CAROLINAS HEALTHCARE SYSTEM

Category: Corporate Compliance
Policy: Conflicts of Interest
Number: COR 40.17
Date of Issue: 08/91 Reviewed / Revised: 11/12

CONFLICTS OF INTEREST

SUMMARY STATEMENT

A conflict of interest occurs when an individual, including his or her immediate family, or an institution enters into any type of relationship that interferes with or compromises, or gives the appearance of compromising, the professional judgment or obligations of the individual or institution. A conflict of interest also may arise if there is a conflict of commitment such that outside activities interfere with the primary obligation of the individual to his or her employer. Any conflict of interest or potential conflict of interest must be fully disclosed, evaluated and, if necessary, managed, reduced or eliminated. The purpose of this policy is to describe conflicts of interest that may occur within Carolinas HealthCare System and to set out the appropriate procedures for addressing any actual or potential conflicts.

APPLICABILITY

The Conflict of Interest Policy applies to all Carolinas HealthCare System employees in their performance of the administration, research, teaching, patient care and other business operations of Carolinas HealthCare System and to non-employees who are appointed by Carolinas HealthCare System to represent its interest on various committees or in other decision making capacities**.**

The Conflict of Interest Policy for Research Related Conflicts of Interest is applicable to all CHS Projects, regardless of funding source. [1]

DEFINITIONS

The definitions are set forth in the Glossary attached as <u>Appendix I</u> and made a part hereof.

POLICIES AND PROCEDURES

The potential for a conflict of interest may arise in a number of different circumstances within CHS. Not only is it possible for there to be a conflict of interest that affects one or more individuals, but the actions of individuals within CHS can lead to an institutional conflict of interest that may affect the entire organization. The areas of potential individual and institutional conflicts, as set forth below, are divided between General Areas of Conflict and Research Related Conflicts of Interest. The subjects addressed in the General Areas of Conflict apply to all individuals covered by this policy. Because the potential for conflicts within the research

1 The research conflict of interest section of this policy is based on 42 CFR part 50 subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought."

arena is so great, the section entitled Research Related Conflicts of Interest includes additional safeguards that apply primarily to researchers and administrators responsible for research activity within CHS. The policies and procedures set forth below are intended to protect the individuals within CHS and the institution itself.

I. General Conflicts of Interest

A. <u>Property/Services</u>

1. *Policy*

a. Prohibited Activity. No Covered Individual or his or her Spouse may acquire any interest, direct or indirect, in any CHS facility or in any property included or proposed to be included in any CHS facility; nor may he or she or his or her Spouse have any interests, direct or indirect, in any contract or proposed contract for materials or services to be furnished or used in connection with any CHS facility. Examples of prohibited activity include:

(1) owning or controlling any interest, directly or indirectly, in any real estate or personal property included or planned to be included in any CHS facility;
(2) participating in any contract or proposed contract for materials or services to be furnished or used in connection with constructing or operating any CHS facility; or
(3) landlord/tenant or vendor/customer relationships involving a CHS entity.

b. Allowed Activity. Notwithstanding the policy set forth above, the contracts, undertakings and/or transactions set forth below are allowed provided that any such transactions are authorized by the Board by specific resolution on which no commissioner having an interest, direct or indirect, votes:

(1) any contract or other transaction with a bank or banking institution or public utility in the regular course of business; and
(2) a contract, undertaking or transaction involving a corporation or other business entity in which the Covered Individual and the Covered Individual's Spouse, together, have a ten percent (10%) or less ownership interest.

c. CHS Committees. All individuals, whether or not employed by CHS, serving on any CHS Committee must complete a Conflict of Interest Disclosure Form each year in accordance with the rules governing membership on such CHS Committees.

2. *Procedure*

a. Disclosure. Each Covered Individual in a Management Position and each member of a CHS Committee will complete an annual Conflict of Interest Disclosure Form at the request of the General Counsel, the Corporate Compliance Department, or the designated facility compliance director.

b. Approval. Any allowed activity set forth above, must be submitted to the Board for approval by specific resolution.

c. Resolution. If a Conflict of Interest is not promptly managed or eliminated, the matter will be brought to the attention of the CEO or his/her designee through appropriate supervisory channels. The CEO or his/her designee, in collaboration with the Chief Compliance Officer, will determine the necessary action in a manner consistent with System policy and practice. The personnel in the following positions have been designated to act on behalf of the CEO for this purpose:

(1) for each facility that is not a physician practice, the facility president in collaboration with that facility's compliance director and in consultation with the Chief Compliance Officer as and when necessary; or
(2) for each physician practice that is a part of CHS, the administrator responsible for that practice.

If the Conflict of Interest matter involves the CEO, the matter will be reported by the Chief Compliance Officer and resolved with the Chairperson of the Finance and Compliance Committee.

B. <u>Consulting</u>

1. *Policy*

Consulting Compensation must never be an inducement or reward for the referral or generation of health care business. External consulting activities must be bona fide services that are documented in writing by a written agreement, and the compensation must be for a demonstrably fair market value. Detailed records of Consulting Compensation must be kept by Covered Individuals for 5 years and given to CHS upon request. CHS does not provide liability protection (insurance) for any consulting activities, except for OGC-approved activities. CHS reserves the right to prohibit any consulting activity if doing so is in the best interest of CHS, regardless of the nature of the activity or the Covered Individual's compliance with this policy.

a. Approval Required. A Covered Individual may not accept any

Consulting Compensation without prior approval from his or her Responsible Administrator. The Responsible Administrator may confer with the OGC prior to granting any such approval. Covered Individuals may not serve as an expert witness in a legal case without prior approval by the OGC. The following are examples of consulting activities requiring prior approval:

(1) Advising a pharmaceutical company about emerging technology
(2) Serving on a scientific advisory board or other pharma advisory committee or any financial investment firm
(3) Speaking at a conference in return for payments from companies providing medical or pharmaceutical services or products (or their affiliates), including payments from medical education companies indirectly supported by industry
(4) Receiving compensation for clinical activities performed outside the scope of CHS employment
(5) Receiving compensation for services provided to competitor of CHS or an organization providing the same types of services offered by CHS
(6) Receiving compensation for work relating to a CHS Project that he or she consulted on

b. Prohibited Activity. Covered Individuals must not do any of the following:

(1) Engage in activities in direct conflict with CHS's mission or business position
(2) Engage in purely marketing activities for the pharmaceutical/biotechnology health industry, e.g., writing papers favoring a company's products or disfavoring its competitors' products; publicly promoting a company's products through advertising or other media outlets
(3) Receive compensation from a non-CHS source for performing any of his or her CHS employment activities (i.e. Covered Individual shall not be paid for time otherwise compensated as reimbursable patient care services)
(4) Receiving Consulting Compensation in the form of stock or stock options

c. Retaining Consulting Compensation. Consulting Compensation may be personally retained by Covered Individuals, unless otherwise indicated by the Covered Individual's departmental polices, the Covered Individual's employment agreement, the Covered Individual's Responsible Administrator or the OGC.

2. *Procedure*

a. Before engaging in any consulting activities that require one's professional competence to earn Consulting Compensation, a Covered Individual must notify his or her Responsible Administrator by submitting to the Responsible Administrator a partially completed Approval Form with all relevant documentation including, but not limited to, the contract documents governing the proposed arrangement. Notification to the Responsible Administrator should occur at least three weeks prior to the proposed engagement is scheduled to begin.

b. The Responsible Administrator will submit the Approval Form and all relevant documentation to the Corporate Compliance Department for review. Where appropriate, the Corporate Compliance Department will submit the Approval Form to the OGC. Situations which may require OGC review include:

(1) Requirement for institutional signature;
(2) Non-conventional compensation model (e.g. stock options, royalties, etc.);
(3) Services involving "observation" of patient care related activities in a CHS facility or via videoconference to other facilities;
(4) Videotaping or other multimedia activities involving CHS employees or property;
(5) Events being held on CHS property;
(6) Services which may be considered "direct-to-consumer marketing";
(7) Agreements involving three or more parties.

The Approval Form and supporting documentation should be submitted to the Corporate Compliance Department no later than two weeks prior to the start date of the proposed engagement.

c. Following its review of the Approval Form, the Corporate Compliance Department will return the Approval Form to the Responsible Administrator indicating approval of the proposed arrangement, approval with recommendations or disapproval of the proposed arrangement. The Corporate Compliance Department will evaluate the appropriateness of the request according to the guidelines outlined in **Appendix III** attached hereto.

C. Conflicts of Commitment

1. *Policy*

a. Allowed Activities. CHS recognizes that Covered Individuals, particularly those in Management Positions, periodically serve in external consulting roles and in other activities that may or may not require the use of their professional competence. These activities are generally permissible (subject to compliance with this policy).

b. Prohibited Activities. Examples of inappropriate roles or activities as follows:

(1) Disproportionate Compensation – If Consulting Compensation to a Covered Individual from outside entities, in the aggregate, exceeds thresholds established from time to time by the Corporate Compliance Department, a potential for a Conflict of Commitment exists.
(2) Conflict of Time – When the time commitments for external activities – related to professional competence or not – encroach upon a Covered Individual's ability to contribute at the level expected of other Covered Individuals in the same specialty, a potential for a conflict of time commitment exists. Activities involving Consulting Compensation for full time employees may not exceed 20% of that portion of a Covered Individual's time that is allocated to his or her primary job responsibilities at CHS, except that vacation time may be used to exceed the 20% limit.
(3) Conflict of Business or Mission – Covered Individuals may not engage in consulting or other external activities that compete or conflict with CHS's business activities or mission, and they must not divulge confidential CHS business information.
(4) Conflict of Resources/Intellectual Property – Covered Individuals may not utilize CHS resources or share intellectual property developed or acquired by CHS unless permitted by other applicable CHS policies.

2. *Procedures*

In general, Conflicts of Commitment should be monitored by the Responsible Administrators. Any questions or concerns about potential Conflicts of Commitment should be disclosed to the Corporate Compliance Department by the Covered Individual and/or his or her Responsible Administrator. The Corporate Compliance Department will notify the Responsible Administrator if it determines that a Conflict of Commitment exists and will advise the Responsible Administrator of any necessary action.

D. Business Gifts and Gratuities

1. *Policy*

a. Prohibited Activity. Covered Individuals must avoid circumstances in which the acceptance of gifts or favors by CHS or the Covered Individual or his or her Family could result in improper influence, or give the appearance of improper influence, upon business decisions made on behalf of CHS. No Covered Individual and/or his or her Family will directly or indirectly solicit any gift or favor, whether in the form of money, services, loans, travel, entertainment, hospitality, trips, or other property of any kind. Examples of gifts that must be avoided:

(1) gifts of cash or cash equivalents (e.g. gift cards, checks) of any kind or amount *cannot* be accepted. Potential donors should be referred to the CHS Foundation;
(2) quid pro quo relationships or transactions are not acceptable (e.g. Covered Individuals may not require that meals be provided to office staff to gain access to the Covered Individual); or
(3) educational programs where more than minimal costs and program time are spent for social content (meals, entertainment, activities, etc.) than for educational content.

b. Allowed Activity. This policy is not intended to prohibit the acceptance or giving of common, non-monetary courtesies, provided that: (a) the value of the gratuity is nominal; and (b) it is not intended to influence a business transaction or a Covered Individual's performance of official job duties. Examples of acceptable gifts and gratuities include, but are not limited to:
(1) advertising or promotional items of nominal value not exceeding $100 provided that the gift does not influence business decision making or give the appearance of influencing business decision making; or
(2) meals served during business meetings or in the furtherance of established business relationships.

2. *Procedure*

If the Covered Individual has any questions about whether a Conflict of Interest may exist with respect to a gift and/or gratuity that has been offered or received, the Covered Individual must disclose the gift and/or gratuity to the Corporate Compliance Department before accepting the gift or gratuity. There are certain instances where business relationships produce gifts and/or gratuities that may be acceptable; however, because the total value of a gift and/or gratuity is in excess of $100 or the gift and/or gratuity may give rise to actual or perceived Conflicts of Interest, the nature and instance of these relationships must be disclosed to the Corporate Compliance Department.

II. Research Related Conflicts of Interest

A. Policy

Without the prior approval of the Corporate Vice President of Research, in consultation with the Chief Academic Officer, a Covered Individual may not participate in any CHS Project if the Covered Individual or his or her family has a Significant Financial Interest (SFI) related to the Covered Individual's institutional responsibilities.

The Corporate Vice President of Research, or his or her designee, is the designated institutional official responsible for soliciting and reviewing disclosures of SFIs of Covered Individuals participating in any CHS Project. In consultation with the Chief Academic Officer, the Corporate Vice President of Research also must approve any CHS Project in which CHS has an Institutional Financial Interest in the sponsor of the CHS Project or any other Financially Interested Company. If the Corporate Vice President of Research, in consultation with the Chief Academic Officer, determines that Compelling Circumstances exist, the CHS Project may be conducted and/or the Covered Individual may participate in the CHS Project but, in either instance, only pursuant to a management plan approved by the Research COI Committee and, where appropriate, ratified by the IACUC or IRB, as applicable.

B. Procedure

1. *Disclosure*

   a. The Corporate Compliance Department in conjunction with CHS Research Administration is responsible for the dissemination, collection and review of research related Conflict of Interest Disclosure Forms. Investigators must disclose SFIs no later than at the time of application for any CHS Project Conflict of Interest Disclosure Forms must be completed and submitted by Investigators at least on an annual basis. Additional updates must be submitted within 30 days of discovering or acquiring a new SFI including, but not limited to, the consideration of a new CHS Project which the Investigator believes may either:

      (1) give rise to a Conflict of Interest, or
      (2) eliminate a Conflict of Interest previously disclosed.

   b. Other situations requiring prior disclosure by Investigators include, but are not limited to, the following:

      (1) Service as an officer or director of any entity;
      (2) investment of more than $5,000 in any one company whose product/service is related to an individual's research or work;
      (3) Equity interest of any value in a partnership or corporation;
      (4) Consulting contracts that yield more than $5,000 a year in remuneration;

(5) Consulting contracts that require more than 26 days per year of outside commitment (more than ½ day per week per year);
(6) Agreements to collaborate in research with a commercial entity, regardless of value;
(7) With respect to Family members, situations as above which must be resolved as to an Investigator also must be disclosed or resolved for members of his or her Family, if the Investigator knows or should have known that a member of his or her Family had such a relationship;
(8) Income related to intellectual property rights and interests, upon receipt of such income;
(9) The occurrence of any reimbursed or sponsored travel (i.e. paid on behalf of the Investigator and not reimbursed to Investigator).

The Conflict of Interest Disclosure Form will be considered strictly confidential and it will be the responsibility of the Corporate Compliance Department and the CHS Division of Research to ensure that the information disclosed in the forms is available only to the individuals duly charged with the responsibility for review. The CHS Director of the Office of Clinical and Translational Research under the Division of Research will review each disclosure form as submitted in consultation with other CHS officials, as appropriate. This review may result in issues of concern being forwarded to the CHS Corporate Vice President of Research for further review. If the CHS Corporate Vice President of Research determines that further review is necessary, he or she will convene a meeting of the Research COI Committee.

2. *Research COI Committee.*

The Research COI Committee will periodically evaluate the reports that it receives and develop a listing of (institutionally) Financially Interested Companies and provide that listing to the IRB, IACUC, OGC and other departments as necessary.

3. Management, Reduction, Elimination, and Reporting of Conflicts of Interest in Research.

If it is determined that appropriate conditions, restrictions or both are necessary to manage, reduce or eliminate a Conflict of Interest, such conditions, restrictions or both will be imposed.

If, upon review of disclosures of SFIs, it is determined by the Corporate Vice President of Research that a management plan is necessary to manage a financial conflict of interest, such management plan will be implemented which specifically details the actions that have been, and will be, taken to manage such financial conflict of interest.

Examples of conditions or restrictions include, but are not limited to:

a. Public disclosure of the Financial Interests or Institutional Financial Interests;
b. Disclosure of Conflict of Interest to research subjects;
c. Divestiture of Financial Interests or Institutional Financial Interests;
d. Monitoring of CHS Project by independent reviewers;
e. Modification of the research plan;
f. Disqualification from Participation by Covered Individual(s) in all or a portion of the CHS Project;
g. Severance of relationships that create actual or potential Conflicts of Interest.

The Institution shall complete a retrospective review of any Investigator's activities and his or her CHS Project if it is determined that a financial conflict of interest was mismanaged or not disclosed properly by the Investigator. This review will be conducted within 120 days of the determination of noncompliance.

In instances where the Investigator's failure to comply with this policy or any associated procedure or with a management plan, and the design, conduct, or reporting of a CHS Project appears to have been biased, the Institution will immediately notify the Awarding Component of corrective actions taken or planned to be taken by the institution.

4. Retention

All financial conflict of interest records, including disclosure forms, management plans, and all other related documents, will be maintained for at least three (3) years from the date of submission of the final expenditures report.

5. Subrecipient Requirements

If a CHS Project is carried out through a subrecipient, such subrecipient shall comply with this policy unless they are able to demonstrate that the subrecipient institution's FCOI policy complies with, at a minimum, all applicable laws and regulations. The subrecipient's requirements to comply with this policy or use the subrecipient institution's FCOI policy shall be outlined in a written agreement between CHS and the subrecipient site.

6. Education Requirements

All Covered Individuals participating in a CHS Project will be informed of this policy and their responsibilities regarding disclosure of significant financial interests. Additionally, each Covered Individual will receive information about applicable regulations and will participate in training on this policy. Education and training will occur prior to beginning any CHS Project and at least every four years thereafter.

III. COMPLIANCE

All Covered Individuals are expected to comply fully and promptly with all requirements of this policy. Examples of non-compliance include, but are not limited to:

- Failure to submit required Conflict of Interest Disclosure Forms or updates according to policy requirements;
- Failure to provide additional information requested by the Corporate Compliance Department, the Research COI Committee or Applicable Administrator;
- Knowingly filing an incomplete, erroneous, or misleading statement;
- Failing to comply with conflict of interest management plans; or
- Knowingly violating applicable laws or regulations.

Failure on the part of a Covered Individual to comply may result in disciplinary action and/or sanctions; examples of possible sanctions include formal reprimand; suspension and/or termination of research privileges (i.e., clinical, basic science, comparative medicine); and/or any other enforcement action mandated by the applicable government granting agency or CHS administration. The Chief Compliance Officer is responsible for investigating instances of non-compliance and determining whether to impose sanctions and what sanctions will be applied. In making these determinations, they may consult with the Applicable Administrator, the Research COI Committee, OGC, human resources or other appropriate individuals. A Covered Individual who is the subject of a disciplinary action may appeal such action in accordance with established CHS grievance and/or disciplinary procedures.

APPROVALS

Policy Coordinator	Melissa Freeman, Director, Corporate Compliance & Privacy
Policy Approver	Sara Herron, SVP, Chief Compliance & Privacy Officer

APPENDIX I
Glossary

A) "Approval Form" means the CHS Consulting Agreement Review and Approval Form that must be submitted by an employee to his or her Responsible Administrator before agreeing to accept Consulting Compensation.

B) "Board" means the Board of Commissioners of The Charlotte-Mecklenburg Hospital Authority or any of its related institutions.

C) "Board Member" or "Board Membership" means a member of the Board or membership on the Board.

D) "CEO" means the Chief Executive Officer of CHS.

E) "Chief Compliance Officer" means the chief compliance officer of CHS.

F) "CHS" means the hospital system known as Carolinas HealthCare System and includes The Charlotte-Mecklenburg Hospital Authority and all of its related and affiliated institutions.

G) "CHS Committee" means an individual or group of people, whether or not employed by CHS, appointed by CHS to make decisions or recommendations for the benefit of CHS.

H) "CHS Foundation" means The Carolinas HealthCare Foundation, Inc.

I) "CHS Project" means any research, testing, evaluation, training, and/or instruction project conducted under the auspices of CHS.

J) "Compelling Circumstances" means those facts that convince the Research COI Committee or its designee that a Covered Individual who has a Financial Interest should be permitted to conduct a CHS Project, taking into account the following factors:

(1) the nature of the CHS Project,
(2) the magnitude of the Financial Interest and the degree to which it is related to the CHS Project,
(3) the extent to which the Financial Interest could be directly and substantially affected by the CHS Project,
(4) if the CHS Project involves human subjects, the degree of risk to the human subjects involved that is inherent in the research protocol,
(5) the extent to which the Investigator is uniquely qualified to perform a research study with important public benefit, and
(6) the extent to which the Financial Interest is amenable to effective oversight and management.

K) "Conflict of Commitment" means a situation in which outside activities interfere with the primary obligations of the Covered Individual to CHS. A Conflict of Commitment is a Conflict of Interest for the purposes of this policy.

L) "Conflict of Interest" means a situation in which a Covered Individual, including his or her Family, or CHS enters into any type of relationship that interferes with or compromises, or gives the appearance of compromising, the professional judgment or obligations of the Covered Individual or CHS. The term Conflict of Interest includes Conflicts of Commitment.

M) "Conflict of Interest Disclosure Form" means the form used by CHS to obtain information about relationships that may pose a potential conflict of interest as defined by this policy.

N) "Consulting Compensation" means compensation from a source other than CHS received by a Covered Individual in exchange for providing/participating in consulting, lectures, training, product/medical technology development, marketing reference, proctoring/preceptorships, advisory boards, focus groups or other external activities. Consulting Compensation may be direct or indirect, financial or otherwise and includes any compensation that is received by the Family of a Covered Individual or an entity controlled or directed by the Covered Individual or his or her Family. Examples of Consulting Compensation include honoraria, consulting fees, lecture fees, royalties, and "in kind" compensation.

O) "Corporate Compliance Department" means the corporate compliance department of CHS.

P) "Covered Individual" means any CHS employee, student or trainee who is performing teaching, research, public service, administration and/or business operations for CHS. This includes subrecipient investigators of PHS-funded research and their family.

Q) "Manager" means a Covered Individual who holds a Management Position.

R) "Management Position" means any position that includes responsibilities for a material segment of the operation, management or oversight of CHS, including Board Membership, or a position with decision-making authority, including executives, physicians, mid-level providers and director-level employees.

S) "Family" means the Spouse and dependent children of a Covered Individual.

T) "Finance and Compliance Committee" means the Board committee known as the finance and compliance committee.

U) "Financial Interest" means anything of monetary value, including, but not limited to, salary or other payments for services, equity interests, and intellectual property rights, whether or not the value is readily ascertainable. Financial Interests include:

(1) Receipts of rights or expectation to receive any income by the Covered Individual or his or her Family from a business whether in the form of a fee (e.g., consulting), salary, allowance, forbearance, forgiveness, dividend, royalty derived from licensing

technology, rent, capital gain, real or personal property, or any other form of compensation.

(2) Any stock, stock option, or similar equity interest in a business by a Covered Individual or his or her Family, excluding any interest that arises solely in a business through mutual, pension, or other institutional investment fund over which the Covered Individual or her or her Family does not exercise control; or

(3) Gifts that have been made to CHS for the benefit of the research or other professional activities of a specific Covered Individual.

Financial Interest does not include salary or other remuneration from CHS.

V) "Financial Conflict of Interest (FCOI)" means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

W) "Financially Interested Company" means an entity with financial interests that would reasonably appear to be affected by the conduct or outcome of a CHS Project. This term includes the manufacturer (including business partners) of the drug or the device or other sponsor of a CHS Project. This term includes any entity acting as the agent of a Financially Interested Company, *e.g.*, a contract research organization. (This term also includes companies that provide *direct* and *primary* competition for the investigational product, if the Covered Individual actually knows that the financial interests of such a company would reasonably appear to be affected by the CHS Project.)

X) "IACUC" means the CHS Institutional Animal Care and Use Committee.

Y) "Institutional Financial Interest" means one of the following circumstances:

- Royalties – When CHS is entitled to receive royalties (payments linked to the sale of a product) that is or was under investigation at CHS.

- Any Equity in a Non-publicly Traded Sponsor – When, through CHS's technology licensing activities or investments related to such activities, CHS has obtained an equity interest or an entitlement to equity of any value (including options or warrants) in a current *non-publicly traded* sponsor of a CHS Project.

- Equity Exceeding $100,000 in a Publicly-traded Sponsor – When, through CHS's technology licensing activities or investments related to such activities, CHS has obtained an equity interest or an entitlement to equity of any value (including options or warrants) in a current *publicly-traded* sponsor of a CHS Project. (*Exception: Mutual Funds and Fiduciary-Managed Funds* – Interests of any amount in publicly-traded, diversified mutual funds or in funds in which the investment decision making is made by fiduciary managers appointed by CHS but not otherwise affiliated with CHS are not Institutional Financial Interests.)

- Managers – When a Manager (or his or her Family or a controlled entity), whether participating in research or not, holds a personal Financial Interest in any commercial research sponsor that is sponsoring a CHS Project or a product being

investigated for clinical use at or by CHS, except that having equity or royalties up to $10,000 from a publicly-traded sponsor is not an Institutional Financial Interest if the Manager is not participating in the research.

Z) "Investigator" means the project director or principal investigator and any other person, regardless of title or position and including collaborators or consultants, who is responsible for the design, conduct or reporting of a proposed or approved CHS Project.

AA) "IRB" means the CHS Institutional Review Board.

BB) "OGC" means the CHS Office of General Counsel.

CC) "Participate(ing)" in a CHS Project means a Covered Individual doing any of the following under the auspices of CHS or pursuant to the review and approval of the IRB or IACUC, whether the CHS Project is conducted at a CHS-owned, leased or managed facility, in a CHS hospital, or anywhere else in the world:

- Designing or directing a CHS Project
- Serving as the principal investigator, co-investigator, or sub-investigator
- Enrolling research subjects (including obtaining human subjects' informed consent, if applicable)
- Making decisions related to eligibility to research subjects' enrollment in a CHS Project
- Analyzing or reporting CHS Project data
- Submitting manuscripts concerning the CHS Project for publication as a primary author or co-author

DD) "PHS" means the Public Health Service of the U.S. Department of Health and Human Services (HHS) and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

EE) "Remuneration" means salary and any payment for services not otherwise identified as salary (e.g. consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option or other ownership interest.

FF) "Research COI Committee" means the committee responsible for review and assessment of real or potential Conflicts of Interest related to CHS Projects. The Bylaws of the Research COI Committee are attached hereto as **Appendix II**.

GG) "Responsible Administrator" means the administrator or business unit leader who is responsible for a particular Covered Individual.

HH) "Senior/key personnel" means the project director/principal investigator and any other person identified as senior/key personnel by the institution in the grant application, progress report, or any other report submitted to the PHS.

II) "Significant financial interest" (SFI) means financial interest consisting of one or more of the following interests of the investigator and their family that reasonably appears to be related to the investigator's institutional, including:

- The value of remuneration received from an entity in the 12 months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated exceeds $5,000.
- Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.
- Reimbursement for sponsored travel related to the covered individual's institutional responsibilities (i.e. that which is paid on behalf of the investigator but not reimbursed to the investigator so that the exact monetary value may not be readily available). This does not include travel reimbursed or sponsored by Federal, state or local government agencies, institutions of higher education, academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

JJ) "Spouse" means the husband or wife of a Covered Individual.

APPENDIX II
BYLAWS OF RESEARCH CONFLICT OF INTEREST (COI) COMMITTEE

The Research COI Committee will include the following members or their designees: Chief Academic Officer (Chair), Chief Compliance Officer, Chair of IRB, Legal Counsel, Corporate Vice President of Research, , Director of Office of Clinical and Translational Research and Experienced Researcher(s). The Research COI Committee will meet as needed as determined by the Chair or his or her designee. Meetings may only proceed with a quorum, which will consist of a simple majority. The Research COI Committee's responsibilities are:

- Operate in accordance with the Standard Operating Procedure for the Disclosure and Management of Significant Financial Interest in Research;
- Recommend policies and procedures to address research related Conflicts of Interest within CHS;
- Review Conflict of Interest Disclosures Forms to determine if Investigators have Conflicts of Interest or Significant Financial Interests that might compromise, or appear to compromise, the protection of human subjects, the integrity of CHS Projects, or otherwise inhibits objectivity in the conduct of a CHS Project;
- Recommend if and how conflicts or SFIs identified in the Conflict of Interest Disclosures Form and through further discussion with the Investigator should be managed, reduced, or eliminated through conflict of interest management plans; and
- Oversee/monitor conflict of interest management plans, with progress reports submitted as needed.

The Chair of the Research COI Committee will make certain that proper records are maintained, specifically:

- Minutes of each meeting with the names of those present
- The issues and disclosures reviewed
- A summary of the discussion of the issues
- Other Research COI Committee actions and discussion

These records will be maintained in the CHS Office of Clinical and Translational Research for at least three years after the termination or completion of the CHS Project to which those records relate or until resolution of any government activity related to those records.

APPENDIX III

Consulting Services Guidelines

1. **Written Agreement** – The arrangement must be set out in writing. Agreements should not be executed prior to approval.

2. **Detailed Description of Services** – The written agreement must contain a detailed description of the services the consultant will be expected to provide including:

    - Frequency of events
    - Length of each event
    - Term of the agreement

    Consulting services provided should be for bona fide educational and product development efforts and should not be intended to *solely* support the Company's marketing or sales initiatives (e.g. training or speaking to groups made up primarily of the Company's sales force, reviewing materials primarily intended to augment sales, etc.). Participation in advisory boards is acceptable as long as the advisory board supports educational discussion and advancement.

3. **Compensation** – The compensation must be on a "pay for service" model, where the Covered Individual receives reasonable, fair market value compensation for the actual consulting services he/she provides. Additional guidelines:

    - Retainers are not permitted.
    - Covered Individual should not receive compensation from Company for time which is otherwise compensated as reimbursable through delivery of patient care services, including time actually spent in surgery, time actually spent in pre-op and post-op patient evaluations, and any time he or she would have actually spent with the patient or providing medical care in the normal course of clinical practice. If hosting visiting physicians in a CHS facility at the request of the Company, nominal time added to the total time of the procedure shall not be compensated by the Company; only significant supplementary time providing consulting services (e.g. review of visiting physician's cases, review and discussion of Covered Individual's clinical experience with the Company's products, etc.) shall be compensated by the Company.
    - The agreement should define an annual cap on compensation.
    - Travel premiums or other flat fee travel payments are not permissible.
    - Compensation for travel time or opportunity cost of travel time may be allowable when the agreement includes a clear, defensible calculation model. Factors that will be reviewed include:

        1. Reasonableness of compensation for travel time compared to compensation for actual time spent providing consulting services.
        2. Flat fee travel payments are not permissible. Compensation for travel time should be based on distance traveled or time spent in travel.

4. **Expense Reimbursement** – The written agreement must include and/or reference the Company's expense reimbursement policy (sometimes referred to as "Travel Policy"). This policy should allow for reimbursement of only reasonable and actual expenses that have been thoroughly documented and invoiced to the Company after expenses have been incurred. CHS policy *Business Travel and Expense Reimbursement* will serve as the guide for acceptable reimbursement of expenditures in the event a Company does not provide a policy.

    - Travel premiums or other flat fee travel payments are not permissible.

5. **Individual Statements of Work** – From time to time, companies employ the use of individual Statements of Work to outline specific details of individual events. All details in the Statements of Work should be consistent with the Master Agreements to which they refer. Individual Statements of Work should be submitted to the Corporate Compliance Department for review and inclusion in applicable files as soon as they are made available to the Covered Individual. Individual Statements of Work do not require Responsible Administrator review prior to submission to the Corporate Compliance Department.

6. **Invitations to participate in written, electronic, and telephonic surveys and interviews –** Covered Individuals are not prohibited from participating in and receiving compensation for participation in written, electronic, and telephonic surveys and interviews provided the following criteria are met:

    - The services are not provided using CHS resources or from a CHS facility;
    - The compensation is reasonable given the time spent providing feedback to the surveying organization;
    - The Covered Individual's Responsible Administrator has reviewed and approved the Covered Individual's participation;
    - The topic of the engagement is relevant to the Covered Individual's expertise and knowledge base;
    - The Covered Individual does not have a decision-making role in the contracting or purchase of the sponsor's products or services;

    It is not required to submit these types of services to the Corporate Compliance Department for review prior to participating in survey engagements; however, Responsible Administrator approval is required. Review by the Corporate Compliance Department should be requested as needed when questions arise.