# CLINICAL STUDY SITE BUDGET

In today's dynamic environment, there is a need like never before for clinical data. In addition to IDE's, companies are finding themselves doing clinical studies for 510(k) products as well as market approved products. Once the protocol is written and the sites are being selected, the next big task is developing a site budget that is comprehensive and defensible. This can be an overwhelming task, especially if you are a not an accountant and are uncomfortable with developing budgets. This paper will provide an overview of clinical study site budgets, describe the importance of creating a defensible study budget, provide a process for building a site budget and discuss tips for negotiating the budget.

## Overview

Changing economic conditions, a difficult reimbursement climate, and an unpredictable FDA are creating a variety of challenges across the industry. The FDA and payors are increasingly requiring "convincing" clinical evidence which generally requires sponsors to conduct large clinical trials. For many companies, such as those who have primarily followed a 510(k) path to market, launching a large clinical research project is a new venture. The process of building a study site budget for these "sponsored" trials can be an added challenge for those who have never previously created site budgets.

## What is a Site Budget?

A site budget includes both the direct and indirect costs associated with the tasks and activities described within a study protocol (Table 1). In other words, the site budget is full compensation for the cost of conducting a study at a research site. Typical direct costs include procedure fees (i.e. radiographic images, ECGs, MRIs) and various patient assessments (i.e. medical history, physical exam, quality of life survey). Direct costs outside of defined procedures or assessments often exist. For instance, when conducting an FDAregulated trial, the agency requires direct oversight by the principal investigator; naturally, this oversight translates into time and cost. The study coordinator will also spend time recruiting patients, working with site monitors, filing regulatory documents, and consulting with the principal investigator regarding the status of the study. The cost of these activities is more difficult to estimate, but "time" is a direct cost and research sites will expect compensation for investigator and coordinator salaries.

The indirect costs associated with a study are sometimes referred to by study sites as the "hidden costs".

Typical indirect fees include facility overhead; such as, electricity, phone charges, space, and use of copy machines. Institutions will also realize indirect administrative expenses such as the time and effort associated with providing trained staff to support the trial. The site may also incur legal and financial service fees associated with contract review and maintenance. Research sites often feel that sponsors do not adequately recognize the indirect costs associated with conducting a clinical study. Therefore, it is especially important to be cognizant of the indirect costs.

**Table 1. Examples of Direct and Indirect Costs**

DIRECT COSTS:

Study Defined Procedures (X-rays, ECGs, diagnostic procedures)
• Study Assessments (Patient reported outcomes, Medical History)
• Investigator and Coordinator Fees
• IRB Fees
• Patient Stipend
• Advertising

INDIRECT COSTS:
Facility Overhead (electricity, space, phone charges)
• Administrative Fees (Staffing, Legal, Financial)
• Record Storage

## Implications

For most medical device companies, clinical trials are the largest single area of R&D operating expense, and within a clinical trial, site budgets typically represent the majority of these costs. In addition to the cost implications, site budgets can have an effect on study success. Research sites do not take on clinical studies lose money. Study site budgets need to represent a fair market value. A site budget that is below the fair market value will lead to limited attention by the study staff and a lackluster rate of subject enrollment. While a low budget can have a negative impact on study success, it is important to point out that “excessive budgets” can also have negative consequences. Namely, over recent years, there has been growing public scrutiny concerning industry payments to physicians. Sponsors need to avoid the appearance that a study budget is an attempt to influence investigator behavior. Across the industry, the process of establishing acceptable levels of payment is becoming more transparent. For instance, many institutions, professional organizations, and sponsor companies have developed physician payment guidelines to avoid the appearance of any impropriety. When developing a site budget it is necessary to walk a fine line – the budget needs to be fair, but not excessive.

**Building the Budget**

Ideally, the study sponsor should drive the budget development process. Budgets are then presented to research sites by the study sponsor or a designee (i.e. CRO). It is generally best to present a draft budget to candidate sites at an early stage of site recruitment. The process of qualifying a site and the effort required to execute a site contract can be lengthy and time consuming. Therefore, it is best to know early in the process if the site feels that your study budget is in the “ballpark”. The budget is ultimately tied to a contract or clinical trial agreement which legally describes what is expected from the investigator and institution.

The contract will also include details of how and when the site will receive payments for study related activities.To build a budget the following information is required:

- Schedule of Events :The schedule of events describes all of the study related procedures and assessments to be performed per the protocol across a defined visit schedule.
- Staff Salary Estimate (principal investigator, study coordinator).
- Facility billing codes and payment rates for tests and procedures occurring in a facility
- Physician billing codes and associated payment rates for tests and procedures performed by the physician.
- Estimated Overhead (e.g. typically, 12%-30%)

Some study-related tasks will not have a corresponding Medicare fee schedule (i.e. informed consent, adverse event review, etc.). For these procedures, you should develop the cost estimate based on the resource(s) to perform the task (i.e. physician and/or coordinator) and the anticipated amount of time required to complete the task. Next you need to decide on an hourly rate for the assigned resource (Note: Several national organizations publish annual salary surveys for research professionals). For example, the process of obtaining informed consent requires time from both the research coordinator and the principal investigator. Let’s assume that the consent process requires 30 minutes of the study coordinator’s time at an hourly rate of $60 and 10 minutes of the principal investigator‘s time at an hourly rate of $300. Therefore, $80 would be budgeted for the cost of the informed consent.

**Site Budget Negotiations**

Each site will have different needs, requests and perspectives, so plan to negotiate. A significant component of a negotiation is mental preparation. If you plan for it to be challenging, difficult and tense—it will be.

Try to view budget negotiations as a dialogue or a discussion—an exchange of information. Expect it to be a discussion with an exchange of information and perspectives and that you will listen as much, if not more, than you speak. Also, consider that the research sites you are speaking with are most likely potential or current customers who you will likely wish to maintain a relationship with. It is also helpful to anticipate variables or objectives from the perspective of the research site and have a plan for how you will respond. The best way to prepare is to identify the potential variables in advance of your conversation and have a prepared response outlining your position and rationale. This should be succinct and defendable. It should also be documented to ensure a consistent message to sites. Finally, if there are any limits or guidelines that you are expected to stay within; know them in advance.

As you start having the conversation with the site—consider it a conversation. Ask questions and seek to understand the site's position. The long term goal of the conversation is to have a solid, respectful relationship no matter the outcome of the negotiation. There will always be questions from sites that you are not prepared for, no matter how much you plan. Rather than trying to create an answer on the spot, it is appropriate to state that you need to do some additional research and will get back to the site in a defined amount of time.

As you proceed through the negotiations, document your decisions, agreements, and areas of difference so you have a record of what has been agreed to and what is still open.

In today's economic environment, sites are sensitive to the costs of clinical research. The additional time to prepare and plan for your budget negotiations will increase your confidence, allow you to defend your assumptions and position, anticipate alternative perspectives, obtain better results and increase the efficiency of the process. The medical community, research staff and industry sponsors must all work together to ensure a mutually beneficial economic arrangement in which everyone benefits.