

OFFICE FOR EDUCATION & QUALITY IN CLINICAL RESEARCH	CATEGORY	Clinical Research: Study Management
	SUBJECT	Developing a Budget
	SOP #	2.5
	EFFECTIVE DATE	August 6, 2008
	REVISION DATE	August 27, 2018

OBJECTIVE

Provide a guideline for preparing or evaluating clinical research trial budgets. These procedures apply to all clinical research activities approved by the Office for Human Subjects Research conducted within the Hennepin County Medical Center campus.

APPLICABLE REGULATIONS AND GUIDELINES

Hennepin Healthcare Research Institute Sponsored Project Administration: Guidance and Procedures
HCMC Research Resource Approval Process

REFERENCES TO RELATED SOPs

- SOP 2.1
- SOP 2.3
- SOP 2.4

ATTACHMENTS

None

- 1) Define all study-related costs and cost recovery. Grant Administrators are available for advice as needed.
 - a) The total study budget is the total anticipated study cost across all fiscal years including appropriate indirect costs.

- 2) Access the study schedule of activities.
 - a) Develop a budget worksheet using the schema and protocol.
 - b) Separate the budget worksheet into two sections for protocol costs and personnel costs.

- 3) Protocol costs
 - a) Protocol costs are costs directly linked with the protocol, subject care, or subject related stipends.
 - b) Protocol costs may be a one-time cost or recurring throughout the life of the subjects' enrollment
 - c) Protocol fees may include, but are not be limited to, IRB fees, test fees (laboratory, ECG, radiology, etc.), pro-fees, rental fees, copying costs, investigational pharmacy costs, advertising costs, mailing fees, or subject remunerations.
 - d) Identify services and tests used in the protocol that are NOT standard care.
 - e) Ensure that a HCMC Research Utilization Checklist is completed when enrolling HCMC patients, even if no HCMC resources will be used.
 - f) Pricing information and contacts of various resources (i.e., Laboratory, Radiology) are available. Ensure that you have the correct research pricing information by contacting researchinquiry@hhrinstitute.org
 - g) Review the schematic design and add up the fees for all tests and services for one subject. Add any other recurring protocol induced costs for one subject.
 - h)

- 4) Personnel (staffing) costs
 - a) Evaluate the time required by study personnel to complete study specific tasks for one subject.
 - b) In addition, do not forget time needed for non-subject duties such as screening, completing case report forms, participating in study monitor visits, answering study queries, corresponding with the sponsor, IRB, laboratory etc., and maintaining regulatory files.
 - c) Ensure that all personnel are accounted for including coordinator, PI, ancillary staff.

- 5) Direct costs
 - a) Once you have the per-subject protocol and personnel costs added, multiply it by the number of subjects to be enrolled at the site.
 - b) Add the one time protocol cost fees.
 - c) The resulting number will be the total direct costs for the study.

- 6) Consider the need to budget time for increased screening. Common characteristics make it more difficult to recruit thus necessitating increased screening time. These common characteristics include:
 - a) The complexity of the protocol
 - b) The time commitment of the protocol
 - c) Length of subject follow-up
 - d) Complicated inclusion and/or exclusion criteria
 - e) It is more difficult to recruit children, minorities, women, and the elderly
 - f) Requiring DNA or genetic sampling as part of the protocol

- 7) Institutional indirect costs
 - a) Add the appropriate indirect costs to the direct costs and you will have the total costs for the study.
 - b) THERE ARE DIFFERENT FORMULATIONS TO USE DEPENDENT ON THE TYPE OF PROJECT (FEDERAL VS. NON-FEDERAL).

- 8) Federal indirect costs
 - a) Indirect costs are taken at the time of expense by the project.
 - b) The federally negotiated indirect cost rate is based on salaries/wages only, therefore the federal indirect cost rate is calculated only on salaries and wages budgeted for the project.
 - c) Total salaries/wages*indirect cost rate = total indirect costs.
 - d) Total salaries/wages and other direct costs + indirect costs = TOTAL COSTS.

- 9) Non-Federal indirect costs
 - a) Indirect costs for non-federal projects are charged based on cash receipts or project income.
 - b) This means that indirect costs are taken at the time of payment by the sponsor instead of at the time of expense by the project.
 - c) This is an important distinction; if non-federal indirect costs are not calculated correctly, a project may not have enough revenue to cover direct cost.
 - d) When calculating indirect costs on a cash receipts basis, determine the total direct costs necessary to complete the work. Divide the total direct costs by one minus the overhead rate. This will calculate the total dollars needed to pay direct and indirect costs.
 - e) $\text{Direct Costs} / (1 - \text{Overhead Rate}) = \text{TOTAL COSTS}$.

- 10) Ensure that the assigned Grant Administrator is aware of budgetary requirements so that s/he may negotiate with sponsor as needed.

11) EPIC Research Billing

- a) Training is required. Contact researchinquiry@hhrinstitute.org for more information and to schedule training
- b) If HCMC resources are utilized, set the study up in EPIC.
- c) The HHRI study becomes the guarantor.
- d) ***It is important that subjects or insurance NOT BE charged for research activities.***
- e) researchinquiry@hhrinstitute.org for assistance with the Medicare Analysis Tool and pricing