



PERSONNEL CORE STUDY COSTS

Estimate how much time and effort study team member will spend on each visit based on any or all of the items listed below. Be sure to prorate an individual's hourly rate and include a fringe rate (ERE).

SUBJECT SCREENING

- Consenting/Reconsenting subjects
- Obtaining financial authorization
- Obtaining outside medical record
- Inclusion/Exclusion Criteria Preparation
- Order tests and assessing subject's eligibility
- Registering subject on study
- Completing documents (e.g. screening log) required by the sponsor
- Patient Education
- Chart Review

SUBJECT COORDINATION

- Coordinating patient care/tests
- Coordinate patient clinical charting and documentation
- Patient communications (phone calls, emails) and charting
- Follow up with SAE patient, track patient status
- Medication Accountability (outside of what is required by pharmacy)
- Assist in subject assessment
- Patient off study

SUBJECT TESTING

- Patient assessments (conmeds/AE's/meds, vitals)
- PK/PD prep/collection & processing
- Biomarker analysis
- Processing, storing and shipping biological samples; Inventory and requisition of study specific laboratory supplies

DATA MANAGEMENT

- Completion of paper or eCRF
- Data entry/SAEs
- Data locks required by sponsor
- SAE reporting
- Communications with sponsor/CRO/PI

MONITORING VISITS

- Setting up and preparing monitoring visits
- Monitor visit
- Audits and query resolution

OTHER ADMINISTRATIVE SUPPORT PER PATIENT

- Quality control
- Processing payment of patient care bills
- Processing payment of patient reimbursements
- Tracking sponsor payments
- Invoicing sponsor reimbursements

ADDITIONAL TIME AND EFFORT

- Subject long-term follow-up
- Attending study related meetings including internal team meetings
- Conference calls
- Ongoing training
- Shipping/Receiving