

Industry Sponsored Research Procedures for Study Initiation and Performance

Pre-Study

1. Prepare and review budget with accountant. Mutually assess areas of potential oversight or omission.
2. Review final study agreement (contract). Identify payment milestones and payment schedule.
3. Design patient enrollment/payment due log to properly request reimbursement when due.

During Study

1. Review budget reports. Ask about discrepancies or areas of concern.
2. Review pre-payments and net balance subject to refund.
3. Review invoices (e.g. Investigational Drug Pharmacy, labs)
4. Submit participant log sheet to accountant.
5. Submit time sheet to accountant.

Post-Study

1. Review study activities (CRF audits, etc.)
2. Identify expected payments due and residual outstanding charges.
3. Review residual balance, if any, and prepare final financial report.
4. Meet with the accountant to initiate study close-out.

Budget Preparation

- The PI and/or Study Coordinator should use the Budget Worksheet to determine an accurate reflection of the study costs (including start-up and close-out costs). This worksheet is an internal document which will assist the accountant in preparing the final budget. This is only a template that can be modified to meet specific study requirements. The accountant will then use this template to convert for effort and prepare the University budget.
- The faculty member's total salary (University and UMP) will be used for budget calculation.
- The level of effort must be approved by your Division Director. This is done by the Peer Review Form.

Charging the grant

- Upon receipt of initial payment, all start-up costs will be charged to the grant, including PI and coordinator time.
- PI salaries will be charged to the grant on a quarterly basis as revenues are received.
- Study Coordinators should complete a time sheet so that hours are charged appropriately. Completed time sheets should be turned in to the accountant.
- All other charges will be charged to the account as they are incurred, regardless of revenue received.

Revenue Collection

- At the beginning of the study, meet with the accountant to review the final contract and design "Study Participant Log Sheet".
- Submit log sheet to accountant monthly. They will work with Sponsored Financial Reporting to collect any outstanding balances.

Grant Close-out

- When study has been completed, the PI should meet with the accountant to initiate study close-out.
- Any balances at the end of the project will be transferred to a fixed price account no later than 6 months after receipt of final payment.
- PI's receive monthly account balances including identification of any pre-paid revenues not earned by actual accrual and thus, subject to refund to study sponsor.
- Any deficits at close out are the responsibility of the PI, regardless of the reason.