

Items To Consider When Negotiating a Corporate Funded Clinical Trial Budget

Overview of the Budget Process

DSP will negotiate the language in the Clinical Study Agreement (contract) and the Research Team member will negotiate the budget with the sponsor. Within the language of the contract, there may be some language related to the budget so it is important for Research Team member to also review language within the body of the contract. At the conclusion of the negotiations, the contract language and budget numbers will be combined in order to have a complete contract. This process will involve dialogue between the Contracts Administrator at the DSP and the Research Team member.

The Research Team member negotiating the budget may not be the research nurse conducting the study visits. If these are different people, the two individuals will need to work together to develop an appropriate budget.

Start Up Fees

Usually approx. \$5000 (some \$8000-11,500) non refundable (in case sponsor cancels trial after UI research team has started IRB application, budget negotiations, etc.) In protocols that use WIRB, this fee will include the Human Subjects Office charge). If using HawkIRB, the Human Subjects Office charges a fee not to exceed \$2000 for the initial review. You may be asked to justify this Start-Up Fee. This Start-Up Fee includes all of your Internal Committee and IRB application preparations, budget negotiations, regulatory document preparation as well as on-site visits and study protocol training. It may also include the Pharmacy Start-Up, Pharmacy Close-Out, Record Storage and overall Study Close-Out.

WIRB Fees

State in the contract or on the budget that sponsor will pay WIRB fees directly to WIRB w/o going through the University of Iowa. If they do go through UI, they will incur additional charges of overhead and possible departmental fees. Some sponsors cannot/will not do this, but it is best to let them know upfront that they will be incurring a 25-40% markup if the invoices go through the University of Iowa.

Research Test Costs

Utilize the protocol's *Table/Schedule of Events/Tests* to as a starting point to developing a budget. Even though the sponsor attaches a budget spreadsheet with the contract, you may be able to submit your own spreadsheet or add in line items not included in the budget spreadsheet the sponsor submits with the contract, ask the sponsor what format they require the budget in. Example budget templates can be accessed by the corresponding link associated with this document.

First figure out which tests/procedures/ exams are standard of care, and which are not. This can be determined by the PI or by the study coordinator; it depends on how much experience the study coordinator has with the type of protocol they are working with. The items that are research only are the items you will need prices for. Read the study protocol thoroughly to identify if tests (blood/urine) will need to be analyzed at UI (local lab) or if the blood/urine tubes will be sent outside the UI (central lab). Consider that certain tests (IE: echocardiogram in Heart and Vascular Center) may involve multiple items (full echo vs. limited echo, adding doppler studies and color flow). In reading the protocol and in questioning the sponsor about the specific data requested, clarification can be obtained if a limited test could be done rather than a full test. (Ask to see case report forms if available) Contact research personnel in the clinical areas within UIHC (IE: cardiology, ophthalmology, radiology, vascular lab, anesthesia) to discuss specific data requested by the study and what type of test is needed.

Personnel Time Expense to Conduct Study

Consider the amount of time that a research team member will utilize in order to complete a visit. (informed consent, Inclusion/Exclusion Criteria Review, collecting vital signs, dealing with the sponsor, prepping for visits, prepping forms, subject visit contact, processing/shipping labs, Adverse Event review, Concomitant Medication Review, completing case report forms and entering data into the study electronic data base) and that research team member's current hourly rate based on salary including fringe. These items can be separate line items or listed under research team member time. If it is listed as separate line item, you will have better documentation justifying the fee.

UI Investigational Drug Service (Pharmacy)

If your protocol involves an Investigational Agent that UI Pharmacy Fees will need to be considered in your budget. Refer to http://research.uiowa.edu/hso/index.php?get=comm_pt and follow the guidelines here for determining the fees for using UI Investigational Drug Services.

Research Test Related Discounts

Be aware that some tests (EKG, Chest Xray) have both a Hospital Charge and Professional Reading Fee Charge. The study budget will need to cover both. Most tests done for research will qualify for a research percentage discount.

Refer to <https://thepoint.healthcare.uiowa.edu/sites/Compliance/researchbilling/default.aspx> for guidance in the research billing process for compliance with current guidelines.

Overhead/Department Fees: UI Facilities and Administrative (F&A) costs are 25% of the Total Direct Costs. Your department may also have a department percentage fee. Discuss this with your department's accounting personnel.

Invoiced Items

Many items could also be added as *"Invoiced Items"*. These are things that the sponsor and research team agree upon in advance (or may be renegotiated after the study has started when a special cases arises). These are items that may not occur with each enrolled subject, but when it does occur, it has a significant cost whether in test expense or time expense. Examples of these types of things are: SAE Reporting, IND Report review by PI, Monitor On-Site Visit, Monitor Visit via telephone w/Research Team member, Monitor Change, Yearly pharmacy fee, subject travel/hotel, Yearly study maintenance fee, IRB/WIRB costs, Consented Screen Failures, Certified Letters, Research Team member prep work for IRB Amendments/Annual Reviews, and Dry Ice.

Some items may be listed on your budget spreadsheet as *"Invoiced Items"* if the sponsor won't pay them as part of your Start-Up Fees. Examples of these are Pharmacy Start-Up, Pharmacy Close-Out, Record Storage and overall Study Close-Out.

Ongoing Budgeting Activities

It is important that you conduct a review (audit) comparing UI expenses with payments received from the sponsor. Also during the life of the trial if UI expenses have increased or you've become aware that enough money wasn't budgeted for an item, you have the right to re-negotiate the budget with the sponsor.

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