Title: **Conflict of Interest for an Individual Involved in Research**	*Applicable to: **Beaumont Health**	Effective Date: **01/11/2018** Last Periodic Review Date: **01/11/2018**
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***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. INTRODUCTION AND OBJECTIVE:

Beaumont Health (Beaumont) and its' Research Institute (RI) are committed to protecting the safety and welfare of participants involved in research, maintaining scientific integrity in basic and clinical research, and stimulating the development of useful knowledge. Principled collaboration between Beaumont researchers and staff, research sponsors and other industry representatives is vital to preserve the public's trust. Beaumont research is regularly conducted under the oversight of several federal bodies, including but not limited to the Food and Drug Administration (FDA), the Public Health Services (PHS) including the Office of Human Research Protections (OHRP) within the National Institutes of Health (NIH), and the United States Department of Agriculture (USDA).

Both PHS and FDA federal regulations require institutions conducting research to have written policies and procedures to identify and manage any significant financial conflict of interest (COI). The purpose of this policy is to assure compliance with all regulations, describe the process for disclosure of any individual potential financial conflict of interest related to research activities, and the steps taken to manage, reduce or eliminate significant conflicts as they relate to conducting research at Beaumont.

II. POLICY STATEMENT:

Individuals responsible for the design, conduct or reporting of research conducted under the auspices of Beaumont must disclose financial or other interests which may be, or appear to be, a conflict of interest. Disclosure requirements are broad and must cover anything related to an

individual's responsibilities at Beaumont, including but not limited to clinical, administrative, research and/or teaching.

III. RESPONSIBILITY:

This policy applies to all individuals involved in Beaumont research, as defined in Research policy Definition of Beaumont Health Research. Disclosures required by this policy are in addition to, and in coordination with, disclosures required by Beaumont's Corporate Compliance Office.

The Research Institute Compliance Committee (RICC) will provide review guidelines and actively participate in the review of complex disclosures. All financial disclosures will be reviewed by the RICC or a designee of the RICC. The RICC works in conjunction with the Corporate Compliance Office and the Business Ethics and Corporate Compliance Committee. COID information may be shared between the Corporate Compliance Office and Research Administration to assure appropriate review and management of conflicts.

IV. DEFINITIONS:

A. Individual Financial Conflict of Research: Any financial interest of a covered individual or their immediate family, or of any foundation or entity controlled or directed by the covered individual or their immediate family which reasonably appears to affect the design, conduct or reporting of Beaumont research. Not all disclosed interests result in a conflict of interest. Disclosures will be reviewed to determine: 1) if the interest is related to the research and 2) whether it results in a financial conflict of interest. Examples of things which may be considered a conflict include but are not limited to:

- Monies received for lecturing.
- Consulting or serving in any position in the company.
- Non-monetary gifts, such as travel.
- Holding of stock, stock options, partnership or ownership interests.
- Ownership of intellectual property (i.e., patent or copyright).
- Potential future personal income from licensing discoveries.

Financial conflicts of interests in research do not include:

- Salary from Beaumont.
- Interest of any amount in publicly traded, diversified mutual funds.
- Payments made to Beaumont RI, or via Beaumont RI to the covered individual which are directly related to reasonable costs incurred in the conduct of research (as specified in the Research Agreement or consistent with RI policies).

- Income from seminars, lectures, teaching engagements or service on advisory committees or review panels sponsored by government agencies (e.g., NIH Study Sections); institutions of higher education as defined at 20 U.S.C. 1001(a); academic teaching hospitals; medical centers; or research institutes that are affiliated with an institution of higher education. Income from these sources does not need to be disclosed.

B. Beaumont Research: For purposes of this policy, Beaumont Research refers to all types of research including but not limited to human, animal, behavioral, social, basic science, or other research activities. This encompasses all laboratory based, translational, clinical and outcomes research conducted at Beaumont, or utilizing Beaumont facilities, patients, staff or data (unless Beaumont is determined not to be engaged in research per RI Policy 120 Institutional Engagement in Research). Any Beaumont research involving human participants requires prior review and approval by the Institutional Review Board (IRB). This includes but is not limited to:
   - Clinical research conducted at Beaumont facilities.
   - Studies based on a medical, clinical or other record or report initiated at Beaumont.
   - Registry or outcome studies where data is being collected in the private practice, but the procedure, surgery or intervention took place at Beaumont.
   - Study key personnel are Beaumont employees, residents or fellows.

   See Research policy Definition of Beaumont Health Research for the complete definition.

C. Individuals Responsible for Design, Conduct or Reporting: Those directly participating in the research project including but not limited to: designing the research protocol; directing the research or serving as principal investigator (PI), co-investigator or sub-investigator; screening potential participants for eligibility; enrolling participants; administering informed consent; administering or providing the test article; conducting research assessments; analyzing or reporting research data; or participation in the preparation of abstracts or manuscripts, presentations or other public dissemination of research results. For projects involving human participants, this includes everyone listed as key personnel with the IRB. For federally funded projects this also includes outside independent consultants and collaborators. This does not include clinical staff performing routine clinical care who are not considered to be "engaged in research" (see Research policy 120 Engagement in Research).

D. Institutional Conflict of Interest: Any financial interest of the institution (e.g., stock holdings, royalties, etc.), or financial or business interests of an individual who makes or participates in committees which make institutional decisions affecting purchasing, research or technology transfer which may result or may be perceived to result in a conflict of interest. Institutional Conflicts of interests are covered by Research policy 105 Institutional Conflict of Interest.

E. External IRB: For purposes of this policy, an AAHRPP (Association for the Accreditation of Human Research Protection Programs) accredited IRB, approved by Beaumont to review certain types of Beaumont research involving human participants (see Research policy 233 Review by an External Institutional Review Board).

F. NCI CIRB: National Cancer Institute Central Institutional Review Board (NCI CIRB).

G. Disclosure: The process of reporting relationships or interests in outside organizations.

H. Covered Individuals: Individuals conducting Beaumont research including:
- Investigators (e.g., PIs, co-investigators, sub-investigators)
- Key research personnel (e.g., research nurses, coordinators, assistants)
- Residents
- Fellows
- Students
- Administrators, or
- Other employees who conduct research or who are involved in an intellectual property transfer.

For purposes of this policy, all research administrator(s) or manager(s) who directly oversee the conduct of the research are considered covered individuals. Covered individuals also include external individuals consulting or collaborating with Beaumont researchers who are involved in conducting research at Beaumont.

I. Immediate Family Member of Covered Individual: Refers to the covered individuals' spouse or domestic partner; birth, step or adoptive parent, child, sibling, grandparents or in laws.

J. Management Plan for Conflicts of Interest: A plan developed to manage, reduce or eliminate an identified conflict. This plan will be developed based on the outcome of the conflict of interest disclosure review process, as described below.

V. DISCLOSURE OF POTENTIAL CONFLICTS OF INTEREST:

A. PHS regulations require each individual involved in the design, conduct or reporting of PHS (including NIH) funded research to submit a conflict of interest disclosure to the Research Institute at least annually. If a current disclosure is not on file, one must be submitted: 1) at the time of the grant application submission, 2) when an individual is assigned to a project, or 3) within 30 days of developing a new relationship or obtaining a new interest. At Beaumont, these same requirements apply to all research, regardless of type or funding. The electronic COI-Smart Annual Research Questionnaire is used for research disclosure.

B. Individuals must disclose any financial interests, regardless of amount, which **reasonably appear to affect the individual's institutional responsibilities to Beaumont, including clinical, academic, administrative, or research.** These include, but are not limited to,

interests in companies who sponsor, fund, or whose products may be used in any research being conducted or which may be proposed. Disclosure must also include any reimbursed or sponsored travel, including the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

C. In the event a conflict of interest arises during the conduct of the research, a new relationship is developed or a new interest is obtained, the individual must complete an updated conflict of interest by revising their most recent Annual Research Questionnaire in COI Smart.

VI. COID REVIEW PROCESS:

A. Review for Grant Applications and PHS Funded Research: When a new grant is being submitted or accepted, or a new federally funded sub-contract is being executed, the key personnel listed for the project will be compared to the list of current annual disclosures on file. Positive disclosures will be identified and pulled for review according to the process below. Any key personnel who do not have an annual COID on file will be required to submit a disclosure prior to the grant submission, acceptance or contract execution.

B. Review Process for all Research: Individual(s) designated by the RICC will be responsible for the initial review of all positive COID's. Questions regarding a disclosure will be directed to the disclosing individual unless otherwise initiated or directed by the disclosing individual. The reviewer will determine whether a disclosure: 1) is related to any current or proposed research, and 2) represents a financial conflict of interest based on one or more of the following:

1. Any equity interest which directly affects, or could reasonably appear to affect, the research being reviewed, funded or proposed for funding. This includes investments in a study sponsor or its parent company (if a publicly or non-publicly traded company is involved), such as ownership interest or stock options.
2. Payments from a study sponsor, its parent company or subsidiary, or the producer/distributor of the product being tested, which in total exceeds $5,000 in the prior year or is expected to in the next year. This includes any and all types of income including consulting fees, honoraria (including from a third party if original source is the study sponsor), gifts or payment for consulting, lecturing, travel or service on an advisory board.
3. Financial arrangements where the value of the compensation could be influenced by the outcome of the study. Examples include:
   - Compensation explicitly for a favorable outcome.
   - Equity interest in the sponsor.
   - Royalty rights.
   - Holding or the promise of a fiduciary role with the sponsor.

- Any payment in connection to research that is not specified in the Research Agreement between the sponsor and the institution.
- A proprietary or financial interest in a test product such as a patent, trademark, copyright or licensing agreement.
- Serving as an officer, director, employee or functioning in any other fiduciary role for a sponsor, sponsor parent company or sponsor subsidiary, regardless of whether compensation for the service is provided.

If a conflict exists, the RICC, along with the IRB and/or ACC will determine whether the conflict can be managed to eliminate the introduction of bias to the research and if so, take steps to manage, reduce or eliminate the conflict.

VII. MANAGEMENT PLANS:

A. If it is determined there may be a conflict of interest or the appearance of a conflict, the reviewer, at the direction of the RICC, will prepare a Management Plan (MP) recommendation. The MP will be designed to address the conflict specific to the individual's role in the study and will reflect the extent of the potential conflict and the level of risk to any human participants. Management Plan requirements may include, but are not limited to:

- A disclosure of the income, relationship or interest in the Informed Consent and Authorization document so prospective participants may make an informed decision about participation in the study.
- A disclosure of the income, relationship or interest in public releases of information about the study (e.g., advertising, press releases, abstracts, presentations, publications).
- Limits on the conflicted individual's role in the study (e.g., may not serve as principal investigator, may not be involved in administering informed consent, may not analyze data, etc.).
- Independent reviewers, either institutional (internal) or external.
- Designation of a co-investigator without a COI and not in a subordinate role to the conflicted individual.
- Placement of his/her investment in escrow for the duration of the study, and for a suitable period after the completion of the research.
- Divestiture of the financial interest.
- Severance of the relationship(s) with the sponsor or competitor, which caused the conflict or perceived conflict.
- Disqualification of the covered individual from conducting the research in part or in its entirety.
- Oversight by a non-conflicted individual.
- Study audits (e.g., patient eligibility, data integrity).
- Non-approval of the study at Beaumont.

Upon approval of the MP by the RICC, the reviewer will send the recommended MP to the appropriate oversight committee or Research Director. An oversight committee may not remove any recommendations made by the RICC, however the oversight committee may add additional safeguards they deem appropriate. For research involving human participants, the IRB has the final authority to determine whether the research may be approved, given the interests disclosed and the MP developed to manage those interests.

B. Human Participant Studies: The chart below describes the guidelines used by the IRB to review COIs. However, any positive disclosures may be reviewed at a full board meeting.

IRB Review Category	Disclosure Amount	Requirement
Exempt/Expedited/Full Board	< $5,000	Not considered to be a significant conflict of interest. No action is required.
Exempt	> $5,000	Disclosure in consent/information sheet, publications and other study related docs, as applicable. Reviewer prepares a recommended MP and forwards to IRB. Exempt review may be conducted administratively by IRB. MP's for exempt studies are not required to be reported to the fully convened IRB.
Expedited	$ 5,000 - $50 000	Disclosure in consent/information sheet, publications and other study related docs, as applicable. Reviewer prepares a recommended MP and forwards to IRB. **Management plans at this level may be reviewed administratively by IRB as part of expedited review and approval but must be reported at the next fully convened meeting.**
Expedited	>$50,000 or involving private equity or IP rights	Disclosure in consent/information sheet, publications and other study related docs, as applicable. Reviewer prepares a recommended MP and forwards to IRB. **Management plans at this level must be presented and approved by the fully convened IRB prior to expedited approval of the study being granted.**
Full Board	All payments > $5,000 or any equity or IP rights	Disclosure in consent/information sheet, publications and other study related docs, as applicable. Reviewer prepares a recommended MP and forwards to IRB. **Management plans at this level must be reviewed and approved by the fully convened IRB as part of the full board study review and approval.**

C. Processing Management Plans: The reviewer will follow guidance provided by the RICC in completing the review and developing the recommended MP. The oversight committee reviewing the study (or Research Administrator if no oversight committee) will prepare the final MP and forward it to the PI for signatures. The conflicted individual, the PI (if other than the conflicted individual), the clinical research manager (if involved in the study) and the department/ division Chairperson (or next higher non-conflicted individual on the applicable organization chart) must sign the MP document acknowledging the MP and return it to the oversight committee or Research Administrator. Upon approval of the fully signed MP, the research may be approved. The MP will be placed on file in the IRB, ACC or RI office, as appropriate. A copy of the MP will be sent to the Director of Research Regulatory and Billing and the Manager of Clinical Research Quality and Process Improvement.

D. Approval of Research: Individuals with a conflict of interest may not provide signature approval for grant applications, project submissions, significant amendments to a project, or

management plans (i.e., department chairs, clinical research managers). Signatures must be obtained from the individual directly above the conflicted individual based on the applicable organizational chart. Similarly, members of research approval committees with conflicts of interests may not engage in research approval activities.

VIII. NOTIFICATION TO PHS:

Consistent with the regulations, if it is determined a significant financial conflict of interest exists related to a PHS funded project, the conflict and MP details will be reported to PHS when the MP is instituted and annually thereafter. If Beaumont is participating as a sub-contractee, Beaumont will report the required information to the sub-contractor for subsequent reporting to PHS.

IX. NON-COMPLIANCE AND CORRECTIVE ACTION:

A. Failure to disclose a financial COI or non-compliance with a MP will result in corrective action, as determined by the IRB, ACC, RICC, the Directors of the Research Institute, Medical Administration, Hospital Administration and/or regulatory agencies. Corrective action may include, but is not limited to:
   - Completion of additional research education as determined by the oversight committee, Research Administration or PHS.
   - Restrictions on the use of data derived from the research.
   - Suspension or termination of the research project.
   - Withdrawal of funding.
   - Loss of research privileges at Beaumont.
   - Formal corrective action.
   - Report of actions to external regulatory agencies.

B. When non-compliance with a COI management plan related to a PHS funded project occurs, a retrospective review will be conducted. If bias in the research is found, a mitigation report will be filed with PHS and include:
   - Key elements documented in the retrospective review.
   - A description of the bias identified in the research.
   - The plan of action(s) to eliminate or mitigate the effect of the bias.

X. MONITORING AND AUDITING:

The RI, in conjunction with each approval committee, will conduct periodic audits of research records to assure compliance with each MP. Audit results will be provided to study PI and the Research Institute Compliance Committee.

XI. EDUCATION AND TRAINING:

A. All individuals responsible for the conduct of research must be knowledgeable about this policy. Conflict of interest policies and procedures will be reviewed with new staff as part of the required Clinical Research Orientation sessions. Additionally, researchers are required to review this policy as part of the annual research compliance training. Education regarding changes or new procedures will be communicated and incorporated into the annual training module. Education will be required immediately when:
   - Financial conflict of interest policies are revised in a manner that changes researcher requirements.
   - A researcher is new to the Hospital.
   - A researcher is non-compliant with financial conflict of interest policies and procedures, including a violation of a MP involving PHS funded research.

B. Consistent with federal regulations, researchers involved in PHS funded research will be required to complete a training course specific to PHS requirements. The training must be completed prior to engaging in PHS funded research and at least every four (4) years thereafter.

XII. PUBLIC ACCESS TO COI INFORMATION:

As required by regulation, this policy will be made available to the public on Beaumont's consumer website. Additionally, within five (5) days of a request, information on conflicts of interest for individuals involved in PHS funded research will be provided.

XIII. RECORD RETENTION:

Consistent with Research policies 232 Research Record Retention and Destruction and 247 IRB Document Management, all records relating to conflict of interest disclosures, review, and management plans will be retained a minimum of 11 years past the completion of the research.

XIV. INQUIRIES:

Inquiries to this policy may be directed to the Administrative Director of the Research Institute or the Director of Research Regulatory and Billing.

XV. ASSOCIATED POLICIES AND PROCEDURES:

Research Institute Policies and Procedures:
RI Policy 102 Grant Proposal and Development Submission
RI Policy 105 Conflict of Interest Disclosure for Oversight Committees
RI Policy 120 Institutional Engagement in Research
IRB Policy 216 Human Investigation Committee Initial Review of Research Protocols
ACC Policy 401 Protocol Review Process for Animal Research Projects

Management Policies and Procedures:
Beaumont Health Business Ethics and Compliance Policy

XVI. REFERENCES:

Research Institute Department Compliance Plan
Guidance on Conflict of Interest from the American Associate of Medical Colleges (12-01, 02-03) 42 CFR 50 Subpart F Promoting Objectivity in Research
45 CFR 94 Responsible Prospective Contractors
21 CFR part 54 Financial Disclosure by Clinical Investigators

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.