

TITLE: FISCAL MANAGEMENT OF RESEARCH PROTOCOLS

PURPOSE: To outline the process for fiscal management of research conducted within the University Health System's Institutional Assurance. This is a new policy. [Key Words: Research Proposal, Fiscal Management]

POLICY STATEMENT:

It is the policy of the University Health System to evaluate and determine the extent of its support, if any, for proposed research protocols based on the feasibility of providing the services or facilities requested, and the financial impact to the Health System of participation.

POLICY ELABORATION:

I. DEFINITIONS:

- A. "Investigator" is an individual who assumes responsibility for conducting a research study to develop or contribute to generalizable knowledge.
- B. "Institutional Assurance" is the documentation of an institution's commitment to comply with Federal regulations and maintain adequate programs and procedures for the protection of human subjects.
- C. "The Research Department" through its Clinical Research Coordinator, is responsible for developing and implementing a Human Protections Administration program and management of the billing for research with the assistance of the Financial Accounting Department.

II. FINANCIAL REVIEW AND IMPLEMENTATION PROCESS

A. All research proposals and contracts will be managed through the Department of Research with the assistance of Financial Accounting. The Research Department will facilitate the review of the proposals.

B. There are two Financial Categories of Research within the Health System:

Category A: Patient seen/admitted for medically indicated care but participating in research. The insurance carrier or patient is responsible for the costs of care including physician fees excluding that which is research and the cost of the research is the responsibility of the grant.

Category B: Patient / subject seen / admitted for research. The patient/subject is not responsible for any costs. All costs are the responsibility of the grant.

C. Each Department Director or Clinical Nursing Director will determine

- The expected cost/revenue associated with any participation in the research project beyond that which is required for the routine care of the patient to include additional labor costs
- For Financial Category B, the expenses for bed costs, supplies, staff time, tools and equipment and miscellaneous charges related to the study
- Rates that cannot be less than the actual cost to the Health System.
- Whether to recommend approval or disapproval based on the financial impact of participating in the study.

- D. When appropriate, and with the advice of the Health System Controller, approved research projects shall include indirect cost reimbursement to the Health System.
- E. The Research Coordinator will compile and summarize all review findings and the impact of the study on the Health System. An Agreement Template written by Legal Services will be utilized to outline Billable Expenses for each study. These expenses will be agreed upon by participating departments, the Clinical Research Coordinator, and the Investigator. A representative who can legally bind the Academic Institution will sign each agreement.
- F. The Research Department assisted by the Financial Accounting Department will provide specific identifying numbers for tracking of billable expenses which will be incorporated into the Agreement.
- G. When studies involve billable expenses, the investigator will provide the Research Department with the identification of each subject enrolled in the study to allow for a complete audit of all charges rendered.
- H. The Investigator is to ensure all charge tickets for research patients are clearly identifiable. Clinical Directors are responsible to ensure front staff personnel are knowledgeable about entry of charges for research participants in their department.
- I. The Research Department assisted by the Financial Accounting will invoice the account and address provided by Investigators on a monthly basis for services required by the protocol and provided by the University Health System.

III. GENERAL ISSUES

- A. The University Health System will comply with the requirements of OMB Circular A-133 and 45CFR Part 74 Appendix E.
- B. Annual statements of fiscal expenditure and revenue related to Research at University Health System will be provided to the CEO, CFO and the Hospital Administrator by the Clinical Research Coordinator.
- C. Research will not take precedence over the treatment of patients; outpatient appointment priority is given to treatment of patients.
- D. Physician's time utilized for research activities must be paid for by the grant or the Academic Institution. The Health System physician contracts are for patient care delivery.
- E. CareLink does not provide financial assistance for any research or investigational services, procedures or medications. The Executive Director and Medical Director of CareLink may authorize exceptions to this policy in situations that are determined to be in the best interest of the Health System and the patient.
- F. Inpatient research studies that require an extended length of stay (LOS) beyond the allowable LOS for their insurance will not be approved by the Health System.

OFFICE OF PRIMARY RESPONSIBILITY:

Associate Administrator, University Hospital