TITLE: FISCAL MANAGEMENT OF RESEARCH PROTOCOLS

PURPOSE: To outline the process for fiscal management of research conducted within the University Health System’s (Health System) Institutional Assurance. This supersedes policy dated 7/22/03. [Key Words: Research, Proposal, Fiscal Management]

POLICY STATEMENT:

The Health System will 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 of participation to the Health System.

POLICY SCOPE:

This policy covers requests to conduct research from non-Health System parties, including academic institutions, consultants, and community groups.

POLICY ELABORATION:

I. DEFINITIONS

A. Research – a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. (See, 45 CFR 164.501 for a complete regulatory definition.) This may include, but is not limited to, clinical investigations, patient, provider or employee surveys, medical record reviews, comparative effectiveness investigations, and process improvement projects. This definition supersedes the Internal Review Board definition of research.

B. Investigator - an individual who assumes responsibility for conducting a research study to develop or contribute to generalizable knowledge.

C. Institutional Assurance - the documentation of an institution’s
commitment to comply with federal regulations and maintain adequate programs and procedures for the protection of human subjects.

D. **CareLink** – A financial assistance program operated by the Health System for eligible Bexar County residents.

II. **RESPONSIBILITIES**

A. **Clinical Research Department**

1. All research proposals submitted to the Clinical Research Department are subject to review, fiscal impact analysis, and approval before research activities begin. The Vice President of Community Initiatives and Translational Research will approve all studies.

2. All research proposals and contracts will be managed through the Clinical Research Department, under the Vice President of Community Initiatives and Translational Research.

3. The Clinical Research Department, through its Clinical Research Director, is responsible for developing and implementing a Human Protections Administration program and management of the billing for research with the assistance of the Manager, Research Operations.

4. The Research Department will facilitate the review of the proposals through all Health System departments affected by the proposed research.

5. The Clinical Research Director will compile and summarize all study review findings and the impact of the study on the Health System resources.

6. The Clinical Research Department will coordinate research billing and provide identifying numbers for
tracking of billable expenses, and a schedule of charges, which will be incorporated into the Research Agreement and contract.

7. The Research Department staff will invoice study accounts monthly for services rendered. Charges are based on research activities and reports as required by the contract, and provided by the Health System.

B. Research Impact Committee

1. The Research Impact Committee will comprise representatives from Clinical Research and any other Health System department directly impacted by research activities per the research protocol. The vice president directly responsible for a department impacted by research will be involved in the approval process.

2. The Research Impact Committee Chair will be the Vice President of Community Initiatives and Translational Research, who will coordinate meetings. The Research Impact Committee will meet periodically based on the volume of incoming research requests.

3. The Director of Clinical Research will receive, review, date and assign research impact analysis requests to the appropriate member(s) of the Research Impact Committee for their specific recommendation regarding the impact of the research protocol and the cost to the Health System. The Research Impact Analysis will be summarized by the Director of Clinical Research and presented to the Research Impact Committee for review and recommendation.

4. Working together, the committee chair and department directors will determine

a. The expected clinical impact 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 to be billed to the study team.

b. Expenses for bed costs, supplies, staff time, tools and equipment and miscellaneous charges related to the study.

c. Development or changes to research orders.

d. Changes to fees for research services by department. These will be reviewed annually, and updated fee sheets will be posted on the Research Web page.

e. Whether to recommend approval or disapproval based on the financial impact of participating in the study.

5. The committee chair will develop a memorandum to the requestor that will include the committee’s recommendation.

6. If the study is approved by the committee, the Director of Clinical Research is responsible for preparing the research agreements for research requestors and the Health System. The research agreement will include the estimated impact to the Health System by department and procedure, and the corresponding estimated fee associated with the research protocol by department.

7. If the approved study is defined by the Impact Committee to be a process improvement, associated fees may be waived. The vice president directly responsible for a department impacted by the process improvement will be involved in the approval process.

8. If a grant or research study is amended or extended, the
vice president directly responsible for the area impacted must be notified for his or her approval.

9. The Health System President/CEO, or designee, serves as the contracting officer for the Health System. No other department or individual is authorized to contractually obligate the Health System to fulfill research agreements.

III. FINANCIAL REVIEW AND IMPLEMENTATION PROCESS

A. There are three financial categories for research within the Health System:

1. The patient is seen/admitted for medically indicated care, but is participating in research. The insurance carrier or patient is responsible for the costs of care, including physician fees exclusive of that which is research. The cost of the research intervention is the responsibility of the Principal Investigator per the signed Research Agreement.

2. The patient/subject is seen/admitted for research only. The patient/subject is not responsible for any costs. All costs are the responsibility of the Principal Investigator per the signed Research Agreement.

3. Research studies associated with patient, provider, or employee surveys, or other activities are deemed as research by the Health System and do not involve direct patient care. Facility Charges will be estimated and applied according to time and space required to conduct research activities. All costs are the responsibility of the Principal Investigator per the signed Research Agreement.

B. Research administration fees will be applied to all research studies approved and conducted in the Health System at $750/study. Research requiring information technology support
will require an additional setup fee of $250/study.

C. All research fees are subject to increase based on annual market adjustment.

D. When appropriate, and with the advice of the Health System Grants and Applied Research Department, approved research projects will include indirect cost reimbursement to the Health System.

E. An agreement template written by Legal Services will be utilized to outline billable expenses for each study based on the impact study. These expenses will be agreed upon by participating departments, the Clinical Research Director and the Principal Investigator. A representative who can legally bind the academic institution will sign each agreement.

F. When studies involve billable expenses, the investigator will provide the Clinical Research Department with the identification of each subject enrolled in the study to allow for a complete audit of all charges rendered using the Research Activity Billing Trigger report (RABT) provided by the study investigator.

G. The Principal Investigator will ensure all research services are reported monthly to the research office using the RABT, and research EMR orders are utilized so research patients and procedures are clearly identifiable.

H. Health System clinical directors are responsible to ensure frontline staff personnel are knowledgeable about entry of charges for research participants in their department.

IV. GENERAL ISSUES

A. The 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 the Health System will be provided to the CEO, CFO and the hospital administrator by the Clinical Research Director.

C. Research will not take precedence over the treatment of patients; outpatient appointment priority is given to treatment of patients.

D. Community Medicine Associates (CMA) physician time utilized for research activities must be paid for by the grant, sponsor or academic institution. The Health System physician contracts are for Health System departmental services or patient care delivery only.

E. CareLink does not provide financial assistance for any research or investigational services, procedures or medications. The CareLink Executive Director and Medical Director 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.

REFERENCES/BIBLIOGRAPHY:

Health System Policy No. 9.01, Protection of Human Subjects in Research and the Conduct of Research within the University Health System

Health System Policy No. 2.10, Fraud

Health System Policy No. 2.11, Compliance Programs

OFFICE OF PRIMARY RESPONSIBILITY:

Vice President, Community Initiatives and Translational Research