BUDGET GUIDELINES

Please note: These guidelines are intended to provide helpful information to Brody School of Medicine (“BSOM”) study personnel. Clinical Trials Working Group members including staff from the Office of Sponsored Programs, Brody Financial Services and Grants & Contracts Administration will assist you in finalizing a contract that will agreeable to the University, the sponsor, and to you and your department.

The sponsor may ask you to develop a budget for their review, or the sponsor may quote a budget amount allocated to each site and ask you to work within it. In the latter case, the quoted amount may be adequate, or even generous; but this is not usually the case. After gathering the figures and getting written approval by the Clinical Trials Working Group, you will negotiate a budget with the potential sponsor (as stated above, assistance can be provided if you require it). Please note that this approved internal budget is the actual cost to do the study. Every effort should be made to maximize financial returns to the university.

Almost always you will be able to reach a reasonable compromise, but occasionally it may be necessary to turn down a study because of an inadequate budget offer.

- **Gather Information**: Review the protocol in detail. Make a complete list of all the required procedures, tests, patient visits, examinations, etc. to guide your thinking. It may be helpful to compare your flow sheet to the sponsor's flow sheet or "Schedule of Events," if one has been included in the protocol.
- **Be sure you understand**: Exactly what is required at each patient visit? This is not always clearly explained in the protocol. Before you build the budget, either attend the investigator's meeting hosted by the sponsor or call the sponsor with specific questions.
- **Verify Prices**: Call the various university and hospital departments to determine prices for each protocol requirement. This is a critical step in building an accurate budget.
- **Start-up Fees**: Include start-up fees as a line item in your budget. Consider making the start-up fees non-refundable. Start-up costs are distinct from the costs of protocol-related procedures and include, for example: the staff and investigator preparation time for the IRB application and protocol review, feasibility assessment, and budget development, time spent away from work at the investigators' meeting, Pharmacy fee, and record storage. When it is time to begin budget talks with your sponsor, discuss your rationale for including non-refundable start-up fees, and be prepared to negotiate. Some investigators have, over time, developed a standard start-up fee, others do the math on each protocol and ask the sponsor to cover start-up fees specific to that protocol.
- **Personnel Costs**: Think carefully about personnel costs. This is the category most likely to include hidden costs. Although your study may be entitled "A Six-Month
Double Blind, Randomized Study To Compare the Efficacy of Drug A with Drug B," study staff will be involved much longer than six months. Study staff will spend significant reimbursable time with start-up tasks such as IRB submission, budget development, routing package, patient recruitment, and patient consent. Consider closeout tasks such as data clean up and sponsor queries. Look behind the study "label". Although a study visit may be labeled as a "blood draw," associated staff time may also include telephone reminders, call-backs, tube setup, lab paperwork, Case Report Form (CRF) entry and filing. Consider staff time associated with patient screening costs -- you may need to screen five patients in order to find one who can be randomized. Visits by study monitors will consume staff time and may occur several times during the trial. For all appropriate staff (P.I., the study coordinator, and administrative support) list both salaries and benefits.

- **Patient Costs**: Include appropriate patient costs such as stipends or reimbursements for travel and parking.
- **Screen Failures**: Look carefully to see how the sponsor proposes to pay for screening failures. Aside from the personnel costs already mentioned, screening may also include expensive tests, and failures should be paid at a prorated amount. Be sure that the sponsor understands that you expect to be paid for work performed.
- **Protocol Revisions/Ammendments**: Discuss with the sponsor, in general terms, how future protocol revisions will be handled. Be sure you are paid for these revisions. Ordinarily such revisions can be anticipated, and they can consume significant time and expense. Procedures or patient visits may be added to the protocol, carrying both their own costs and associated administrative costs. Include a "contingency" provision in your budget stating that if these revisions occur, the sponsor will pay for them. Do not accept contract language that from the outset includes a "cap" on the budget.
- **Budget Comparison**: Refer to the sponsor's suggested budget (if provided) only after you have developed one of your own. Be sure that the total contracted amount covers your costs.
- **UMCIRB Review Fee**: Include this fee as a separate line item in budgets for all new industry-sponsored clinical trials. This fee is non-refundable.
- **Indirect Costs**: Don’t forget to add the current Facilities and Administrative percentage required for clinical trials.
- **Separate Accounts**: Do not promise to set up separate study bank accounts outside of the BSOM’s established procedure for creating study accounts.

**BEST PRACTICES FOR DEVELOPING A PAYMENT SCHEDULE**

- **Proposed Payment Schedule**: Read the proposed payment schedule in the sponsor's contract. Make sure that you understand the proposed payment schedule, and analyze its impact on your study. If the payment schedule seems almost impossible to understand, it's likely that the sponsor doesn't understand it, either, and that it will be unworkable for both of you. Consider writing and negotiating your own payment schedule.
• **Up Front Payment**: Ask for an upfront payment, payable upon execution of the agreement, not upon study initiation or patient enrollment. If you have negotiated a start-up fee, be sure to include it as part of the upfront payment. The upfront payment helps not only to cover your start-up costs but also to cover early study events such as patient recruitment and screening. Consider carefully the size of the upfront payment that you will require in order to keep afloat until interim payments are due. (Check with your department first because it may have its own policies for the amount of upfront money required.) Remember that if you don't request payment at execution of the contract, you will incur both start-up expenses and patient expenses before being reimbursed. Do not agree to clauses requiring interest payments be made back to sponsor on any upfront/initial payments or other payments.

• **Written Reminder**: Consider sending to the sponsor a written reminder for the upfront payment after the contract has been signed. Without such a reminder, the sponsor may overlook this obligation, even though you have included it in the contract.

• **Reimbursement for early termination**: Ask for reimbursement of actual, reasonable start-up costs if the trial is terminated prior to initiation at your site or to enrollment of the first patient at your site.

• **Interim Payments**: Negotiate the interim payments to fit the protocol and your particular situation. If 90% of the work is done in the first two months of a twelve-month study -- or if expensive procedures are scheduled early in the study, get paid accordingly. Interim payments are usually tied to milestones such as number of "enrolled," "completed," "randomized," or "evaluated" patients. Discuss with the sponsor the meaning of these terms, and consider the impact on your cash flow. Other milestones for interim payments may be determined by the number of completed patient visits, by monthly schedule, or by a hybrid of the above. Remember that it can take weeks for the sponsor to process a payment after they have ascertained that your milestones have been met. To avoid payment problems caused by sponsor monitoring delays, you might consider setting up a payment schedule by which you bill the sponsor as the work is performed.

• **Overestimating Enrollment**: Do not overestimate, for the purpose of ensuring a comfortable cash flow, the number of patients you can enroll. The success of the sponsor's overall study plan depends on accurate enrollment estimates at each site. If your patient recruitment does not closely match your estimate, you will lose credibility with the sponsor, and the sponsor may go elsewhere with future trials.

• **Document Tracking**: Keep track of which records the study monitors have reviewed during their site visits. Because interim payments may be generated from the study monitor's review of your case report forms, this parallel tracking will help to assure that you are paid correctly.

• **Final Payment**: Discuss with the sponsor how the final payment will be triggered. Consider again the study protocol and your specific situation. The sponsor may, for example, want to withhold a substantial percentage of the total budget until it reviews and approves all case report forms (CRFs). This may take additional weeks or months. After the study is completed at your site, the sponsor will have collected your completed CRFs, so the sponsor may be less motivated to
pay promptly. It is also possible that the sponsor will choose to review your forms only after the study is over and close-out has occurred at all sites. Therefore, you may want to ask for the final payment (perhaps 20 percent or more of the total budget) when you submit your completed CRFs to the sponsor. Again, this is a negotiable item. Communicate your needs to the sponsor and prepare to compromise, as necessary.

EXAMPLES OF PAYMENT SCHEDULES

- **Best payment schedules**
  - For work completed (Define work completed. Sponsor's scrutiny? Your finish?)
  - Monthly payments
  - Invoiced

- **Above Average payment schedules**
  - Initial payment
  - Initial payment deducted from subsequent earned income

- **Good payment schedules**
  - Averaged payments
  - Payment by milestones, e.g., number of visits completed

- **Bad payment schedules**
  - Percent of total contract withheld until end of study
  - Reimbursements withheld until end of study at all sites
  - No regular payments, no regular milestones
  - Interest payments to sponsor on upfront/initial payments