

Subject: COST PRINCIPLES		Issued By: OFFICE OF CONTRACT ADMINISTRATION	
		Approved By: Kathleen R. Hurtado President & CEO	
Policy #: 1050	Issue Date: May 26, 2005	Revised Date: March 29, 2006	Effective Date: March 31, 2006

Reference:
PSA P&P GAC-004

PURPOSE

The purpose of this policy is to establish guidelines concerning costs that are associated with HRA-administered, industry-sponsored, clinical research projects.

GENERAL INFORMATION ON PROJECT COSTS & FUND ACCOUNTING

Each HRA clinical research project will be established and accounted for as a distinct entity. Funds and/or expenses for any particular project or activity may not be commingled with funds and/or expenses for any other projects or activities. This type of accounting is known as “Fund Accounting.”

Fund accounting is defined as having three attributes:

1. Segregation of funds by purpose or restriction,
2. The incorporation of budgetary controls into the accounts to ensure that expenditure limits are not exceeded, and
3. The tracking of outstanding commitments as well as expenditures.¹

Each project number, assigned by HRA’s Office of Contract Administration, identifies a particular project/activity funded by a particular agency or sponsor. An individual project’s costs can be further divided into direct costs – such as patient reimbursements, lab fees, etc... – and indirect costs – such as overhead, division tithing, etc....

POLICY

1. **DIRECT COSTS:** Direct costs are those costs which can be identified specifically with a particular cost objective or expense category relating to a specific project. Most awarding agencies have certain restrictions on the types of direct costs which would be allowable to any specific grant or contract;

¹ University of Toronto definition located here: <http://www.internalaudit.utoronto.ca/English/Glossary-of-Terms.html>

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2. **ALLOWABLE COSTS:** Only research costs may be billed to a project, and only when provided for in the project’s IRB-approved budget. “Standard of care” charges must be billed to the patient or to their health insurance company. Additional factors which must be considered in determining whether a particular cost is an allowable charge to any particular grant or contract are:
 - a) Reasonableness;
 - b) Allocability – application of generally accepted accounting principles and practices, and;
 - c) Any limitations or exclusions established for the particular grant or contract award.

3. **DEFINITION OF REASONABLENESS:** A cost is reasonable if, in its nature or amount, it does not exceed that which would ordinarily be incurred by an ordinarily prudent person in the conduct of competitive business. The cost must be of a type which is recognized to be necessary to perform the activities of the particular grant or contract;

4. **DEFINITION OF ALLOCABILITY:** A cost is allocable if the amount charged to the particular grant or contract is in accordance with the relative benefits received by that grant or contract. A cost is allocable if it:
 - a) Is incurred specifically for a particular grant or contract,
 - b) Benefits the grant and/or the contract and can be distributed to a project in reasonable proportion to the benefits received, or
 - c) Is necessary to the overall operation of the institution, although a direct relationship to any particular cost objective cannot be shown.

5. **INDIRECT COSTS:** Indirect costs are those costs which are difficult to identify with a particular grant/contract/project and are, consequently, pooled and distributed to all grants/contracts/projects which allow indirect costs. The indirect cost rate is not a measure of efficiency, nor is it a duplication of costs. It is simply a way of recovering costs which are not directly applicable to a particular project but which are general costs spread to all projects. These costs include administrative personnel, purchasing and accounting services, insurance, IRB Fees, Research Pharmacy Fees and General Clinical Research Center support;

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6. **OVERHEAD AS DIRECT CHARGES:** The policy of HRA is to direct charge those projects which do not allow indirect costs to be recovered by charging a flat overhead rate. Indirect costs must be recovered for the necessary services required to administer the grant, which are not provided directly by the investigator's staff, such as bookkeeping, payroll, personnel, property inventory, purchasing, etc. This policy is utilized only when it does not conflict with the policies of the grantor;
7. **ESTIMATING DIRECT CHARGES WHEN BUDGETING:** At the time that the Office of Contract Administration is working on a particular project's initial budget, it is necessary to accurately estimate the amount of direct charges to be made to the project. In all instances, at the time a project is submitted for approval, an attempt is made to include funds for administrative services in the budget. This can be done on an hourly basis, per position, with a corresponding dollar amount. In some instances, it may not be possible to bill the project for these services; however, every effort will be made toward this end;
8. **CURRENT COST RATES:** (effective for 2003 and 2004 fiscal years). The current indirect cost rates established within HRA are effective until amended.

<u>PROGRAM</u>	<u>O/H RATE</u>	<u>BASE</u>
Education Programs	10.0%	Total Direct Costs
Therapeutic Research Studies	25.0%	Total Direct Costs
Miscellaneous Projects (Foundations, Associations, Donations, etc., unless otherwise stipulated by the agency)	25.0%	Total Direct Costs

RESPONSIBILITY

HRA Office of Contract Administration
Principal Investigators
OCA Department Staff