RESEARCH FISCAL PROCESSES

The Office of Grant Administration

February 21, 2019

Grady

Learning Objectives

This educational session will review the Financial Clearance process and fiscal responsibilities for a billable research study/clinical trial, including:

- An overview of the function of the Office of Grant Administration
- Guidance on translating your study into the data required on the Financial Clearance Form
- A better understanding of the mechanisms that facilitate the daily activity of a study and subsequent billing
- A brief overview of ethical, legal, and regulatory considerations

The Office of Grant Administration (OGA)

What is the function of OGA?

- Evaluate a study's proposed conduct within the Grady Health System
- Oversee the financial clearance review process and execute approvals from a study's commencement to completion
- Perform feasibility analysis; facilitate the operationalization of a study; and provide support for the daily conduct of each study
- Implement standardized processes to monitor study activity and manage the financial aspects of each study
- Provide guidance on collaborating with Clinical Departments, and Grady Key Personnel according to Institutional policies
- Assist each PI/Research Team in determining a **Grady FIT** instead of having to come up with a **Grady FIX**

What is Financial Clearance?

Financial Clearance:

- Is the amalgamation of the submission of **study documents** with **standardized processes** to operationalize each study
- Is **continuous** as it facilitates the **oversight** of research conducted at Grady and it's related sites
- Is a **required component** of the Grady Research Oversight Committee (ROC) Application
- **Relies on** the **collaboration** between Affiliate Institution Personnel and Grady's Key Personnel for its effectiveness
- Is an **essential element of research patient care** in the Grady Health System

Financial Clearance is a Requirement

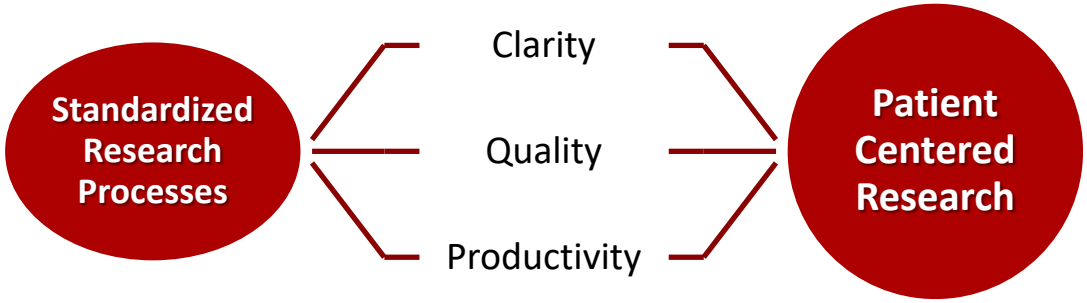
Financial Clearance is required:

- For all research and/or clinical trials conducted within the Grady Health System
- From the study's commencement to completion
- Whether a study does or does not involve billable activity
- Independent of study funding
- Independent of intended patient contact

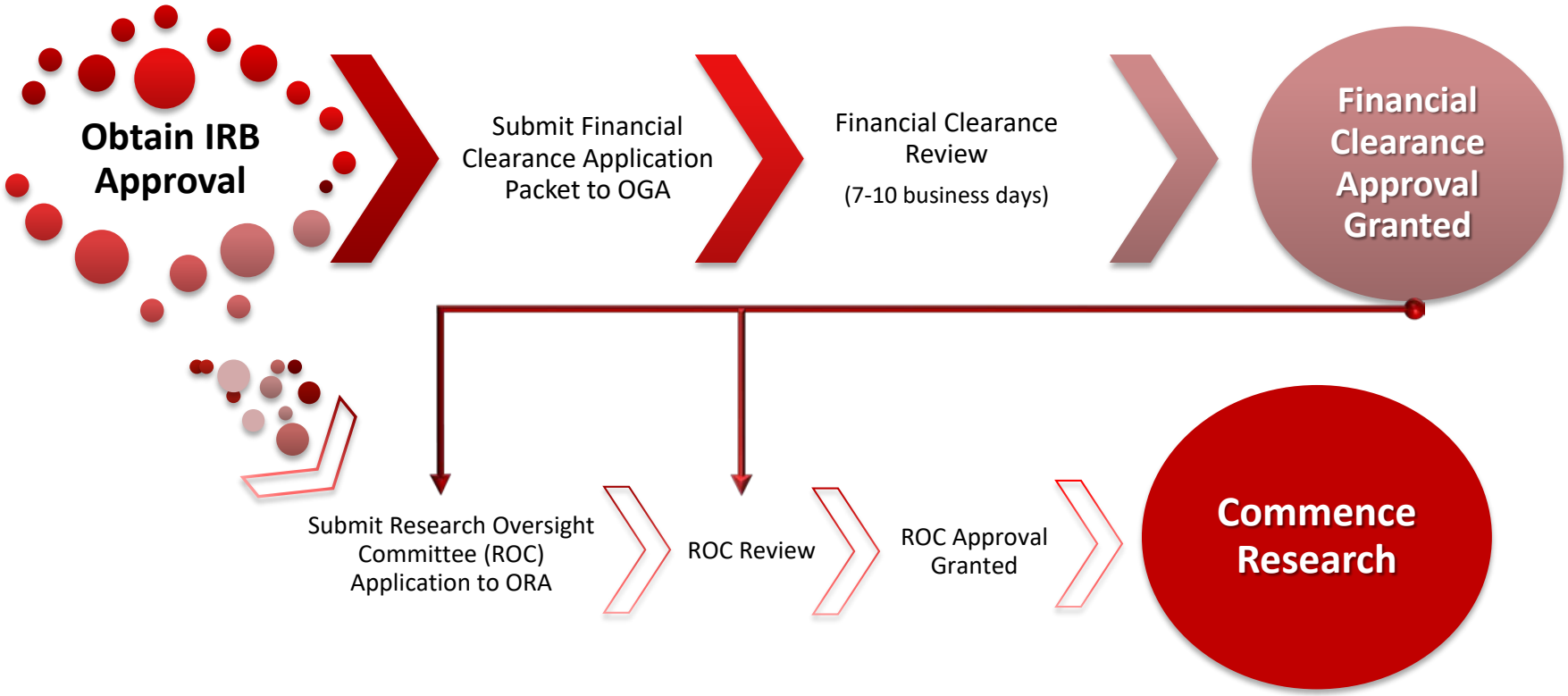
OGA's Standardized Processes

Financial Clearance involves standardized processes that:

- Are applicable to **EVERY** study but take into consideration the unique requirements of each study
- Facilitate the management of each study in an organized manner
- Give thoughtful consideration of resource use at Grady, examine the potential for related fees and financial recovery
- Are key to the appropriate management of research that has billable activity
- Enable the successful management of research patient visits and support Grady's Common Goal for **PATIENT CENTEREDNESS**



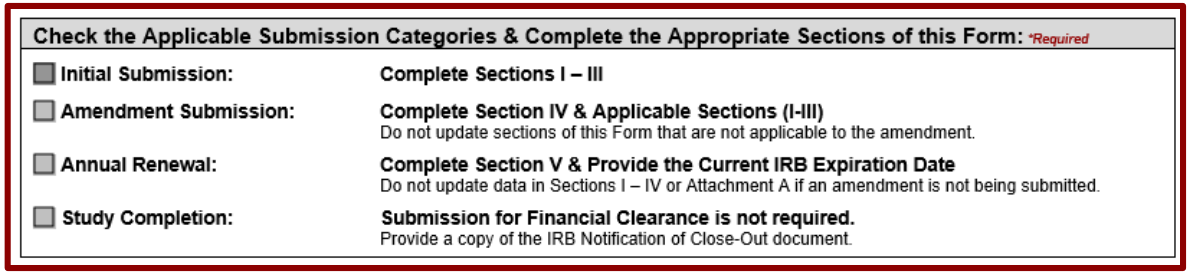
Financial Clearance Review & Approval Process



The Financial Clearance Form (FCF)

Submission Categories:
The instructions tell you which Sections to complete.

***Don't forget** the SPECIAL instructions for First Time Use



Check the Applicable Submission Categories & Complete the Appropriate Sections of this Form: *Required	
☐ Initial Submission:	**Complete Sections I – III**
☐ Amendment Submission:	**Complete Section IV & Applicable Sections (I-III)** Do not update sections of this Form that are not applicable to the amendment.
☐ Annual Renewal:	**Complete Section V & Provide the Current IRB Expiration Date** Do not update data in Sections I – IV or Attachment A if an amendment is not being submitted.
☐ Study Completion:	**Submission for Financial Clearance is not required.** Provide a copy of the IRB Notification of Close-Out document.

The Support Document List:
Tells you what documents are required for each Submission Category.

SUPPORT DOCUMENT LIST	INITIAL REVIEW	CONTINUING REVIEW	AMENDMENT	STUDY CLOSURE
Study Protocol *A current version of the protocol must remain in the OGA file*	Required	Required	Required if Amended	N/A
IRB Approval Document	Required	Required	Required	Required
IRB Submission Document(s) *See the ORA ROC Application for details*	If Requested	Required	Required	N/A
Informed Consent Form *Required if participants will consent*	Required if Applicable	If New or Amended	If Applicable	N/A
List of Clinical Procedures/Services *(i.e., itemized budget or PRA)* *Required if there are Grady billable or SOC items, services or procedures*	Required if Applicable	If New or Amended	If Applicable	N/A
Grady Pharmacy Estimate for IDS *Required if there are investigational drug services (IDS) at Grady*	Required if Applicable	If New or Amended	If Applicable	N/A
Research Equipment Questionnaire *Required if non-Grady equipment will be used on Grady's campus*	Required if Applicable	If New or Amended	If Applicable	N/A
Clinical Trial Agreement / Subcontract *Required if GHS is being subcontracted*	If Applicable	If New or Amended	If Applicable	N/A
Investigational Product, Device & Supply Approval *This approval is obtained from the Grady Value Analysis (VA) Committee. Refer to the "OGA Product-Device Tip Sheet" for instructions.*	If Applicable	If New or Amended	If New or Amended	N/A

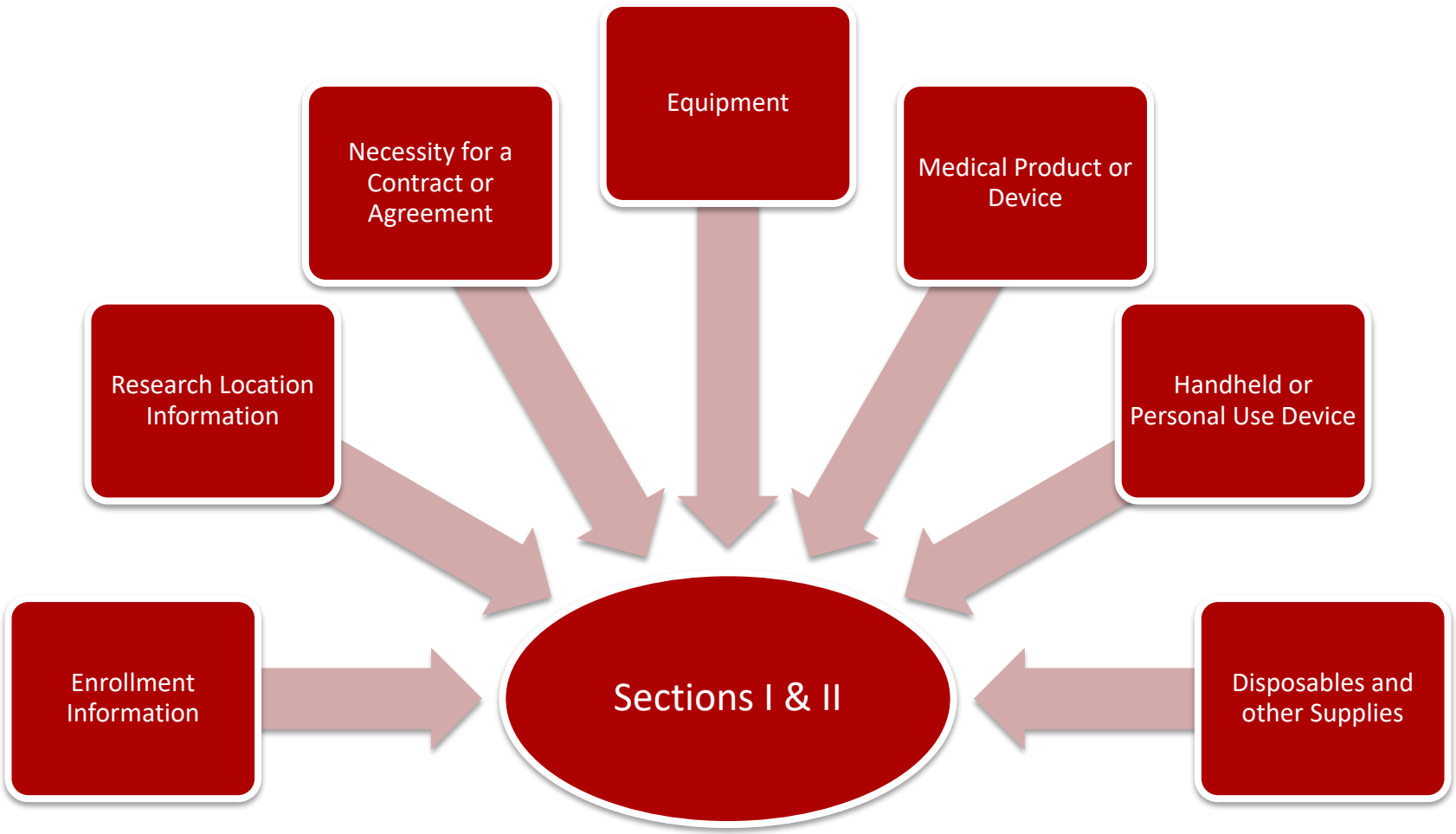
The Financial Clearance Form (FCF)

The FCF is divided into sections. Each section collects different information about the study/clinical trial.

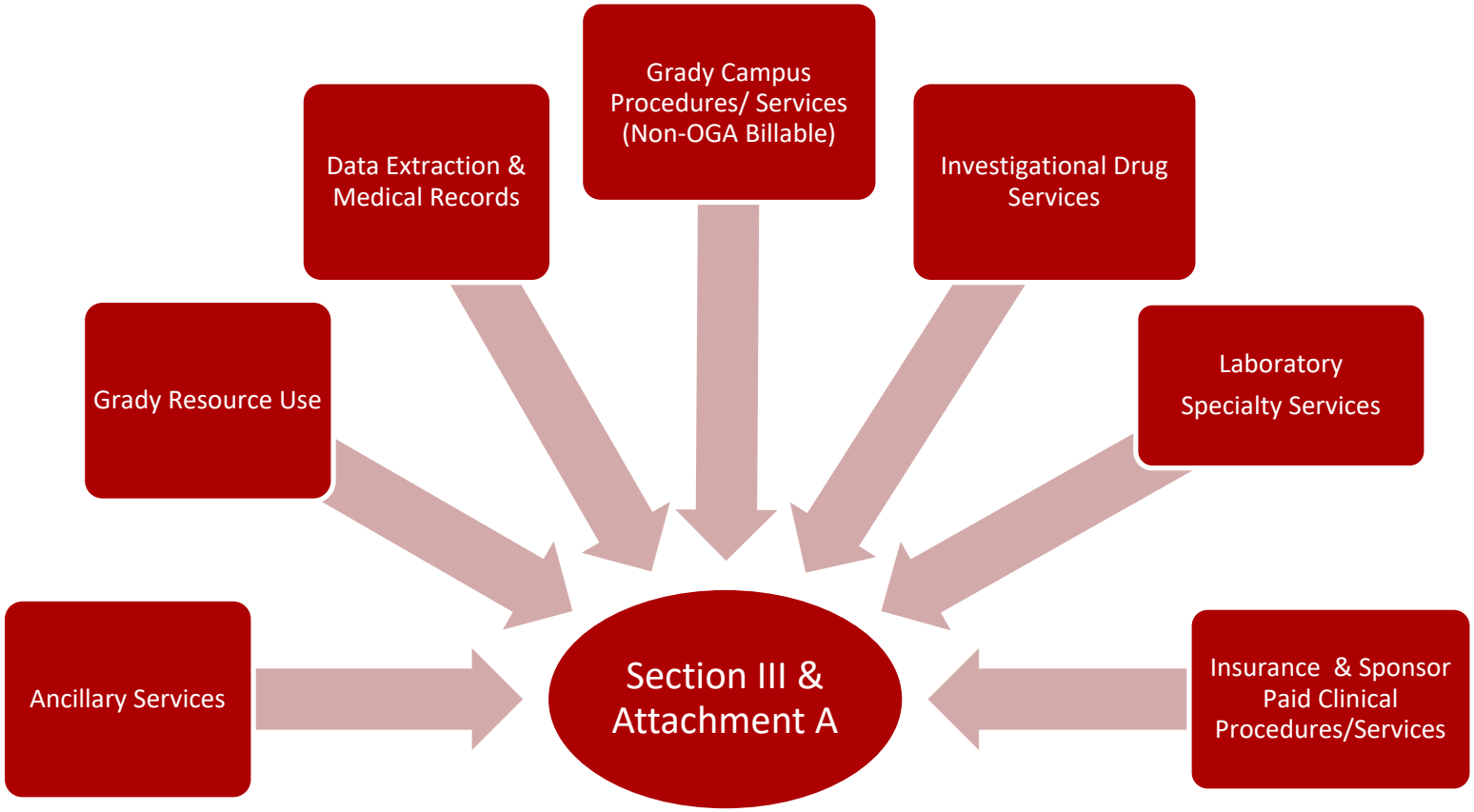
Sections I, II & III	• **General Study Information** •The Content of each section is designated by subsection headers •The data in these sections is constant except if there is/has been an IRB approved amendment •Exception - the IRB Expiration Date must be current
Section IV	• **Amendment Information** •The information summarized in this section should be captured in other sections of the FCF
Section V	• **Annual Renewal Information** •Renewal information should only be provided in this section unless there is also an amendment
Attachment A	• **Clinical Billable Procedures & Services** •Detailed information about clinical procedures/services

IMPORTANT: **First Time Use** of the new FCF for an Amendment or Renewal submission requires that Sections I-III be completed to capture the general study information.

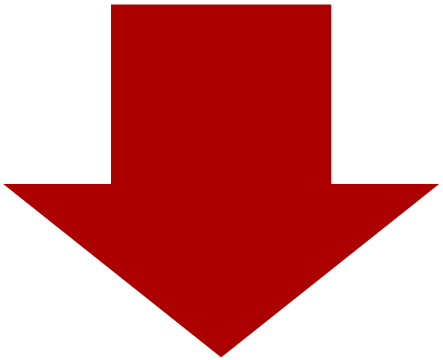
Financial Clearance: Study Details



Financial Clearance: Study Details

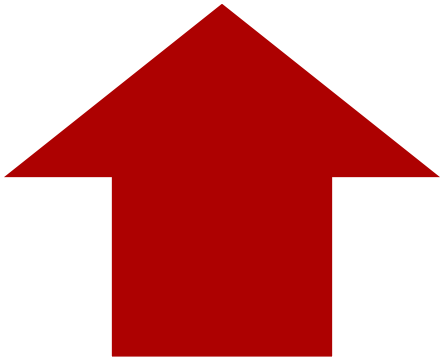


Approval & Commencement



Proposed Study Conduct

Study Operationalization at Grady



Key Components for Study Management

- A Uniquely Identifiable Study
- Specifying Investigational vs. Routine Clinical & Pharmacy Services
- Enrolling & Scheduling Research Participants
- Managing Research Participant Visits
- Providing Encounter Notifications
- Managing Study Accounts

Uniquely Identifiable Study

The Affiliate Institution facilitates:

- The Institutional Review Board (IRB) review and the provision an IRB Number.
- Registration of the study/trial with the National Library of Medicine (NLM) to obtain a National Clinical Trials number (NCT#).

SECTION I - STUDY INFORMATION

GENERAL INFORMATION

IRB Number: _____ *Required

Current IRB Expiration Date: _____ *Required

☐ N/A if an *IRB Exemption* was granted. Please provide the IRB Determination Letter

STUDY TYPE

Instructions: *Choose the most applicable research category below. The choice should correspond with the study type indicated in the Protocol, IRB submission, and ROC Application Form.*

Note: Some categories are inclusive of several types of research activities. For example, a clinical research study involves data collection, a survey, and tissue collection you would only check "Clinical Research." A study will look at medical records with no patient interaction, only check Data and provide inclusion dates.

☐ Clinical Trial – NCT# _____ *Required

☐ Clinical Research – NCT# _____ *(If Applicable)*

☐ Qualitative / Observational Research

☐ Survey / Questionnaire

☐ Registry ☐ Public Health Surveillance

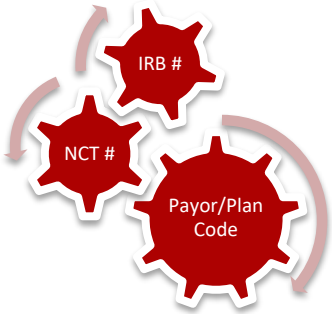
☐ Data Only Study *(i.e., medical record review or data retrieval)*

Data collection inclusion dates: from _____ to _____ *Required

☐ Tissue / Sample Collection *(No participant interaction)*

☐ Humanitarian/Emergency Use Device, specify # _____

☐ Other: _____



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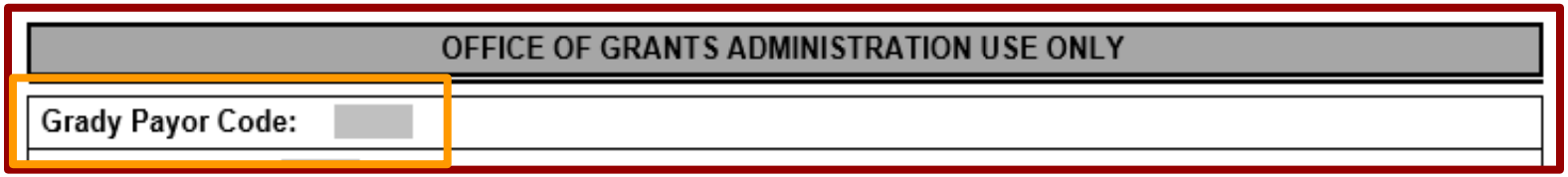
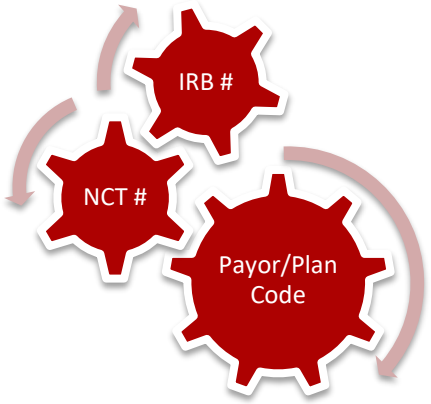
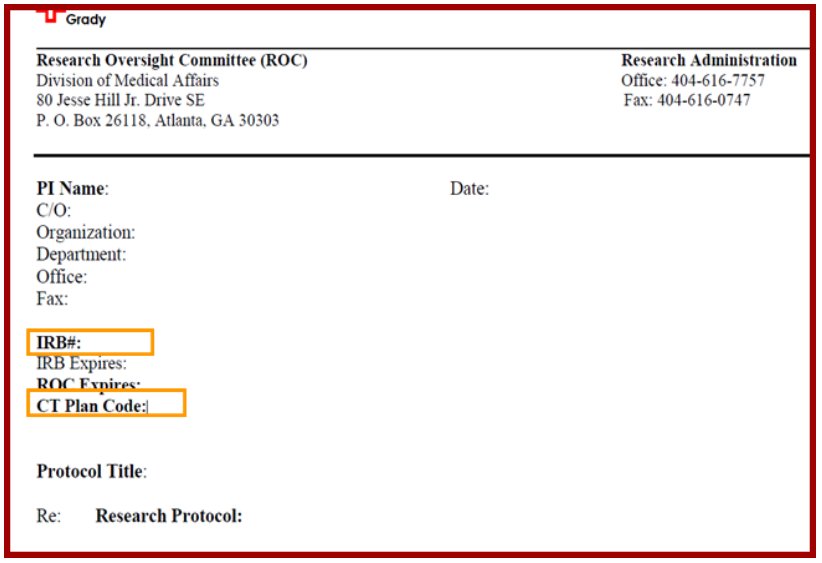
Uniquely Identifiable Study

Grady's Office of Research Administration (ORA):

- Assigns a unique Payor/ CT Plan Code to billable studies.
- The Payor/Plan Code is subsequently used on other official ORA/OGA documents as the Grady Identifier in conjunction with the IRB number.







Grady

Research Oversight Committee (ROC)
Division of Medical Affairs
80 Jesse Hill Jr. Drive SE
P. O. Box 26118, Atlanta, GA 30303

Research Administration
Office: 404-616-7757
Fax: 404-616-0747

PI Name:
C/O:
Organization:
Department:
Office:
Fax:

Date:

IRB#:
IRB Expires:
ROC Expires:
CT Plan Code:

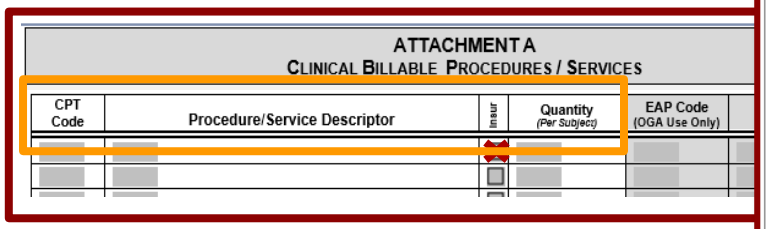
Protocol Title:

Re: **Research Protocol:**

Investigational vs. Routine Clinical Procedures/Services

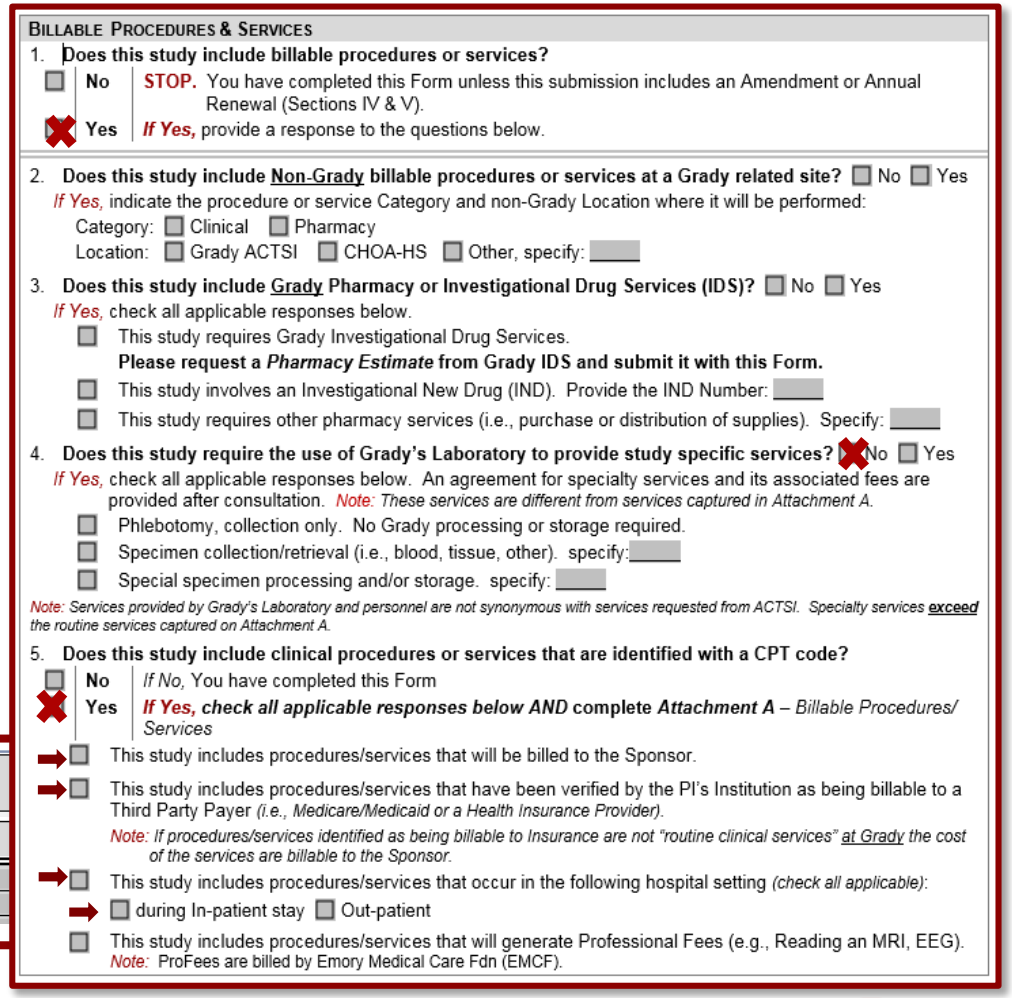
The Affiliate Institution or Principle Investigator will:

- Provide general and specific details about the proposed procedures/services as outlined in the Affiliate Institutions' budget.
- Specify clinical procedures/services that will be paid by the Sponsor.
- Specify routine or standard of care (SOC) clinical procedures/services that will be paid by a Third Party. This is based on the National Coverage Determination (NCD) criteria.
  - The NCD facilitates required research coding



ATTACHMENT A
CLINICAL BILLABLE PROCEDURES / SERVICES

CPT Code	Procedure/Service Descriptor	Insur	Quantity (Per Subject)	EAP Code (OGA Use Only)
		☒		
		☐		



BILLABLE PROCEDURES & SERVICES

1. **Does this study include billable procedures or services?**
   - ☐ **No** — **STOP.** You have completed this Form unless this submission includes an Amendment or Annual Renewal (Sections IV & V).
   - ☒ **Yes** — ***If Yes,*** provide a response to the questions below.

2. **Does this study include Non-Grady billable procedures or services at a Grady related site?** ☐ No ☐ Yes
   If Yes, indicate the procedure or service Category and non-Grady Location where it will be performed:
   Category: ☐ Clinical ☐ Pharmacy
   Location: ☐ Grady ACTSI ☐ CHOA-HS ☐ Other, specify: ____

3. **Does this study include Grady Pharmacy or Investigational Drug Services (IDS)?** ☐ No ☐ Yes
   If Yes, check all applicable responses below.
   - ☐ This study requires Grady Investigational Drug Services.
     Please request a *Pharmacy Estimate* from Grady IDS and submit it with this Form.
   - ☐ This study involves an Investigational New Drug (IND). Provide the IND Number: ____
   - ☐ This study requires other pharmacy services (i.e., purchase or distribution of supplies). Specify: ____

4. **Does this study require the use of Grady's Laboratory to provide study specific services?** ☒ No ☐ Yes
   If Yes, check all applicable responses below. An agreement for specialty services and its associated fees are provided after consultation. *Note: These services are different from services captured in Attachment A.*
   - ☐ Phlebotomy, collection only. No Grady processing or storage required.
   - ☐ Specimen collection/retrieval (i.e., blood, tissue, other). specify: ____
   - ☐ Special specimen processing and/or storage. specify: ____

   *Note: Services provided by Grady's Laboratory and personnel are not synonymous with services requested from ACTSI. Specialty services **exceed** the routine services captured on Attachment A.*

5. **Does this study include clinical procedures or services that are identified with a CPT code?**
   - ☐ **No** — *If No,* You have completed this Form
   - ☒ **Yes** — ***If Yes, check all applicable responses below AND** complete **Attachment A** – Billable Procedures/ Services*
     - ☐ This study includes procedures/services that will be billed to the Sponsor.
     - ☐ This study includes procedures/services that have been verified by the PI's Institution as being billable to a Third Party Payer *(i.e., Medicare/Medicaid or a Health Insurance Provider).*
       Note: If procedures/services identified as being billable to Insurance are not "routine clinical services" at Grady the cost of the services are billable to the Sponsor.
     - ☐ This study includes procedures/services that occur in the following hospital setting *(check all applicable)*:
       ☐ during In-patient stay ☐ Out-patient
     - ☐ This study includes procedures/services that will generate Professional Fees (e.g., Reading an MRI, EEG).
       Note: ProFees are billed by Emory Medical Care Fdn (EMCF).

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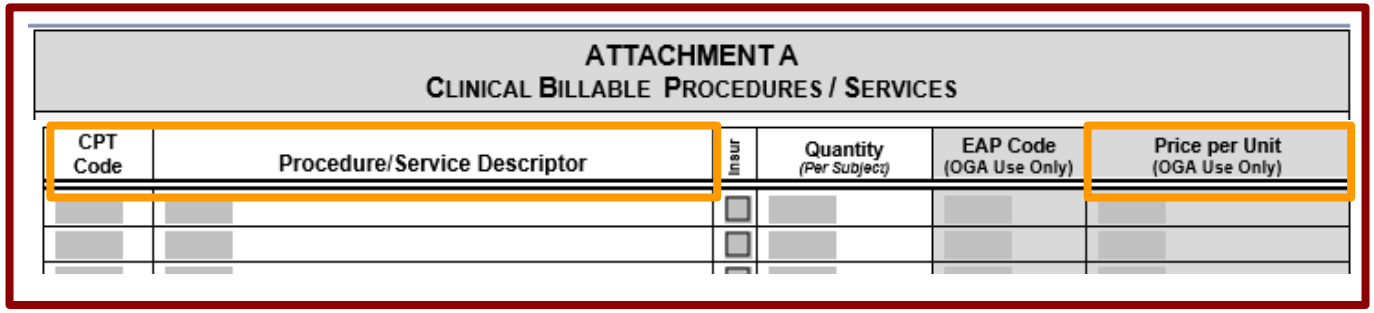
Investigational vs. Routine Clinical Procedures/Services

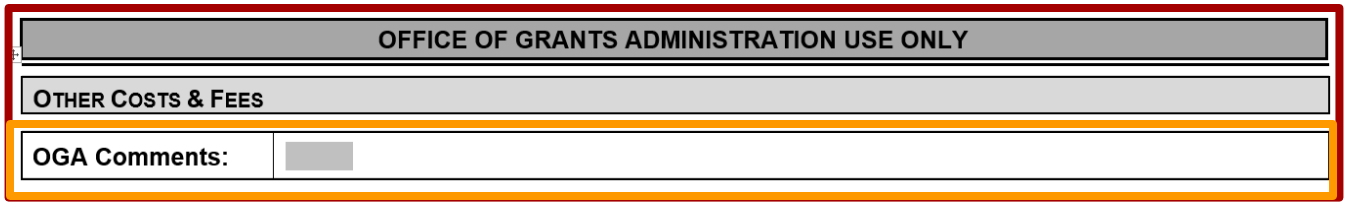
The Office of Grant Administration (OGA) will:

- Advise about Grady's clinical procedural norms, and service or departmental standards and provide fee information.
- Use the payment source details to outline study specific research fiscal & compliance guidance.



ATTACHMENT A
CLINICAL BILLABLE PROCEDURES / SERVICES

CPT Code	Procedure/Service Descriptor	Insur	Quantity (Per Subject)	EAP Code (OGA Use Only)	Price per Unit (OGA Use Only)
		☐			
		☐			



OFFICE OF GRANTS ADMINISTRATION USE ONLY

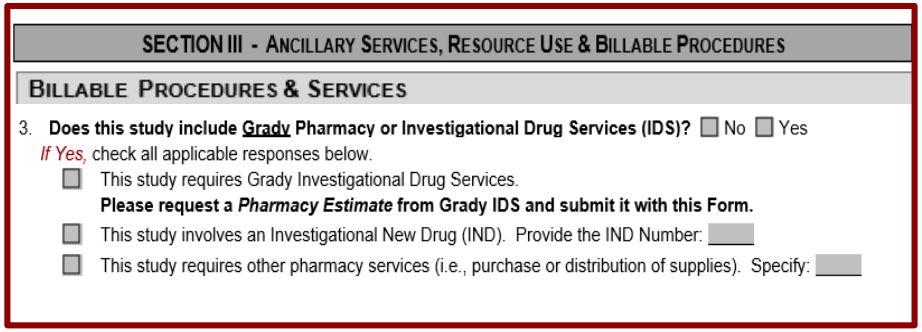
OTHER COSTS & FEES

OGA Comments:	

Investigational Drug Services

The FCF Section III

- Collects general information about the need for investigational drug and 'other' pharmacy services



SECTION III - ANCILLARY SERVICES, RESOURCE USE & BILLABLE PROCEDURES

BILLABLE PROCEDURES & SERVICES

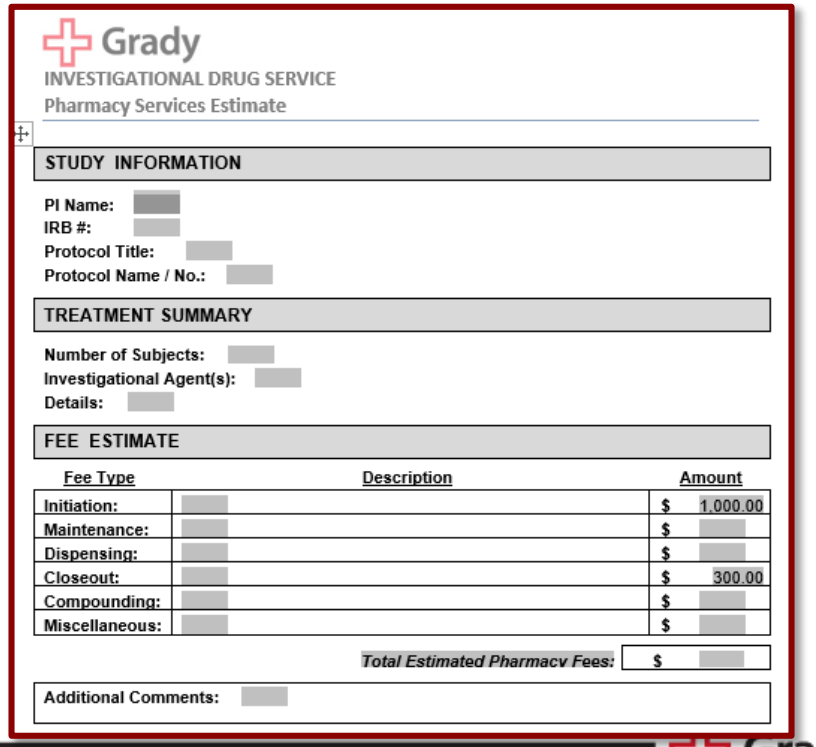
3. **Does this study include Grady Pharmacy or Investigational Drug Services (IDS)?** ☐ No ☐ Yes

If Yes, check all applicable responses below.

- ☐ This study requires Grady Investigational Drug Services.
  Please request a *Pharmacy Estimate* from Grady IDS and submit it with this Form.
- ☐ This study involves an Investigational New Drug (IND). Provide the IND Number: _____
- ☐ This study requires other pharmacy services (i.e., purchase or distribution of supplies). Specify: _____

The Pharmacy Estimate:

- Is facilitated by Grady's Investigational Drug Services (IDS)
- Captures the detailed drug services required by the protocol.
- Is applicable to patient services and invoicing



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INVESTIGATIONAL DRUG SERVICE

Pharmacy Services Estimate

STUDY INFORMATION

PI Name:
IRB #:
Protocol Title:
Protocol Name / No.:

TREATMENT SUMMARY

Number of Subjects:
Investigational Agent(s):
Details:

FEE ESTIMATE

Fee Type	Description	Amount
Initiation:		$ 1,000.00
Maintenance:		$
Dispensing:		$
Closeout:		$ 300.00
Compounding:		$
Miscellaneous:		$

Total Estimated Pharmacy Fees: $

Additional Comments:

Ancillary Services & Resource Use

Ancillary services & the use of Grady's resources:

- Require an approval, acknowledgment, authorization, a contract or agreement prior to commencement of the use.
- May incur a fee for use.

SECTION III - ANCILLARY SERVICES, RESOURCE USE & BILLABLE PROCEDURES

GRADY ANCILLARY SERVICES / RESOURCE USE

Does this study require Grady services or the use of resources that are not directly billable to the patient?

Note: *(**) indicates that fees may apply for the service or resource use.*

☐ **No.** Skip to Billable Procedures/Services

☐ **Yes.** ***If Yes,*** Indicate the services and/or resources below

☐ **Grady Nursing / Patient Care Services.**
All research studies involving Grady Nursing services must be submitted to the Nursing Research Committee. Refer to the ROC Application Form for additional information.
Note: Support services provided by Grady Nurses are not synonymous with services provided at ACTSI.

☐ **Use of Departmental Space or Clinical Staff.**
Grady Clinical Department: _____ **Required*
Grady Department Administrator Name: _____ **Required* *Note:* This person is not the Chief of Service
Specify the space request** (e.g. room 2b2): _____
Specify Grady Staff participation requirements (e.g., study-specific training, etc.): _____

☐ **Data Extraction and Reporting.**
Data extraction and Reporting services are provided by the Grady Business & Clinical Intelligence (BCI) Department**. Refer to the ROC Application Form for additional information.

☐ **Medical Records or Imaging CD Request.**
Medical records and CD requests are processed by Grady Health Information Management (HIM) Department**. Refer to the ROC Application Form for additional information.
Note: BCI and HIM services are not synonymous with the extraction of patient data from Epic by the PI/Research team.

☐ **Other**, specify (e.g., patient billing data): _____

4. **Does this study require the use of Grady's Laboratory to provide study specific services?** ☐ No ☐ Yes
If Yes, check all applicable responses below. An agreement for specialty services and its associated fees are provided after consultation. *Note: These services are different from services captured in Attachment A.*
   - ☐ Phlebotomy, collection only. No Grady processing or storage required.
   - ☐ Specimen collection/retrieval (i.e., blood, tissue, other). specify:_____
   - ☐ Special specimen processing and/or storage. specify: _____

Note: Services provided by Grady's Laboratory and personnel are not synonymous with services requested from ACTSI. Specialty services ***exceed*** *the routine services captured on Attachment A.*

Grady

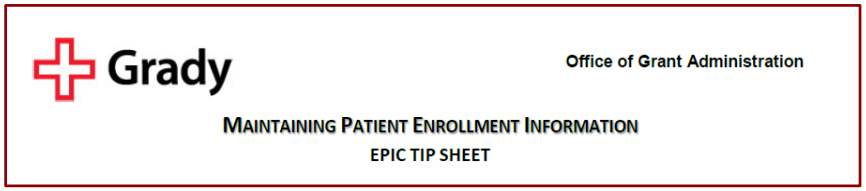
Patient Enrollment & Visit Scheduling

Patient Enrollment:

- Is captured in Epic by linking the patient's medical record to the Payor/Plan Code.
- Indicates that the patient has consented to participate in a research study.
- Is a KEY component for research billing.

Scheduling a Visit:

- For **Out-Patient** services requires the use of the standardized Pre-Registration process.
- For a participant who is an **In-Patient** does not require scheduling
- In a **Specialty** service area may differ from the Out-Patient process
- To use the **Georgia CTSA** requires the use of the Clinical Research-Assist (CR-Assist) system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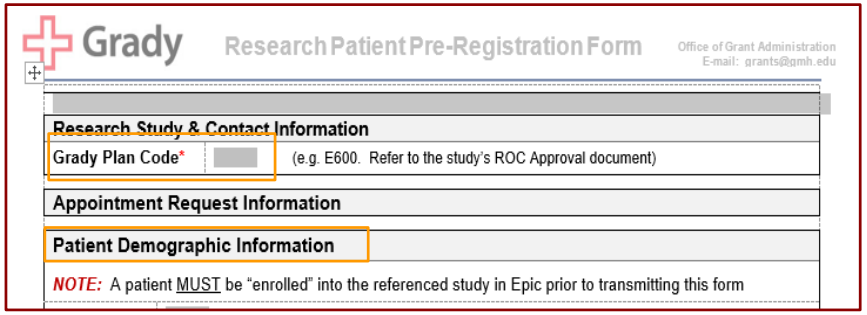
Office of Grant Administration

MAINTAINING PATIENT ENROLLMENT INFORMATION

EPIC TIP SHEET


Grady Research Patient Pre-Registration Form

Office of Grant Administration
E-mail: grants@gmh.edu

Research Study & Contact Information

Grady Plan Code* (e.g. E600. Refer to the study's ROC Approval document)

Appointment Request Information

Patient Demographic Information

NOTE: A patient MUST be "enrolled" into the referenced study in Epic prior to transmitting this form

Managing a Research Visit

Patient Check-in

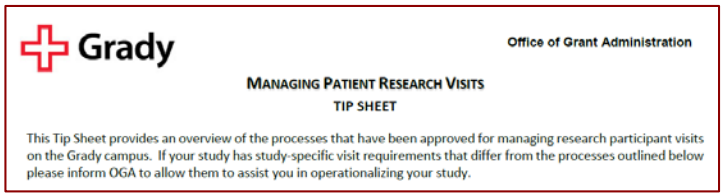
- Is required to open an **out-patient** visit or encounter
- Provides a virtual location where charges can connect

Research Orders

- Preferably are placed in Epic
  - Limited locations use Paper Requisitions
  - "Orders Only" must be used with a research encounter
- Use the ICD10 procedural code Z00.6 to identify the order as being "Research" related
- Should match the procedures/ services on the approved FCF

Patient Check-out

- Is required to close the encounter
- Initiates the billing process



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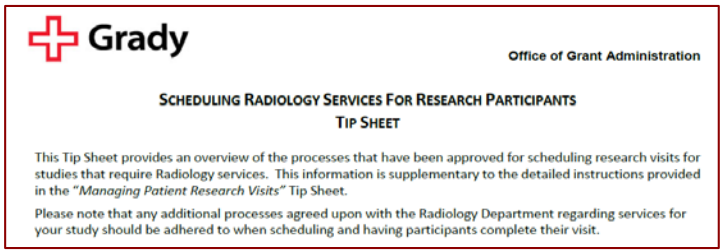
Office of Grant Administration

MANAGING PATIENT RESEARCH VISITS
TIP SHEET

This Tip Sheet provides an overview of the processes that have been approved for managing research participant visits on the Grady campus. If your study has study-specific visit requirements that differ from the processes outlined below please inform OGA to allow them to assist you in operationalizing your study.



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Office of Grant Administration

SCHEDULING RADIOLOGY SERVICES FOR RESEARCH PARTICIPANTS
TIP SHEET

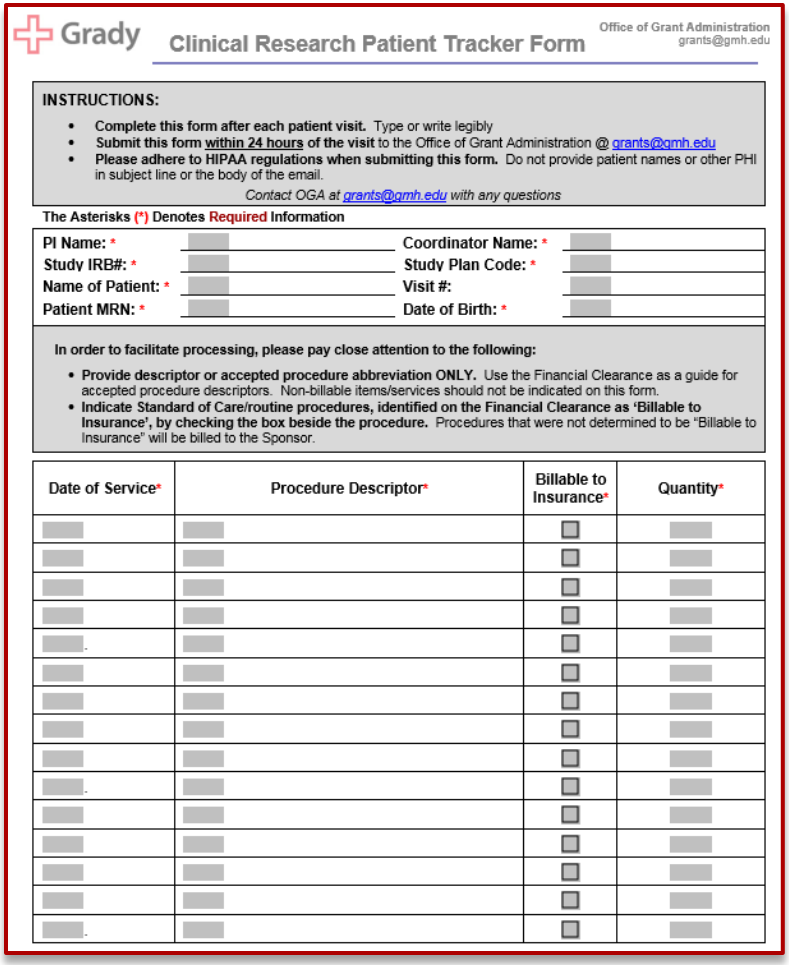
This Tip Sheet provides an overview of the processes that have been approved for scheduling research visits for studies that require Radiology services. This information is supplementary to the detailed instructions provided in the "*Managing Patient Research Visits*" Tip Sheet.

Please note that any additional processes agreed upon with the Radiology Department regarding services for your study should be adhered to when scheduling and having participants complete their visit.

Encounter Notification

Encounter Notification

- Is accomplished by sending a Patient Tracker Form to OGA
- Facilitates charge verification, billing and coding
- Is a crucial step for preventing patients from receiving a bill from Grady Health Services



Grady

Clinical Research Patient Tracker Form

Office of Grant Administration
grants@gmh.edu

INSTRUCTIONS:

- **Complete this form after each patient visit.** Type or write legibly
- **Submit this form within 24 hours of the visit** to the Office of Grant Administration @ grants@gmh.edu
- **Please adhere to HIPAA regulations when submitting this form.** Do not provide patient names or other PHI in subject line or the body of the email.

Contact OGA at grants@gmh.edu with any questions

The Asterisks (*) Denotes Required Information

PI Name: *		**Coordinator Name:** *	
Study IRB#: *		**Study Plan Code:** *	
Name of Patient: *		**Visit #:**	
Patient MRN: *		**Date of Birth:** *	

In order to facilitate processing, please pay close attention to the following:

- **Provide descriptor or accepted procedure abbreviation ONLY.** Use the Financial Clearance as a guide for accepted procedure descriptors. Non-billable items/services should not be indicated on this form.
- **Indicate Standard of Care/routine procedures, identified on the Financial Clearance as 'Billable to Insurance', by checking the box beside the procedure.** Procedures that were not determined to be "Billable to Insurance" will be billed to the Sponsor.

Date of Service*	Procedure Descriptor*	Billable to Insurance*	Quantity*
		☐	
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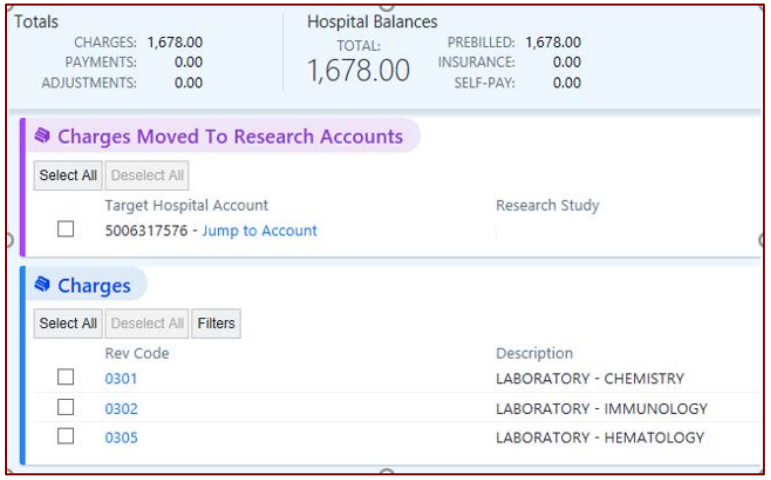
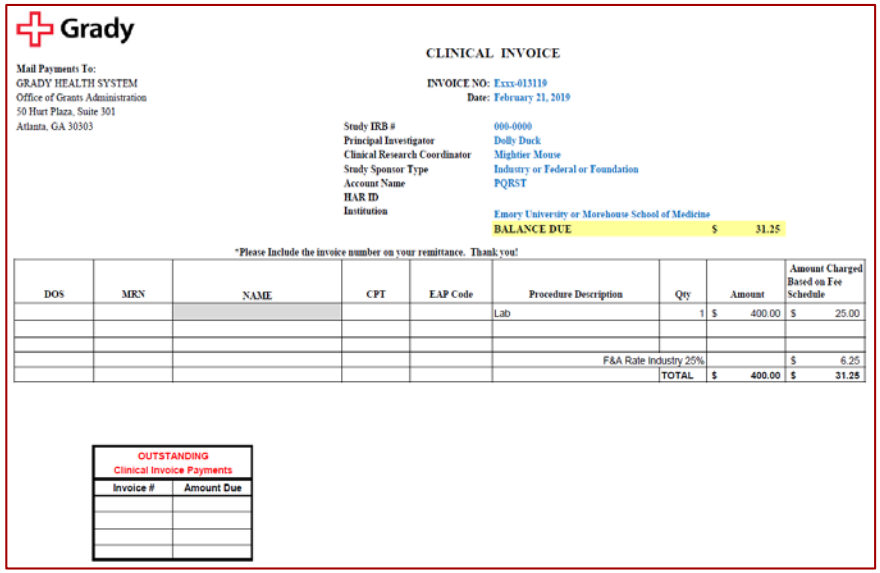
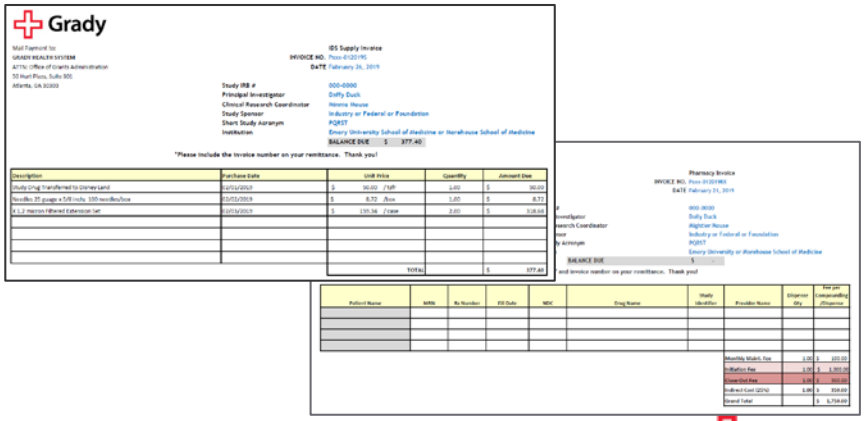
Grady

Billing & Account Management

- OGA Charge Verification *(Clinical, IDS, Other)*
- OGA Invoice Preparation

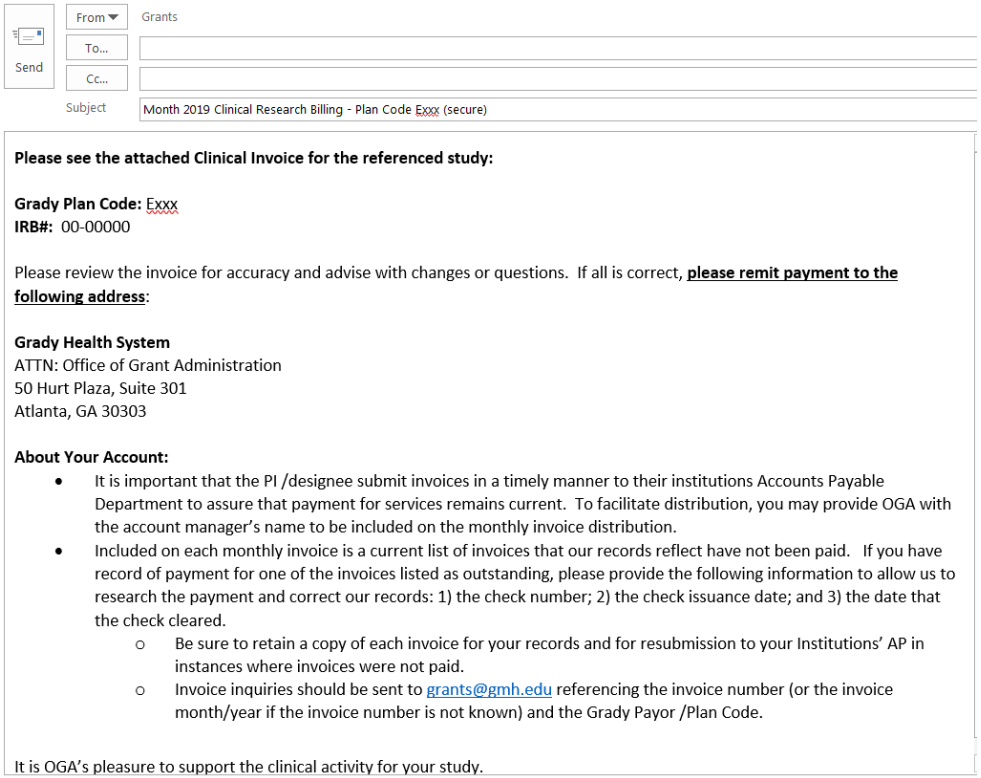






Billing & Account Management cont.

- OGA Invoice Dissemination
- PI/Designee Invoice Review
- Institutional Invoice Processing & Payment Remittance
- OGA Account Reconciliation



Send | From: Grants | To... | Cc... | Subject: Month 2019 Clinical Research Billing - Plan Code Exxx (secure)

Please see the attached Clinical Invoice for the referenced study:

Grady Plan Code: Exxx
IRB#: 00-00000

Please review the invoice for accuracy and advise with changes or questions. If all is correct, **please remit payment to the following address**:

Grady Health System
ATTN: Office of Grant Administration
50 Hurt Plaza, Suite 301
Atlanta, GA 30303

About Your Account:

- It is important that the PI /designee submit invoices in a timely manner to their institutions Accounts Payable Department to assure that payment for services remains current. To facilitate distribution, you may provide OGA with the account manager's name to be included on the monthly invoice distribution.
- Included on each monthly invoice is a current list of invoices that our records reflect have not been paid. If you have record of payment for one of the invoices listed as outstanding, please provide the following information to allow us to research the payment and correct our records: 1) the check number; 2) the check issuance date; and 3) the date that the check cleared.
    - Be sure to retain a copy of each invoice for your records and for resubmission to your Institutions' AP in instances where invoices were not paid.
    - Invoice inquiries should be sent to grants@gmh.edu referencing the invoice number (or the invoice month/year if the invoice number is not known) and the Grady Payor /Plan Code.

It is OGA's pleasure to support the clinical activity for your study.

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Project Close Out or Completion

The PI/Designee is Responsible For:

- Verifying that each patient's participation status is updated in Epic
- Submitting a FCF to notify OGA the following activity has concluded:
  - Patient related billable activities (Pharmacy & Clinical)
  - The use of Grady resources
  - The use of an approved investigational product or device
- Notifying OGA that Official IRB Close Out document has been received

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

OGA Documents

RESEARCH FORMS

- OGA Research Financial Clearance Form
- OGA Research Patient Pre-Registration Form
- OGA Research Patient Pre-Registration Form – Radiology
- OGA Research Patient Tracker Form
- OGA Research Medical Equipment Use Tip Sheet
- OGA Research Product-Device Use Tip Sheet
- OGA Visit Management – Patient Enrollment Tip Sheet
- OGA Scheduling Radiology Services – Patient Enrollment Tip Sheet
- FAQs Conducting Clinical Trials and Research at Grady
- ORA/OGA Research 101: Educational Session (March 2018)
- ORA Research Oversight Committee (ROC) Forms

Regulations & Consequences for Non-Compliance

Regulations

- The **False Claims Act**
- The **Anti-Kickback Statute**
- The **Fraud Enforcement and Recovery Act of 2009 (FERA)**
- The **2010 Patient Protection and Affordable Care Act (PPACA)**

Consequences for Non-Compliance

- Loss of community trust and damaged reputation with industry
- Staff time lost by correcting billing errors
- Financial Penalties – FDA & Regulatory Sanctions
- Potential endangerment of federal funding and federal health care programs
- Civil Enforcement Actions (qui tam suits)
- Criminal Prosecution and Fines

False Claim Settlements

The Department of Justice obtained more than $2.8 billion in settlements and judgments from civil cases involving fraud and false claims against the government in the fiscal year ending Sept. 30, 2018.

Recovery Categories: drug and medical device industry other health care providers

https://www.justice.gov/opa/pr/justice-department-recovers-over-28-billion-false-claims-act-cases-fiscal-year-2018

OGA Contact Information

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Email: ybenjamin@gmh.edu

OGA Central Email: grants@gmh.edu
This email address should be used for ALL submissions (e.g. Financial Clearance Applications, Patient Tracker Forms, etc.). Do not send or copy personal work email addresses on submissions.

Web Address: http://www.gradyhealth.org/static/office-of-grants-administration


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