

April 1, 2009

KUMC Department of Biostatistics
KUMC Center for Biostatistics and Advanced Informatics
913-588-4703

TO: Principal Investigators Seeking Biostatistical Support

FROM: Matthew S. Mayo, PhD, MBA
Professor and Chair
Dept. of Biostatistics, Center for Biostatistics and Advanced Informatics

RE: *Department and Center Budget and Invoicing Policy for *Privately Sponsored
Investigator- Initiated Research*

The Department of Biostatistics, through the Center of Biostatistics and Advanced Informatics (CBAI), works to enhance investigator-initiated research conducted on this campus. Federal and not-for-profit sponsored projects are our highest priority; however, we are willing to support the development and conduct of privately-sponsored research. It must be emphasized that 90-100% of the Department/CBAI costs associated with our services are fixed, regardless of patient accrual. The complexity of the study is the main determinant of the budget regardless of patient accrual. Therefore, **the budget cannot be assembled based on a per-patient basis**. For example, with respect to database development, the Department/CBAI is required to take the same steps to create a database regardless of whether the Principal Investigator (PI) enrolls 10 patients or 50 patients. Typically we do not charge for study development, and as collaborators on the project, we expect a level of support that is in line with the scope of the study and the services needed to conduct the study. However, if the investigator and/or sponsor do not want CBAI support during the conduct of the study or if the final budget does not allow for this support, then we will invoice for the time in the development process by departmental faculty and staff.

Prior to any formal discussions with the Department of Biostatistics faculty and/or staff, the PI must submit a project registration form online, using the following link:
<http://biostatistics.kumc.edu/projectReg.aspx> When this is submitted, project details will be assessed, the current resource allocation taken into consideration, and the department administrative staff will contact the investigator(s) and identified departmental faculty and staff

to schedule an initial meeting. The initial meeting with identified personnel is a required step, one necessary to better assess the scope of the project, deadlines/timelines and to determine appropriate budgets. Please note that the budget submitted to the project sponsor or funding agency must include a fixed cost payment for biostatistical services. Projects that faculty and staff are requested to participate in must be approved by Dr. Mayo.

As previously stated, the budget will be created based on the assessment of needs from the initial meeting. Wendy Anderson, Associate Director of Finance and Administration, Department of Biostatistics, will provide the PI a detailed budget as a fixed, flat fee cost that must be paid regardless of enrollment size, source of funding, or continuing funding by the project sponsor. Any questions related to the budget, prior to submission, should be directed to Ms. Anderson, which may require further meetings/discussion. There are two invoicing options available: Option one is to submit an invoice for 100% of the budget to the Research Institute upon receiving the executed contract; option two is to submit an invoice for 75% of the budget to the Research Institute upon receiving the executed contract and submit an invoice for the remaining 25% to the Research Institute one year later.

If you have any questions about this policy, please contact Ms. Wendy Anderson at 913-588-4706 or wanderson@kumc.edu.

Sincerely,

A handwritten signature in black ink, appearing to read 'Matthew S. Mayo', with a long horizontal flourish extending to the right.

Matthew S. Mayo

*Privately Sponsored = for profit funding agency (e.g. pharmaceutical company, biotech company, etc.).