CAROLINAS HEALTHCARE SYSTEM
OFFICE OF CLINICAL AND TRANSLATIONAL RESEARCH
STANDARD OPERATING PROCEDURE

Procedure No.:	A-106	Title: Disclosure and Management of Significant Financial Interest in CHS Research Projects
Date of Issue:	09/12, 6/17	Page: 1 of 9
Description:	Procedures for FCOI	Version: 001

SUBJECT: Procedure for disclosures and management of significant financial interest in CHS research projects conducted within Carolinas HealthCare System to determine adherence with all applicable regulations, related guidelines, and with the policies and procedures of this institution.

POLICY: The Disclosure and Management of Significant Financial Interest in CHS research projects SOP 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

APPLICABLE REGULATIONS, GUIDELINES, POLICIES AND STANDARD OPERATING PROCEDURES (SOPs):
CHS SOP IRB 07 Documentation of Financial Interests of the Investigator
IRB Policy and Procedure Manual
Investigators Guide to the IRB
COR 40.12 Handling reports of Compliance Violations
COR 40.14 Enforcement and Discipline
COR 40.17 Conflict of Interest (ADM 240.04 merged into this policy)
CHS Research COI Committee Bylaws
NIH Public Health Service:
http://grants.nih.gov/grants/policy/coi/index.htm
National Science Foundation:
http://nsf.gov/policies/conflicts.jsp
Food and Drug Administration:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=54&showFR=1

DEFINITIONS:

For purposes of this policy, the following definitions shall apply:

1. Bias means Prejudice in favor of or against one thing, person, or group compared with another, usually in a way considered to be unfair
2. Covered Individual means any Carolinas HealthCare System teammate, student or trainee who is performing teaching, research, public service, administration and/or business operations for Carolinas HealthCare System. This includes sub-recipient investigators of PHS-funded research and their family

3. COI means Conflict of Interest
4. Disclosure means an Investigator's disclosure of financial interests to the Institution related to his or her institutional responsibilities.
5. Entity means an organization other than the Institution, whether public or private. Examples include the following: a company, partnership, professional associations, voluntary health organizations, etc.
6. Human Subject means a living individual about whom an Investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.
7. IACUC means CHS Institutional Animal Care and Use Committee
8. Institution means Carolinas HealthCare System.
9. Institutional Responsibilities means an Investigator's professional responsibilities on behalf of the Institute, including, but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels
10. Investigator means the project director or principle 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.
11. IRB means the CHS Institutional Review Board or designee
12. Mitigation- means to moderate (a quality or condition) in force or intensity; alleviate
13. OGC means the CHS Office of General Counsel
14. Participate(ing) in a CHS Research 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, where 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 principle investigator, co-investigator, or sub-investigator
    - Enrolling research subjects (including obtaining human subject's 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
15. PHS means the Public Health Service of the U.S. Department of Health and Human Service (HHS) and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH)
16. 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 options or other ownership interest

17. Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
18. Research COI Committee means the committee responsible for review and assessment of real or potential Conflicts of Interest related to CHS projects.
19. Responsible Administrator means the administrator or business unit leader who is responsible for a particular Covered Individual
20. Senior/key personnel means the project director/principle 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
21. Spouse means the husband or wife of a Covered Individual
22. Significant Financial Interest (SFI) for the purpose of this policy significant financial interest means anything of monetary value or potential monetary value held by an Investigator (and by the Investigator's spouse and dependent children), and that reasonably appears to be related to the Investigator's institutional responsibilities, as follows:
    - Outside payments such as consulting fees, honoraria, and travel reimbursements from companies and organizations outside the investigator's current institution if the value within the past 12 months as of the date of disclosure exceeds $5,000.
    - Equity such as stock or stock options in companies and organizations, excluding the investigator's current institution.
    - Royalties related to intellectual property rights paid by any source other than the investigator's current institution.
    - Any reimbursed or sponsored travel (e.g. air and taxi fare, car rentals, etc.) paid by an entity, including non-profit organizations, but not including travel sponsored by or reimbursed by:
        - a government agency,
        - a U.S. institution of higher education or
        - a research institute affiliated with such,
        - a medical center, or an academic teaching hospital.

    The following are not required to be disclosed:
    - Salary, royalties, or other remuneration paid to the investigator from the institution that currently employs the investigator.
    - Income from investments in mutual funds or retirement accounts, as long as the Investigator does not make the investment decisions.
    - Payment for services (honoraria, advisory committees, review panels, etc.) or travel expenses paid by a U.S. federal, state, or local government agency, a U.S. institution of higher education or a research institute affiliated with such, a U.S. medical center or academic teaching hospital.

PROCEDURE:

A. Training

1. All Covered Individuals participating in a CHS Research 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 Research Project and at least every four years thereafter.
2. Prior to engaging in any research project, all Covered Individuals must complete the following CITI Training Modules under this SOP in addition to, any other mandatory Citi Training.
    - Module 1: Financial Conflicts of Interest: Overview, Investigator Responsible, and COI Rules
    - Module 2: Institutional Responsibilities as They Affect Investigators
    - Module 3: CHS FCOI Policy
3. CITI Training must be repeated every three years and must be completed immediately if this SOP:
    - Is revised to affect the Covered Individual's obligations
    - If a Covered Individual is new to the Institution
    - Or if the Institution finds a Covered Individual to have violated this policy or any applicable management plan.

B. Disclosure and Administrative Review

1. Investigator completes online Conflict of Interest Disclosure via COI-Smart
2. The Corporate Compliance department reviews submitted Conflict of Interest on COI-Smart.
    - If an Investigator reports an SFI or an issue of concern is detected, as defined in COR 40.17:
        a. Corporate Compliance will flag the Conflict of Interest Disclosure and notify the VP of Research or his/her designee.
        b. The VP of Research or his/her designee will notify grants and contracts to hold the release of funding.
3. The VP of Research or his/her designee will review the Conflict of Interest Disclosure on COI-Smart and determine:
    - Whether the SFI is related to PHS funded research
    - Whether the SFI was disclosed timely and whether there is a potential conflict of interest.
        a. If there is a potential conflict of interest or untimely disclosure, the VP of Research or his/her designee will provide a summary report for deliberation by the Research COI Committee at a convened meeting.

4. The Research COI Committee will determine whether a COI exists.
    - If the Committee determines that an SFI is not a COI, no management plan is required.
        a. The COI Chair will send notification of determination to the Corporate Compliance Department and authorize Grants and Contracts to release funding.
    - If the Committee determines that the SFI is a COI;
        a. The Committee will develop a plan to eliminate the COI or develop and implement a plan to manage the COI
        b. The plan will be filed with the Corporate Compliance Department.

C. Monitoring of COI Management Plans

1. Ongoing monitoring
    - The VP of Research or his/her designee will monitor Investigator's compliance with management plans until completion of project.
2. Noncompliance
    - If a COI is not identified or managed within a timely manner or a failure to disclose an SFI is discovered, the COI Committee will complete a retrospective review within 60 days.

D. Reporting to NIH

1. When a COI exists for a PHS funded project, the institution will provide initial, annual, revised, and retrospective review reports to the PHS Awarding Component within 60 days of identifying the COI.

E. Maintenance of Records

1. The Corporate Compliance department is responsible for soliciting and reviewing all Conflict of Interest Disclosures. COI Disclosures are maintained in COI-Smart by the institution for at least three years from the date the final expenditure report is submitted for a research project and/or at least three years from the date the final report is submitted for a research project.

F. Enforcement

1. Any SFI that were not disclosed by an investigator in a timely manner or, for whatever reason, was not previously reviewed by the Institution during an ongoing research project (e.g., was not timely reviewed or reported by a sub-recipient), the VP of research or his/her designee will, within 60 days, determine if the disclosed conflict of interest is a SFI and, if so:
    - Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward;
    - Perform a retrospective review of the investigator's activities and research project to determine if during the time period of the

noncompliance, any bias exists in the design, conduct, or reporting of such research.

2. Within 120 days of the Institution's determination of noncompliance, the retrospective review process will be performed and documented. Such documentation shall include, but not necessarily be limited to, all of the following key elements:

    - Project number;
    - Project title;
    - PD/PI or contact PD/PI if a multiple PD/PI model is used;
    - Name of the Investigator with the COI;
    - Name of the entity with which the Investigator has a financial conflict of interest;
    - Reason(s) for the retrospective review;
    - Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
    - Findings of the review;
    - Conclusions of the review.

3. Based on the results of the retrospective review, if appropriate, the previously submitted COI report will be updated to the appropriate funding agency, specifying the actions that will be taken to manage the financial conflict of interest going forward.

4. For PHS-funded projects, if bias is found, the Institution is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.

    - The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable).
    - COI-Smart disclosures must be submitted annually
    - Depending on the nature of the financial conflict of interest, additional interim measures may be necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of the Institution's retrospective review.

5. Whenever a management plan is implemented, compliance with the management plan will be monitored on an ongoing basis until the completion of the research project.

G. **Remedies and Noncompliance**

1. If failure to comply with CHS policy COR 40.17 Conflicts of Interest or a conflict of interest management plan appears to have biased the design, conduct, or reporting of the research project, corrective action will be taken. Corrective actions may include:
    - Formal reprimand
    - Suspension and/or termination of research privileges
    - Other enforcement mandated by CHS administration as described in CHS policy COR 40.12 Handling reports of Compliance Violations and COR 40.14 Enforcement and Discipline
    - Other enforcement action as mandated by the applicable government granting agency.
2. With respect to PHS-funded research projects, the Institution will promptly notify the PHS Awarding Component of the corrective action taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the PHS-funded research project. PHS may, for example, require Institutions employing such an Investigator to enforce any applicable corrective actions prior to a PHS award or when the transfer of a PHS grant(s) involves such an Investigator.
3. The Institution is required to submit, or to permit on site review of, all records (including any retrospective review) relating to compliance of any Investigator disclosure of SFI by the applicable granting institution, HHS or the PHS Awarding Component at any time before, during, or after award.
    - On the basis of its review of records or other information that may be available, the PHS Awarding Component may decide that a particular financial conflict of interest will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that the Institution has not managed the financial conflict of interest in accordance with this subpart.
    - In any case in which it is determined that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution as required by this subpart, the Institution shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

H. Sub-recipient Requirements:

1. If CHS carries out research through a sub-recipient, CHS will incorporate as part of a written agreement with the sub-recipient terms that establish

whether CHS's or the sub-recipient's policy on conflict of interest in research will apply to the sub-recipient Investigators.

2. If the sub-recipient's policy will apply, the sub-recipient will certify as part of the agreement that its policy complies with the PHS regulations on Objectivity in Research. In addition, the agreement shall specify time period(s) for the sub-recipient to report all identified financial conflicts of interest to the Institution to enable the Institution to provide timely reports to PHS.
3. Alternatively, if CHS policy COR 40.17 Conflicts of Interest will apply, the agreement shall specify time period(s) for the sub-recipient to submit all sub-recipient Investigator disclosures of significant financial interests to the Institution. Such time periods shall be sufficient to enable CHS to comply with timely review, management, and reporting obligations under the PHS regulations.

I. Public Accessibility

1. The COI Policy is accessible on the Carolinas HealthCare System website. If the COI Policy is unavailable due to website maintenance, then the policy will be made available within five (5) business days of a request.
2. The Institution will make available to the public upon request, information concerning any significant financial interest disclosed to the Institution that meets the following three criteria:
    - The disclosed significant financial interest is still held by the senior/key personnel of the active PHS project;
    - The Institution determines that the significant financial interest is related to the PHS funded research; and
    - The Institution determines that the significant financial interest is a financial conflict of interest.
    - The information request must be made to the Corporate Compliance department who will respond within five (5) business days of receipt of the request. Disclosed information will be provided to the extent required by applicable PHS regulations and state law.

APPROVALS

Director, Research	Christine Becker, PhD, MBA/HCM, RN
Vice President, Research	George McLendon, PhD

Appendix A

Carolinas HealthCare System

CONFLICT OF INTEREST MANAGEMENT PLAN

Name:	
E-Mail Address:	
Responsible Administrator:	
Risk Area:	
Name of Company:	
Description:	

Item #	Proposed Conflict Resolution Action	Proposed Implementation Date	Initial

Responsible Administrator

Signature

Printed Name

Date

Teammate

Signature

Printed Name

Date

One Carolinas HealthCare System