

How to Determine RESEARCH STUDY BUDGETS AND FINANCES:

Calculating the research study budget is one of the study coordinator's most critical tasks. While funding may be one of the most difficult subjects to discuss the fact of the matter is private institutions don't take on clinical research studies to lose money. The sponsor is fully aware of this and expects the institution to make a profit on the work performed. In determining the study budget do not sell the institution short. In order to make sure this does not occur use a budget worksheet (in many cases the sponsor will provide a worksheet). By doing so it is unlikely costs that might otherwise be left out of the budget will be over looked.

One of the most valuable tools in determining a study budget is the study protocol. By reviewing this document carefully the study coordinator can get an excellent idea of all necessary procedures which should be taken into account in determining the study budget.

Since each study patient will be proceeding through the same protocol an easy way to calculate the budget is to figure the cost of one study patient (studies are usually funded on a per patient basis) and then multiply this figure by the number of expected enrollees. Start the process by developing a budget worksheet (See Example Document 8.1, Page 57). Proceed through the protocol and write in each expense. It is important to remember the figures placed on the budget worksheet are not the cost of the procedure to the institution but are instead the institutions usual and customary charge (speak with the accounting department or clinic administrator to get an idea of these costs). There are of course many types of expenses which need to be included in the study budget.

It is important to remember that only expenses which are covered by the protocol will be reimbursed by the sponsor. Any additional procedures (not covered within the protocol) should be billed as usual to the patient or their insurance. For example in an inpatient study the patient would still be billed for the stay in the hospital but all procedures included in the study budget (x-rays, lab tests, drug therapy etc.) would not be billed to the patient. A procedure needs to be worked out by the study coordinator and the medical billing department within the hospital so patients on study are identified (and their expenses handled appropriately) so these items are not double billed to the patient or their insurance. It is also important that all department heads (lab, radiology, pharmacy etc.) are informed of the protocol requirements for each patient and how their individual departments will handle the actual billing process for the study patients.

By studying the protocol carefully the study coordinator will be able to gauge a fair budget for both the institution and the sponsor.

In many cases the sponsor will offer the institution a per patient budget amount rather than having the coordinator decide what would be required. Figuring the institutions costs ahead of time will allow the study coordinator to access the fairness of the sponsors offer. In many cases the sponsor will be willing to barter if the study coordinator can show additional costs which will need to be reimbursed. Some of the costs which should be considered are listed below.

A. Visit costs:

There are costs associated with each patient visit to the institution. Assuming the study patient is visiting the institution on an out patient basis then each visit will need to be charged. Figure the time required for each visit and bill appropriately. Naturally the initial visit may require more detailed work (and thus more of the investigators time) and should be billed accordingly. Charge both for the physicians and the nurses time. Figure in the cost of the physical exam, medical history, and all other procedures as detailed in the protocol as well as any specialist fees (i.e.: cardiologist, neurologist) if referrals are required in the protocol. Many follow up visits may require just a short amount of the physicians time or maybe just a visit to see the study coordinator. All these costs associated with each visit need to be charged.

B. Paper work costs:

During and following each study patient visit the study coordinator and other members of the study team will perform a good deal of paper work. This time consuming work needs to be calculated into the study budget. Paperwork is usually factored in as coordinator fee and/or institutional overhead.

C. Study coordinator costs:

The study coordinator will spend a good deal of time recruiting patients, working with the site monitor and training and consulting with other members of the study team. These time costs must be part of the study budget. The coordinator may also be active in patient care; assessing vitals, performing interviews and preparing specimens for shipment so this time and effort must also be figured into the budget.

D. Administrative costs:

There are many types of administrative fees involved in running a clinical trial including IRB fees, parking fees, transportation fees, courier fees, supply fees etc. There may also be a good deal of over night mailing (establish with the sponsor prior to accepting a study who will be paying these shipping fees). Try to make a realistic prediction of the administrative fees involved in the study and include those fees in your budget analysis. Administrative fees are usually considered institutional overhead.

E. Procedure costs:

These are the costs to the institution of all procedures defined by the protocol. This may involve lab work (if a local lab rather than a central one is being used), x-rays, CAT scans, EKG's etc. It is important to figure in the costs of materials (x-ray film, syringes etc.) if these costs have not already been included.

F. Additional Overhead Costs:

These are costs which exist simply because the study is taking place at the institution. Examples of these costs would include electricity, copier use, fax use, telephone, storage, square footage use etc. The most significant of these costs is usually the phone as there are a great number of phone calls made during the course of a clinical trial. These costs are usually figured as a percentage of the entire budget. Depending on the institution, overhead ranges from 10-100% (10-20% is a good rule of thumb).

G. Pharmacy Costs:

Although the test article will be provided for free there still will be work performed by the pharmacy. Dispensing of the test article (especially in the case of an inpatient trial, many of which involve IV's) involves costs that must be figured into the study budget.

H. Physician or Staff Stipends:

Physicians involved in clinical trials will be paid a stipend from the study budget for their time and effort. This must be calculated into the budget as will be stipends for staff personnel or physicians who refer study patients.

I. Patient Participation Stipend:

In many cases some reimbursement will be necessary for the time and effort of the study patients. This is a budgetary consideration.

J. Advertising Costs/Study Promotions:

Depending on the type of advertising utilized to locate study patients this may or may not be a budgetary consideration.

After totaling up all these costs for a single study patient multiply that figure by the number of enrollees to arrive at the study budget total.

II. THE FINANCIAL AGREEMENT:

After all the budgetary details are finalized the sponsor and the research site must come to an understanding on when and how the institution will be paid for their hard work. The document which will contain this information is the investigator agreement. The investigator agreement defines exactly what is expected from the investigator and what in return the investigator can expect from the sponsor. Details usually specified in this document include:

A. The amount of up front money the research site will receive. In most cases the sponsor will forward the research site the equivalent payment of one or two completed protocols. This money is usually paid to the site upon completion of all critical documents and after the study initiation visit has taken place.

B. The time frame of payment for patients completing the entire protocol as the study progresses. In most cases the institution will be paid quarterly for all patients who have completed the study (This is why it is vital to have all paper work completed during site visits by the study monitor). In studies which require patients to be followed for prolonged periods sites are often paid quarterly for completion of stipulated portions of the study protocol.

C. Monetary reimbursement for patients which drop out of the study or do not complete the entire protocol (these are usually paid on a prorated basis).

III. NEGOTIATING PHYSICIAN FEES:

It is vital to be fair with physicians when negotiating their portion of the budget. Without the help of physician investigators the research department will be unable to operate so physicians must be treated fairly. By doing so contract clinical research becomes a win-win scenario for everyone. It is important to explain to study physicians they will be paid after patients have completed the protocol and the research department is paid by the sponsor, so there may be a lag from the time of patient recruitment until actual payment is received.

IV. CASH FLOW AND CHECKING ACCOUNTS:

Although contract clinical research is an exciting and dynamic arena it is important to realize there will be an initial lag in cash flow. Up front money from the sponsors will not be received until the site is study ready and the initiation visits are completed for the sites initial studies. Further funds will not be received until patients have completed the protocol. Therefore it is important to be realistic about cash flow for at least the first six months after opening a research department. Everyone involved in the research department from the study coordinator to the hospital administration will need to exhibit patience during this time.

It is also important to keep a handle on the cash flow once the studies begin. The research department will need a checking account to pay bills and store funds collected from sponsors. To minimize cash flow management problems the hospital may want to assign an administrator to co-sign all checks the coordinator will be issuing. These checks will be for a variety of expenses (physician fees, patient reimbursement, study advertising/promotions etc.) and the coordinator will need ready access to the funds to make sure of timely bill payments.

Careful record keeping of all study expenses is vital. The study coordinator will need to make use of an accounting program (preferably one that the hospital is already utilizing) to keep close records of all study debts and credits. By doing so the study coordinator will be prepared to demonstrate the financial success of the research department at annual budget meetings and to interested administrators.