Clinical Trials & Research
At Grady

September 16, 2015

Presented By:
Offices of Research and Grants Administration
Research & Grants Administrative Offices

Research Administration
(Medical Affairs)

The Office of Research Administration (ORA) provides oversight and support for the initiation and execution of research within Grady Health System.

Grants Administration
(Finance)

The Office of Grants Administration (OGA) partners research personnel and staff in the administration of sponsored funds for clinical research and trials.
Learning Objectives

By the end of the session, you will:

- Receive an overview of What’s New in Grady’s Offices of Research & Grants Administration.
- Understand the key steps, processes & responsibilities involved in conducting Clinical Trials and Research at Grady
- Be familiar with the departments that support research at Grady
- Know your Key Contacts at Grady
This Is A Partnership

- Research Oversight (ROC / ORA)
- Research Finance (OGA)
- Investigators & Clinical Pharmacy
- Investigation Drug & Clinical Pharmacy
- Data Management (IS & HIM)
- Specialty & Ancillary Services (e.g. Laboratory, Cardiology)
- Equipment & Device Oversight (GCE & VAC)
- Scheduling & Registration
- Medical Team Support (MD, RN, Techs etc)

PATIENTS
What’s New...

❖ Office of Research & Grants Administration Web pages
  http://www.gradyhealth.org/static/office-of-research-administration
  http://www.gradyhealth.org/static/office-of-grants-administration

ROC Forms
- ROC Application
- ORA Personnel
- EPIC Research Request Form
- Medical Records Request Form

Financial Clearance Process & Forms
- FAQs Conducting Clinical Trials and Research at Grady
- OGA Research Financial Clearance
- OGA Research Patient Pre-Registration
- Visit Management - Patient Information Tip Sheet

❖ ROC Meeting Date & Submission Deadline
  2nd Tuesday of each month
  Submission is required the Monday (week prior) to the ROC meeting

❖ Financial Clearance Renewal / Pharmacy & Research Study Close Out
  Submission Requirements
Process Overview

- IRB Approval
- Departmental / Committee Approvals
- Clinical Pharmacy Estimate
- Financial Clearance
- Research Oversight Committee
- Project Start-Up
- Administrative Responsibilities for Project Continuation
- Financial Responsibilities for Project Continuation
- Maintaining Patient Information & Managing Visits
- Audits and Close-Out
Research Administration

PI / CRC Obtain IRB, OCR & OSP Approvals

PI / CRC submit the ROC Application to ORA for ROC Review

ORA Project Initiation
• Notice of ROC Approval to PI/CRC listed on ROC application
• Establish Epic usernames and passwords for access, if required
• Enter / maintain study profile in Epic (Billable/SOC)
• Research Data Requests, if required

* Concurrent submission to research@gmh.edu and grants@gmh.edu is encouraged *
Research Administration

PI/CRC Continuation Responsibilities
- Submission to ROC annually to obtain approval for study continuation
- Submission to ROC for approval of study amendments / modifications, *which includes study team members being added and removed

Audits and Close-Out
- PI/CRC Notifies GHS OGA, ORA and appropriate department of Audit
- PI/CRC notifies GHS ORA and OGA of Study Close-Out

* ALL ROC submissions include a current Financial Clearance approval *
As soon as you know that Grady will be a participating site, contact GHS Office of Grants Administration (grants@gmh.edu) to discuss and obtain financial costs analysis and initiate any contractual requirements.
Grants (Financial) Administration

**PI/CRC Responsibilities**
- Annual Submission of Financial Clearance *(All Studies)*
- Submission of Financial Clearance amendments/ modifications
- **Patient Enrollment in Epic***
- **Manage Patient Visits & Notification of charges*** *
- Remit Invoices for payment *

**OGA Responsibilities**
- Review & Approve Financial Clearance amendments/ modifications
- Process Patient charges
- Invoicing and Accounting - distribution of monthly statements to PI/CRC for review and payment

**Financial Clearance Close Out**
- **PI/CRC** - Submit final Patient Tracker Forms to initiate final invoicing
- **PI/CRC** – Update Patients’ research accounts in Epic
- **OGA** - Distribution of final invoices / account reconciliation

* If there are services / billable items related to the research as identified in the financial clearance process *
The Research Oversight Committee In Action!!
Partners in the ORA & OGA Processes
<table>
<thead>
<tr>
<th>Description:</th>
<th>Oncology Research</th>
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<tbody>
<tr>
<td>Submission Process/ Form(s):</td>
<td>GCRC approval required prior to submission to Grady’s Research Oversight Committee</td>
</tr>
<tr>
<td>Contact:</td>
<td>Merri Sudduth at <a href="mailto:Merri.Sudduth@emoryhealthcare.org">Merri.Sudduth@emoryhealthcare.org</a> GCRC in the Cancer Center</td>
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# Nursing Research Counsel Review

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<tr>
<th>Description</th>
<th>Nursing Research Counsel Review</th>
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<tbody>
<tr>
<td>Submission Process/ Form(s):</td>
<td>Approval required prior to submission to Grady’s Research Oversight Committee</td>
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</table>
| Contact:          | For information - Rosiland Harris at rharris1@gmh.edu  
For submission - nursing_research@gmh.edu |
## Epic Access

<table>
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<tr>
<th>Description:</th>
<th>Access to Epic for Research</th>
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<tbody>
<tr>
<td>Submission Process/ Form(s):</td>
<td><a href="#">Epic Research Request Form</a></td>
</tr>
<tr>
<td>Contact:</td>
<td>Grady Information Security at <a href="mailto:infosec@gmh.edu">infosec@gmh.edu</a></td>
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# Grady Badging

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<tr>
<th>Description:</th>
<th>Grady Badging (Specific for research)</th>
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<tbody>
<tr>
<td>Submission Process/ Form(s):</td>
<td><a href="mailto:ora@grady.edu">ORA Personnel Confirmation Form</a></td>
</tr>
<tr>
<td>Contact:</td>
<td>ORA at <a href="mailto:research@gmh.edu">research@gmh.edu</a></td>
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# Data Requests / Extraction

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<tr>
<th>Description:</th>
<th>Research Data Request/Extraction</th>
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</table>
| Submission Process/ Form(s): | **Research Data Request Form**  
EPIC Reporting Tip Sheet  
Data Elements Tip Sheet  
Fees are associated |

| Contact: | ORA at research@gmh.edu |
## Obtaining Medical Records

<table>
<thead>
<tr>
<th>Description:</th>
<th>Medical Records (Paper Charts)</th>
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<tbody>
<tr>
<td>Submission Process/ Form(s):</td>
<td>Medical Records Request Form</td>
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<tr>
<td></td>
<td>Fees are associated</td>
</tr>
<tr>
<td>Contact:</td>
<td>Health Information Management at 404-616-4277, <a href="mailto:HIMResearch@gmh.edu">HIMResearch@gmh.edu</a></td>
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# Investigational Drug / Pharmacy Services

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<tr>
<th>Description:</th>
<th>Investigational Drug &amp; Pharmacy Services</th>
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<tbody>
<tr>
<td>Submission Process/ Form(s):</td>
<td>Study Protocol &amp; PRA or Budget submitted to Clinical Pharmacy for the preparation of Fee Estimate</td>
</tr>
</tbody>
</table>
| Contact: | Rondell Jaggers at 404-616-4320  
| | Philip Powers at powers@gmh.edu  
| | Kay Woodson at kwoodson@gmh.edu |
# Research Devices & Supplies

<table>
<thead>
<tr>
<th>Description:</th>
<th>Use of Research Devices, Supplies, Equipment in the OR, Recovery &amp; Ambulatory Surgery</th>
</tr>
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</table>
| Submission Process/ Form(s): | [OGA Research Device Form](#)  
Initiated through OGA-Financial Clearance process |
| Contact: | Value Analysis Committee at [valueanalysis@gmh.edu](mailto:valueanalysis@gmh.edu) |
# Non-Grady Research Equipment

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<tr>
<th>Description:</th>
<th>Use / Storage of Non-Grady Research Equipment or Supplies on Grady Campus</th>
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<tbody>
<tr>
<td>Submission Process/ Form(s):</td>
<td><a href="#">Research Equipment Request Form</a> Initiated through OGA-Financial Clearance process</td>
</tr>
<tr>
<td>Contact:</td>
<td>Grady Clinical Engineering /BioMed Department Contact Cheneda Nelson at <a href="mailto:cnelson@GMH.edu">cnelson@GMH.edu</a> or 404-616-3941</td>
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# Research Pathology Services

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<tr>
<th>Description:</th>
<th>Pathology slides</th>
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| Submission Process/ Form(s): | **OGA Research Pathology Request Form**  
Submit to Cytopathology lab |
| Contact: | Karla Hathorn at [khathorn@gmh.edu](mailto:khathorn@gmh.edu) |
In Summary

You now have an overview of the processes that Grady has implemented to ensure that all research-related procedures are conducted in compliance with the appropriate policies and regulations. We have reviewed:

- **What’s New** in Grady’s Offices of Research & Grants Administration
- The **Key Steps, Processes & Responsibilities** involved in conducting Clinical Trials and Research at Grady
- The **Departments that Support Research** at Grady
- **Key Contacts** at Grady
Q & A

Research Administration
Central Email: research@gmh.edu
Web: http://www.gradyhealth.org/static/office-of-research-administration

Grants Administration
Central Email: grants@gmh.edu
Web: http://www.gradyhealth.org/static/office-of-grants-administration