THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center
Making Cancer History®

Basic Budgeting Principles for Clinical Trials

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Clinical Trial Overview

- What is clinical Trial?
- Who are the players?
- What are things we should consider?
- What are the key components?

Key Components

- Protocol
- Informed consent
- Clinical trial agreement
- Clinical trial budget

Clinical Trial Budget - Purpose

- Key component
- Cost of conducting trial
- Includes coverage analysis
- Promotes compliance
- Supports informed consent
- Version of budget attached to agreement
- Participants know their financial responsibility

Budget Considerations

- It is your cost to conduct the trial
- Budget includes direct and indirect costs
- Coverage analysis to capture patient care costs
- Total cost of conducting trial / Per patient cost

Budget Line Items

- Personnel (Salary and fringe benefits)
- Office and Clinical Supplies
- Patient reimbursement (e.g., travel, parking etc)
- Consulting or other miscellaneous expenses

Budget Line Items

- Pharmacy fees
- IRB fees
- Protocol activation fees
- IND fees
- Other start up / Institutional fees
- Data management (storage, retrieval, copies etc?
- Adverse events
- Close out costs
- Coverage analysis

Purpose Served?

- Does it support the protocol and informed consent?
- Support your contract negotiation?
- Reflect actual / reasonable costs?
- Support billing compliance?
- Good to go!

Other Considerations

- Institution's charge master
- CMS guidelines
- NCD Vs. LCD
- Cost sharing
- Other Federal, State and Institutional policies
- How does it align with Institutional objectives

Thank you

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