

Personnel Time Calculator

Job Description and Tasks	Staff Personnel	Salary	Time	Total
Review Protocol				
Facilitate Site Selection Visit				
Participate in Investigative Meeting				
Regulatory: Regulatory Document Submission CV's, Lab normals & certification, 1572, Financial Disclosures, IRB membership list Binder Setup				
IRB Submission: General Information Sheet Medical Research Description Informed Consent Assent Form Advertising Photocopy & package submission Other reviews or requirements IRB Correspondence				
Develop Study Documents: Standard Orders Enrollment checklist Study Specific Source Documents Lab Kits Enrollment Log				
Budget Preparation: Prepare Budget Submit Research Discount Form Negotiate Budget w/ Sponsor Prepare Internal Paperwork (Internal Approval, Fixed-Price Budget, UK Disclosure of Financial Interest) Pharmacy Cost & Correspondence				
Financial Management: Manage Study Costs & Payments Invoice Per Payment Schedule Manage Grant Account				
VA R&D Submission: Informed Consent Biohazard & Safety Information Project Data Sheet Investigator Data Sheet Investigational Drug Form				
GCRC Submission: Application process				

Recruitment: Develop Screening Questionnaire Develop Advertizing/Flyers etc. Staff Time Phone Calls Scheduling Letters and Mailing				
Provide Staff Training				
Patient Screening: Informed Consent Process Medical History Vital Signs Physical Exam Laboratory Procedures Lab Specimen Processing Other Tests and Procedures Questionnaires				
Patient Counseling				
Patient Enrollment: Physical Exams Laboratory Procedures Other Tests and Procedures Questionnaires				
Study Visits & Closeout Visit: Number of hours per visit Length of Study Test and Procedures Questionnaires Follow up letters - Phone calls				
Maintain Source Documents				
Completing CRF's				
AE's and SAE's: Assessment Reporting and Correspondence Paper work				
Facilitate Monitoring Visits				
Sponsor Correspondence: Faxing Screening Logs Letters Data Queries/Clarifications				
Regulatory Files Management				
Study Drug Management: Drug Dispensing Accountability Records Inventory				
Total Time				
Total Amount				
Number of Patients in Study (times total amount)				

Indirect (26%), times total amount	
Personnel Cost to Perform Research Study	

TIPS: This is a formula one department at UK uses to estimate their budgets.

Study Requirements

Screening This is reviewing medical history, physical exam, inclusion/exclusion criteria, labs, ordering labs. Most research coordinator screen for at least 2 to 3 hours, for each patient actually enrolled.

Follow-up Visits This is actual time spent with a randomized patient. A minimum time required for each patient contact (non-OR or ICU time) is calculated at 2 hours. This is because it usually requires interviewing the patient for adverse events, reviewing the chart, physical exam, vital signs, lab draws, and processing central labs.

Case Report Forms Completion/Administrative This is calculated at a 3:1 ratio with follow-up visit hours. This not only includes case report form completion (which is a great deal of paperwork!), but coordination with the sponsor (for such things as weekly phone conferences, faxing weekly screening logs, etc.) pharmacy (arranging drug shipments, actual randomization, drug preparation) and clinical trials office. Additional, time is required to meet with the sponsor for monitoring/ audits visits, site initiation visits, follow-up on adverse events or queries.