



Negotiating Clinical Trial Agreements



Q

How do you approach a sponsor about changes to fees (annual increases) and addition of new fees?

A

Sponsors look at previous contracts expecting to have the same costs from year to year. Sites can definitely use a previous clinical trial agreement in their favor. Providing justification puts you in a better negotiating position. Point out how many years have gone by and calculate the purchasing power of our dollar over time (there are free online 'inflation calculators' that will do this for you). With the passage of time, you are likely paying more for space, staff, utilities, etc. to run a trial, and the sponsor must recognize this. Identify specific financial pain points your site suffered on the last study you conducted for that particular sponsor. For example, if you had several SAEs that were not reimbursed for, cite that number and calculate the amount of hours that your staff spent filing SAEs, and appropriately state that you can't agree to a scenario which puts you at risk to experience these losses again.

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Should we include overhead for invoiced advertising, recruitment and IRB fees?

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While we see sites handle this differently, the most common approach we see is for sites to include overhead on most budget items except pass through costs.

Q

There is a significant disincentive for prompt enrollment and timely completion of the target number of subjects, as 10-20% of earnings may be held for months or years before the database is locked. How can this be avoided?

A

Always try to eliminate or reduce holdback. Remember you can get creative and request a monetary cap or time limit. Also try to negotiate the holdback to be released when the data is locked at your site,

versus study wide. Strike language that refers to data lock for the entire study, and insert verbiage along the lines of "with final payment payable upon Institution completion of all obligations under this Agreement and any exhibits thereto."

Q

Months may go by with no queries and then many are received with short deadlines. What statement can be made in the clinical trial agreement to avoid this?

A

Usually sponsors require deadlines for the resolution of queries. During your contract negotiation, give the sponsor a similar deadline in regards to data review. For example, "Payment shall be made upon Sponsor's review and approval of all Case Report Forms submitted, which shall occur no more than ten (10) business days after submission of Case Report Forms." If delays have happened in the past with certain sponsors, be sure to note that as strong reasoning for such a deadline.

Q

What can you do to prevent the sponsor from sending you un-itemized payments?

A

Unfortunately, not much. The sponsor usually has a process in place with their accounts payable department that is sending you the check. However, you can request this information from your accounting contact at the sponsor when you receive the check and they almost always have a breakdown of what you are getting paid for.

Q

Can you charge interest on late payments?

A

If the sponsor approves this in writing in your clinical trial agreement, yes! However, it is very unlikely that a Sponsor will approve such an item. If you know a sponsor or CRO is notorious for doling out late payments, request it.