



Budgeting for Clinical Trials; Industry Sponsored and Investigator Initiated Research (IIR) Studies



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Overview

- Role of Research Services
- Purpose of a Research Budget
- Phases of budget development
 - I. Preparation
 - II. Review of protocol
 - III. Development of internal budget
 - IV. Negotiation
 - V. Approval/Acceptance



Role of Research Services In Budgeting

- Assist in the development of budgets
- Negotiate on behalf of or assist Investigator and research team in budget negotiations
- Review of and advice on budgets being submitted for IIR funding/support



Purpose of Budgets

- Ensure sufficient funds to cover cost of research
- Accountability/transparency
- Common expectations among Sponsor/Funder, Investigator and participating sites (if applicable) are outlined
 - Milestones
 - Payment schedule
 - Terms of payment
 - Reporting



Capital Health

Healthy People, Healthy Communities

Budget Development Process





I. Preparation

- Know your abilities and therapeutic area
 - Patient population and numbers
 - Available services and resources
 - Quotes
 - Outsourcing



Budget preparation (Cont'd)

- Know funding agencies' and institution guidelines and allowable budget items (eligible/ineligible costs)



II. Review of Protocol

- Know the protocol before you develop the budget
- Have an up-to-date listing of common procedures and associated costs at your site.
- Differentiate standard of care vs. study procedures and treatments
- Consider whether there will be participating sites and the costs associated.



III. Development Of An Internal Budget

- Direct Costs
- Overhead/Indirect Cost
- Administrative Start Up Fee
- Additional Fees and budgetary considerations
- Invoiceable Items
- Eligible/Ineligible costs (IIR granting situation)



Direct Costs

- Per patient procedures (above standard of care)
- Investigator/coordinator fees
- Patient reimbursement for expenses
- Screen failures and unscheduled visits
- Supplies (i.e., drugs)
- Departmental/Third Party fees
 - Pharmacy fees
 - Lab Support Services
 - Biomedical engineering
 - Monitoring
 - Statistical Support



Overhead/Indirect Cost

- Percentage of total direct costs associated with the **Industry Sponsored** research study – 30% Capital Health
- Percentage of total direct costs associated with the **Industry Supported** Investigator Initiated research study – 15% Capital Health



Administrative Study Start Up Fee

- Determine study start-up fee – overhead exempt
 - Non-refundable
 - Not study start or enrollment dependent
 - Covers all up front work to REB submission
 - Review/training of protocol
 - Preparation for ethics submission
 - Pre-site/Site visits
 - Regulatory document preparation
 - Study file maintenance
 - Miscellaneous expenses (long distance calls, courier fees, photocopying)
- Study start up fee only applicable to IIR Studies if feasible.

*Difference between advance payment and start up fee



Additional Established Costs

- Annual REB Approval
- Safety IND/SAE Reports
- Protocol/ICF amendments

Paid to Research Team. Not commonly included in IIR Study budgets

- REB Fee
- Archiving Fee

Paid Directly to Institution. Currently not applicable to IIR Research Studies



Additional Budgetary Considerations

- Payment schedule
- Payment milestones
- Payment terms/reporting (IIR Studies)



Invoiceable Items

- Screen failures
- Monitoring visits
- Query resolution
- Dry ice
- Department start up fees
(Pharmacy, Radiology, Lab Services)
- Advertising
- Participant reimbursement
- Safety reports
- Protocol amendments
- REB review/approval fee
- Archiving
- Completed CRF



IV. Negotiation/Submission

- Enter into negotiations or apply for funding only when you have prepared your final internal budget or the overall cost of your research project
- Know the amount of your minimum acceptable budget
- Ask Sponsor to provide you with its budget expectations. Be prepared if you are lead site for a multi site IIR study to provide the same to participating sites



Negotiation/Submission

- Provide Funder Agreement template to funder and understand provision terms
- Familiarize yourself with terms of funding application reviews and submission
 - deadlines,
 - Electronic submission
 - signatures



V. Approval/Acceptance/Receipt of Support

- When Sponsor or Funder, Investigator and Research Team, and Research Services are satisfied with the budget it is either incorporated into the main contract/agreement, as a separate document to be signed and is legally binding, or as part of a funding request or application.



Tips!

- ❖ Always have a detailed budget before the onset of the Study
- ❖ Ensure that a budget is reviewed by the PI, research team and Research Services before signing or submitting
- ❖ Speak with colleagues and other research teams in multi-centered trials
- ❖ Create a toolbox of budget templates/resources
- ❖ Understand/Review thoroughly funding guidelines and processes of funding agencies/competitions



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QUESTIONS???

