

TIP SHEET For the Completion of the Financial Clearance Form

The information requested on the Financial Clearance Form (FCF) focuses on the conduct of the study at Grady or a Grady related site (i.e. CHOA-HS, Grady GCRC (CTSA/ACTSI), or a neighborhood clinic). If the submission requires clarification specific to activity that will happen at an Affiliate site, provide a brief overview of the non-Grady activity in the related Comment Section(s), not in response to a FCF question.

Financial Clearance Form Completion by Section:

1. Sections I-III

Sections I-III of the FCF collects general information that captures the overall study conduct at Grady. For subsequent FCF submissions, these responses should remain unchanged unless there is/has been an amendment. The only exceptions are that the responses to **b.** and **d.** (see below) should remain current.

The FCF is not complete if responses identified as “Required” are unanswered. An incomplete FCF will be returned to the submitter. The 10-14 business day review time does not go into effect until a complete Financial Clearance Application Packet is received.

a. Requesting Organization

The Requesting Organization is the Principle Investigator (PI) affiliation. The response is “Grady” only if the PI is a Grady employee and Grady is receiving the funding.

b. The IRB Expiration Date

The IRB expiration date must be current (not expired) on every Financial Clearance submission to be accepted and processed. If the study has received IRB Exemption or approval under the *2018 Common Rule*, the response should be “Exemption” or “Common Rule” respectively. Submission of the IRB approval document is required.

If the study’s review category changes to review under the *2018 Common Rule*, an amendment to the Financial Clearance is required even if the IRB document does not specify it as an amendment. The IRB approval document is required.

Please note: Annual renewal is required for every study approved by the Grady ROC. Every ROC application requires a current Financial Clearance approval.

c. The Estimated Enrollment

A response to this question is required. On the FCF, the definition of “Enrollment” is the number of patients or patient level data that will be collected at Grady. If the total enrollment is unspecified in the protocol, the response can be an estimated enrollment per year (i.e. ~100/year). This response should not change unless there is an amendment.

d. The Anticipated Date of Completion

A response to this question is required. The target date will inform ORA about the length of time the study will be open at the Grady site (i.e. data collection, analysis, through IRB Closeout). The response to this question is: 1) not regulatory in nature; 2) unrelated to the IRB annual approval term; and 3) not meant to be annually updated. If the study continues past the target date an updated response is necessary. This change is not considered a Financial Clearance Amendment.

Please note: The ROC does not officially close a study until the IRB closeout document is submitted and accepted.

e. Equipment, Resource use, and Billable Procedures/Services

The use of equipment or services as indicated in the protocol requires responses to the questions in Sections II & III of the FCF. The responses should be specific to activity at Grady only. Provide clarification regarding activity at affiliate sites in the “Comments” Sections. Please contact ORA Finance for assistance, as some activities require submission and approval to other Grady Departments and/or Committees.

2. **Section IV - Amendments**

An amendment submission is required for all proposed modifications to a ROC approved study or clinical trial.

For a Formal Submission, indicate “Amendment” as the Submission Category (page 2). At the top of Section IV, place a check next to the appropriate section(s) where amended data is located on the FCF. Provide a short summary of the amendment including a statement about what, if any, portion of the amendment is applicable to the study’s financial clearance. The IRB submission and approval document are required to support the changes. When approved, an electronic approval is provided.

An Informal Submission is accepted for an IRB amendment that does not alter the FCF, the financial profile, or the study’s financial status. An Informal Submission requires that ORA-Finance (researchfinance@gmh.edu) is copied on the email submission to the ROC. The email text should include an overview of the amendment and address if the amendment is applicable to the Financial Clearance. The study is granted an electronic acknowledgment upon approval.

3. **Section V- Annual Renewal**

The responses provided in this section reflect the current state of the study. Every renewal submission requires the provision of the new IRB Expiration Date (page 2) unless the study was Exempted or approved under the Revised Common Rule. Only as necessary, the Anticipated Date of Completion is updated. If there is an Amendment submission current with the Renewal, the amendment information should be provided as indicated in 2.