Frequently Asked Questions (FAQs)

Conducting Clinical Trials and Research at Grady Health System

This FAQ will answer many of your questions on pre-award and post-award requirements, including approvals, Epic, invoicing, and payments. This is part of a series of communication, education and training to notify staff and research partners of new processes and policies underway at Grady.

PRE-AWARD

1. Who do I contact if I want to conduct Clinical Trials/Research at Grady Health System?

All clinical trials and research studies conducted at Grady Health System (GHS) must receive approval from the Office of Grant Administration (OGA) followed by the GHS Research Oversight Committee (ROC).

OGA: ALL studies conducted within the Grady Health System must receive financial clearance by the Office of Grant Administration within the Finance Department. "Financial Clearance" includes costs of the research procedures required, as well as ancillary (Lab, Pharmacy, and Radiology) fees, personnel costs, startup fees, overhead, etc. Contact the Office of Grant Administration at grants@gmh.edu or call 404.616.5791 to initiate the Pre-Award application process. This mechanism also applies to studies with non-billable services, such as those involving patient registries and retrospective data review.

ROC: ALL research conducted at GHS must have Hospital ROC approval as demonstrated by an approval letter signed by the GHS Chief of Staff. In order to submit the GHS ROC application form, the research study must have an Institutional Review Board (IRB) approval from a recognized IRB as noted in Grady's submitted Federalwide Assurance (FWA00004534). The ROC committee meets once per month on the first Monday. All applications must be submitted by the last Monday of each month to be reviewed for the first Monday of the following month. Contact Office of Research Administration at 404.616.7289 for more information.

2. Who do I contact if a subcontract or other contractual arrangement is required with Grady?

All subcontracts and other contractual arrangements should be directed to the Office of Grant Administration for review, negotiation, routing and execution by the authorized signatory. Contact Leticia A. Jones, Director, at 404.616.5791 or ljones2@gmh.edu.

POST-AWARD

3. Now that the study has received all Grady Pre-Award approvals, what happens next?

Following GHS ROC approval, the Office of Research Administration will create the Research Study in Epic, Grady's new electronic medical record system, for items with grant-billable procedures. At a minimum, this includes the study information, approved research procedures and allowed count for each. Research personnel will receive an Epic username and password to access Epic following the registration process as identified within Item 4 below.

4. How do I obtain access to Epic for the study?

All non-Grady employee research personnel who require Epic view-only access must adhere to the following:

a. First, you must be identified by your respective institution's IRB as clinical research personnel. Please submit the IRB approval letter and evidence of CITI training to Chad VanDenBerg at 404.616.7289 or cvandenberg@gmh.edu to ensure that you are on the list.

b. Second, you must complete the following:
   i. Go to this website http://www.gradyhealth.org/gradytrain/
   ii. Use the following user name: grady
   iii. Use the following password: g3n3ral

iv. Complete the "Non-Employee Epic Training" (for researchers)

c. Third, submit all completed documents as identified within the Epic VO Training Acknowledgement to Angelique Culver (aculver@gmh.edu).

5. Now that I have access to Epic, what is my responsibility as research personnel?

Research personnel are responsible for obtaining patient consent, as appropriate, and ensuring all study related documentation is secured and immediately retrievable upon request.

Specific to EPIC, if there are grant/research-billable services, the coordinator is responsible for "enrolling' the patient in EPIC immediately after obtaining the patient's consent for participation in the study Please contact Amaka Wright for more instructions on Epic enrollment.

6. What forms must I complete as part of conducting clinical research at Grady Health System? Where can I access?

Effective March 2011, the following forms are required to be completed as part of the research study:

- **Patient Visit Notification (Research Pre-registration Form)**
  Within 48 hours of patient visit, fax or e-mail Patient Pre-notification form to L. Rae Watford (lwatford@gmh.edu; Fax: 404-616-7166) at GHS Central Scheduling so that patients are pre-registered and the study visit is appropriately linked as "Research."

- **After the Patient Visit (Patient Tracker Form)**
  Complete the Patient Tracker Form after each study billable visit and submit to the Office of Grant Administration as denoted by the Form. The Patient Tracker Form will serve as a confirmation of patient's visit and billable items/services.

7. Will I receive regular statements detailing research patient activity by study? GHS

OGA will send monthly statements to PI/CRC for review by the 15th of each month.

8. Who do I contact for questions regarding invoices or if my patient receives a bill?

Please contact the assigned Grant Manager, email the Office of Grant Administration at grants@gmh.edu or contact Leticia A. Jones, Director, at 404.616.5791 or ljones2@gmh.edu.

9. Where do I send payments?

Effective March 2011, **all payments** should be sent to the Grady Health System's Lock Box: PO Box 930704, Atlanta, GA 31193-0704.

Payments are to be made payable to Grady Health System. Each check payment **must** reference the invoice number, IRB number, and the name of the Principal Investigator for proper identification. Supporting documentation should concurrently be submitted to appropriately reconcile payment and provided research services.

10. Who can I contact with additional questions?

In an effort to streamline the overall Clinical Trials and Research efforts at Grady Health System, questions should be fielded through the following two offices:

Office of Research Administration

- Chad VanDenBerg, Director @ 404.616.7289 / cvandenberg@gmh.edu

Office of Grant Administration

- Leticia A. Jones, Director @ 404.616.5791 / ljones2@gmh.edu