

Building A Clinical Trial Budget

The Vanderbilt Way

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Budget Development

- The Sponsor of the clinical trial will send a protocol and budget overview for the trial.
- After reviewing the protocol, modify the budget to reflect your costs to conduct the trial at Vanderbilt.

Important Questions

- Does the protocol provide scientific value?
- Can I recruit subjects?
- Does the budget support the work to be performed?

If you can't answer yes to each of these questions – then decline the trial.

Budget Development

- Find the study overview in the protocol. This is often a one page visit-by-visit outline of the study.
- Determine if the labs and testing procedures such as EKG's, MRI scans, etc. will be analyzed at our local Vanderbilt lab or at the sponsor's site.

Budget Development

- Determine if there will be professional charges required for the technical tests performed. An example would be an ECG with interpretation by a Cardiologist.
- Either edit the sponsor's budget or create an Excel spreadsheet to reflect all costs of the trial.

Standard of Care vs Research

- Vanderbilt negotiates a cost per subject to complete a clinical trial, not a cost per test or procedure.
- You may use a standard of care test result for clinical research.
- You may not bill insurance for a test, device, or service paid for by the Sponsor.

Budget Development

- For multi-year trials, consider adding an inflation rate of 10% to the per-completed-subject cost.

Study One Time Fees

- **One time costs:**

- IRB Review Fee $\$1744 + 29\% = \$2250.$
- IRB Continuing Review Fee $\$ 581 + 29\% = \$750.$
- IRB Amendment Review $\$ 388 + 29\% = \500
- IRB Preparation Fee $\$ 1500$ (suggested fee)
- Administrative Fee $\$ 3000$ (suggested fee)
- Investigational Drug Pharmacy set-up fee
- Archive document storage fee $\$100 / \text{year} * 7 \text{ years}$
- Source document binders $\$8.00 \text{ per patient} * X \text{ patients}$
- Advertising for Recruitment Fee

- **Total**

- **Indirect Cost 29%**

- **Total One time costs**

Using the Research Charge Master

- To obtain information about the VUMC charges for tests and procedures, send Kelly Willenberg the follow information by e-mail and she will return the cost data to you.
 - Name of test or procedure
 - CPT code if known

Indirect Rate Tips

- The average Academic Medical Center indirect rate is 25%.
- Some sponsors may resist paying the Vanderbilt indirect rate of 29%.
- The indirect rate is non-negotiable. You may be able to increase the direct costs to make up the difference between what the sponsor will pay and the 29%.

Sample Budget

Principal Investigator:

Division:

Protocol Title:

Protocol Number:

Sponsor:

IRB Approval Number:

Start date:

Study duration:

List all procedures and all visits

Procedure	Baseline	Visit 1	Visit 2	Visit 3	Final Visit	Total per patient	Payer		
							Insurance - Standard of Care	Sponsor	Other
History and Physical	\$ 200	\$ 50	\$ 50	\$ 50	\$ 50			X	
Lab tests	\$ 300	\$ 300	\$ 250	\$ 50	\$ 300		X	X	
MRI scan	\$ 1,500				\$ 1,500			X	
Study Drug administration		\$ 35	\$ 35	\$ 35				X	
Sub total	\$ 2,000	\$ 385	\$ 335	\$ 135	\$ 1,850				
Indirect rate 29%	\$ 580	\$ 112	\$ 97	\$ 39	\$ 537				
Total per visit	\$ 2,580	\$ 497	\$ 432	\$ 174	\$ 2,387	\$ 6,069			

* Consider 10% inflation per year for multi-year trials

Start-Up Costs: (One Time Fees)		Start-Up Costs
IRB Initial Review Fee		1,744.00
IRB Amendment Review		581.00
IRB Continuing Review		388.00
IRB Preparation Fee		1,500.00
Subject Recruitment		5,000.00
Investigational Drug Pharmacy set-up Fee		1,000.00
Data Archival fee (100/yr for 7 years)		700.00
Direct Costs		10,913.00
Indirect Costs (29 % of Direct Costs)		3,164.77
Sub Total Start-Up Costs:		\$14,077.77

Negotiating the budget with the Sponsor

- Provide detailed, line-item cost for each activity.
- Use the words, “Our costs of participating in the trial”
- Remember, the Sponsor wants Vanderbilt and the PI involved in the trial as a thought leader.

Vanderbilt Internal Budget

- **Points to Remember**

- University Expenses (Direct Costs and F&A Costs) Must Be Reflected In The Budget.
 - Personnel (salary and fringe benefits)
 - Office and Clinical Supplies
 - Pharmacy Fees
 - Laboratory Fees
 - Patient Reimbursement Fee (e.g., travel, parking)
 - Publication Costs
 - Institutional Review Board – IRB Review Fees

Vanderbilt Internal Budget

- The budget must total the estimated patient costs plus all one-time allowable fees.
- All industry sponsored expenses are subject to F&A (Facilities and Administrative Costs) or Indirect Costs – (Overhead)
- Industry sponsored clinical trials must use the Indirect rate of 29%. Federally sponsored clinical trials indirect rate is 54%. You do not pay indirects on patient care costs in Federal trial budgets.
- IRB Review Fees
 - Initial review - \$2250 (\$1744 + \$506 indirect rate)
 - Continuing review - \$ 750 (\$ 581 + \$169 indirect rate)
 - Amendment review - \$ 500 (\$ 288 + \$112 indirect rate)

Internal budget

- Most Department of Medicine division budgets must cover 5% of the Principal Investigator's salary and benefits
- If the study budget is very low or the effort of the PI is small, this can be negotiated. Contact Jennifer Barrett for an exception.

Correcting billing errors

- Set-up a D&H account for each trial.
- Charge all research related tests and procedures to the D&H account.

If there is a mistake in billing, contact patient accounting to correct.