

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)

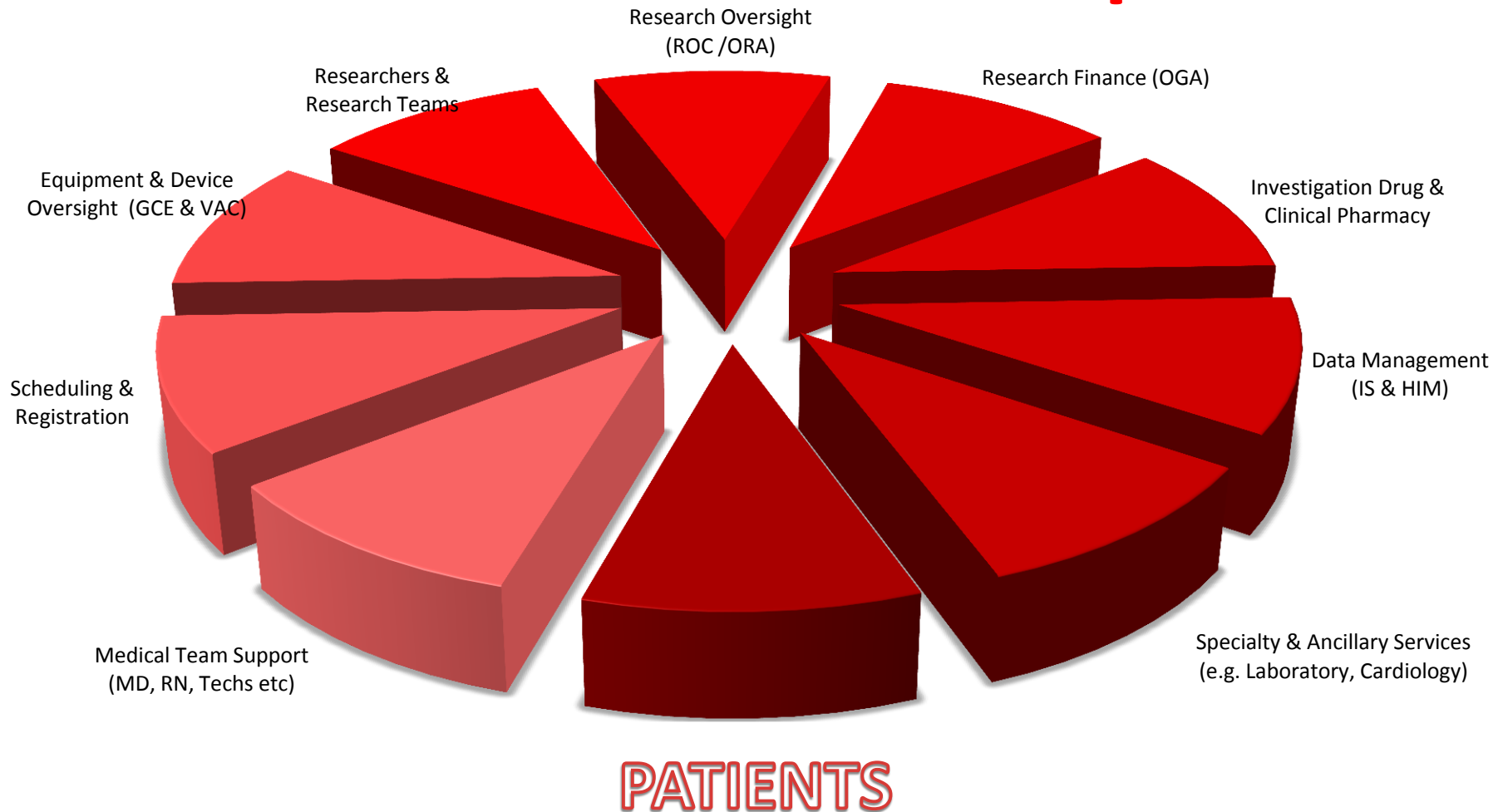
The Office of Grants Administration (OGA) partners research personnel and staff in the administration of sponsored funds for clinical research and trials.

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



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

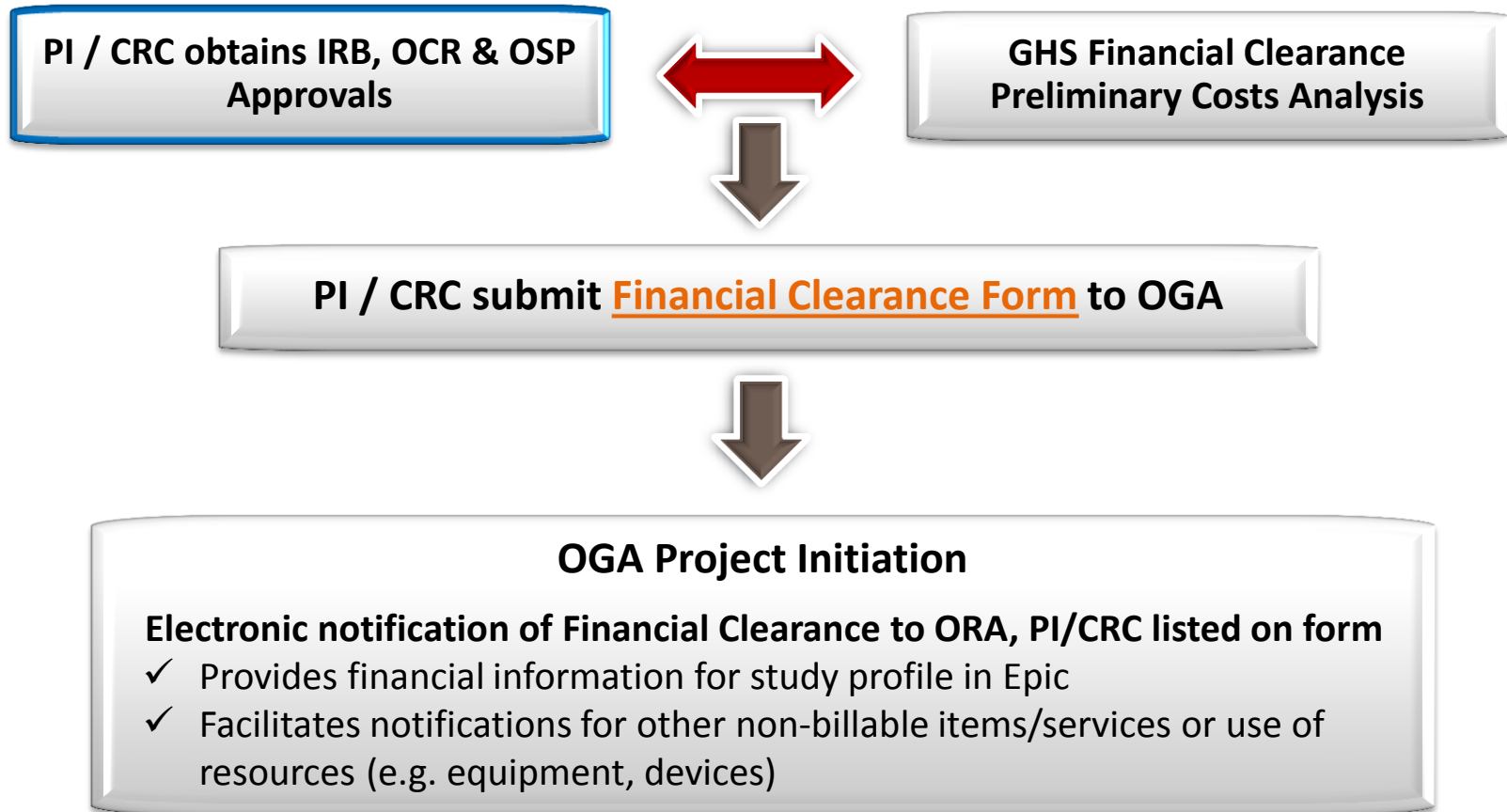


Audits and Close-Out

- **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 ***

Grants (Financial) Administration



TIP: 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



GCRC

Oncology Research Review Board

Description:	Oncology Research
Submission Process/ Form(s):	GCRC approval required prior to submission to Grady's Research Oversight Committee
Contact:	Merri Sudduth at Merri.Sudduth@emoryhealthcare.org GCRC in the Cancer Center

Nursing Research Counsel Review

Description:	Nursing Research Counsel Review
Submission Process/ Form(s):	Approval required prior to submission to Grady's Research Oversight Committee
Contact:	For information - Rosiland Harris at rharris1@gmh.edu For submission - nursing_research@gmh.edu

Epic Access

Description:	Access to Epic for Research
Submission Process/ Form(s):	<u>Epic Research Request Form</u>
Contact:	Grady Information Security at infosec@gmh.edu

Grady Badging

Description:	Grady Badging (Specific for research)
Submission Process/ Form(s):	<u>ORA Personnel Confirmation Form</u>
Contact:	ORA at research@gmh.edu

Data Requests / Extraction

Description:	Research Data Request/Extraction
Submission Process/ Form(s):	<u>Research Data Request Form</u> EPIC Reporting Tip Sheet Data Elements Tip Sheet Fees are associated
Contact:	ORA at research@gmh.edu

Obtaining Medical Records

Description:	Medical Records (Paper Charts)
Submission Process/ Form(s):	<u>Medical Records Request Form</u> Fees are associated
Contact:	Health Information Management at 404-616-4277, HIMResearch@gmh.edu

Investigational Drug / Pharmacy Services

Description:	Investigational Drug & Pharmacy Services
Submission Process/ Form(s):	Study Protocol & PRA or Budget submitted to Clinical Pharmacy for the preparation of Fee Estimate
Contact:	Rondell Jagers at 404-616-4320 Philip Powers at powers@gmh.edu Kay Woodson at kwoodson@gmh.edu

Research Devices & Supplies

Description:	Use of Research Devices, Supplies, Equipment in the OR, Recovery & Ambulatory Surgery
Submission Process/ Form(s):	<u>OGA Research Device Form</u> Initiated through OGA-Financial Clearance process
Contact:	Value Analysis Committee at valueanalysis@gmh.edu

Non-Grady Research Equipment

Description:	Use / Storage of Non-Grady Research Equipment or Supplies on Grady Campus
Submission Process/ Form(s):	<u>Research Equipment Request Form</u> Initiated through OGA-Financial Clearance process
Contact:	Grady Clinical Engineering /BioMed Department Contact Cheneda Nelson at cnelson@GMH.edu or 404-616-3941

Research Pathology Services

Description:	Pathology slides
Submission Process/ Form(s):	<u>OGA Research Pathology Request Form</u> Submit to Cytopathology lab
Contact:	Karla Hathorn at 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>