SYSTEM POLICY AND PROCEDURES

SUBJECT: Financial Conflicts of Interests in Public Health Service Sponsored Clinical Research

SCOPE: All healthcare facilities owned by Baptist Healthcare System, Inc., Baptist Healthcare Affiliates, Inc., Baptist Health Madisonville, Baptist Health Richmond, and Baptist Community Health Services, Inc.

AUTHORIZATION: Tommy J. Smith, President & CEO and Janet M. Norton, Vice President & General Counsel

I. PURPOSE.

This policy governing financial conflict of interests in Public Health Service ("PHS") sponsored clinical research applies to all Baptist Healthcare System ("Baptist") hospitals, facilities and each of its wholly-owned entities. This policy also applies to all Project Directors, Principal Investigators, members of the research team identified as senior/key personnel on a PHS grant application, project or other report, Baptist employed physicians, physicians who provide services in connection with clinical research sponsored by PHS and performed at any Baptist facility and physicians conducting or performing research in a Baptist facility. The Institutional Official at each Baptist facility is responsible for ensuring implementation of this policy and may suspend all relevant PHS sponsored clinical research until the financial conflict of interest is resolved or until other action deemed appropriate by the Institutional Official is implemented. Violation of any part of this policy may also constitute cause for disciplinary or other administrative action.

Baptist encourages the participation in clinical research and other educational activities that may involve relationships with outside sources. At the same time, Baptist recognizes that these relationships carry with them a potential for perceived or actual Conflicts of Interest. Individuals performing or conducting PHS sponsored clinical research within a Baptist facility have a duty to perform research and services in connection with a clinical trial free from the influence of impropriety or significant conflict of interest. Conflicts of Interests are of significant concern when financial interests create the potential for inappropriate influence over the institution’s research related activities. This policy is intended to protect against exposure from risks related to Conflicts of Interest in connection with PHS sponsored clinical research conducted or performed in Baptist facilities.

To that end, this policy informs individuals about situations that may generate conflicts of interest related to PHS sponsored clinical research conducted or performed in a Baptist facility, provides mechanisms for individuals and the institution to manage those conflicts of interest that arise, and describes situations that are prohibited. Individuals performing or conducting PHS sponsored clinical
research or services in connection with a PHS sponsored clinical trial within a Baptist entity have an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raising questions of conflict of interest related to PHS sponsored clinical research arises, the situation should be discussed with the designated Institutional Official.

II. DEFINITIONS.

Clinical Trial means any research study that involves interaction with human subjects, those research studies that involve concurrent or retrospective medical chart review, and the concurrent investigative use of drugs, biologics, devices or medical or other clinical procedures, such as surgery.

Conflict of Interest in Clinical Research means a situation in which an individual’s external interests compromise, appear to compromise, or have the potential to compromise the individual’s ability to perform his or her ethical, legal, or professional duties related to clinical research. The potential for personal gain or the existence of competing interests must not jeopardize or appear to jeopardize the integrity of the research duties or obligations of an individual.

Conflict of Interest Committee (COI Committee) means the Institution’s committee or individual that advises the Institutional Official on conflict of interest matters. Each Baptist facility that performs or conducts PHS sponsored clinical research shall appoint a multi-disciplinary COI Committee.

Family means any member of the individual’s immediate family, specifically, any dependent children and spouse.

Financial Interest means anything of monetary value received or held by an individual or an individual’s Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); any equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

Financial Interest does not include:

a) salary, royalties, or other remuneration from the Institution;
b) income from the authorship of academic or scholarly works;
c) income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies, U.S. institutions of higher education; U.S. research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or
d) equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the physician does not directly control the investment decisions made in these vehicles.

For individuals performing or conducting PHS sponsored clinical research within a Baptist facility, Financial Interest also includes any reimbursed or sponsored travel undertaken by the individual and related to his/her institutional responsibilities. This includes travel that is paid on behalf of the individual rather than reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.
**Significant Financial Interest** means a Financial Interest that reasonably appears to be related to the individual’s Institutional Responsibilities, and:

a) if with a publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure, and the value of any equity interest during the 12 month period preceding or as of the date of disclosure, exceeds $5,000; or

b) if with a non-publicly traded entity, the aggregate value of any salary or other payments for services received during the 12 month period preceding the disclosure exceeds $5,000; or

c) if with a non publicly-traded company, is an equity interest of any value during the 12 month period preceding or as of the date of disclosure; or

d) is income related to intellectual property rights and interests not reimbursed through the Institution.

**Financial Conflict of Interest** means a Significant Financial Interest (or, where the Institutional Official requires disclosure of other Financial Interests, a Financial Interest) that the Institution reasonably determines could directly and significantly affect the design, conduct or reporting of Institutional research or the individual’s Institutional Responsibilities.

**Institution** means the BHS facility in which an individual conducts or performs PHS sponsored clinical research or provides services in connection with a PHS sponsored clinical trial.

**Institutional Official** means the individual within the applicable Baptist facility that is responsible for the solicitation and review of disclosures of significant financial interests related to clinical research including those of the individual’s Family related to the individual’s institutional responsibilities related to research. Each Baptist facility should designate an Institutional Official.

**Institutional Responsibilities** means the individual’s responsibilities associated with the Baptist facility where he or she performs or conducts PHS sponsored clinical research.

**Investigator** means any listed or identified clinical investigator or sub-investigator for a clinical protocol, including any individual who is responsible for the design, conduct, or reporting of research, or proposals for such funding. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, or graduate students. The definition may also include collaborators or consultants as appropriate.

**Outside Source** means individuals or entities (whether for profit or not-for-profit) that are involved directly or indirectly with the healthcare industry including, but not limited to, hospitals, pharmaceutical companies, medical device companies, biotech companies, software vendors, other suppliers of products, equipment or services, referral sources to a Baptist entity and professional service firms (e.g., legal, accounting or consulting).

**Public Health Service or PHS** means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration.
Research means a systematic investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

III. POLICY.

Baptist requires individuals with Institutional Responsibilities within its facilities to obtain advance approval for, and annually disclose, certain Financial Interests and relationships with Outside Sources so that an impartial decision-maker may assess whether a situation involves an actual or potential Conflict of Interest.

A. DISCLOSURE OF POTENTIAL CONFLICTS OF INTEREST RELATED TO PHS SPONSORED CLINICAL RESEARCH.

Clinical trials involve particularly sensitive issues if the Investigator has a Financial Interest related to the clinical trial. An Investigator shall not ordinarily participate in any research involving human subjects that encompasses evaluation of such a strategy or product if he/she has a Significant Financial Interest that could directly affect the design, conduct or reporting of the research unless he/she presents a compelling justification for a waiver of this policy based on his/her unique qualifications as an Investigator. The Institution will manage, minimize, or eliminate significant financial interest of Investigators of PHS sponsored Clinical Trials to ensure that clinical research will be free from bias resulting from Investigator financial interests. All Investigators are required to report to the Institution Financial Interests that could affect or be affected by PHS sponsored clinical research on which they are working. The Institutional Official is responsible for the distribution, receipt, processing, review and retention of disclosure forms. All disclosures must be made using the Baptist Financial Interest Disclosure Form attached to this policy. The COI Committee will assist with the review of those forms and processes. With each submission of a PHS sponsored protocol for human subject research to an Institutional Review Board (IRB), the Investigator must complete and submit a Financial Interest Disclosure Form for the specific project (or such other form required by the particular IRB to which the PHS sponsored clinical protocol is being submitted for consideration). It is the responsibility of each Investigator to update this information at any time that it changes. It is also the responsibility of the Principal Investigator to ensure that each Investigator working under his or her direction on a research project or receiving support from his or her grant or contract receives a copy of this Policy and submits disclosure forms as required by this policy.

1. Annual Disclosures.
All individuals who perform or conduct PHS sponsored research at a Baptist hospital must disclose their Significant Financial Interests to Baptist, through the applicable facility Institutional Official on an annual basis. All forms should be submitted to the Institutional Official March 1 for the previous calendar year or as otherwise determined by the Institution. The disclosure form must be updated at the time of the annual progress report, twelve (12) months following the notice of award, or the initiation of research, whichever date is earliest.
2. Reporting Significant Financial Interests.
Prior to entering into any PHS sponsored clinical trial agreements or applications for PHS sponsored clinical trials where the Investigator or individual conducting or performing research has a Significant Financial Interest, the Investigator(s) or individual(s) conducting or performing research must submit to the applicable facility Institutional Official and the appropriate IRB, an updated Financial Interest Disclosure Form. The Institution will not approve a research proposal unless the Investigator(s) or individual(s) have submitted such disclosures.

3. Change in Status and Updating Reports.
All individuals performing or conducting PHS sponsored clinical research in a Baptist facility must also submit to the applicable Baptist Institutional Official disclosure of any Significant Financial Interest they acquire during the course of the clinical research within fifteen (15) days of learning about or acquiring such Significant Financial Interest (e.g., through purchase, marriage, or inheritance). Individuals must comply with requests from the Committee for additional information.

4. Travel.
Individuals performing research in a Baptist facility must disclose reimbursed or PHS sponsored travel related to their Institutional Responsibilities, as defined above in the definition of Financial Interest. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The applicable facility Institutional Official will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a Financial Conflict of Interest with the individual’s scope of services or performance of research.

B. REVIEW AND DECISION OF THE COI COMMITTEE.
If the disclosure form reveals a Significant Financial Interest, it will be reviewed promptly by the Institutional COI Committee for a determination of whether it constitutes a Financial Conflict of Interest. When an individual submits a potential Conflict of Interest Disclosure, and the potential Conflict of Interest is related to a PHS sponsored Clinical Trial, the COI Committee will determine whether the Conflict of Interest is a significant Financial Interest that must be managed, reduced, eliminated or reported to the PHS funding agency. Should any reported Conflict or non-compliance require reporting to PHS, the Institutional Official will report in accordance with PHS regulations. If the funding for the research is made available from a prime PHS awardee, such reporting shall be made available to the prime awardee such that they may fulfill their reporting obligations to the PHS. If a Financial Conflict of Interest exists, the Institutional Official will take action to eliminate, reduce, or manage the conflict, as appropriate.

A Financial Conflict of Interest will exist when the COI Committee determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS-supported research or to the extent that financial interest from Outside Activities would be likely to significantly influence the design, conduct, performance, or reporting of any other clinical research at the Institution. If the COI Committee determines that there is a Financial Conflict of Interest that can be managed, the COI Committee will require and approve a written management plan before any related research or business activities go
forward. The affected Physician, Investigator, or individual is responsible for developing and submitting a proposed management plan to the COI Committee, in consultation with the applicable Baptist facility Institutional Official. The affected Physician, Investigator, or individual will be notified by the Institutional Official when a Significant Financial Interest requiring disclosure must be managed and when a Financial Conflict of Interest exists.

To address complex situations, oversight committees may be established by the Institutional Official to periodically review the ongoing activity, to monitor the conduct of the activity (including use of students and postdoctoral appointees and others with specialized expertise in a particular subject matter), to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management plan.

1. Plans for Management, Reduction or Elimination of a Significant Financial Interest Requiring Disclosure.
   A management plan will focus on the steps by which the objectivity of the PHS sponsored Clinical research may be ensured. The Plan may include but is not limited to:

   a. Requiring the physician or Investigator to recuse him/herself from particular research;

   b. Requiring the physician or Investigator to inform certain persons or institutions (such as patients, journals, professional audiences) about the outside interest as proscribed by the management plan;

   c. Public disclosure of an Investigator’s Significant Financial Interest;

   d. Appointment of an Independent reviewer of data, manuscripts, and/or presentations;

   e. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from an Investigator’s financial interest;

   f. Modification of any research proposal or plan; and/or

   g. Reduction or elimination of the financial interest.

   In cases where Baptist determines that it cannot manage the conflict, it may require that the conflict be eliminated or that the research not proceed. Factors involved in this decision might include such considerations as the involvement of human subjects in research, the level of risk involved, the amount of remuneration involved, the time required to perform the activity, the nature and significance of the conflict, the potential for having a serious adverse impact on the scientific field or on the reputation of Baptist, and the level of difficulty involved in managing the conflict relative to the benefit of doing the clinical research.

2. Notification of Committee’s Decision and Recommended Approval of Plan.
   When the COI Committee determines that an Investigator’s Significant Financial Interest must be managed, reduced, or eliminated, the Committee will inform the facility’s Vice President responsible for research administration, the Investigator and the IRB of this
recommendation and the management plan. The IRB may require additional measures to protect the safety and welfare of clinical research subjects.

C. REPORTING AND EXPENDITURE OF FUNDS

No expenditure of PHS funding for clinical research shall occur with respect to any clinical research protocol for which the COI Committee has determined that a management plan is required unless and until all reporting requirements have been met. The Baptist facility shall report to the funding agency any management plans or Financial Conflicts of Interest within sixty (60) days of the identification of the same.

1. Reports to Funding Agency.
Baptist shall report the following information regarding Financial Conflicts of interest to the funding agency:

a. Project Number;

b. Name and contact information of Principal Investigator;

c. Name of the Investigator with the financial conflict of interest;

d. Name of the entity with which the Investigator has a financial conflict of interest;

e. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);

f. Value of the financial interest, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measure of fair market value;

g. A description of how the financial interest relates to the PHS-funded research and the basis for Baptist’s determination that the financial interest conflicts with such research; and

h. A description of the key elements of the Institutions management plan, including:

   i. Role and principal duties of the conflicted Investigator in the research project;
   ii. Conditions of the management plan;
   iii. How the management plan is designed to safeguard objectivity in the research project;
   iv. Confirmation of the Investigator’s agreement to the management plan;
   v. How the management plan will be monitored to insure Investigator compliance; and
   vi. Other information as needed or requested by the funding agency

Each year, the Institution will provide the funding agency an annual Financial Conflict of Interest report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the project period. The annual report
will specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists.

2. Reports to Public.
Prior to the expenditure of funds, the Institution will publish on a publicly-accessible website or respond to any request or within five (5) business days of the request, information concerning any Significant Financial Interest, as follows:

a. Project number;
b. Name of Investigator with a conflict;
c. Investigator’s title and role with respect to the research project;
d. Nature of the financial interest (e.g. equity, consulting fee, travel reimbursement, honorarium); and
e. Value of the financial interest, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or their reasonable measure of fair market value.

The information to be made available shall be consistent with the requirements of 42 CFR § 94.4 and shall include, at a minimum, the following: the Investigator’s name; the Investigator’s title and role with respect to the research project; the name of the entity in which the Significant Financial Interest is held; the nature of the Significant Financial Interest; and the approximate dollar value of the Significant Financial Interest (or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value).

D. RETENTION.
The Institutional Official will retain all disclosure forms, conflict management plans, and related documents for a period of three (3) years from the date the final expenditure report is submitted to PHS or to the prime PHS awardee.

E. TRAINING.
Each Investigator must complete training on this Policy prior to engaging in PHS sponsored research within a BHS facility, and at least every four years thereafter. Each Investigator must also complete training within a reasonable period of time as determined by the Institutional Official in the event that this Policy is substantively amended in a manner that affects the requirements of Investigators, or if it is determined that the Investigator has not complied with this policy or with a management plan related to their activities.

F. SANCTIONS FOR NON-COMPLIANCE.

In the event of an Investigator’s failure to comply with this Policy, the Institutional Official may suspend all relevant research activities of such Investigator or take other disciplinary action
until the matter is resolved or other action deemed appropriate by the Institutional Official is implemented.

An Institutional Official’s decision to impose sanctions on an Investigator because of his/her failure to comply with this Policy, or failure to comply with the decision of the Institutional Official, will be described in a written explanation of the decision to the Investigator, the COI Committee and, where applicable, the IRB.

In addition, if the applicable Baptist facility Institutional Official determines that a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an Investigator’s failure to disclose a Significant Financial Interest that is determined to be a Financial Conflict of Interest, or failure by an Investigator to materially comply with a management plan for a Financial Conflict of Interest, a committee appointed by the Institutional Official will complete a retrospective review of the Investigator’s activities and the research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research.

Documentation of the retrospective review shall include the project number, project title, name of principal Investigator, name of Investigator with the Financial Conflict of Interest, name of the entity with which the Investigator has the Financial Conflict of Interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

The Institutional Official will update any previously submitted report to the PHS or the prime PHS-awardee relating to the research, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. If bias is found, the report will include a mitigation report in accordance with the PHS regulations, including a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

G. CONFIDENTIALITY.

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be maintained as confidential. However, the Institution may make such information available to an agency funding research of the faculty member, to a requestor of information concerning financial conflict of interest related to PHS funding or to the primary entity who made the funding available to the Institution, if requested or required or to others, in accordance with any regulations governing the confidentiality of such information. If the Institution is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure. All information provided by Physicians and Investigators in connection with this Conflict of Interest policy may be shared amongst the various Baptist facilities.
H. REGULATORY AUTHORITY.

This policy implements the requirements of 42 CFR 50 and 45 CFR 94; where there are substantive differences between this policy and the requirements, the requirements shall take precedence.

Approved by:

[Signature]

Tommy J. Smith, President and CEO
EXAMPLES OF SITUATIONS THAT MIGHT ENTAIL OR CREATE A CONFLICT OF INTEREST

The following examples are not intended to be exhaustive, and are provided only as samples of some commonly encountered situations.

- Financial relationships (consulting fees, lecture fees, etc.) with companies or their agents that supply medical equipment or pharmaceuticals to a Baptist facility for use in PHS sponsored clinical research.
- Ownership, stock, or other securities, membership on board of directors or any other activity with an organization that provides medical equipment or pharmaceuticals for use in PHS sponsored clinical research for whom Physician performs research through a Clinical Trial Agreement.
- Accepting gratuities or special favors from companies or their agents that provide medical equipment or pharmaceuticals for use in PHS sponsored clinical research.
- Holding any management position (e.g., director, officer, trustee, management employee) in an entity that supplies medical equipment or pharmaceuticals for use in PHS sponsored clinical research.
BAPTIST HEALTHCARE SYSTEM
CONFLICT OF INTEREST IN CLINICAL RESEARCH
DISCLOSURE STATEMENT

Name of person submitting statement:

Name of Clinical Trial impacted by potential conflict of interest:

This statement is submitted (check the appropriate response below):

As a new, renewal annual or an ad hoc disclosure statement
as to my financial relationship with a company for whom I perform clinical research that
is sponsored by PHS.

1. Did you (or members of your immediate family, i.e., spouse or dependent children as
determined by the Internal Revenue Service, or domestic partner) have an employment,
consulting or other financial relationship, including ownership of any equity (or at least
$5,000 worth of ownership interest) with a sponsor of your research activities or providing
services, supplies or products in connection with PHS sponsored clinical research? Please
include only that equity which is directly under your control, not that managed by a third
party such as a mutual fund. If yes, please list each such arrangement and provide an
attached written explanation.

2. Will any members of your immediate family, (i.e., spouse or dependent children as
determined by the Internal Revenue Service, or domestic partner) derive any financial benefit
from a project you control or are involved with?

3. Did you submit a proposal to or receive funding from or conduct research, which could
benefit a company in which you either had a consulting arrangement, or had significant
financial holdings (defined as any equity interest or at least $5,000 of ownership
interests)? If yes, were those arrangements or financial interests disclosed at the time of proposal
submission?

4. Were you an inventor of intellectual property which has been or will be licensed through
Baptist to any outside entity in which you (or members of your immediate family, as
described above) have an employment, consulting or financial or other significant
relationship, including ownership (at least $5,000 of ownership interests)? If yes, please list
and explain.
5. Did you create, discover, or reduce to practice an invention(s) using Baptist resources to which title has not been assigned to Baptist? If yes, please list and explain. ______________

6. Please describe any other relationships, commitments, or activities you or any members of your immediate family have that might present or appear to present a conflict of interest with your performance of any PHS sponsored clinical research. Such relationships might include financial or fiduciary interest or uncompensated activities.

**CERTIFICATION**

In submitting this form, I certify that the above information is true to the best of my knowledge, that I have read the Baptist Physician Clinical Research Financial Conflicts of Interest policy, and that I am in compliance with this policy.

________________________________________  ______________
Signature                                      Date

________________________________________
Print Name