



CENTRE FOR INNOVATIVE MEDICINE – CIM

BUDGET SPECIALISTS

NEGOTIATING A BUDGET

1. Documents needed for Review

- Start-Up, REB & Pharmacy Fees- non-negotiable & non-refundable- a must in the budget.
- Protocol – need the table of assessment to either build or compare the procedures listed in the sponsor budget
- ICF – patient compensation as well have information about the visits
- Exhibit – language around payment schedules, terms, holdback, invoicing, archiving, etc
- 3rd party Quotes – from other department or external vendors (ex: nursing, ophthalmology, labs, pathology, etc.)

2. Negotiating your sponsor's external budget

- Start-Up, REB & Pharmacy Fees- non-negotiable & non-refundable- a must in the budget.
- Overhead- 30% - applicable to direct costs on pharma studies with the exception of Start up, REB, and pharmacy fees.
- Study Coordinator/Data Entry/PI Fee/ Patient Stipend - add to every patient visit
- Re-consenting, Local labs, Pathology, Ophthalmology- add in patient budget if applicable
- Archiving, Close Out Visit- add in budget

3. Optional Fees Recommended

- Lead site submission Fees
- On-site Monitoring Fees
- Remote Monitoring Fees
- Administration fee for submissions of annual renewals and amendments
- Audits
- SAE reporting
- Screen failure/ Rescreening
- Unscheduled visits
- Holdback
- Advertising
- Invoice uploading to sponsors site

NEGOTIATING AN EXHIBIT

1. Negotiating your sponsor's Exhibit

- Start-Up, REB & Pharmacy Fees- non-negotiable & non-refundable- when and how you will be paid. Always have it state upon Fully Executed CTA.
- REB Terms – How will this be paid
- Currency of Budget - important when receiving funds or invoicing to sponsor
- Taxes – we are non-profit organization – tax exempt
- Holdback – some sponsors will hold back some of the funds, usually 10%, try to remove or lower it to 5%
- Unscheduled visits – identify what is needed in the unscheduled. Remember to include the PI, SC fee as well as the patient stipend.
- Screen failure – Ratio –ex: 1:3, will pay one screen failure for every 3 subject randomized. Negotiate to no ratio's
- Payment terms - how will the sponsor pay for the patient budget, ex: automatic or invoiceable by visit or per assessment? how often will they pay.- monthly, quarterly, etc
- Instructions and address of where invoice items are to be sent
- Address of payee – insert RI address

2. Finalizing Budget

- Once negotiations are finalized, the sponsor will forward you the clean final copies of the budget and the exhibit
- Review those documents to confirm that they are the correct ones you have agreed to.
- Reply to the sponsor and include your Contract Officer, reply with approved documents as the final version and the Contract Officer will complete the rest of the process with them.
- Remember to include the OCC file # that has been provided to you by the Contracts office.
- It is the Contract Officers responsibility to do a last review of the CTA which includes your final budget before signature process. * As a precautionary note, before signing the agreement, review the budget to confirm that the one that you approved is the one that is attached.



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Developing a clinical trial budget can be confusing exercise for all parties involved. There are many cost variables to account for. Here a some key cost points for clinical trials.

SITE COSTS

Site Start-Up, Pharmacy & REB Fees, Overhead, Archiving.

SITE MANAGEMENT COSTS

Pre-study visits, Monitoring – Remote or On-site, Document Translation, Amendments, Annual renewals, Close-out

PATIENT COSTS

Pre-Screening, Screening, treatment and follow-up visits, screen failure, overnight stays, non-standard of care tests, 3rd party cost (imaging, lab, etc..) Patient reimbursement (parking & meals),

PATIENT ADMIN COSTS

Principal Investigator Fees, Study Coordinator/ Nurse Fee, Data entry fee, Pharmacy admin, dispensing and yearly fees. SAE reporting

