

## Eight Steps to Create a Winning Clinical Research Study Budget

### Part 3 - Determine All Non-Staff Costs of Conducting Study Visits

By John P. Neal

#### About the Author

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In Part 2 of this series I explained how to identify the various study related tasks that must be performed per the protocol and to comply with good clinical practice (GCP). It takes teamwork to break a protocol into its many detailed components. Without a detailed list of tasks required (not just those included in the "Schedule of Procedures"), it is impossible to accurately calculate the costs of conducting the trial and, consequently, a fair budget.

Clinical staff are frequently expected to negotiate budgets, but often don't fully understand how to go about it in a way that leads to a fair budget. 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 an average increase in budgets of over 53%, with many in excess of 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 confidence 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.
- Step 4** - Determine the time and cost of all the tasks necessary to start-up the study.
- Step 5** - Determine the time and cost for each study visit.
- Step 6** - Summarize all visits and add the totals for each visit.
- 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 will address Step 3. In each subsequent article I will cover the next step until we have covered them all.

## Determining the Non-Staff Costs of Conducting the Study Visits

The **third step** in the eight step process is to determine all the non-staff costs of conducting the study visits. These will include such things as outside lab costs, radiology, outside consultations and procedure costs, and many more items. I want to emphasize how important it is for a broad range of personnel, including non-clinical staff, to review the study protocol in detail. Different backgrounds bring different perspectives and increases identification of hidden costs.

Frequently, expensive or time consuming tasks or procedures are omitted from the Schedule of Procedures. This can lead to costly budgeting omissions if not detected and addressed prior to finalizing the budget with the Sponsor.

I prefer to read the entire protocol *before* looking at the Schedule of Procedures. By performing your analysis in this sequence it is more likely that nuances contained in the protocol that are not specified in either the Schedule of Procedures or budget template will stand out. You can then add them to the procedures list and account for them in your budget.

After identifying all the various non-staff items related to the study visits, research the cost of each. With some vendors you may have contracted pricing, which makes your analysis a bit easier. In other cases though, you may have to review prior invoices from vendors in order to establish a baseline cost. You may also need to obtain written quotes from labs and other outside providers with which you don't have a standard pricing agreement.

After completing your research, create a table of non-labor study items. Figure 1 contains an example of a partial list of non-labor items.

Please note that this is only a partial list. The actual list for any particular study will vary and can be quite extensive. In addition to simply listing each item, it is helpful to capture CPT and other codes, where applicable, to facilitate future budget analysis when rates change. So as not to accidentally use outdated rates, I recommend adding a footnote to your table indicating the last date rates were updated.

**Figure 1 – Non-Labor Study Costs (partial list)**

Non-Labor Study Costs	Contracted Unit Cost
Bed Fee	\$900
Blood Culture	\$25
Chest X-Ray	\$400
CT Scan	\$600
Drug Screen	\$22
HIV Test	\$24
Lactic Acid	\$20
MRI	\$600
PICC Line Insertion	\$800
Radiology Consult	\$100
Serum Chemistry Panel	\$22
Serum Pregnancy Test	\$22
Urinalysis	\$25
X-Ray Other	\$200

**Note:** The "Contracted Unit Cost" column contains prices that are for illustration purposes.

Some of the elements of the budget you will negotiate with the Sponsor or CRO for each study are a non-refundable start-up fee (intended to cover the cost of start-up *and* close-out), a refundable advance (intended to offset the long delays in payment typical in the industry), and certain pass-through items like IRB submission fees, translation fees, and the cost of recruitment activity specific to the study.

To ensure you capture each of those items in your analysis, and ultimately in your budget request, create a separate table of pass-through costs and other invoiceable costs. The table will be used later when you prepare the budget request for submission to the Sponsor or CRO.

After completing this step you only have one more step before beginning to work with the individual visit budgets.

In my next article I will explain **Step 4, determining the time and cost of all the tasks necessary to start-up the study**. I will explain how to analyze and determine the full cost associated with the start-up and close-out processes required to be prepared to conduct the study and eventually the close-out of the study at your site.

As we work through all **Eight Steps**, you will find that completing a budget analysis will become easy. Once you have created a defensible budget and understand the detail behind the costs, you can negotiate the budget with Sponsor's or CRO's with confidence. The negotiation itself is the topic of a future article that will include negotiating the budget as well as the Clinical Trial Agreement (CTA).

A solid budget analysis is critical to understanding the fair value for conducting a study. With continued study to understand what is customary and possible, you will get better budgets as well as better contract terms. Successfully negotiating better budgets contributes greatly to the success of a site. Prepare to be a hero!

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*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 at The RAN Institute for the low introductory price of just \$169 for a limited time. **It would take over 200 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 sites capabilities and unique requirements.*

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*This is Part 3 of an eight part series that is available at [www.premiercmo.com](http://www.premiercmo.com) or [www.raninstitute.com](http://www.raninstitute.com).*

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