The NCRR/NIH guidelines require the GCRC to charge an hourly rate for all industry-initiated studies. The guidelines further state that all services provided by the GCRC are to be reflected in the fees (i.e. program directorship, administration, bionutrition, nursing, core laboratory, informatics and biostatistical services, and space charges). In accordance with these guidelines, the GCRC is obligated to recover the cost of conducting research initiated by industry. The cost recovery requirement applies regardless of the scientific or clinical significance of the research.

- All industry-initiated research is subject to the same regulatory guidelines and requirements (IRB and other pertinent approval processes) and scientific standards as all other research conducted under GCRC auspices.

- When submitting an Industry-Initiated protocol to the GCRC Scientific Advisory Committee (SAC), investigators **MUST** include the IND number and the contract.

- To determine approximate costs, refer to the Industry-Initiated Budget Worksheet which can be downloaded from the GCRC website: [http://gcrc.med.cornell.edu](http://gcrc.med.cornell.edu).

- The inpatient rate reflects a space/room charge, normal food service and reasonable nursing time. Reasonable nursing time is dependent on protocol procedures and will be determined at the time of review.

- The rates do not include the following specialty fees:
  - Special dietary meals
  - Special nursing needs
  - Assays done by the Core Lab
  - Processing samples – spinning, labeling and storage
  - Informatics consulting
  - Biostatistical analysis

Please indicate your need for these services on your budget form and costs will be assigned by the Administrative Manager.

- Ancillary tests, pharmaceuticals and labs indicated on the SAC-approved budget will be billed at the standard NYPH rate. The GCRC is not responsible for billing of ancillary charges not listed on the SAC approved budget.

- To cover administrative costs (i.e., GCRC administrative staff time for SAC review and nursing in-service), a one time administrative fee of $500 per protocol will be reflected on the first invoice. This fee must be paid in full regardless of whether subjects are ever enrolled in a protocol.
Invoicing Procedures:

- Fees are due regardless of the outcome or evaluability of the case studies; investigators are advised to allow for dropouts in their budgeting process.
- The GCRC will invoice the investigator monthly for use of the outpatient GCRC. Payments are expected to be timely.
- All labs and inpatient admissions will be billed directly to the industry account. The investigator must provide the GCRC with an account number at the start of the study. Bed-days and ancillary services MAY NOT BE CHARGED TO GCRC ACCOUNTS for eventual reimbursement.