



## Budget Quick Tip Guide:

- Understand the Cost Elements of Clinical Study/Trials
- Understand how to Estimate Costs Associated with Protocol Events
- Protocol Assessment:
  - ♣ Feasibility – Does the budget support the work to be supported?
  - ♣ Degree of Difficulty – Easy, moderate or difficult?
  - ♣ Study Costs – Realistic, consistent, flexible and justifiable?
    - Start up-costs: Non-refundable and one time charges. Examples include -> coordinator time, IRB and pharmacy fees.
    - Per-patient costs – direct costs, supplies, test/procedures, etc
    - Develop a billing plan to determine what is standard of care (SOC) vs. non-standard of care costs. Use the Human Research Billing Analysis Form (HRBAF) to determine SOC and delineate responsibility for payment. This is required for every clinical research proposal.
    - Variable costs (as needed) – Bill (invoice) only if they occur. **Not** included in list per-patient costs.
    - **Budget Tip** – Don't look at proposed budget. Figure your costs first.
- Commonly Overlooked Budget Items:
  - ♣ Start-up & close-out costs
  - ♣ Increase in operating cost for multi-year study
  - ♣ Visits not considered visits by the sponsor
  - ♣ Advertising
  - ♣ Record storage
  - ♣ Payments for unscheduled procedures, adverse events, visits, tests, screen failure compensation
  - ♣ Audits from sponsors, CRO or FDA
- Underestimated budget items:
  - ♣ Consent "Process"
  - ♣ Start-up costs
  - ♣ Administrative costs
  - ♣ Equipment use and depreciation
  - ♣ **Support staff time - #1**
- **Top Five Budget Mistakes:**
  - ♣ Accepting the Sponsor's proposed budget
  - ♣ Ignoring details of the protocol
  - ♣ Not seeing case report forms before finalizing budget
  - ♣ Not obtaining accurate professional and technical fees for procedure/tests
  - ♣ Accepting any loss – no matter how small
- SUMMARY:
  - ♣ **NEVER** accept initial proposed budget
  - ♣ **ALWAYS** figure costs of study procedures
  - ♣ **DON'T** rely on sponsor template of costs
  - ♣ **FIND** hidden costs in protocol