

Clinical Trials & Research At Grady

Presented by

The Office of Research Administration

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.

The ORA consists of Administrative and Financial units.

Learning Objectives

By the end of this session you will:

- ❖ Be familiar with the process to obtain Grady Research Oversight Committee (ROC) approval
- ❖ Be familiar with the process to obtain Financial Clearance
- ❖ Have an understanding of how to operationalize your study at Grady
- ❖ Be familiar with the Key Contacts for research support at Grady

Process Overview

- ❖ Affiliate Institution Processing & **IRB Approval**
- ❖ Grady Departmental & Other Committee Approvals
- ❖ Grady Clinical Pharmacy Estimate
- ❖ **Grady Financial Clearance**
- ❖ **Grady Research Oversight Committee (ROC)**
- ❖ Grady Ethics Review
- ❖ Project Start-Up
- ❖ Maintaining Patient Information & Managing Visits
- ❖ Administrative Responsibilities for Project Continuation
- ❖ Financial Responsibilities for Project Continuation
- ❖ Audits and **Close Out**

The Office of Research Administration (ORA)

What We Do -

- ❖ Administration of the ROC Approval Process
 - Research Oversight Committee (ROC) Combined Forms Review/Approval
 - Financial Clearance Application Packet Review/Approval
- ❖ Provide Research Team Study Start-up Support
 - Establish Epic research study profiles for billable accounts
- ❖ Provide Administrative Support for Study Conduct
 - Language & Interpretive Services
 - Laboratory & Pharmacy (i.e. order sets, etc.)
 - Special Processes (i.e. MRNs, patient enrollment, registration, etc.)

ORA What We Do – cont.

❖ Assist with Access for Personnel

- Badging - Onboarding, Employee Health, Personnel Records
- Information Security – Epic Access, Compliance

❖ Assist with Data Access

- Clinical Business Intelligence (CBI) – Data Access/Extraction
- Health Information Management (HIM) – Medical Records

❖ Facilitate Access for Vendors & CRAs

- Vendor Mate Registration –
- Access to Patient Files through HIM
- Release of Information (ROI) Keys

ORA What We Do – cont.

❖ Ethical Considerations

- **IRB Review**
 - focuses on ethical conduct of research with human subjects
- **Ethics stage of ROC review**
 - focuses on ethical considerations of research with Grady's patient population
- **Special Considerations**
 - ✓ Especially vulnerable populations specific to Grady
 - ✓ Ensuring that our patient population bears a proportionate burden of multi-site research

Hospitals in medical study tested epilepsy drugs without telling patients

Two Atlanta hospitals were part of nationwide study drawing criticism from watchdog group



NEWS

By Ariel Hart

June 8, 2021



ORA-Finance What We Do-

- ❖ Administration of the Financial Clearance Process
 - Preliminary Consultation/Feasibility Considerations
 - Financial Clearance Application Packet Review/ Approval
- ❖ Research Team Study Start-up Support
 - Research Teams access to Grady systems specific to participants' visit management
 - Patient Clinical Support Services (i.e. labs, samples, etc.)
 - Investigational Drug Services (i.e. pharmacy, supplies, etc.)
 - Departmental Resource Use Assessment (i.e. equipment, devices, Grady personnel, space etc.)

ORA-Finance What We Do – cont.

❖ Oversight of Study Conduct:

- Maintenance of patient participation in relationship to Epic Research Study Profiles (i.e. enrollment, scheduling, visit management etc.)
- Management of Services Rendered (i.e. receiving Patient Tracker Forms and IDS reporting)
- Billing (i.e. charge management and Research Team verification)
- Account Maintenance (i.e. invoice distribution, receipt of remittance)

Information, Processes & Forms

Office of Research Administration

Central Email: Research@gmh.edu

ORA-Finance Email: Researchfinance@gmh.edu

Web: <http://www.gradyhealth.org/static/office-of-research-administration>

ROC Meeting Date & Submission Deadline

- 2nd Tuesday of each month
- Submission is required the Monday (week prior) to the ROC meeting

Emory Contact

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Q & A

