

**Department of Medicine
Corporate Clinical Trial Budget Policy**

February 26, 2003

Regulatory Environment for Policies on Research Programs at MUSC:

OMB Circular A21 (Time and Effort, Allowable Costs, Accounting)

46 CFR 9903 (Cost Accounting Standards Regulations-CASB)

MUSC's Office of Research Policies (Research;Humans/Animal;Budgets;Administration)

MUSC's Grants and Contracts Accounting Office

Compliance:

Necessary for continuing research activities; avoiding fines and penalties; avoiding negative impact on indirect cost rates; avoiding dis-allowances; maintaining institutional integrity and reputation.

Corporate Clinical Trials:

MUSC's published policy in 1998 Cost Accounting Disclosure Statement;

Compliance with A-21 Time and Effort Reporting;

Managing studies within the framework of the regulations;

Department of Medicine Policy on Clinical Trials:

Compliance with Institutional and Federal Policies.

MUSC policy requires reporting and charging of "actual" effort by Personnel (including PIs) on a current basis. MUSC's Effort system requires actual (sponsored research) effort (including hands on and supervised effort) reported each quarter, and this effort is either charged to the respective grant budget, or to a "cost share" budget in a timely manner.

MUSC policy requires the use of combined institutional base salary (MUSC and UMA base salary) for charging investigator effort to corporate studies.

The Principal Investigator and the Division Director are given the responsibility of determining the relative value and cost of a corporate study. They propose a study budget to the Department Chairman for approval. Appropriate estimated investigator effort is budgeted for the study. The Department of Medicine suggests that for planning at least 10% of the direct cost estimated budget for the study should be allocated toward investigator(s) support for corporate clinical trial studies. Exceptions are considered on a case by case basis. As stated above, MUSC requires actual effort for personnel involved in these studies.

Investigators are responsible for monitoring their studies to avoid cost overruns that cannot be covered by residuals from the investigator's other studies. The investigator provides the Division Director with a quarterly summary of study status for each study (including a categorical financial summary of budget and actual expenses). The Division Director reviews the report, and determines if any action is needed with regard to study finances.

The Division Director provides the Department Chairman a quarterly report listing active studies in the Division, status of each study, and a categorical budget summary for each study.

Completed studies are closed, and the investigator makes arrangements for any cost overruns. Residual funds are distributed to the investigator's residual study funds with the approval of the Division Director in accordance with MUSC's Clinical Trials Cost Accounting policy.

