BAPTIST

OPERATIONS POLICY, PROCEDURE AND GUIDELINE MANUAL

Effective Date: 10/82 **Last Revised: 4/04, 4/09, 9/10** **Last Reviewed: 10/13** **Reference #: S.AD.1006.03**	**CONFLICT OF INTEREST AND COMMITMENT**

Purpose:

I. This policy is intended to protect patient safety and welfare, safeguard the reputation and integrity of the Institution as well as preserve the integrity of affiliated research, ensure fulfillment of obligations to Personnel and Trainees, clarify that the employment obligation of employees is to the Institution and require disclosure of all potential or actual conflicts of interest, while permitting the pursuit of relationships with for-profit entities that further the mission of Baptist Memorial Health Care Corporation (BMHCC) and each of the entities in which it is the sole corporate member (hereinafter referred to as "BMHCC Affiliate"). BMHCC and BMHCC Affiliate may be collectively referred to as "Baptist."

II. Baptist has adopted a policy on Conflict of Interest and Commitment in order to provide meaningful guidance to its Physicians and Personnel in structuring their relationships with industry and outside organizations, consistent with their primary responsibilities to the organization. This policy is consistent with the Public Health Service guidelines (http://grants.nih.gov/grants/policy/coi/nih_review.htm) and is made publicly available on Baptist's website.

III. To preserve the integrity of all terms and conditions of employment and/or affiliation with Baptist.

IV. To provide reasonable assurances that Baptist employees and health care providers performing functions on behalf of Baptist do not use their positions or knowledge gained therefrom, in ways which result in conflicts between the interest of the entity and that of the individual.

V. To affirm the organization's commitment to fair and consistent terms and conditions of employment or affiliation without regard to an individual's age, sex, race, color, religion, national origin, handicap, disability, or financial status.

VI. To comply with legal, regulatory, and accreditation requirements.

Definitions:

Cash: Remuneration in the form of consulting fees, honoraria, milestone payments, educational grants, preceptorships, salary or wages (other than salary and wages), and

cash equivalents, which include anything of fixed and/or publicly-traded value; excludes up-front and annual maintenance fees and royalties received from Baptist and travel.

Competitor: Any institution or organization that competes for business with Baptist.

Conflict of Commitment: An external activity that interferes in a substantial way with an individual's responsibilities to Baptist.

Conflict of Interest (COI): A financial interest or relationship that could directly and significantly influence (or be perceived to directly and significantly influence) patient care, the design, conduct and/or reporting of research or any other Institutional Responsibilities.

Conflict of Interest Committee (COIC): The body designated by the Institution to review and manage or eliminate Conflicts of Interest.

Family Members: Defined as financially dependent persons, including a spouse, dependent child, stepchild, domestic or civil partner, common law spouse or equivalent same-sex partner. Also included are persons owning joint financial interests with individuals covered by this policy (e.g., businesses, accounts or property) that could reasonably influence the individual's decisions or exercise of professional responsibilities at the Institution.

Federal Funding Source: A federal organizational unit, including but not limited to Public Health Service (PHS), that funds research.

Financial Conflict of Interest–Research (FCOI-R): When the Conflict of Interest Official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct or reporting of the research.

Financial Interest: Anything of monetary value, whether or not the value is readily ascertainable.

Institutional Decision Maker: Includes the President, Executive Vice Presidents, Senior Vice Presidents, Vice Presidents, Administrators, Chief Executive Officers, Chief Financial Officers and any written designees.

Institutional Responsibilities: Any of the professional responsibilities of an individual subject to this policy on behalf of the Institution, including research, research consultation, teaching, professional practice or patient care, Institutional Committee membership, or service on an institutional panel such as an Institutional Review Board (IRB) or Data and Safety Monitoring Board (DSMB).

Institutional Review Board (IRB): The board that is formally designated by Baptist to review and approve the initiation of, and to conduct periodic reviews of, biomedical

research involving Human Subjects. The primary purpose of such review is to assure the protection of the rights and welfare of Human Subjects.

Investigator (Covered Individual): An individual who, regardless of title or position, is responsible for the design, conduct, or reporting of research, including a principal investigator, a co-investigator, collaborator, consultant, or project director. Individuals considered "responsible" in this definition include any person who is independently accountable for data, in any form, addressing the objectives of the funded or proposed research, as identified by the principal investigator. This necessarily places responsibility on the accountable supervisory staff to identify who is an investigator and potential Conflicts of Interest in their research team as it relates to funded or proposed investigation.

IRB Approved Protocol: Human Subjects research that has been reviewed and approved by the IRB.

Manage: Taking action to address a Financial Conflict of Interest, which can include reducing or eliminating the Financial Conflict of Interest, to ensure, to the extent possible, that the design, conduct, or reporting of research will be free from bias.

Outside Employment: Work of a continuing nature for a third party, such as supervising, consulting or advisory services, or other regular continuing employment for which compensation, regular or occasional, is received; specific work, usually of limited duration, for which compensation is received.

Ownership Interest: An ownership interest in any corporation, partnership, or other legal entity, including stock, stock options, or other equity interest; excludes mutual funds and stock or stock options held in blind trusts (to the extent that the identity of the companies in the portfolio in the blind trust is unknown). Ownership interest also includes any License Equity to the extent the individual is entitled to share in the proceeds upon liquidation of the License Equity.

Principal Investigator: The individual(s) who is the responsible leader of an investigative team and responsible for the design, conduct, or reporting of a research project or program.

Research: A systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge including Human Subjects Protocols and all laboratory research disciplines, as well as behavioral and social-sciences research. The term encompasses basic and applied research and product development. As used in this policy, the term includes any such activity for which research funding is available from any source, including any Public Health Service (PHS) awarding component through a grant or cooperative agreement.

Research Team: Co-Investigators, Trainees, staff members, classified employees involved with research, and internal collaborators.

Scholarly Work: Work created by an Institution's Personnel or Trainee within his/her scope of employment and in his/her area of expertise or area in which he/she teaches. This definition especially applies to creative work that is peer reviewed and publicly disseminated. Specifically excluded from this definition is consulting work for for-profit companies, including subscription-based content providers. Paid authorship must be disclosed.

Significant Financial Interest (Research): A Financial Interest that reasonably appears to be related to the individual's Institutional Responsibilities, as defined by 42 CFR Part 50, Subpart F. This definition includes the Financial Interests of the individual's spouse or dependent children, or other financially dependent persons (Family Members). Includes any of the following interests that reasonably appear to be related to an individual's responsibilities and meets $5,000 or above threshold: (a) Equity interests (such as stock, stock options, or other ownership interests); (b) Income (such as licensing fees or royalties) from intellectual property rights (such as patents or copyrights); (c) Payments or other remuneration (such as salary, consulting fees, honoraria, paid authorship or travel reimbursement) from commercial research sponsors or private organizations; (d) Fiduciary Relationships with commercial research sponsors or private organizations; (e) Gifts, endowments, sponsored travel, or other in-kind contributions from commercial research sponsors or private organizations.

Supervisor: Any person who is the primary formal evaluator of another person.

Supporting Entity: An entity that (a) sponsors an IRB Approved Protocol or other research study; or (b) provides funding for a research study either directly or through a subcontract or grant; or (c) provides a study drug, device, or other materials for use in an IRB Approved Protocol; or (d) has licensed technology and/or patents that cover the study drug, device, or other material, or its uses that are covered in an IRB Approved Protocol for which the Principal Investigator may receive a portion of license consideration. This definition does not include non-profit or philanthropic groups unless the COIC and/or the IRB determine otherwise.

Trainee: Graduate or other student, postdoctoral fellow, or clinical fellow.

Policy:

I. Expectations

A. All Baptist employees and health care providers are to interact with patients, families, customers, suppliers, or other business representatives in a professional and ethical manner.

B. All individuals at a Baptist facility are to act in the best interest of Baptist at all times.

C. Individuals performing functions on behalf of Baptist are not to solicit, accept, offer or give any gifts, favors, cash or cash equivalents or hospitality that might influence their entity-related decisions or actions or that of a vendor. This includes instances where individuals representing Baptist are serving with community organizations in a fund raising capacity.

D. The purchasing of materials, supplies, and services is under the direction of the President, who is not to make purchases from any organization in which members of the administrative staff, department directors and members of the Boards of Directors of Baptist entities or their immediate families have a substantial interest.

E. Baptist prohibits any professional or business conduct, which is or has the potential for being, a Conflict of Interest. This includes, but is not limited to, transacting business with a patient who is actively under the care of the individual or his immediate family member/authorized representative. Another example is having secondary employment with a company whose products the individual uses in his/her employment at Baptist.

F. From time to time, Baptist employees may seek to accept secondary employment with physicians, vendors or other licensed independent practitioners associated with Baptist. Examples of a secondary job for Baptist employees include, but are not limited to, a member of the medical staff hiring a Baptist employee to see the member's hospital patients. If the Baptist employee elects to undertake the secondary employment the following guidelines apply:

1. The Baptist employee is to comply with the provisions of the Baptist policy on Secondary Employment and other relevant Baptist policies, including, but not limited to, completing the required Allied Health Professional processing if the secondary employment role meets the eligibility requirements and the employee is employed by a member of the medical staff.

2. Confidential or propriety information about Baptist is not to be shared in the context of the second job;

3. The Baptist employee is not to access information about any patient for whom he/she is not assigned at the particular time in his/her work, whether in the Baptist job or the second job.

4. The Baptist employee is not to perform any functions for the second job while in his/her Baptist job.

5. While working in the Baptist job, the Baptist employee is not to show favoritism to any patient of the secondary employer and is not to show any

favoritism to the secondary employer or any members of the secondary employer's organization, practice or business.

6. The Baptist employee is not to use Baptist identification while on the second job and is to identify himself/herself to patients as working for the secondary employer at the time. [Patients and families/representatives may need clarification when the Baptist employee works with them as an employee of the secondary employer]

7. While in the Baptist job, the Baptist employee is not to participate in discussions or decisions about the potential selection of the secondary employer for a contract or relationship with Baptist.

II. Conflicts of Interest and Commitment in Research

A. Conflicts of Commitment

A Conflict of Commitment occurs when external activities significantly interfere with an individual's responsibilities to Baptist. Therefore, possible Conflicts of Commitment must be disclosed and managed to assure that individuals do not engage in external activities that prevent them from fulfilling their clinical, instructional, and/or administrative responsibilities to Baptist. Conflicts of Commitment shall be reviewed and managed by the appropriate Baptist Official(s).

B. Conflicts of Interest

It is the policy of Baptist that Institutional Decision Makers, Trainees and individuals responsible for the design, conduct, or reporting of all research activities will follow established federal and state laws, regulations and guiding principles that govern disclosure, reporting, and management of potential Conflicts of Interest.

1. Objectivity in Research:
   a. It is the policy of Baptist that all research, including PHS-funded research, must be conducted in compliance with federal requirements, including those set forth in 42 CFR Part 50, Subpart F to ensure there is a reasonable expectation that the design, conduct, or reporting of research will be free from bias resulting from Investigator Conflict of Interest.
   b. Subgrantees, contractors, and collaborating Investigators are also required to be in compliance with PHS regulations.
   c. The Institution's designated official(s) must review all financial disclosures (including those that meet the definition of Significant Financial Interest as defined in 42 CFR Part 50, Subpart F) and determine whether a FCOI-R exists, and, if so, determine what actions, if any, should be taken by the Institution to manage such conflict of interest. The designated Institutional Official for reporting FCOI-R for

Baptist is the Corporate Compliance Officer in consultation with the COIC (and the IRB, if involving Human Subjects Research).

d. If the Conflict of Interest Official(s) determines that a covered individual has an FCOI-R, the official, in cooperation with the covered individual and other appropriate individuals as designated by the Conflict of Interest officials, shall develop a Conflict of Interest Management and Monitoring Plan governing that FCOI-R. This Plan shall specify the steps that have been taken to manage the FCOI-R.
e. Neither the Institution nor a covered individual may expend research funds unless the Conflict of Interest Official(s) have determined that no FCOI-R exists or that any FCOI-R is manageable in accordance with the terms of Conflict of Interest Management and Monitoring Plan that has been adopted and implemented.
f. The Institution will follow all requirements for management and reporting of a FCOI-R (including any instance where an FCOI-R was not properly identified or managed prior to expenditure of federal funds) as outlined in 42 CFR Part 50, Subpart F.
g. For PHS-covered research projects, FCOI-R identified subsequent to an earlier report are required to be reported to the PHS-Awarding Component within 60 days and also require annual updating of reports regarding previously disclosed FCOI-R in compliance with 42 CFR Part 50, Subpart F.
h. Additionally, if an FCOI-R was not timely identified or managed, or if a covered individual fails to comply with a Conflict of Interest Management and Monitoring Plan, the Institution shall, within 120 days of identification of a FCOI-R, complete a retrospective review of the individual's activities conducted during the period of noncompliance to determine whether such noncompliance biased the design, conduct, or reporting of related research. This retrospective review shall be conducted and documented in accordance with the requirements of 42 CFR Part 50, Subpart F and in accordance with the Institution's policies and procedures. For PHS-covered research projects, the retrospective review shall cover key elements as specified by federal regulations and may result in updating a Conflict of Interest disclosure, notifying the PHS, and submitting a mitigation report, as required by federal regulations.
i. If the Department of Health and Human Services determines that clinical research funded by PHS to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an individual covered by this policy who has an FCOI-R that was not managed or reported by the Institution as required by federal regulations, the Institution will require the individual to disclose the FCOI-R in each public presentation of the results of the research and to request an addendum to previously published presentations. Certain information concerning each identified FCOI-R (as determined by the COIC in cooperation with the designated Institutional Official) shall be made

available on a publicly accessible Web site in a manner consistent with 42 CFR Part 50, Subpart F. Additionally, this policy and each update of this policy must also be publicly accessible through the Internet.

j. All Covered Individuals shall be provided a copy of this policy, and shall complete training in regard to this policy and other applicable policies, regulations, and laws before engaging in research at the Institution and at least every three years thereafter. A Covered Individual who is new to the Institution must complete the training before engaging in research at the Institution or provide evidence of having completed the training at another Institution within the last three years. A Covered Individual must complete re-training immediately if the Institution finds that the individual is not in compliance with this policy or the individual's Conflict of Interest Management and Monitoring Plan, or if the Institution revises this policy in a manner that affects the individual's duties.

2. Non-Human Subjects Research:
   a. If a Principal Investigator for any Non-Human Subjects Research protocol or sponsored research agreement or his/her spouse and/or dependent children holds any Ownership Interest in the Supporting Entity, review and approval by the COIC is required prior to beginning the research in order to implement appropriate management or restrictions in order to ensure and maintain the objectivity and integrity of the research.
   b. An individual and/or his/her spouse and/or dependent children may not receive Cash of $5,000 or more within a 12-month period from a Supporting Entity that funds the Non-Human Subjects Research, unless a Conflict of Interest Management and Monitoring Plan has been implemented to manage such Conflicts of Interest. A Plan is also required when: (1) an individual and/or his/her spouse and/or dependent children has an Ownership Interest in an entity and the individual collaborates with that entity on research activities; and/or (2) an individual and/or his/her spouse and/or dependent children holds a decision-making role in the Supporting Entity and the individual collaborates with that Supporting Entity on research activities.

3. Human Subjects Research:
   a. Payment to Baptist on a per-patient basis should be limited to costs incurred, reflect the fair market value of services performed, and be commensurate with the efforts of the individuals performing the research.
   b. An individual may not serve as the Principal Investigator for an IRB Approved Protocol or sponsored research agreement if he/she or his/her spouse and/or dependent children has any Ownership Interest in the Supporting Entity, or has received Cash of $5,000 or greater within the previous 12-month period from the Supporting Entity. Additional

restrictions apply to any covered clinical study as defined by the FDA in CFR Title 21 Part 54.

c. The following must be disclosed in the informed consent document:
   - All relevant financial relationships of an Investigator;
   - All relevant Ownership Interests in the Supporting Entity of Personnel involved as a Collaborator in the IRB Approved Protocol (non-Principal Investigator) or his/her Family Members;
   - Cash of $5,000 or more received by Personnel involved as a Collaborator in the IRB Approved Protocol or his/her Family Members from the Supporting Entity in the 12-month period prior to the approval of each continuing review until termination of the protocol;
   - Any royalty income received by any of the foregoing from the Supporting Entity or their Family Members;
   - Any significant financial relationship held by Baptist itself in a Supporting Entity;
   - The IRB may impose additional requirements in consideration of the interests of the research subjects. Primary physicians who care for a patient on a clinical trial and who receive $5,000 or more or have equity in a supporting company should be aware of the potential conflict, inform the patient, and document his/her efforts to inform the patient.

d. Because of the unconditional priority of patient care, there may be exceptional situations wherein an individual and/or Institutional Decision Maker who has a financial interest in the Supporting Entity that is otherwise prohibited, must serve as Principal Investigator on an IRB Approved Protocol. In such cases, the COIC may give written permission to an individual with a potential FCOI-R, authorizing that individual to act as the Principal Investigator of that IRB Approved Protocol. This information will be disclosed to all patients, prior to their enrollment on that IRB Approved Protocol, in the informed consent document, and to the COIC. In all cases of COIC waivers involving an IRB Approved Protocol, the waiver is subject to the approval of the IRB. The IRB may determine that an unmanageable conflict exists and the waived activity affecting the IRB Approved Protocol cannot proceed.

e. The Corporate Compliance Office will maintain a database listing of companies in which Personnel, Investigators, Trainees, Institutional Decision Makers and their Family Members hold financial interests. Patients on any IRB Approved Protocol, or their Immediate Family, will have access to pertinent information from this database upon request, and patients shall be notified of this right of access in the informed consent document.

f. The Conflict of Interest Official(s) and the appropriate IRB shall cooperate in the consideration of whether an Investigator (including his/her Family Member) has an FCOI-R in regard to Human Subjects Research and in the development and implementation of a Conflict of

Interest Management and Monitoring Plan for that FCOI-R. The IRB may impose additional requirements or restrictions, and shall convey its final decision to the COIC and Investigator.

III. Disclosure

A. All Conflicts of Interest and Commitments

1. Upon hire or commencement of other relationship (e.g. signing a contract) with Baptist, and annually thereafter, Personnel must disclose all Conflicts of Interest and Commitments, including FCOI-Rs and outside activities, that are reasonably related to their Institutional Responsibilities.

2. Personnel must update their Disclosure Forms within 30 days of receiving equity or remuneration for a new outside activity or when they or their Immediate Family or Household Members acquire a new Conflict of Interest and Commitment related to their Institutional Responsibilities. The Executive Decision Makers are also required to report to the Chairman of the Board of Directors.

B. Research Conflicts of Interest and Commitments

1. Principal Investigators planning to engage in research or consulting should update their Disclosure Forms when:
   a. applying for externally-funded research applications (e.g. PHS or industry sponsored applications); or
   b. research protocols are submitted to the IRB; or
   c. consulting agreements are signed.

2. In addition to the requirements set forth above, Research Personnel must also disclose the Conflicts of Interest and Commitments of their Immediate Family and Household Members when such interests relate to their Institutional Responsibilities.

3. Violations of full and prompt disclosure may result in the loss of grant funding and sanctions regarding future funding from federal agencies. In addition, individuals may also be subject to criminal sanctions or civil liability under federal or state law.

4. The Institution shall maintain records of financial disclosures with respect to each conflicting interest related to PHS grants or cooperative agreements for research other than Small Business Innovation Research (SBIR) Program Phase I applications, as well as records regarding any actions taken on those disclosures for a minimum of three years from the date of submission of the final expenditures report for such PHS grant or cooperative agreement, or

where applicable, from other dates specified in 45 CFR 74.53 (b) for different situations.

IV. Exceptions

The following relationships do not require disclosure:

A. Consulting agreements or other contracts for outside relationships that involve the payment of anything of value for editing Scholarly Work.

B. Non-promotional speaking engagements or other oral presentations at federally sponsored meetings.

C. Honoraria or lecture fees from any branch of the U.S. Government, including entities acting as federal government subcontractors, and professional societies.

D. Mutual funds and stock or stock options held in blind trusts (to the extent that the identity of the companies in the portfolio in the blind trust is unknown).

V. In determining whether a financial interest should be disclosed, doubt should be resolved in favor of disclosure.