

Title: Establishing a Research Study Budget and Management of Research Funds	*Applicable to: Beaumont Health	Effective Date: 04/04/2018
		Last Periodic Review Date: 04/04/2018
Policy Owner: Administrative Director	Document Type: Policy	Functional Area: Research Finance and Billing, Research Institute

***For This Document, Beaumont Health Includes:**

- Beaumont Corporate Shared Services
- Beaumont Hospital, Dearborn
- Beaumont Hospital, Farmington Hills
- Beaumont Hospital, Grosse Pointe
- Beaumont Hospital, Royal Oak
- Beaumont Hospital, Taylor
- Beaumont Hospital, Trenton
- Beaumont Hospital, Troy
- Beaumont Hospital, Wayne
- Beaumont Medical Group
- Beaumont Pharmacy Solutions
- Post Acute Care

I. PURPOSE:

The purpose of this policy is to provide guidelines for developing individual budgets for research studies conducted at Beaumont Health (BH) and describing the management of study funds.

II. GENERAL:

- A. This policy applies to all BH research, including but not limited to research using BH facilities, staff, patients or the BH name and to the use of Beaumont resources for Capstone projects conducted by students of the Oakland University William Beaumont School of Medicine.
- B. Accurate knowledge of research costs and the corporation’s investments in research are essential to the successful administration of the research enterprise at Beaumont. An accurate budget for research projects or grant applications with external sources of funding (e.g., federal, commercial, non-governmental organization, philanthropy/Foundation), allows the Research Institute (RI) to negotiate reimbursement to fully cover the costs of conducting the research. For internally funded (e.g. Beaumont funded a.k.a. “unfunded”) projects, an accurate budget enables leadership to understand, assess and potentially approve the investment of institutional resources for a particular project or a research program overall.
- C. Costs incurred to conduct research include both **direct** and **indirect costs**. Direct costs include but are not limited to personnel, supplies, non-standard of care patient costs, shipping and handling, etc. Indirect costs include, but are not limited to, facilities/space, legal review, Corporate, Medical, and Research Administration resources utilized.

Disclaimer: User must ensure that any printed copies of this policy/procedure are current by checking the online version of the policy/procedure before use.

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D. Externally sponsored clinical trials must have a clinical trial agreement (CTA) in place with the sponsor, documenting their financial obligations to support the study. A sponsor’s budget must be included as part of the CTA. The CTA will also cover other sponsor obligations, including, but not limited to, plans for disseminating findings from the research and the roles Researchers and Sponsors will play in the publication or disclosure of results and communicating any information that could directly affect the health or safety of past or current study participants or influence the conduct of the study, including but not limited to the study results and information in site monitoring reports and data safety monitoring committee reports as required by the protocol.

III. POLICY:

A. Budget consideration must be given for every research project (e.g., clinical trial, bench, animal, outcome, translational) conducted at or under the authority of BH. General guidelines for determining which projects require budget development include:

1. All **full board IRB review requests** require study budget development.
2. All **funded projects** require study budget development.
3. All **unfunded projects** require study budget development except those with no resources utilized other than resident/fellow effort.

The PI and Chair must acknowledge by signature and the RI must approve the budget prior to the start of any work on the project. All funding associated with BH research must be administered by the Research Institute.

B. **Responsibilities** - The PI bears primary responsibility for the conduct of the research project, including budgeting, fiscal management, and compliance with all BH and Research Institute policies and procedures.

The PI, under the approval of his/her Chair, is responsible for working with the Clinical Research Manager (CRM) or Research Lab Manager and the Research Finance and Accounting, Grants and Contracts Administration (RFAGCA) analyst to prepare the budget. For projects originating from departments without a CRM or Research Lab Manager, the RI Administrative Director or designee will determine who the PI should contact prior to engaging an RFAGCA analyst to develop the budget. RFAGCA is responsible for collaborating with the PI and CRM/Research Lab Manager to develop the study budget.

C. **Budgetary Requirements** - Requirements for preparing a research study budget include:

1. The PI must provide a protocol or research plan which includes a detailed explanation of the study and for studies involving human participants, a chart of events.
2. The budget must be well defined to ensure the revenues and costs associated with all research activities are included.

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3. All research project budgets and funds must be approved by the appropriate Chair as well as approved and administered by the Research Institute.
 4. Budgeted revenues must include those expected from all sources. All payments received in connection with research at Beaumont must be disclosed.
 5. The budget must include all expenses directly associated with the project, regardless of the division or department ID in which they are originally incurred. For example, the costs of research activities which take place outside of Business Unit 10108 and must be included in the research study budget.
 6. Salaries, FICA, and fringe benefits must be budgeted and will be based on reasonable estimates of time expected to be spent on the study by each staff member, whether the individual(s) normally work in Business Unit 10108 or another division. FICA and Fringe Benefits cost will be applied at the established rates.
 7. During budget preparation, the protocol schedule of events, the IRB Application, and the sponsor's budget will be reviewed to identify tests and procedures being paid for by the sponsor and/or those considered to be non-standard of care. These tests and procedures will be included in the research budget at the Medicare reimbursement rate. The study budget and IRB Application must be consistent in listing the items to be paid for by the study.
 8. Fees for protocol-required professional clinical services reimbursed by the sponsor, or clinical services not considered as standard of care, must be incorporated into the study budget. This requirement applies whether the services are provided by study investigators or another clinician.
 9. All budgeted travel expenses must conform to Beaumont Health policy [Employee Expense Reimbursement](#). Travel for seminars must have a research business purpose directly related to the project Department ID to which it is charged.
 10. All consulting services provided to external entities will be budgeted in accordance with rates and calculation addressed in Research policy [External Research Consulting Services](#).
 11. For commercial/non-federal funded projects, the research budget should include indirect costs at 25% of expected revenue, typically corresponding to 33.33% of direct costs. For federally funded projects, the rate negotiated with the Division of Cost Allocation of the Department of Health and Human Services (DHHS) will apply. Studies funded internally (by BH operating budget) or with funds from the Beaumont Foundation in most instances will not be assessed indirect costs.
- Other budgetary requirements may be identified based on the individual characteristics of the research study.

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- D. **Sources of Funds** - All monies, including those for research, received by and recorded on the books of BH, regardless of their source, are the property of the hospital and are “hospital funds,” as all contracts or grant awards related to Beaumont Research will be awarded to the Institution not the individual.
- E. **Processing Payments Received** - All payments received in connection with research activities conducted at BH must be directed to the RI. Direct payments to individuals related to BH research from outside sources are not allowed. Research payments must not be directed to private practices or other entities. Funding organizations must be instructed to make checks payable to the legal entity that conducts the research (i.e. Oakwood Health System, Botsford General Hospital, William Beaumont Hospital).
- F. **Expenditures of Research Funds** - All research expenditures must be approved by the RI, in compliance with Beaumont Health policy *Authority Matrix*. There is only one set of standards for the use of hospital funds, regardless of the division, Department ID or “fund” in which the monies are recorded:
1. Costs must be reasonable and necessary.
 2. All costs incurred must be charged or assigned to the research projects to which they relate.
 3. Costs must be given consistent treatment through application of Generally Accepted Accounting Principles.
 4. Costs must conform to any limitations or exclusions set forth in the terms and conditions of the individual grant/award or applicable laws and regulations.
 5. Costs must be net of all applicable credits that result from transactions, e.g., purchase discounts, rebates or allowances.
 6. Costs must be adequately documented i.e. charging of salaries and wages must be based on time and attendance payroll records, personnel activity reports or other time and effort records on the basis of the amount of effort applied to the project (in accordance with RI policy #302 *Employees Working on Beaumont Research Outside Their Normal Employment Duties* and #303 *Research Time and Effort Reporting*).
 7. Requests for payments to vendors or service providers must be accompanied by an invoice and documentation of receipt of the products or services being invoiced.
- G. **Deferred Revenue for Dormant Research** - Unless specifically prohibited by law or contractual agreement, deferred revenue for dormant research projects may be used to offset the costs associated with carrying the staff required to complete the project.

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H. **Residual Net Income/Loss** - In the event revenue either exceeds or is insufficient to cover those costs directly charged to the project, the Net Income/Loss is retained/borne by BH.

IV. REFERENCES:

- Beaumont Health policy - *Authority Matrix*
- Beaumont Health policy - [Employee Expense Reimbursement](#)
- RI Policy [Research Administration Oversight](#)
- RI Policy [Competitive Grant Proposal Development and Submission](#)
- RI Policy [External Research Consulting Services](#)
- RI Policy #300 *Professional Activity Fee and Indemnification*
- RI Policy [Clinical Trials Billing Cycle](#)
- RI Policy [Employees Working on Beaumont Research Outside Their Normal Employment Duties](#)
- RI Policy [Research Time and Effort Reporting](#)

CORPORATE AUTHORITY:

Beaumont Health (“BH”) as the corporate parent to William Beaumont Hospital, Botsford General Hospital, and Oakwood Healthcare Inc., (“Subsidiary Hospitals”) establishes the standards for all policies related to the clinical, administrative and financial operations of the Subsidiary Hospitals. The Subsidiary Hospitals, which hold all health facility and agency licenses according to Michigan law, are the covered entities and the providers of health care services under the corporate direction of BH. The Subsidiary Hospitals’ workforces are collectively designated as BH workforce throughout BH policies.