



## Tips

- ◆ Perform a [feasibility analysis](#) on the study protocol to determine if you have the facility resources, staff and potential study candidates for the trial. In other words, do a reality test. Reject studies that are unrealistic, unnecessarily demanding or under funded. In addition to resources, determine if the inclusion-exclusion criteria is realistic, the trial is scientifically sound, and if it requires too much of the research subjects.
- ◆ Consider the number of subjects. If recruitment is competitive with other sites, it is more efficient to continue to enroll if you have the capacity and potential subjects. . Additional subjects may provide the volume to make the study cost effective
- ◆ To determine the number of patients (potential subjects) with the desired diagnosis seen by the investigator or UK clinic, contact Donnie Belden (257-7910 x 632) at Kentucky Medical Services Foundation (KMSF). Contact KMSF for a logon to complete an Adhoc-Report Request available under the Information Systems section of the [KMSF website](#).
- ◆ Best practice budgeting always includes carefully creating a line item (Cost) budget to determine where you stand relative to the sponsor's budget.
- ◆ Using protocol and study schematic (with routine care, billable and research items indicated) determine full rate costs for research procedures/services (Fair Market Value = Retail or reasonable value)
- ◆ Carefully match protocol required tests with the accurate CPT/CDM code in the excel [budget template or charge master](#).
- ◆ Consult the [UK Lab](#) for questions regarding lab tests; budget for any required automatic re-test to confirm positive results.
- ◆ Consult technical staff to determine all associated costs with a procedure (anesthetic, tools, equipment) and any professional reading fees.
- ◆ Request written cost estimates for any interdepartmental services
- ◆ Using the protocol, carefully estimate required personnel time. [The Personnel Time Calculator](#) or can help identify study related tasks and estimate time required.
- ◆ Incorporate cost escalation for multi-year projects.
- ◆ Once you have estimated your total cost to conduct a study, add on institutional overhead. Ensure that the sponsor is willing to cover the full overhead amount required.
- ◆ Based on your budget, negotiate for a fair price based on fair-market value. Most sponsor budgets have some measure of flexibility. A properly developed budget substantiates the cost and justifies negotiation.

### Budgeting for Compliance:

All costs of the clinical trial are IDENTIFIED and BILLED to the appropriate payor

- Third-party payors billed only if services not paid by sponsor
- Third-party payors billed only if services are covered
- Patient billed in accordance with informed consent
- Each research trial that enrolls human subjects (potential Medicare beneficiaries) and will have billable services will need to complete a [Medicare Analysis](#) .

- ◆ Past performance documented by study metrics gives the sponsor documentation of your productivity. Sites that are top performers are in the best position to negotiate.
- ◆ Negotiate an up-front, non-refundable payment to cover start-up expenses (IRB preparation, regulatory document submission, pharmacy start-up, contract negotiation). If the sponsor decides to discontinue the study prior to initiation and you have incurred these administrative start-up costs, invoice the sponsor.
- ◆ Learn what you can about the sponsor and study. How many sites are interested and how many will be selected, what time pressures are they under, etc? You may have some added benefit to offer such as geographic location or ability for quick start-up.
- ◆ .Don't forget additional overall costs such as screening and recruitment costs, advertising, supervision, staff training, source document preparation, supplies, or other hidden costs etc
- ◆ Renegotiate costs for significant or unanticipated requests such as added procedures, excess protocol modifications, unexpected administrative time processing adverse event documentation, sponsor audits, etc.
- ◆ Negotiate a reasonable payment schedule that is spaced throughout the trial. Payments may be based on a variety of triggers or milestones (number of subjects enrolled, patient visits or procedures, case reports completed, etc.)
- ◆ Don't agree to a final holdback payments of large amounts or those that are tied to performance at other sites. If budget is significantly modified - >10% resubmit to [OSPA Request for Action/Revision Form](#)
- ◆ Industry funding can frequently lag behind. Learn the name of the person in the company who generates payments and what the expected turn-around time is.
- ◆ Keep track of services rendered and expected payments. Proactive invoicing can provide a friendly nudge to move things along. Request that payments be accompanied by an itemization of services rendered.

## Potential Hidden Costs



- Delayed study start
- Preparing source document forms
- Telephone pre-screening
- Receiving and managing clinical or lab supplies
- Processing stipend requests
- Responding to data queries
- Obtaining documentation of SAEs from other hospitals/facilities
- Protocol or contract amendments Training of staff
- Rescheduled missed visits
- Monitoring visits: poorly trained monitors, monitor turn-over
- Processing of study amendments including consent revision and re-consenting of subjects
- Long-term storage
- Lost work time when attending investigator start-up meetings