

In This Issue

- Building an Accurate Budget

Quick Links

- [University Hospitals](#)
- [Center For Clinical Research](#)
- [Office of Research Compliance](#)
- [UHCMC IRB](#)
- [UHCMC Grants and Contracts](#)
- [William T Dahms Clinical Research Unit](#)
- [Clinical Trial Listing **NEW!**](#)



Questions, Comments, Suggestion?

If you have questions, comments or have a suggestion about how we can improve our human research protection program (HRPP) at UHCMC, send an email to: clinicalresearch@uhhs.com or contact Carol Fedor, Clinical Research Manager at (216) 844-5524

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The Importance of Building an Accurate Budget

The Grants and Contracts Pre-Award team provides support to the research community by assisting with the creation and negotiation of study budgets for foundation grants and industry sponsored clinical trials. The Grants and Contracts Pre-Award office has identified some commonly overlooked items in detailed budgets submitted to the Center for Clinical Research and Technology. All study budgets should include in detail, each procedure or service outlined in the clinical trial agreement or grant. The optimal way to capture all study related procedures is to ensure that the budget corresponds with the schedule of events found in the study protocol. Below is an example of a detailed budget and the most common overlooked budget items.

Clinical Trial Budget - Dr. Denton - Cost per subject							
Direct Cost Procedure	Charge per procedure	Start-Up	Visit 1	Visit 2	Visit 3	Study Closure	Total
Stress Test*	\$ 0	\$ 0					\$ -
Informed Consent	\$ 100	\$ 100					\$ 100
History and Record Review	\$ 50	\$ 50					\$ 50
Physical Exam	\$ 75	\$ 75	\$ 75	\$ 75	\$ 75		\$ 300
Blood Draw	\$ 35		\$ 35				\$ 35
EKG	\$ 75		\$ 75				\$ 75
EKG Reading	\$ 50		\$ 50				\$ 50
CRF Completion	\$ 25	\$ 25	\$ 25	\$ 25	\$ 25		\$ 100
Subject Reimbursement	\$ 10	\$ 10	\$ 10	\$ 10	\$ 10		\$ 40
CRC Fee	\$ 50/per hour	\$ 50	\$ 50	\$ 50	\$ 50	\$ 150	\$ 350
Principal Investigator Fee	\$ 75/per hour	\$ 75	\$ 75	\$ 75	\$ 75	\$ 225	\$ 525
Sub-Total		\$ 385	\$ 395	\$ 235	\$ 235	\$ 375	\$ 1,625
Overhead (F&A Cost)	30%	\$ 96	\$ 99	\$ 59	\$ 59	\$ 94	\$ 407
		\$ 481	\$ 494	\$ 294	\$ 294	\$ 469	\$ 2,032
Total Expected Subjects							10
							\$ 20,320
STUDY TOTAL							\$ 20,320
* Standard of Care (SOC)							

Commonly overlooked items in budget building

- The Institutional overhead rate for industry sponsored trials is currently 30%.
- Study Start -Up Fees - Should cover the costs associated with beginning a study such as the time taken to submit an agreement or grant to the Grants and Contracts Office.
- Early Termination Fees - If a study is terminated early, the sponsor is responsible for compensating the Institution not only for all the work which has been performed up through the date of termination, but those non-cancelable obligations incurred as well.
- Institutional Review Board Fees - This should include not only the initial submission to the Institutional Review Board, but each amendment to the protocol, each continuing review, as well as termination of a protocol.
- Standard of Care (SOC) - If a procedure in the study is considered SOC then this should be listed on the detailed budget as in the example shown above.
- Investigational Pharmacy Fees - If the study requires the use of the investigational pharmacy, these fees should be built into the budget. This fee can be listed as flat fee or as a per patient fee.
- Patient Stipends - Most sponsors will provide an amount to the Institution to compensate patients for their participation in the study. This is normally used to compensate the patient for the time taken to participate in the study.
- Advertising Fees - Covers the cost associated with advertising.
- Record Retention/Archiving Fees - Will cover the cost associated with storing study records.