

University of Rochester Budget Guidelines for Industry-Sponsored Clinical Trials

The following is intended as guidance in the establishment of industry-sponsored clinical trial budgets, and is reflective of the requirements of the University of Rochester Medical Center. Proper allocation and monitoring of clinical trial expenditures, as well as close-out, are also discussed. For the purposes of this document and the recommended guidelines, a “clinical trial” is broadly defined as the testing of a drug or device on human subjects.

While this document focuses primarily on the budgetary aspects of industry-sponsored clinical trials, it should be noted that the other compliance issues intrinsic in clinical studies (IRB approval of the protocol and consent form) should be resolved in parallel to the budget process. Medical Center faculty, study coordinators and administrators should use this guidance in conjunction with the *RSRB Investigator’s Manual* and the *ORPA Manual* for the proper administration of clinical studies. Any questions with respect to these guidelines may be directed to ORPA (x5-5373).

A. Budget Preparation

Budget preparation and negotiation are primarily the responsibility of the Principal Investigator (PI); however, several factors must be considered. The PI is usually presented with a per patient cost that the pharmaceutical company feels is fair and reasonable for the conduct of the study, and a payment schedule. The PI must consult with his/her Department/Unit PRIOR to agreeing to a per patient amount. (Note that the Department/Unit should notify ORPA as soon as possible as well, so that contract negotiations may proceed in a timely manner. ORPA is also available to assist in budget negotiation if necessary.)

The PI and Department/Unit must carefully review the protocol to ascertain whether the per patient amount is adequate to cover all trial expenses. If Departments require assistance with this assessment, assistance can be obtained from the Clinical Research Institute, (x5-5244). Similarly, payment schedules should minimize cash deficits and be set at realistic milestones. Clinical trials budget negotiations should consider the following programmatic components that incur costs (i.e., personnel, supplies, materials, etc.):

Pre-Trial Planning

- Pre-Enrollment Activity (protocol development and acceptance, surveillance, IRB submission, budget preparation, etc.)
- Recruitment and Enrollment (pretreatment costs, screening, payment to patients, etc.)
- Pharmacy (at this time, the Pharmacy charges a \$500 study management fee for all industry-sponsored studies, in addition to per patient charges. Please contact the Pharmacy for information.)
- Laboratory Studies (including the CBC, SMA-12, X-ray and other laboratory studies required by the protocol)
- Conduct of the Study (administration of drug/treatment, testing, monitoring, etc)
- Case Report Preparation and/or Acceptance
- Statistical Analysis
- Administrative Support (Department/Unit administration, protocol review, secretarial assistance, etc.)
- IRB Fee - Required
- Indirect Costs (25% of Total Direct Costs less IRB fee) - Required

Attached is a budget checklist to be used as a tool for developing an internal budget for study costs. If it is determined that the per patient amount does not cover the costs of the study, a higher per patient rate should be negotiated with the sponsor. If such a rate can not be negotiated and the PI still wishes to proceed with the study, then the Department/Unit and Dean’s Office must agree that cost sharing of the study is appropriate and the Department/Unit must identify where the unrecovered costs will be absorbed. **Please note that cost sharing is normally not encouraged and will be reviewed on a case-by-case basis. In no instance can a study be subsidized by Federal or other restricted funding, including Medical Center practice accounts.** Approval to cost share a clinical study is obtained via the University Proposed Cost Sharing Commitment Form.

Once the per patient amount is found to be acceptable to the Department/Unit (and Dean’s Office if cost sharing is involved), contract negotiation can proceed. Note it is the University, rather than the PI, that will make the decision on the acceptability of the contract agreement, including all provisions covering publications, intellectual property, confidentiality and liability. ORPA, in consultation with the PI, Department/Unit, Clinical Research Institute and Legal Affairs when necessary, maintains this responsibility.

B. University Sign-Off

Clinical trial documentation can go through University Sign-Off at the time that the protocol and the per patient budget have been determined. The per patient budget, along with a statement of the work scope or description of the protocol as submitted to the IRB (generally NOT a copy of the protocol as that may be considered company-confidential), must be routed through University Sign-Off prior to the start of the study. Sign-Off is completed using the Sign-Off Form for Industry-Sponsored Clinical Trials. **The clinical trial agreement will not be signed and, therefore, the study may not begin, until University Sign-Off has been completed.**

Sign-off Form for Industry-Sponsored Clinical Trials - <http://www.rochester.edu/orpa/forms>

Departments/Units normally require the PI to present an internal-to-the-University budget for the study. The internal budget for Department/Unit review should indicate the estimated costs of conducting the trial, taking into account the types of program elements noted above. **The Department Chair is ultimately responsible for the review of the description of the protocol and study budget, inclusive of any back-up documentation necessary for the substantiation of proposed expenses.** While there is no specified format for the internal budget, it should provide sufficient information in order to assess whether the costs of the trial are covered; a sample budget and budget checklist are attached. The internal budget may vary from the estimated income. For instance, personnel costs should indicate percentage of effort for the individuals working on the trial and the corresponding salary and benefit charges. While it may not be possible to provide the names of individuals, the budget should reflect adequate staff time for the purposes of conducting the study (i.e., Study Nurse, 50% effort, \$xx,xxx). Testing expenditures should reflect the total cost of all tests necessitated by the trial. All other costs (i.e., consultants, travel, office and communication expenses, pharmacy, biostatistics, case report preparation, and respondent honoraria) should be identified. It is especially critical to coordinate study costs with other Medical Center offices and labs that will be utilized during the course of the study. The clinical trial indirect cost rate of 25% of total direct costs must be applied. (Note that the University of Rochester's research indirect cost rate is 59% on a modified total direct cost basis.)

C. Allocation and Monitoring of Clinical Trial Expenditures

Ledger 5 account numbers are requested upon receipt of a fully-executed contract from the pharmaceutical company; the Department/Unit is notified of the account number by ORPA. Contingent account numbers may be requested; however, these will only be approved in rare situations and the study may not begin until the contract has been signed. A Sponsored Programs Award Notice (SPAN) will not be issued (and thus a budget will not be set up) until the start-up payment has been received.

Expenses should be charged to the clinical trial account as soon as practicable. It is understood that the account may initially have a deficit until the first payment is received and booked. Once a study is underway, on-going costs should be charged appropriately to the account. At this time, patient enrollment can be reasonably predicted. There may, however, be short-term deficits in the interim period of the study as expenditures will fluctuate with case (patient) income.

Appropriate salary costs should be captured in clinical trial accounts as soon as feasible. When the percent of effort devoted to a study is minimal (less than 3%) and not allocated to the clinical trial account number, the person's distribution to other accounts should be adjusted to properly reflect the clinical trial activity. For instance, any personnel participating in a clinical trial can not be listed as 100% effort on another sponsored project account.

Clinical trial monitoring includes not only a review of ledgers for the current period, but close coordination between the Department/Unit, the PI, and the Study Coordinator. The Department/Unit should have a good handle on patient enrollment and a reasonable assessment of the progress of the study. Only in this way can "real" deficits be avoided. Department/Units should:

- closely monitor earned income and actual trial expenditures
- be aware of patient enrollment and the timeliness of case reporting
- make adjustments to the project expenses if/when patient enrollments vary significantly from the budget, i.e. reduce expenses, if supporting revenue does not develop

Note: The PI and Department/Unit are ultimately responsible for assuring that the original internal budget is used as a guideline for charges which are allocated to the ledger 5 account.

In summary, the following practices should be followed by the Department/Unit in administering clinical trial accounts:

- charge clinical trial costs to the appropriate ledger 5 accounts as soon as possible to avoid excessive cost transfers
- staff effort, including that of the Principal Investigator, should be properly allocated to the clinical trial ledger 5 account. If effort is less than 3%, this effort should be normally associated (cost-shared) with a non-ledger 5 discretionary account
- communicate with Study Coordinators and Principal Investigators in order to assess the trial's progress and budgetary impact
- bill third-party payers only for routine tests that would have been done regardless of the trial

D. Account Close-Out

The University's Sponsored Programs Accounting *Non-Federal Clinical Trial Close Out Procedure* is attached. To ascertain whether all costs have been applied, the same steps are followed as in monitoring costs during the trial.

Any balance left at the end of a trial should be used to further the educational, research or clinical missions of the Department/Unit. As stated in the attached document, close-out review by the Dean's Office is required if the balance is greater than 25% of the total study budget. The close-out review by the Dean's Office includes a comparison of budget to actual expenditures and a determination that the balance is reasonable. The Department/Unit should be prepared to explain significant variances, and to provide the certifications called for in the close-out procedure.

In the case of larger trials that exceed three (3) years and \$250,000 in direct costs, arrangements may be made to transfer account balances throughout the life of the trial, upon completion of specified milestones or programmatic components. Transfers will be made on a case-by-case basis after approval by the Department/Unit Chair and Dean's Office.