **Notification of Payor Code:** Based on the Financial Clearance Letter, you may also receive a Payor Code assigned to this study. This code will be located on your ROC Approval letter and is a way to identify / search for studies located in our electronic health record.

**The Designated Grady Chiefs Of Service Permitted To Sign This Application:**

Department	Chief of Service	Contact #
Anesthesiology	Raphael Gershon, M.D. (Chief)	404-616-8760
Cardiology	Allen Dollar, M.D. (Chief)	404-616-0539
Dental Services	David Reznik, DDS (Chief)	404-616-0414
Dermatology	Sareeta Parker, M.D. (Chief)	404-616-7023
Emergency Medicine	Leon Haley, Jr., M.D. (Chief)	404-616-6419
Extended Care (Crestview)	Harry Strothers, III, M.D. (Chief)	404-616-9765
Family Medicine (MSM)	Valens Plummer, M.D., Ph.D. (Chief)	404-756-1284
Family, Community & Prev. Medicine	Hogai Nassery, M.D. (Chief)	404-616-3570
Gynecology & Obstetrics (EUH)	Michael Lindsay, M.D (Chief)	404-616-5416
Gynecology & Obstetrics (MSM)	Franklyn Geary, Jr., M.D. (Chief)	404-251-8801
Laboratory Medicine	Andrew Young, MD (Chief)	404-616-4800
Medicine (EUH)	Jeffrey Lennox, M.D. (Chief)	404-251-8784
Medicine (MSM)	James Reed, M.D. (Chief)	404-756-1358
Neonatology	George Bugg, MD (Chief)	404-778-1463
Neurology	Michael Frankel, M.D. (Chief)	404-616-4013
Neurosurgery	Sanjay Dhall, M.D. (Chief)	404-778-1398
Ophthalmology	Geoffrey Brocker, M.D. (Chief)	404-616-4675
Orthopedics	George Wright, M.D. (Chief)	404-778-1550
Otolaryngology	Charles Moore, M.D. (Chief)	404-616-8261
Pathology	George Birdsong, M.D. (Chief)	404-616-4126
Pediatrics (EUH)	Robert Geller, M.D. (Chief)	404-616-4403
Pediatrics (MSM)	Frances Dunston, M.D., MPH (Chief)	404-756-1330

Psychiatry	William McDonald, M.D. (Chief)	404-616-4807
Radiation Oncology	Jerome Landry, M.D. (Chief)	404-778-6350
Radiology	Jack Fountain, M.D. (Chief)	404-616-9874
Rehabilitation Medicine	Vaddadi Rao, M.D. (Chief)	404-616-4081
Surgery (EUH)	David Feliciano, M.D. (Chief)	404-616-5456
Surgery (MSM)	Harvey Bumpers (Chief)	404-616-3562
Urology	Jeff Carney, M.D. (Chief)	404-778-4954
Hematology/Oncology	Ruth O'Regan, M.D.	404-778-1306
IDP (Infectious Disease Program) at IDC	Wendy Armstrong, M.D.	404-616-2493