

## BUDGET GUIDELINES

**Please note:** These guidelines are intended to provide helpful information to Division of Health Sciences (“DHS”) study personnel, as well as to those ECU study personnel outside of the Division who are conducting clinical trials. The Clinical Trials Office will assist you in finalizing a contract that will be agreeable to the University, the sponsor, and to you and your department.

If this is an investigator-initiated study, 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 Clinical Trials Office, you may further negotiate budget details 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 cover all costs to the University. PI is responsible to cover any deficit.

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. However, Schedules of Events are not always complete. Differentiate standard of care tests and procedures from those which would not be performed if it were not for participation in the trial. You cannot charge the sponsor for tests and procedures which are also being charged to the trial participant's insurance, Medicaid or Medicare. When preparing your budget, calculate based upon the number of subjects you expect to enroll.
- **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. ECU and PCMH cannot charge the sponsor and the participant's insurance/Medicaid/Medicare for the same fees.
  - For drug trials or trials involving biologics, it is very important to determine whether the trial will be a “qualifying clinical trial” for Medicare purposes. If the trial is not a “qualifying clinical trial,” neither BSOM nor PCMH is permitted to bill Medicare for items or services that are “routine costs” even if those items or services would be considered “standard of care” if provided absent the clinical trial. See the Financial Services Review Form for further instructions at [www.ecu.edu/irb/FormsListAll.htm#GeneralForms](http://www.ecu.edu/irb/FormsListAll.htm#GeneralForms)
  - For device trials, it is important to determine whether the investigational device will be provided free of charge by the sponsor or whether it will be billable to Medicare or any other payer. It is also important to determine if items or services provided as part of the device trial will be paid for by the sponsor or the payer. Typically, if an investigational device has an Investigational Device Exemption (“IDE”) number, the standard-of-care costs associated with the conduct of the trial are covered by third

party payers. However, you should confirm this with the Sponsor. If the devices are not being provided by the sponsor free of charge, third party payers will often cover their cost. However, you should also confirm this with the sponsor and the third party payers. You should determine if it is a qualifying trial. If your conclusion conflicts with that of the sponsor, work with the sponsor to determine which is correct.

- **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, budget development and time spent away from work at the investigators' meeting. Pharmacy fees and record storage are often separate invoiceable fees which should be captured in the budget. Some sponsors may include them in the start-up fees. Any invoiceable fees should be included in the internal budget worksheet. 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 (PI, the study coordinator, and administrative support) calculate salaries with 24% benefits and 4% cost-of-living adjustment. **The highest paid PI and study coordinator should be used when preparing the internal budget.**
- **Unscheduled Visits:** Some sponsors include reimbursement for unscheduled visits; others are willing to do so if asked. If the nature of the study indicates a strong possibility for unscheduled visits, try to negotiate reimbursement. More often than not, fees for unscheduled visits are payable by invoice.
- **Patient Costs:** Include appropriate patient costs such as stipends or reimbursements for travel and parking. This should only be included if the sponsor agrees to pay stipends. Otherwise, the stipend funds will be taken from other areas of your budget.
- **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.
- **Local SAEs and IND Safety Reports:** If you expect numerous IND Safety Reports and local serious adverse events (SAEs) are a reasonable possibility, you should request payment for processing the associated reports. Although an individual IND Safety Report may not require a lot of time to process, one hundred of them will. Also, local SAEs can take a

tremendous amount of time, and unless this cost is captured in the budget, it will likely never be recovered.

- **Protocol Revisions/Amendments:** 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, including IRB submission and time to re-consent active study participants. 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 these fees (initial review, review of amendments and continuing review) as separate line items in budgets for all new industry-sponsored clinical trials. These fees are non-refundable. Facilities and Administrative (F&A) costs are charged against IRB fees.
- **Indirect costs:** Don't forget to add the current Facilities and Administrative percentage required for clinical trials. The F&A rate for clinical trials is currently 26%.
- **Separate accounts:** Do not promise to set up separate study bank accounts outside of the DHS'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. **The CTO Office typically negotiates this in the contract language, but PI/Coordinator input is welcome.**
- **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:** Send the sponsor a written reminder for the upfront payment after the contract has been signed. Without such a reminder/invoice, 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. The CTO Office typically negotiates this in the contract language, but PI/Coordinator input is welcome.

- **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. The CTO Office typically negotiates this in the contract language, but PI/Coordinator input is welcome.
- **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.
- **Financial Tracking:** In conjunction with the records tracking throughout the life of the study, monitor payments received and payments due to assure that you have received all appropriate proceeds of the study. Send follow-up reminders/invoices when payments have not been received within an appropriate period (60 days). **This is a coordinated effort between the coordinator and finance tech.** **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. (The CTO Office typically negotiates this in the contract language, but PI/Coordinator input is welcome.) Submit a follow-up reminder/invoice when the final payment has not been received within an appropriate period (60 days). **This is a coordinated effort between the coordinator and finance tech.**

## 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
  - Payments withheld until end of study at all sites
  - No regular payments, no regular milestones
  - IRB and pass-through costs not separately billed/paid; included in rate
  - Interest payments to sponsor on upfront/initial payments