FREQUENTLY ASKED QUESTIONS (FAQS)

Conducting Clinical Trials and Research at Grady

1. **I have a study that I would like to conduct at Grady. Is there an approval process?**

   Yes, every study that is conducted at Grady requires approval by the Grady Research Oversight Committee (ROC) prior to initiation. The ROC reviews IRB approved research.

2. **Where can I get the most current versions of the Office of Research Administration (ORA) and Grant Administration (OGA) forms?**

   Please visit the ORA and OGA webpages.

3. **What is the submission deadline for ROC Applications?**

   The submission deadline is the Monday one week prior to the ROC meeting. The ROC meeting schedule and submission deadlines can be found on the ORA webpage.

4. **What happens if my ROC Application is not received before or on the submission deadline?**

   The application will be held until the next ROC meeting.

5. **The Study has been deemed Exempt by my IRB, should I still proceed with the Grady ROC application?**

   Yes, you should proceed with the Grady ROC. The ROC will review the initial study after which, we require a yearly notification that the study is ongoing. However, if there are any amended changes, a continuing review is required.

6. **My study is being conducted at Hughes Spalding Children's Hospital, do I need to submit to ROC?**

   Yes, please contact ORA for guidance at research@gmh.edu.

7. **Is there an expedited ROC Review process?**

   No, the Research Oversight Committee does **NOT** have an Expedited Review or Approval Process. **ALL** studies are reviewed at the monthly meetings.

8. **Can I start my study after the Research Oversight Committee (ROC) has reviewed and approved the submission?**

   No, after the ROC has reviewed and provided conditional approval, final approval is required from Grady's Chief of Staff. This occurs up to seven days after the ROC meeting has been held.

9. **What types of studies are required to submit for Financial Clearance review?**

   Financial Clearance is required for ALL studies conducted within the Grady Health System. The requirement for Financial Clearance is independent of study funding or intended patient contact. Instructions for submission are provided on the Financial Clearance Form.

10. **When should I submit my Financial Clearance form to OGA?**

    Submission for Financial Clearance review should be initiated as far in advance as possible especially if the study has billable items, procedures, services or requires the use of Grady resources.

11. **How long does it take to get Financial Clearance approval?**

    Once OGA has received a **complete** Financial Clearance Application packet, the review process takes approximately 10 business days.

12. **Can I submit my ROC application while waiting for Financial Clearance approval**?

    Yes, we encourage you to complete and submit your ROC application according to the established deadlines while waiting on your Financial Clearance approval. Simultaneous submission to ORA and OGA is also acceptable. You may do so by sending all documents, in the format(s) required for each submission, by email to research@gmh.edu and grants@gmh.edu. OGA will disseminate the Financial Clearance approval to the PI and to ORA to be included with the ROC application.

13. **How often do I need to obtain Financial Clearance?**

    Financial clearance is required:

    - At initial ROC submission
    - For study modifications/amendments, especially if there are changes specific to:
      - Contacts pertinent to the financial matters of the study
      - Funding and sponsor information
      - Changes in study status that affect billable activity (i.e. study procedures and billable items)
      - Before study closure, to begin financial closeout processes
    - For ROC renewal

14. **Can a study receive Financial Clearance approval if it has not received IRB approval?**

    No, a study must have IRB approval to receive Financial Clearance approval but OGA will perform preliminary review and provide pricing information and/or guidance for patient related procedures without IRB approval.

15. **The study requires a subcontract or other contractual arrangement, who do I contact for assistance?**

    All subcontracts and other contractual arrangements should initially be submitted to grants@gmh.edu.

16. **Where do I get the information required to populate the billable procedure/service section of the Financial Clearance Form?**

    This information is obtained from the budget that the PI's institution approved for the study. The PI is responsible for completing the first four columns of this section of the FCF, which are labeled CPT code, Description, 'Insur' (Insurance Coverage), and Quantity.

17. **Who do I contact to get fee information for the procedures/services (e.g. labs) in my study?**

    OGA is responsible for providing fee information for research procedures/services. The list of clinical procedures/services must be prepared by the PI for fee information to be requested. Fees obtained from other Grady Departments may not valid for Financial Clearance.

18. **What is a National Clinical Trial number (NCT)?**

    A study or trial that is registered on the www.clinicaltrials.gov site is given a NCT number as its identifier. The NCT number should be provided on the Financial Clearance form.

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19. **My research proposes the use of equipment, supplies, and investigational product and/or a device, are there specific requirements for their use?**

    Yes, these items MUST obtain approval prior to initiating their use at Grady. Contact OGA as soon as possible to facilitate contracts or other agreements and provide guidance for obtaining these approvals.

20. **I do not have access to the medical records I need for my study. How do I obtain them?**

    Medical records are obtained through services provided by Grady's Health Information Management (paper charts) or Grady's Clinical Business and Intelligence (Epic data) departments. Guidance for obtaining these services is provided by ORA.

21. **How do I coordinate clinical pharmacy services for my study?**

    Investigational Drug Services (IDS), at Grady Hospital or IDP, require a Pharmacy Estimate that is provided by Philip Powers at powers@gmh.edu or Kay Woodson at kwoodson@gmh.edu, respectively. The pharmacy estimate must be submitted with the Financial Clearance Form.

22. **Can I engage a Grady department in providing services for my study prior to obtaining ROC approval?**

    No, services of Grady employees and/or departments should not be sought outside of obtaining financial clearance and ROC approval. The financial clearance process coordinates the use of departmental resources at Grady.

23. **Does my EPIC access expire?**

    Yes, the EPIC access expiration date may expire if a ROC Renewal application is not submitted prior to the ROC Expiration date of the study.

24. **Do I have to submit for EPIC access annually?**

    No, ORA will communicate EPIC renewal information with Grady's Information Security team when a complete ROC Renewal application is submitted.

25. **Does my badge expire when my EPIC access expires?**

    No, the badge expiration and EPIC access expiration dates are different. Badges should be renewed annually using the ORA Personnel Confirmation Form located at the ORA webpage.

26. **We simply want to add personnel to the study. What is the process each time we want to add someone to the study?**

    Only submit the IRB approval letter and receipt, that adds the staff member, to research@gmh.edu. However, if the staff member requires EPIC access, you are required to complete and submit the EPIC Request form along with evidence of CITI training. Remember to copy grants@gmh.edu on your submission to notify OGA of the personnel amendment.

27. **Do I have to enroll patients in Epic if my study is non-billable (i.e. survey)?**

    No, a non-billable study will not have a Plan Code/Payor ID or Epic profile thus patient enrollment is not required. However, patient enrollment in Epic is required for **ALL** studies that involve billable procedures/services and Standard of Care (SOC) procedures. Please refer to the Visit Management -Patient Enrollment Tip Sheet for guidance.

28. **Do potential research participants need to be a Grady patient?**

    Yes, for someone to obtain services at Grady they must have or be issued a Grady medical record number (MRN). Study personnel must facilitate the financial counseling process at Grady for the patient. Please refer to the Visit Management -Patient Enrollment Tip Sheet for guidance.

29. **Where can I obtain instructions for management of patient research visits?**

    Written instructions are provided in the *Visit Management -Patient Enrollment Tip Sheet*. You may also contact grants@gmh.edu to obtain additional guidance if the conduct of the study involves unique circumstances.

30. **Do I need to submit a Patient Tracker Form (PTF) for every patient visit?**

    Yes, the submission of a PTF is required within 48 hours of a research visit to provide notification to OGA that services have been provided to a participant. The PTF allows OGA to verify and differentiate between research and routine care services on the same day of service.

    The exception to this daily PTF submission requirement is for research activity while the participant is an in-patient. One (1) PTF can be submitted that captures services for the entire in-patient stay.

    Note: The notification requirement for specialty services (e.g. Oncology) may involve different processes. Please contact OGA for instructions.

31. **Who do I contact if a participant received a Grady invoice or bill?**

    A member of the Research Team should send a copy of the patient's bill to grants@gmh.edu.

32. **Does the ORA & OGA require notification of study closure?**

    Yes, notification of study closure is required. This notification is provided by submission of the IRB Notification of Close-Out to research@gmh.edu and grants@gmh.edu.

    If the study involves billables, OGA requests informal written notification of study closure at least 2 months in advance to begin financial closeout processes.