

Budget 15% Overhead Breakdown

This overhead charge is accurate and charged the same to all Sponsors. This charge is somewhat negotiable.

Administrative Costs

- Development/revision and training of site SOP's
- Attendance at weekly staff meeting (review of protocol, IND safety reports, recruitment issues, protocol amendments and SOP training)
- Weekly review of enrollment logs
- Quality Assurance internal review
- Budget/Contract Development/ Processing
- IT support

Study Conduct Costs

- Regulatory Document Preparation
- Continual training in ICH and GCP guidelines (provided through workshops/webinars)
- Development of study specific source document worksheets
- Submission of all required regulatory documents to sponsor and/or designated IRB
- Development of a Recruitment program that is study specific
- Investigator and CRC compensation for attendance at Pre-Study Visit, Initiation and Investigator's Meeting.
- Principal Investigator time for other study related activities other than patient evaluations (i.e. laboratory results reviews, amendments, IND safety reports, AE's, weekly case report form review, training Sub Is on protocol procedures/amendments)
- Compensation for the loss of office revenue due to cancellation of practice patients during attendance at the pre-study, initiation and Investigator's Meeting
- Cost of prescreening of patients through chart review, laboratory results monitoring and patient phone contact (CRC time which is usually grossly underestimated in the main body of the budget)
- IRB contacts; regulatory document filing, SAE's, amendments, interim and annual reviews.
- CRF/EDC completion and Regulatory Binder Maintenance.
- Coordinator time during monitoring visits, both on site and remote phone visits
- Timely completion of data clarification forms (request of turnaround time has become 24 to 48 hours from sponsors).
- Principal Investigators review and reconciliation of source documents to data clarification forms.

Site Specific overhead costs

- Rent Accountant Business Development
- Office Supplies
- Utilities
 - Building maintenance and security
 - Janitorial services