



Procedure Name: Protocol Budget Development Procedure
Effective Date: March 29, 2010
Revision: 01
Initiating Department: Office of Clinical Trials
Procedure Number: OCT-011
Application: Protocol Budget Development
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OBJECTIVE:

The objective of this procedure is to define the process for developing budget counter proposals.

SCOPE:

This procedure applies to all proposed clinical trials governed by OCT

BACKGROUND:

When the Principal Investigator (PI) receives a study proposal, the proposal contains two documents: a protocol and an initial proposed budget prepared by the sponsor. Before proceeding further, the PI must answer two questions:

1. Is the PI interested in conducting the study?
2. Does the sponsor's budget proposal appear reasonable to the PI?

If the answer to both questions is "yes", the PI will confirm his interest in the project to the Office of Clinical Trials (OCT) and the budgeting process will begin.

DEFINITIONS:

Initial proposed budget – the original budget prepared by the sponsor accompanying the initial proposal.

Counterproposal – suggested revisions to the sponsor's initial proposed budget presented to and negotiated with the sponsor.

PROCEDURE:

Once the PI decides he/she wants to conduct the study, the PI notifies OCT and forwards a copy of the protocol and the initial proposed budget to the OCT Financial Manager for initial review.

1. After review, the Financial Manager forwards the budget documentation and the protocol to the Director of Clinical Trials, along with any suggestions for counterproposals.

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2. From this point forward, the Director of Clinical Trials (Director) will be the sole point of budget contact between the sponsor and the Health Science Center on budget negotiations.
3. The Director will develop the counterproposal and submit it to the sponsor for negotiation.
4. At a minimum, the budget counterproposal will be in substantially the same format as the original budget provided by the sponsor and will address following:
 - i. Invoice items such as initial IRB fees, startup fees, document storage fees, pharmacy setup fees, SAE fees, change in consent form fees, and pass through fees such as advertising will be addressed separately from fees related to subject visits. Please refer to OCT Appendix A: Standard Fees for a complete list to cover.
 - ii. An appropriate indirect cost rate on a subject visit basis of at least 25%.
5. Once the counterproposal is completed, the Director will submit the counterproposal to the sponsor and will be solely responsible to conduct and conclude negotiations with the sponsor.
6. When the Director and sponsor jointly agree to a budget which, in the opinion of the Director, is in the best possible interest of the Health Science Center, the Director will discuss the final budget with the PI.
7. Upon agreement with the PI, the Director will include the budget in the packet submitted to the IRB.

REVISION HISTORY

Rev	DCO	Description of Change	Approved by
1	10-111	Replacement of "policy" with "procedure"; "original" with "initial proposed" budget; "patient" with "subject" and addition of change history.	MVWB

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