

NEGOTIATING BETTER RESEARCH CONTRACTS

It is a fact-based mission.

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Unfortunately, many doctors feel that their lack of negotiation skills detracts from the overall experience of participating in clinical research. Sure, a simple search will produce thousands of resources on becoming a master negotiator, but who has the time to look at them all? Is there a surefire way to improve at negotiations? My answer is yes.

In my 15 years of providing clinical research training and consulting for ophthalmic research practices, something that has never failed my clients or me is this motto: you can't fight the facts.

I have found that these five words, when applied to individual concepts, can actually force change.

Better contracts and budgets require you to know *your* facts. This solid foundation will validate your need for specific contract amendments, increased budgetary demands, and so on. Without fact-based knowledge, your negotiations are at risk of failure, and important relationships may be damaged.

FINDING YOUR BUDGETARY FACTS

Few sites know to the penny the cost of operating overhead (see *Know Your Site's Overhead*). Many fail to obtain input from consultants or their personnel. Instead,

KNOW YOUR SITE'S OVERHEAD

BASIC MATH

The profit equation

$$\text{Projected Protocol Budget} - \text{Actual Operating Expenses} = \text{Profit or Loss}$$

OPERATING EXPENSES

The operating cost equation

$$\text{Salary} + \text{Benefits} + \text{Overhead} = \text{Operating Cost (research costs only)}$$

CUSTOMARY FEES

- Normal/customary fees for procedures
- Insurance reimbursement for procedures



practitioners and administrators look only at the final figure and hope that it will cover the cost of participating. Know your numbers!

Undisclosed fees are potential out-of-pocket expenses that may not be reimbursed if they are not negotiated at the time the contract is signed. These expenses include

- Travel expenses (eg, meetings, subjects' travel expenses)
- Photography/fluorescein angiography/video (USB, CD, or cloud storage expenses, time involved for collection, storage preparation)
- FedEx/UPS fees: verify that the sponsor will supply an account number, and add this to the contract
- Binders/materials: verify what the sponsor supplies, and add this information to the contract
- Surgical site fees: verify what the sponsor will cover if the subject's insurance fails to cover the cost of the ambulatory surgery center, and add this information to the contract
- Pharmacy fees: verify sponsor reimbursement, and add this information to the contract
- Laboratory fees: verify sponsor reimbursement, and add this information to the contract
- Patient insurance copayments: verify sponsor reimbursement, and add this information to the contract

- Long-term study data archive costs: verify sponsor reimbursement, and add this information to the contract
- Potential marketing/advertising: clarify this matter prior to finalizing the budget agreement. If you are unable to determine a monetary number, add an element to the contract stating that the site will “invoice” the sponsor for any “sponsor-approved” marketing/advertising costs associated with the recruitment of study subjects
- Additional office expenses such as paper and toner: monitors make copies, which cost your practice money
- Remote source data verification/centralized monitoring activities: these require additional time of the study coordinator, who must upload the source documents. This work/time is not usually covered in the budget. There is also the potential cost of scanners, copies, etc.

FINDING YOUR CONTRACT FACTS

Recruitment, randomization, and retention (R-R-R) numbers are extremely important for successful contract negotiations. If asked to enroll 40 subjects, the best R-R-R numbers would be 40-40-40. Based on past study participation, I would say that consistently even R-R-R numbers support the following facts:

- High recruitment numbers display to a sponsor your ability to engage patients’ desire to participate in studies at your site.
- High randomization numbers demonstrate your ability to select the best patients meeting inclusion and exclusion criteria and to minimize wasted time and screening failures.
- High retention numbers show your ability to maintain subjects’ desire to contribute their time through a study’s completion.



FOCUS ON FACTS: EXAMPLES

When negotiating your next project, do not worry that you lack negotiating skills. Instead, focus on your facts for success. Here are some examples:

- I am unable to agree to a budget that clearly does not identify whose responsibilities these potential expenses will be. Who can provide clarification on this matter?



AT A GLANCE

- Many doctors feel that their lack of negotiation skills detracts from the overall experience of participating in clinical research.
- Better contracts and budgets require you to know your facts. For example, what is the cost of operating overhead to the penny?
- Recruitment, randomization, and retention numbers are extremely important for successful contract negotiations.

- I politely disagree. Nor can I accept that statement, because the industry standard for reimbursement of A, B, and C is D. I can provide exact reimbursement numbers. With whom should I discuss this?
- I understand that there are limitations on what you can approve. Please provide me with details on the person who can make a final decision.

When a contract fails to provide clarity, here are some strategies to consider:

- If unable to confirm solid responses regarding these potential unexpected fees, then a comment must be added to the contract that will allow for invoicing of these items as the need arises.
- Per the contract/protocol, the study data must be archived for 99 years. Because exact costs therefore cannot be calculated, a line item for direct invoicing of the sponsor for the annual expense of data storage will be added.
- Obviously, this contract was designed for a site with lesser experience. My site’s experience and recruitment numbers support a significant increase. With whom should we discuss this?
- High recruitment/randomization is established by direct advertising, website maintenance, etc., a portion of which has been added to the budget.
- The sponsor will be invoiced a nonrefundable startup fee of \$3,500 after Institutional Review Board approval has been obtained. ■

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