RESEARCH 101:

THE KEYS TO GETTING APPROVAL & CONDUCTING RESEARCH AT GRADY

MARCH 22, 2018

Presented By:

The Offices of Research & Grant Administration

Grady

Learning Objectives

By the end of the session, you will:

- **Be familiar with**
  - NEW or improved processes in ORA & OGA
  - The Grady Departments that support research
  - Key Grady Research Contacts
- **Understand the key components for**
  - Submission and getting approval of your study or trial
  - Successfully conducting your study or trial at a Grady site

What's New….

Office of Research Administration (ORA)

- Research Oversight Committee (ROC) Application Packet (New)
  - ROC Application Form (Revised)
  - ORA Personnel Confirmation Form
  - Request Form for Epic and/or Remote Access
  - Research Data Request

Office of Grant Administration (OGA)

- OGA Research Financial Clearance Form (FCF) (Revised)
- OGA Research Patient Pre-Registration (Revised) / Radiology Services (New)
- Research Equipment Questionnaire (Revised)
- Using Radiology Services – Tip Sheet (New)

- FAQs Conducting Clinical Trials and Research at Grady (Revised)

The Office of Grant Administration

Mission

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

Services

OGA provides the following services:

1. Review of all research protocols and required documents pertinent to the use of Grady's billable and non-billable resources.
2. Financial reporting and standard invoicing.
3. Serve as liaisons for, but not limited, to Grady's Research Oversight Committee, Clinical Pharmacy; and for Grady Departments and Committees that provide approval for the use of equipment, products, devices in research.

The Office of Research Administration

Mission

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

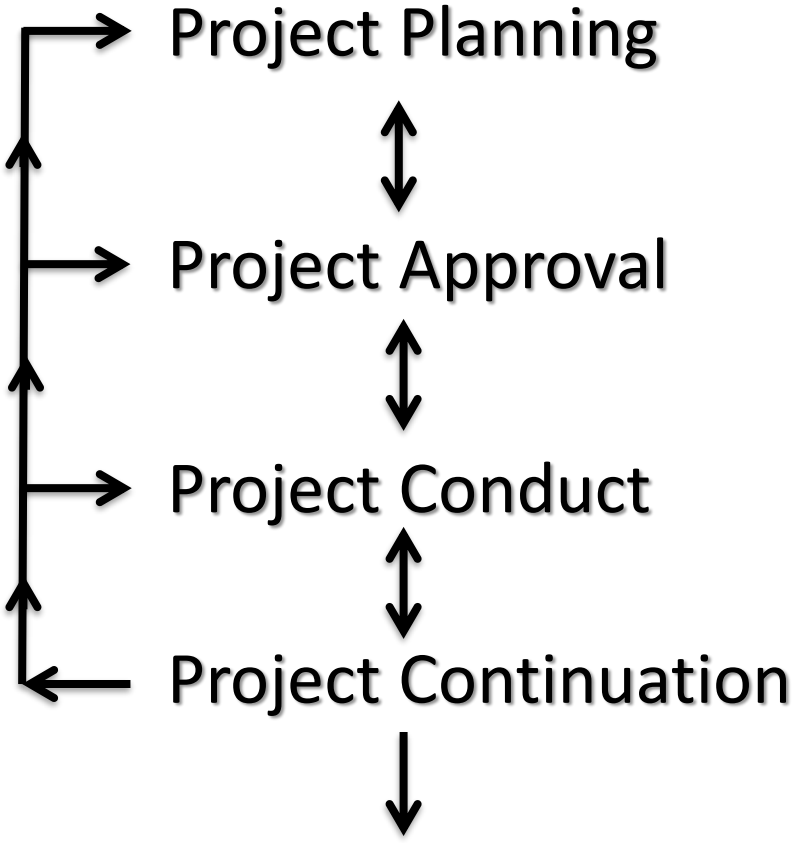
Services

ORA provides the following services:

1. Review of all research protocols and required documents in order to support Grady's Research Oversight Committee in determining risks and benefits to patients.
2. Serve as liaisons for, but not limited, to Grady's Research Oversight Committee, Compliance, Information Security, Information Technology, Legal, and On-Boarding/Training departments.

THE KEY CONSIDERATIONS

FOR CONDUCTING RESEARCH AT GRADY



OGA/ORA Project Planning

- Establish a Time Line
- Determine Project Feasibility
- Preliminary Costs Analysis
- Determine if Other Approvals are Required
- **Obtain Institutional IRB Approval**
- Submit to OGA to obtain Financial Clearance
- Submit to ORA to obtain Research Oversight Committee (ROC) Approval

FINANCIAL CLEARANCE APPROVAL

- **Financial Clearance Approval is administrated by OGA**
- **Financial Clearance Approval:**
  - Is required for **ALL Studies** conducted at Grady independent of study funding or intended patient contact.
  - Must be obtained at Initial Review; for Annual Renewal and Amendments
  - Requires the submission of a Financial Clearance Application Packet (FC Application)
- **The Financial Clearance Form:**
  - Is the KEY component of the FC Application
  - Provides guidance for the need, preparation and submission of other documents in the FC Application
  - Collects pertinent information about the study, including but not limited to study personnel, billable items/procedures/services, and the use of Grady's resources.

Research Oversight Committee (ROC) Approval

- **ROC Approval is administrated by ORA (on behalf of the ROC)**
- **ROC Approval:**
  - Is required for ALL research conducted at Grady sites
  - Requires the submission of a ROC Application Packet (ROC Application)
  - Is not granted without Financial Clearance Approval

- **ROC Application Form**
  - Is the KEY Component of the ROC Application Packet
  - Provides guidance for the need, preparation and submission of other required documents

Note: **ROC Applications must be received by the submission deadline**

OGA – Project Startup

OGA Manages and Supports Research by:

- **Providing Study Start-up guidance for Non-Billable and Billable Studies**
- **Assisting Research Teams in the Identification of:**
  - **Grady participant needs**
  - Grady specific items, procedures and services
  - The use of Grady systems and departmental resources
  - Non-Grady devices, products, supplies & equipment and obtaining approval for use
  - Fiscal & Compliance Responsibilities
  - Opportunities for Fostering Relationships & Communication

OGA – Project Startup

OGA Management and Support Cont.:

- **Providing Guidance for Obtaining IDS Services**
  - Each **study is provided a Pharmacy Estimate to be submitted with the Financial** Clearance request

ORA – Project Startup

ORA Manages and Supports Research by:

- **Providing Research Team Study Start-up Assistance**
- **Facilitating Access for Personnel**
  - Badging
    - Onboarding (ACEMAPP)
    - Employee Health
    - Personnel Records
- **Facilitatin Access to Data**
  - Clinical Business Intelligence (Data Access)
  - Health Information Management (Medical Records)
  - Information Security
    - Epic Access
    - Compliance

ORA – Project Startup

ORA Research Management & Support Cont. :

- **Facilitating Access for Vendors & CRAs**
  - Vendor Mate Supplier Registration https://registersupplier.ghx.com/reg/network/vendor/
  - Access to Patient Files
    - Health Information Management (HIM)
    - Provide MRN, Date of Service, Date of Birth
  - Release of Information (ROI) Keys

OGA- Project Conduct

Visit Management = Caring for Grady Patients

The PI is Responsible For:

- **Adhering to Grady's Approved Processes for:**
  - Identifying Grady patients as research participants in Epic
    - Patient Enrollment
  - Scheduling & managing research visits
  - The identification of research clinical services / procedures
    - The ICD10 diagnosis code Z00.6 must be used for ALL research orders
  - Requesting and using Investigational Drug Services

Applicable Forms

- ✓ Visit Management-Patient Enrollment Tip Sheet **Revised**
- ✓ OGA Research Patient Pre-Registration Form **Revised**
- ✓ OGA Research Patient Pre-Registration Form - Radiology **New**

OGA – Project Conduct & Continuation

The PI is Also Responsible For:

- **Reporting Services Rendered**
  - Services rendered must be reported to OGA within 24 hours of a patient's visit
    - The submission of a Patient Tracker Form facilitates the reporting services rendered and allows for the identification of billable vs. SOC procedures.
- **Financial Account Maintenance**
  - Includes but is not limited to:
    - The review of invoices distributed monthly
    - The submission of invoices timely remittance
    - Reconciliation of accounts prior to study completion

- **Requesting Financial Clearance approval for EVERY ROC amendment submission.**

Note: Please use the prior version of your approved FCF to maintain consistency of the data being provided.

ORA – Project Conduct & Continuation

During the Conduct Of the Study the PI is Responsible For:

- **Notification of Study Amendments**
- **Notification of Audits & Monitoring Activities**
  - ORA/OGA may perform study verifications at any time
- **Submitting a Renewal Application**
  - Prior to the ROC Expiration date
  - IRB Approval is required prior to submission for review

OGA- Project Close Out & Completion

The PI is Responsible For:

- **Verifying that Patients' Participation Status is Updated in Epic**
- **Submitting a Financial Clearance Amendment to Notify OGA the Following Have Concluded:**
  - Patient related billable activities (Pharmacy & Clinical)
  - The use of Grady resources
  - The use of an approved investigational product or device

  ** ***Always*** *provide official IRB support documentation with an amendment*
- **Notifying OGA When the Study Receives Official IRB Closure**
  - The PI must provide the IRB study closure or completion document. The submission of a Financial Clearance form is not required.

NOTE: Allowing the ROC approval to expire is NOT the same as initiating study close out or completion

ORA – Project Close Out & Completion

The PI is Responsible For:

- **Notification of Study Close Out & Completion**
  - Official communication is required for study close out and/or completion
  - The PI must provide the IRB study closure or completion document to Grady's ORA & OGA departments

NOTE: Allowing the ROC approval to expire is **NOT** the same as providing notification of study completion

Departments Involved in Research at Grady

- Medical Affairs
- Badging
- Laboratory
- Radiology / Imaging
- Epic Support Team
- Value Analysis (VBSC Review)
- Information Systems
- Medical Coding
- Patient Financial Services (PFS)
- Human Resources
- Business/Clinical Intelligence
- Compliance
- Medical Records
- Grady ACTSI / CRN
- Legal
- Central Scheduling / Call Center
- Nursing
- Pathology
- Pharmacy
- Clinical Engineering / Biomedical Department

In Summary

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

- **The KEY Components** for getting approval and conducting research at Grady
- **New Processes** in Grady's Offices of Research & Grant Administration
- The **Departments that Support Research** at Grady
- **Key Contacts**

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