

**Research Oversight Committee (ROC)**

Grady Health System (GHS)

80 Jesse Hill Jr. Drive SE, P.O. Box 26290

Atlanta, GA 30303

Office# 3H005

Office: 404-616-7757

Office: 404-616-7349

Email: [research@gmh.edu](mailto:research@gmh.edu)

**Guidelines:** Please type or write legibly (*see page 4 for additional instructions*)

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

New Protocol: A study not previously reviewed by the ROC. **Please include all documents listed in Documents, if applicable.**

Renewal: A study that has been previously approved by the ROC. **Please include the IRB Renewal Approval letter, the current IRB approved Informed Consent with date stamp, HIPAA Authorization, Lay Summary, IRB Submission Form, the currently approved Financial Clearance form, updates to equipment inspection dates and any other IRB approved documents that have been renewed.**

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: A study that has been previously approved by the ROC and contains amendments. **Please include the IRB “Request for Modification” form, IRB Approval letter for Modification, Lay Summary, any other documents that have been modified, approved and date stamped by the IRB and updates to Financial Clearance form (if applicable).**

**Check all that apply:**

Informed Consent    Protocol    Personnel    Other \_\_\_\_\_

Reportable Event: **For all reportable events that are reported to the sponsor and institutional IRB (Unanticipated Problems Involving Risk to Participants or Others, Non-Compliance, Safety Reports, or Protocol Deviations), please include identical information given to sponsor and institutional IRB and their acknowledgement/approval.**

# ROC APPLICATION

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

- ROC Application form (signed by the appropriate Grady Chief of Service)
- Financial Clearance Form (see Section H 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)
  
- Please note that all research studies involving Oncology patients must be presented and approved by the Clinical Research Committee in the Cancer Center prior to being submitted to Grady's Research Oversight Committee. Please submit the study to Merri Sudduth at [Merri.Sudduth@emoryhealthcare.org](mailto:Merri.Sudduth@emoryhealthcare.org) who will assure the documents are reviewed and approved. The Oncology Clinical Research Committee Approval Letter should be submitted with a completed ROC application.
  
- Please note that all research studies taking place in the Operating Room, Recovery Room or Ambulatory Surgery Unit must have supplies, devices and or equipment must be reviewed by the Value Analysis Committee prior to submitting to Grady's Research Oversight Committee. Please submit to [valueanalysis@gmh.edu](mailto:valueanalysis@gmh.edu) and copy [grants@gmh.edu](mailto:grants@gmh.edu). Supporting documentation should be provided along with the completed ROC Application.
  
- Please note that all research studies involving Nursing services and/or any form of participation by Nursing staff must be presented and approved by the Nursing Research Committee prior to submitting to Grady's Research Oversight Committee. For information contact Rosiland Harris at [rharris1@gmh.edu](mailto:rharris1@gmh.edu). Please submit the study to [nursing\\_research@gmh.edu](mailto:nursing_research@gmh.edu). Nursing Research Committee Approval Document should be submitted with a completed ROC application.
  
- Please note that all research studies involving Pharmacy services and/or any form of participation by Pharmacy staff must be submitted to the Investigational Drug Pharmacist and approved by the Executive Director of Pharmacy or his/her designee. Contact information for the Executive Director of Pharmacy is located on page 5.

B. **Study Information:** IRB #: \_\_\_\_\_ IRB Expiration Date: \_\_\_\_\_

Institutional IRB:  Grady  Morehouse  Emory  Other: \_\_\_\_\_

Title of Study: 

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C. **Principal Investigator:** (Person noted as "Principal Investigator" on the IRB Approval Letter.)

PI's Name: \_\_\_\_\_

PI's Institution:  Emory  Morehouse  Other: \_\_\_\_\_

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

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

Grady Based Investigator Phone #: \_\_\_\_\_

Grady Based Investigator Email: \_\_\_\_\_

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

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

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

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

F. **Funding:**

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

G. **Services:**

Will services at GHS be utilized which **are not** considered part of routine medical care?  No  Yes  
**Check appropriate boxes below.**

- |  |  |  |
|--|--|--|
| <input type="checkbox"/> Cath Lab  | <input type="checkbox"/> Medical Records | <input type="checkbox"/> Non-Invasive Cardiology       |
| <input type="checkbox"/> CT Scan   | <input type="checkbox"/> MRI             | <input type="checkbox"/> Nursing/Patient Care Services |
| <input type="checkbox"/> General Radiology   | <input type="checkbox"/> Pharmacy        | <input type="checkbox"/> Nuclear Medicine              |
| <input type="checkbox"/> Laboratory  | <input type="checkbox"/> Ultrasound      | <input type="checkbox"/> Data/Report Requests          |
| <input type="checkbox"/> Other special Services or Equipment: (please specify) _____ |  |  |

**\* Non-Grady Research Equipment must be inspected and tagged by Grady’s Clinical Engineering Department. Please complete the OGA Research Equipment Clearance Form and contact the Clinical Engineering Department at 404-616-3941 with any questions. Please be prepared to provide the study protocol and equipment information including the maintenance and schedule for inspection.**

H. **Financial Clearance Form (Version 01/2016):**

**ALL studies conducted within the Grady Health System MUST receive financial clearance from the Office of Grants Administration (OGA) within the Grady Finance Department.** Financial Clearance includes costs of research procedures required, as well as ancillary (Lab, Pharmacy, Radiology, Etc.) fees, personnel costs, startup fees, overhead, etc. **This mechanism also applies to studies with non-billable services, such as those involving patient registries and retrospective data review.**

OGA Forms can be obtained at <http://www.gradyhealth.org/static/office-of-grants-administration>.

For additional assistance contact Yvette Benjamin at 404-616-4731 or grants@gmh.edu.

**Submit completed Financial Clearance forms to [grants@gmh.edu](mailto:grants@gmh.edu) for approval.**

I. **Requirements for Consent Form:**

a. **GHS Disclaimer:** This statement must be included on the Informed 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. **\*\*NEW\*\* Patient Rights:** This statement must be included on the Informed Consent Form and should read as follows:

“If you are patient receiving care from the Grady Health System and you have a question about your rights, you may contact the Office of Research Administration at research@gmh.edu.”

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J. **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.**

K. **EPIC Access** (This includes study team members with previous 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 the IRB Approval letter or associated IRB Submission form.**
1. \_\_\_\_\_ 2. \_\_\_\_\_
3. \_\_\_\_\_ 4. \_\_\_\_\_

L. **Signatures:** The signatures below are required before submitting to the ROC. See Page 5 for a listing of Grady Chief of Services and Executives Directors. By signing the Research Oversight Committee Application as the Principal Investigator, you are accepting responsibility for all communication and logistical concerns with Medical, Nursing and Administrative staff associated with the above referenced research study.

_____ Signature of Principal Investigator	_____ Printed Name	_____ Date
_____ Signature of Grady Chief of Service	_____ Printed Name	_____ Date

**General Guidelines & Instructions:**

- When requesting ROC Approval, please type all requested information and submit along with applicable documents to [research@gmh.edu](mailto:research@gmh.edu) .
- **Research at GHS:** A research study must be submitted to the ROC and receive ROC approval prior to starting any research procedures in the Grady Health System.
- **Application:** **Complete pages 1-4 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:** The research study must have IRB approval **prior** to submitting for ROC approval.
- **Submission Deadline:** All submissions are due **Monday** week prior to the ROC meeting, which takes place on the **second Tuesday** 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 **7 business days** after the ROC meeting.
- **Notification of Payor Code:** Based on the Financial Clearance Letter, the research study may be assigned a Payor Code. This code will be located on the ROC Approval letter. A research study may be identified in Grady's Electronic Health Record (EPIC) using the Payor Code.
- **Current ORA forms are available at** <http://www.gradyhealth.org/static/office-of-research-administration>.

# ROC APPLICATION

The Designated Grady Chiefs of Service Permitted To Sign This Application:

Revised 02/2016

Department	Chief of Service	Contact #
Anesthesiology	Raphael Gershon, M.D.	404-616-8760
Cardiology	Allen Dollar, M.D.	404-616-0539
Cardio-Thoracic	Brent Keeling, M.D.	404-616-0539
Community Health	Hogai Nassery, M.D.	404-251-8861
Dental Services	David Reznik, DDS	404-616-0414
Dermatology	Laura Delong, MD	404-778-5225
Emergency Medicine	Hany Atallah M.D.	404-616-6419
Extended Care (Crestview)	Harry Strothers, III, M.D.	404-616-8110
Family Medicine	Denise Bell-Carter	404-756-1248
Family Medicine (MSM)	Valens Plummer, M.D., Ph.D.	404-756-1284
Gynecology & Obstetrics (Emory)	Michael Lindsay, M.D	404-251-8801
Gynecology & Obstetrics (MSM)	Franklyn Geary, Jr., M.D.	404-616-1692
Hematology/Oncology	Sidney Stein, M.D.	404-778-1493
IDP (Infectious Disease Program)	Wendy Armstrong, M.D.	404-616-2493
Laboratory Medicine	George Birdsong, M.D. (Interim)	404-616-5481
Medicine (Emory)	Jeffrey Lennox, M.D.	404-251-8784
Medicine (MSM)	James Reed, M.D.	404-756-1358
Neonatology	George Bugg, MD	404-778-1463
Neurology	Michael Frankel, M.D.	404-616-4013
Neurosurgery	Gustavo Pradilla, M.D.	404-778-1398
Nursing Services	Dr. Rhonda Scott (SVP, CNO)	404-616-3141
Ophthalmology	Yousuf M. Khalifa, MD.	404-616-4675
Oral Maxillofacial Surgery	Gary Bouloux, M.D.	404-778-4555
Orthopedics	William Reisman, M.D.	404-778-1558
Otolaryngology	Charles Moore, M.D.	404-616-8261
Pathology	George Birdsong, M.D.	404-616-4126
Pediatrics (Emory)	Robert Geller, M.D.	404-616-4403
Pediatrics (MSM)	Yasmin Tyler-Hill, M.D.	404-756-1332
Pharmacy Services	Rondell Jagers (Executive Director)	404-616-4320
Plastic Surgery	Robert Fang, M.D.	404-251-8914
Psychiatry	Grayson Norquist, M.D.	404-616-4755
Radiation Oncology	Jerome Landry, M.D.	404-616-6350
Radiology	Jack Fountain, M.D.	404-616-9874
Rehabilitation Medicine	Lisa Ann Wurmser, M.D.	404-616-4080
Surgery (Emory)	Sheryl Gabram, M.D.	404-251-8914
Surgery (MSM)	Ed W. Childs, MD	404-616-3562
Urology	Jeff Carney, M.D.	404-616-7370