

Chapter 20

FINANCIAL ASSESSMENT AND COST MONITORING OF CAMC PATIENTS ENROLLED IN A RESEARCH STUDY

A. Purpose

The purpose of financial assessment is to ensure that patients who have agreed to participate in research studies at CAMC/CAMC INSTITUTE are fully informed of the financial responsibility that may result from their participation in a research study, and to ensure that CAMC is properly billing patient charges to the third-party payors or the appropriate Institutional Grant Account.

B. Role of the Investigator

The PI will be responsible for itemizing all potential patient care costs in the form of a budget and then determining which costs will be 1) covered by the sponsor/grant; 2) uncovered by the sponsor/grant and charged to the patient or third party payor and 3) and notifying CAMC Patient Accounts of this information.

C. Procedures for Obtaining Special Patient Billing Account for Research Patients

As part of the research approval process, the PI or Study Coordinator shall do the following:

1. Determine and itemize all patient charges in detail as a prepared budget.
2. If investigational drugs or other study related procedures (i.e., bone marrow transplant) are a required part of the study and the sponsor will not cover these charges, the PI/Study Coordinator must contact the **Medicare Office in Columbus, OH at 703-853-3936 and the Medicaid Office in Charleston, WV at 926-1765** to determine whether the product or procedure will be "covered" or "uncovered" by the patient's preferred insurer. Note: Commercial insurers routinely follow the Medicare/Medicaid Guidelines for investigational products. Medicare and Medicaid Guidelines will be referenced as the common standards.
3. If an investigational device is involved, you will need to determine from the sponsor/manufacture whether the device is designated as "Category A" or "Category B" by the FDA or contact the RESEARCH AND GRANTS ADMINISTRATION... Office at 388-9970 to assist in this determination.
4. Complete Form 8, Research Patient Billing Identification Form. The PI/Study Coordinator will need to determine which department(s) (i.e., CAMC Laboratory, Nuclear Medicine, Radiology etc.) will be impacted by research patient billing and note these on Form 8.

5. The PI and/or study coordinator must contact the Research Patient Accounts Representative at 348-7413 to schedule a meeting to discuss the information contained on the form. A "special billing" account number will be assigned to the study.
6. The financial obligations of the patient participating in a research study must be stated as clearly as possible in dollar amounts on the patient consent form.
7. Prior to commencement of the study, the PI or Study Coordinator shall notify CAMC's Research Patient Accounts Representative of the start date for the study, forward a copy of the approved administrative signature form and copy of the IRB approval letter, and shall request that the account number previously assigned to the study be activated. The Patient Accounts Representative must be notified of any changes at that time.
8. In the event that a patient is going to be admitted, the Study Coordinator or PI will need to notify the designated Research Patient Accounts Representative.

D. Patient Cost Monitoring

1. The Research Patient Charges Identification Form shall become a part of the PI's orders upon admission of the patient for the study.
2. Patient Cost Reporting: On a monthly basis, beginning on the first of the month following the formal start date of the study, the PI shall submit a list of: (a) **all** patients participating in the study to date; (b) the dates of each service/procedure performed on or provided to the research patient in connection with the study; and (c) the account number and the CAMC admission number for each outpatient or inpatient participating in the study, to Patient Accounts, via facsimile at FAX No. 348-3726.

Note: If this information is not reported within three (3) working days of the patient's admission, the PI will be responsible for the patients' Non-Covered Charges. In addition, if the PI consolidates information for more than one Clinical Trial and fails to use the account number assigned to each respective Clinical Trial, the PI will be responsible for the patients' Non-Covered Charges.