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 only reviews IRB approved research.

2. **What is considered IRB approved research?**

   IRB approved research is submitted to and approved by the IRB of note. IRB approval is granted with annual renewal requirement, for Exemption and, under the Common Rule. However, Exemption and Common Rule approvals do not have an IRB expiration date.

3. **Where can I get the most current versions of the Office of Research Administration (ORA) forms?**

   Please visit the ORA webpage to obtain the ROC Application Combined Form, the Financial Clearance Application and other ORA forms.

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

   The Submission Deadline is on the Monday week prior to the ROC meeting. The ROC meeting occurs on the second Tuesday of every month unless the Tuesday is an observed holiday. The ROC meeting schedule, which includes the submission deadlines, is located on the ORA webpage.

5. **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.

6. **The study has been deemed Exempt or approved under the Common Rule by my IRB, should I still proceed with submission to the Grady ROC?**

   Yes, you should proceed with the Grady ROC submission. The ROC will review the study and annual review is required according to the ROC expiration date on the ROC approval letter.

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

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

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

   No, the Research Oversight Committee does **NOT** have an Expedited eview or Approval Process.

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

   No, after the ROC meeting has transpired final approval is required from Grady's Chief of Staff. This occurs within 10-14 business days after the ROC meeting has been held. You can begin your research once you receive the ROC Approval letter.

10. **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.

11. **When should I submit my Financial Clearance Application Packet?**

    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. Submission for Financial Clearance is sent to researchfinance@gmh.edu.

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

    The review process takes between 10-14 business days once a **complete** Financial Clearance Application packet is received.

13. **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 of the ROC and Financial Clearance applications 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 researchfinance@gmh.edu. The Financial Clearance approval is disseminated to the PI and to ROC to be included with the ROC application.

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

    Financial clearance is required:

    - At initial ROC submission
    - For a study modification, 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)
    - For ROC renewal

15. **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 a preliminary review can be conducted and provide pricing information and/or guidance for patient related procedures without IRB approval.

16. **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 researchfinance@gmh.edu.

17. **Where do I get the billable procedure/service information required to populate Attachment A 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, which are labeled CPT code, Description, 'Insur' (Insurance Coverage), and Quantity.

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 is required on the Financial Clearance form to facilitate billing.

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 ORA Finance as soon as possible to facilitate contracts or other agreements and provide guidance for obtaining these approvals.

20. **How do I obtain clinical pharmacy services for my study?**

    Investigational Drug Services (IDS), at Grady Hospital or IDP, require a Pharmacy Estimate that is obtained by contacting the Executive Director of Pharmacy or his/her designee (see Contact Information on page 7 of the ROC Form). The pharmacy estimate is a required document in the Financial Clearance Application Packet.

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

    No, services from 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.

22. **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.

23. **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 approved.

24. **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.

25. **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 the receipt that adds the staff member to the study 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 researchfinance@gmh.edu on your submission.

26. **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 CT Plan Code 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.

27. **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 MRN Request Form for guidance.

28. **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 researchfinance@gmh.edu to obtain additional guidance if the conduct of the study involves unique circumstances.

29. **Do I need to submit a Clinical Research 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 ORA Finance that services have been provided to a participant. The PTF allows ORA Finance to verify and differentiate between research and routine care services on the same day of service.

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

30. **How do I know if all of the Clinical and/or Pharmacy charges for the participants have been billed to the study?**

    Each month a study specific Clinical and/or Pharmacy invoice is provided to the PI and designees for review and validation. If charges have been omitted ORA Finance should be notified. If the invoice is accurate the PI/designees should submit the invoice to the Institution's Accounts Payable for remittance.

31. **Who do I contact if a participant receives a bill from the Grady Health System for research related procedures/services?**

    A member of the Research Team should send a copy of the patient's bill to researchfinance@gmh.edu. The bill will be handled by ORA staff on behalf of the participant.

32. **Does the ORA 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 researchfinance@gmh.edu.

    If the study involves billable procedures/services, ORA Finance requests written notification of study closure at least 1 month in advance to begin financial closeout processes.