

Eight Steps to Create a Winning Clinical Research Study Budget

Part 7 - Determine the Appropriate Overhead Rate

By John P. Neal

About the Author

John P. Neal is CEO of Premier Clinical Management Organization, a leader in clinical research site consulting services, located in Encinitas, CA. He has served as the COO or CFO of several multi-site clinical research companies and has over twenty-five years experience working with biotech and pharmaceutical start-up companies. He received his BS in Accounting at San Diego State University and his CPA Certificate while with Deloitte Touche in San Diego, CA and is a certified Clinical Research Contracting Professional (CRCP). He can be reached at jneal@premiercmo.com.



In Part 6 of this series I explained how to summarize the time and cost for all of the study visits in order to determine the direct costs of conducting the study, a crucial step in the budget development process.

Frequently I find that staff that is expected to prepare and negotiate study budgets for investigative sites do not have a background in accounting or contracts and have little or no training on how to properly approach developing a study budget that properly captures all the costs involved in conducting a study. That is why I created a simple, eight step approach to developing a clinical research study budget modeled after the process I have successfully followed for years that has resulted in increased budgets, often exceeding 70% higher than what was originally offered by the Sponsor.

Following my eight step process will make your task of creating study budgets easier and give you the confidence you need to negotiate better budgets.

The Eight Steps

The process is broken down into the following distinct steps:

Step 1 - Determine the fully loaded, productivity adjusted cost of each staff member
(Part 1 of this series)

Step 2 - Identify all the study related tasks that must be performed per the protocol
(Part 2 of this series)

Step 3 - Identify all the non-staff costs of conducting the study visits
(Part 3 of this series)

Step 4 - Determine the time and cost of all the tasks necessary to start-up the study
(Part 4 of this series)

Step 5 - Determine the time and cost for each study visit
(Part 5 of this series)

Step 6 - Summarize all visits and add the totals for each visit
(Part 6 of this series)

Step 7 - Determine the appropriate overhead rate to use

Step 8 - Summarize all the costs and expected revenue and determine whether the study, as budgeted, will be profitable

In this article I address **Step 7**, determining the appropriate overhead rate to use. In the final article I will cover the last step of the budget development process, summarizing all the costs to determine the budget needed to be profitable.

Determine the Appropriate Overhead Rate

The **seventh step** is to determine the appropriate overhead rate to use for the study budget. It may be easiest to think of “overhead” as the total of all of the non-clinical activity at the site. This will include all expenses not directly related to conducting studies, plus an amount for profit. Often misunderstood, overhead rates vary greatly by institution, but generally run between 25% and 40%.

Some of the key components to include in overhead are:

- ✓ Business development
- ✓ Insurance
- ✓ Information Technology
- ✓ Supplies
- ✓ Human resources
- ✓ Depreciation
- ✓ Profit
- ✓ Costs to attend industry conferences
- ✓ Occupancy (rent, power, security)
- ✓ Legal & accounting services
- ✓ Laundry & waste disposal services
- ✓ Internal accounting
- ✓ Interest expense

Frequently, those unfamiliar with financial management overlook several crucial components, in particular a factor for profit. Alternatively, you may think of this component as opportunity cost. Regardless of what you call it, it represents a required return on the assets utilized to conduct the study (cash, property, furniture, equipment, supplies, etc.) that might otherwise be invested in some other activity or pursuit that could generate a return on those assets.

Including an amount for profit (or opportunity cost if you prefer) is equally important for not-for-profit research organizations as it is for for-profit sites. In the absence of a reasonable contribution in excess of costs across all studies, not-for-profit organizations must rely on donations to sustain financial viability, which can lead to significant funding peaks and valleys. The old adage “No money, no mission!” clearly applies.

If you are in doubt about how to assess and establish an appropriate overhead rate, get assistance from someone familiar with financial statements. Since the overhead amount is frequently the single largest line item in the budget, getting the overhead rate correct is frequently the key difference between a losing budget and a profitable budget.

We will start our process by looking at the income statement of a fictitious clinical research site, Best Practices Research Institute. While income statement formats will vary slightly from one organization to another, the statement generally is segmented into the three primary categories of revenue, direct operating costs (in our example those would be the clinical costs), and general and administrative costs.

By adding “General & Administrative Expenses” to a factor for profit, you arrive at “overhead”. Figure 1 below shows the income statement for our fictitious research site.

Figure 1- Example Income Statement

| Best Practices Research Institute | | | |
|--|--------------|---------------|---------------------|
| EXAMPLE INCOME STATEMENT | | | |
| <i>In Thousands</i> | | | |
| | Annual Total | | |
| Operating Revenue | | | |
| Research Revenue | \$ 2,000 | 92.6% | |
| Study Cost Recoveries | 160 | 7.4% | |
| Total Operating Revenue | <u>2,160</u> | <u>100.0%</u> | |
| Direct Operating Costs | | | |
| Clinical Salaries & Benefits | 1,192 | 55.2% | |
| Subcontract Clinical Staff | 120 | 5.6% | |
| Subject Stipends | 110 | 5.1% | |
| Pass-Through Expenses | 70 | 3.2% | |
| Clinical Supplies | 40 | 1.9% | → 1.9% |
| Total Direct Cost | <u>1,532</u> | <u>70.9%</u> | |
| Operating Margin | 628 | 29.1% | |
| General & Administrative Expenses | | | |
| Salaries & Benefits | 100 | 4.6% | |
| Information Technology | 12 | 0.6% | |
| Legal Fees | 20 | 0.9% | |
| Outside Accounting & Tax Preparation | 20 | 0.9% | |
| Insurance Expense | 30 | 1.4% | |
| Office Supplies | 25 | 1.2% | |
| Travel Expenses | 20 | 0.9% | |
| Telecommunications | 12 | 0.6% | |
| Equipment Rental | 6 | 0.3% | |
| Postage and Delivery | 6 | 0.3% | |
| Licenses & Permits | 3 | 0.1% | |
| Business Development & Marketing | 34 | 1.6% | |
| Miscellaneous Expenses | 30 | 1.4% | |
| Leases & Occupancy | 82 | 3.8% | |
| Disposal and Shredding Services | 20 | 0.9% | |
| Depreciation | 36 | 1.7% | |
| Total Gen & Admin Expenses | <u>456</u> | <u>21.1%</u> | → 21.1% |
| | | | <u>23.0%</u> |
| Pre-tax Net Income | <u>\$172</u> | <u>8.0%</u> | → 8.0% |
| | | | <u><u>30.9%</u></u> |

Adapted from John P. Neal, 2009, *Clinical Research Budgeting Made Easy*. Used with permission.

Line item descriptions and classifications of some items between “Direct Operating Costs” and “General & Administrative Expenses” vary slightly with each organization. For the purposes of our budgeting exercise we will consider those items for which you would have an equivalent line item in your study budgets to be included in direct operating costs. Notice that “Clinical Supplies”, which typically is not a

separate study budget line item, is included in the section with other direct operating costs. In this case we will add the cost of clinical supplies to other general and administrative expenses to arrive at the pre-profit overhead rate of 23%. By adding the pre-tax profit of 8%, we arrive at a total overhead rate of 30.9%. The rate you ultimately apply to your budgets may be higher or lower depending on the target profit rate for your organization, a number typically established by senior management or the Board of Directors.

After applying the overhead rate to the budget you developed in **Step 7**, you arrive at a final budget figure per subject, frequently referred to as the Cost Per Patient (CPP).

The financial success of each study starts with negotiating a fair budget. By understanding your overhead costs and the financial contribution each study must make to your organization, you are able to *Start with the Finish Line in Sight*ⁱ and be prepared to negotiate successful budgets.

In my final article of this series I will explain **Step 8**, which is to summarize all the costs and expected revenue and determine whether the study, as budgeted, will be profitable. After making final adjustments and establishing your negotiation strategy (a topic I will cover in a future series of articles) you will be ready to submit your budget request to the Sponsor or CRO and confidently begin the negotiation process.

*The entire clinical research budgeting model incorporating all **Eight Steps**, together with the book “Clinical Research Budgeting Made Easy: The Step-by-Step Guide for Non-Accountants” that leads you through the model, is available for purchase at The RAN Institute. **It would take hundreds of hours to create the same budgeting model from scratch!** In just a few hours you can create a winning clinical research budget. The model gives you the ability to perform “what if” calculations to determine the impact of varying scenarios so you can maximize the budget based on your site’s capabilities and unique requirements.*

Visit www.raninstitute.com today to purchase your copy!

Budget development and negotiation services are also available from Premier CMO. Visit www.premiercmo.com for more information.

This is Part 7 of an eight part series that is available at www.premiercmo.com or www.raninstitute.com.

ⁱ Linda Pinson and John Neal. 2006. Develop an Exit Strategy: Start the Race with the Finish Line in Sight. *Anatomy of a Business Plan*.