

Title:	*Applicable to:	Effective Date:
Competitive Grant Proposal Development and	Beaumont Health	01/11/2018
Submission		Last Periodic Review Date:
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Policy Owner:	Document Type:	Functional Area:
Administrative Director	Policy	Research Administration,
		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. <u>PURPOSE</u>:

The purpose of this policy is to provide Beaumont Health (Beaumont) researchers with guidelines for competitive grant proposal development and submission to sponsor organizations.

II. BACKGROUND:

Researchers are strongly encouraged to seek external funds for research, instruction, curriculum development, training, equipment, and community service from government agencies, private foundations, corporations, non-profit organizations, and professional societies. For awards made to the organization, Beaumont is legally responsible for the performance of the work and the administration of the award. Approval of grant proposals indicates an institutional commitment to the sponsor to provide the oversight, resources, and support necessary to complete the research outlined in the application. The Beaumont Research Institute (RI) has responsibility for the management and oversight for all Beaumont research activities. An Authorized Organizational Representative (AOR) through the Beaumont RI must approve all extramural research grant proposals, awards, and contracts. The RI's Office of Sponsored Programs Administration (SPA) is responsible for all pre- and post-award grants management inclusive of research proposal development and submission.

SPA provides centralized, coordinated support services to Beaumont researchers pre-award (e.g., proposal preparation and submission for external funding) and post-award (administration of research grants and contracts). This pre-award grant development support includes assistance with competitive funding opportunity identification and proposal preparation as well as research



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design, grant writing, editing and proofreading assistance available by special request through the office of the Vice President, Research.

Quality and expedient service will be provided and completed within the constraints of regulatory compliance and institutional policies. One of the most important activities to assure Beaumont's credibility and reputation as an academic medical center involves the timely and thorough review of funding proposals. Appropriate persons within Beaumont must review and approve the proposed research project prior to SPA's administrative review. The respective service line, research unit, or department will provide initial approval of a proposal for submission. In addition, all Beaumont units engaged in the proposed project (e.g., Radiology, BioBank, or Pathology) must approve any commitments involving them in a specific proposal, prior to submission to the sponsor. The PI will then forward a final and complete application package to SPA for administrative review prior to submission to the sponsor. The SPA administrative review assesses the complete proposal's compliance with sponsor requirements, institutional approvals, and federal regulations, as appropriate.

Once a proposal has been reviewed for administrative and regulatory compliance, a Beaumont Authorized Signatory Official/AOR (RI Vice President, Administrative Director, or Director of SPA) will sign the proposal and approve it for submission. Submission may require several sponsor-specific procedures. SPA has established internal deadlines to allow sufficient lead time for preparation, review and approval of a proposal in anticipation of sponsor requirements and technical issues which may delay approval and submission.

III. POLICY:

A. Submission Procedure

Beaumont requires SPA to review and approve all proposals, pre-proposals, concept papers, letters of intent, letters of support, contracts, and subcontracts submitted to external agencies requesting funds and/or committing Beaumont resources (e.g., personnel, space, funds, equipment and facility use, etc.) for the purposes of research and clinical trial programs prior to submission. SPA must complete an administrative review of final complete proposals and confirm appropriate institutional commitments before approving a proposal for submission.

This policy applies to all competitive investigator-initiated grant proposals whether Beaumont RI is the lead agency submitting directly to a funder, or Beaumont RI will be a subcontractee under another organization's submission to a sponsor.

This policy also applies regardless of the method of transmission to the potential sponsor (e.g., via paper copy or electronic submission).



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Once all approvals have been granted, SPA will either transmit or authorize the transmission of the proposal to the sponsor. Any competitive investigator-initiated grant proposal submitted to a sponsor without proper approval may be withdrawn by Beaumont.

B. **Notification**

An investigator planning to submit a competitive grant (investigator-initiated) proposal requesting outside funds from any federal, state, or local government agency, foundation, corporation or individual for any investigator-initiated research project, irrespective of whether it is called a grant, gift, or contract, must contact the research department contact [e.g., Clinical Research Manager (CRM) or Lab Manager (LM)] immediately. The CRM/LM/department designate will then engage SPA with the principal investigator (PI).

C. Assistance/Special Services

Interested faculty at Beaumont may request research support such as assistance with research design, grant writing, pre-peer review/scientific review, and editing and proofreading through the office of the Beaumont Vice President, Research.

- 1. **Research Design Assistance** should be requested at least 16 weeks prior to an anticipated or published sponsor deadline along with a summary of the defined concept, significance, and scientific rationale;
- 2. **Grant Writing Assistance** should be requested at least 12 weeks prior to the published sponsor deadline and requires a well thought out hypothesis, summary of significance, and defined research design;
- 3. **Scientific Review** by an internal or external clinical and/or research colleague in a related field that is separate from the post-award Scientific Review Committee evaluation should be requested at least 8 weeks prior to the published sponsor deadline accompanied by a near final draft of, at minimum, the specific aims and research strategy; and
- 4. **Editing and proofreading** should be requested at least 6 weeks prior to the published sponsor deadline accompanied by a near final draft of all the scientific/scholarly text.

Assistance with proposal planning and preparation is also available. A SPA representative can help plan for proposal development (e.g. drafting a timeline of key deliverables based upon sponsor requirements to assure a timely submission or helping to coordinate among collaborative research sites). This SPA support for proposal preparation, if requested, must occur at least ten (10) business days prior to sponsor's deadline.

A SPA representative may also assist with proposal preparation inclusive but not limited to the completion of sponsor forms and preparation of biographical sketches. **This SPA** support for proposal preparation, if requested, must occur at least three (3) business days prior to sponsor's deadline.



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D. Proposal Development

During proposal development, the PI must include the designated department representative (CRM/LM/other designate) in proposal development to assure and facilitate approval of the project by SPA. This may include guidance on RI policies and procedures as well as providing information related to resource commitments, cost-sharing requirements, personnel issues, appropriateness of research plan, or any partnership issues. Per RI policy, <u>Cost Sharing Policy</u>, cost-sharing requires additional review by the department/unit chief and final approval by SPA.

E. Budget Preparation

Per RI policy <u>Establishing a Research Study Budget and Management of Research Funds</u>, SPA will assist in all elements of budget preparation. The budget will be completed by SPA. The designated department representative (CRM/LM/other designate) should initiate contact with SPA, together with or on behalf of the PI. SPA, in consultation with the CRM/LM/other designate and the PI, will draft the budget. To expedite budget preparation and create a draft budget spreadsheet for review, SPA will require as close to a final copy of the technical research plan or protocol as possible, a listing of the key procedures associated with the research, all key research personnel who will perform each task, all subcontracts and consultants, and, in clinical research projects, all standard of care and non-standard of care activities including CPT4 codes where applicable. Minimally, a detailed outline of the protocol is necessary to start the budget preparation process.

These materials, along with the signed Grant Proposal Routing Form (PRF) completed by the CRM/LM/other designate and signed by the department/unit Chief, must be submitted to SPA ten (10) or more business days prior to the sponsor agency deadline. Please note proposals utilizing Beaumont Core Facilities (e.g., Biostatistics, BioBank, Molecular Core, Research Services, Coordinating Center), proposing complex Centers of Excellence, or developing large multi-site clinical trials will require longer preparation time. An effort must be made by the PI and designated department representative to provide SPA with adequate time to develop and prepare the budget. The budget will not be considered final and advance for SPA approval until the PI and the designated department representative (CRM/LM/other designate) have approved the budget request.

F. Conflict of Interest and Compliance Certifications

Conflict of interest (COI) disclosures and submission of certifications are required prior to final proposal approval by SPA. The PI and all Beaumont key research personnel must complete an annual conflict of interest disclosure in COI-Smart prior to their first grant submission (PI or Key Personnel), and annually thereafter. Embedded within this form is a



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section certifying she/he has read and understands the Beaumont RI policy 101 *Intellectual Property Policy*, RI Policy *Inquiries and Investigations of Alleged Research Misconduct*, and RI Policy, Conflict of Interest for an Individual Involved in Research.

If anyone listed as key personnel has made a disclosure, the project will require a review by Research Compliance to determine whether the disclosure is related to the proposed research and if related, whether it represents a COI with the project and if it can be reasonably managed to assure objectivity in the research. Request for this review is initiated by the submission of the Grant PRF upon review of the key personnel listed, by SPA staff. Insufficient review time when there are positive disclosure(s) related to the proposed research may delay submission of the application to the sponsor.

G. Institutional Letters of Support

Letters of support are frequently included within the proposal to affirm an institution's commitment and support of the investigator and the proposed project. These letters should be provided by the respective department chair and included within the proposal. If an additional institutional letter, prepared on behalf of Beaumont, is required as part of the submission, the SPA representative will help prepare and obtain the requested letter for the specific project from a Beaumont AOR.

H. Authorized Approval

All proposals must obtain SPA approval **before** submission, even when the sponsoring agency allows direct electronic submissions from the PI. **To obtain SPA approval to submit, a copy of the complete and final proposal must be submitted to the SPA representative at least three (3) business days prior to the sponsor's deadline. This requirement applies to competitive investigator-initiated research grant proposals submitted electronically and to those submitted on paper. A complete and final proposal includes:**

- 1. the signed RI Grant PRF on file with SPA;
- a hard or electronic final version of the proposal including the final scope of work or technical research plan, budget, budget justification, all completed required sponsor forms, compliance certifications, and any subcontractor documentation; and
- 3. a hard or electronic copy of (or link to) the sponsor's Request for Proposal (RFP) and/or guidelines.

The appropriate Beaumont Research Oversight Committees (e.g., Institutional Review Board, Animal Care Committee, and/or Institutional Biosafety Committee) must review sponsored projects involving human participants, animal subjects, biohazards, or radioactive materials in accordance with federal regulations. The Research Oversight Committee's certification of approval may be required to be submitted with applications. Many sponsoring



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organizations, including the Public Health Service agencies, allow approval to be obtained after proposal submission but granted prior to acceptance of the award.

The SPA representative will email the PI and the designated department contact with any issues identified during the administrative review. These must be addressed and resolved before recommendation for approval of the proposal by an AOR is made. Comments on the scientific aspects of the proposal will be provided only upon request.

I. Proposal Submission

Once the SPA internal review is complete (e.g., confirmation of compliance with agency requirements, state and federal regulations and guidelines, and Beaumont standards and policies) and PI approval of the final application package obtained, a Beaumont AOR in the RI will sign the proposal and approve it for submission.

- 1. **Hard copy submission** will be the responsibility of the PI unless otherwise agreed upon by the RI. The appropriate forms bearing the AOR signature will be forwarded to the PI with copies kept on file with SPA. One (1) copy of all final documentation submitted to the sponsor organization must be forwarded to SPA.
- 2. **Electronic submission by the PI** requires the approval of a Beaumont AOR **PRIOR to submission** and must follow the standard submission procedure. Approval will be documented by a signed Grant PRF and forwarded to the PI, with a copy kept on file with SPA. The PI must notify the SPA representative when the submission is sent or uploaded to the sponsor agency. Electronic approvals by the Beaumont AOR or Signing Official (SO) will be done as specified by sponsor guidelines. One (1) copy of all the final documentation uploaded to the sponsor organization must be forwarded to SPA.
- 3. **Electronic submission by only the AOR.** Certain sponsor organizations and electronic submission interfaces permit only designated AORs to submit proposals on behalf of Beaumont. The only AORs at Beaumont for research proposal submission are the RI's Vice President, Administrative Director, and Director of SPA. The SPA representative will coordinate AOR approval and proposal submission. An e-mail to the PI from SPA will confirm proposal submission. Requests for modifications and other follow up made by grants.gov, NIH eRA Commons, or another sponsor agency e-submission hub are typically sent directly to the PI upon validation of the proposal by the sponsor. The PI must coordinate with the SPA representative to address and submit any necessary revisions within the deadline specified by the sponsor.

IV. ASSOCIATED POLICIES:

RI policy Inquiries and Investigations of Alleged Research Misconduct

RI policy 101 Intellectual Property Policy

RI policy *Research Administration Oversight*



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RI policy Conflict of Interest for an Individual Involved in Research

RI policy Cost Sharing Policy

RI policy Establishing a Research Study Budget and Management of Research Funds

V. <u>APPENDICES</u>: (See attachment tab, upper right corner)

Appendix A: Process Flow for Grant Development Submission

Appendix B: Grant Proposal Routing Form

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.