CAROLINAS HEALTHCARE SYSTEM

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RESEARCH-RELATED CONFLICTS OF INTEREST

SUMMARY STATEMENT

Research-related conflicts of interest ("COI") occur when an institution or an individual, including his or her Family, enter into any type of relationship that interferes with or compromises, or gives the appearance of compromising, the professional judgment or Research obligations of the institution or individual. A Research-related COI also may arise if there is a Conflict of Commitment regarding outside activities that interfere with the primary Research obligation of the individual to his or her employer or Sponsor. Any research-related COI or potential COI must be fully disclosed, evaluated and, if necessary, managed, reduced or eliminated. The purpose of this policy is to describe the research conflicts of interest that may occur within Carolinas HealthCare System (CHS) and to set forth procedures for disclosure and management of these conflicts with adherence to applicable regulations, related guidelines and the policies and procedures of CHS.

APPLICABILITY

The Research-Related Conflicts of Interest Policy applies to all Carolinas HealthCare System teammates, students or trainees, in their performance of the administration, Research, teaching, patient care and other business operations of Carolinas HealthCare System and to non-teammates who are appointed by Carolinas HealthCare System to represent its interest on various committees or in other decision-making capacities**.** Covered Individuals and Investigators may be subject to different requirements, as set forth below.

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

DEFINITIONS

A) "Applicant" means the party who submits a marketing application to FDA for approval of a drug, device, or biologic product or who submits a reclassification petition.

B) "Awarding Component" means the organizational unit of either the Public Health Service or other sponsor that sponsors/funds a particular Research grant. The Awarding Component typically makes case-by-case determinations on steps to be taken to ensure that the design, conduct, and reporting of the Research will not be biased by any conflicting Financial Interest of a Covered Individual.

C) "CHS Research Project" means any Research, testing, evaluation, training, and/or instruction project conducted under the auspices of Carolinas HealthCare System.

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."

D) "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 Research Project, taking into account the following factors:

(1) the nature of the CHS Research Project,
(2) the magnitude of the Financial Interest and the degree to which it is related to the CHS Research Project,
(3) the extent to which the Financial Interest could be directly and substantially affected by the CHS Research Project,
(4) if the CHS Research 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.

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

F) "Conflict of Interest" (COI) means a situation in which a Covered Individual, including his or her Family, or Carolinas HealthCare System 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 Carolinas HealthCare System. The term Conflict of Interest includes Conflicts of Commitment.

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

H) "Covered Clinical Study" means any study of a drug or device in humans submitted in a marketing application or reclassification petition subject to this part that the Applicant or Food and Drug Administration (FDA) relies on to establish that the product is effective or any study in which a single Investigator makes a significant contribution to the demonstration of safety.

I) "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 Investigator of PHS-funded Research and his/her Family.

J) "Disclosure" means an Investigator's disclosure of Financial Interests to the Institution related to his or her institutional responsibilities.

K) "Disclosable Financial Interest" (DFI) means financial interest consisting of one or more of the following interests:

(1) Any compensation made to the Investigator by any sponsor of the Covered Clinical Study in which the value or compensation could be affected by study outcome.
(2) A proprietary interest in the tested product including, but not limited to, a patent, trademark, copyright or licensing agreement.

(3) Any equity in any sponsor of the Covered Clinical Study, i.e., any ownership interest, stock options, or other financial interest whose value cannot be readily determined through reference to public prices.
(4) Any equity interest in any sponsor of the covered study if the sponsor is a publicly held company and the interest exceeds $50,000 in value.
(5) Significant payments of other sorts (SPOOS) are payments that have a cumulative monetary value of $25,000 or more and are made by any sponsor of a clinical study to the Investigator or the Investigator's Institution during the time the Investigator is carrying out the study and for one year following completion of the study. This would include payments that support activities of the Investigator (e.g., a grant to the Investigator or to the Institution to fund the Investigator's ongoing Research or compensation in the form of equipment), exclusive of the costs of conducting the clinical study or other clinical studies, or to provide other reimbursements such as retainers for ongoing consultation or honoraria.

The requirement applies to the above interests held during the time the Investigator is carrying out the study and for one year following the completion of the study.

L) "Entity" means an organization other than the Institution, whether public or private. Examples include the following: companies, partnerships, professional associations, voluntary health organization, etc.

M) "Family" means any of the following in relation to a Covered Individual:

(1) Spouse, as defined below.
(2) Natural or adoptive parent, child or sibling.
(3) Stepparent, stepchild, stepbrother, or stepsister.
(4) Father-, mother-, daughter-, son-, brother, or sister-in-law.
(5) Grandparent or grandchild.
(6) Spouse of a grandparent or grandchild.

N) "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 Carolinas HealthCare System for the benefit of the Research or other professional activities of a specific Covered Individual.

Financial Interest does <u>not</u> include salary or other remuneration from Carolinas HealthCare System.

O) "Financial Conflict of Interest (FCOI)" means a Significant Financial Interest or Disclosable Financial Interest that could directly and significantly affect the design, conduct, or reporting of Research, regardless of funding source.

P) "Financially Interested Company" means an Entity with financial interests that would reasonably appear to be affected by the conduct or outcome of a CHS Research Project. This term includes the manufacturer (including business partners) of the drug or the device or other Sponsor of a CHS Research Project as well as 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 has actual knowledge that the financial interests of such a company would reasonably appear to be affected by the CHS Research Project.)

Q) "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.

R) "IACUC" means the Carolinas HealthCare System Institutional Animal Care and Use Committee.

S) "Institution" means the Carolinas HealthCare System.

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

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

(2) Any Equity in a *Non-Publicly* Traded Sponsor – When, through Carolinas HealthCare System's technology licensing activities or investments related to such activities, Carolinas HealthCare System 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 Research Project.

(3) Equity Exceeding $100,000 in a *Publicly*-traded Sponsor – When, through Carolinas HealthCare System's technology licensing activities or investments related to such activities, Carolinas HealthCare System 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 Research 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 Carolinas HealthCare System but not otherwise affiliated with Carolinas HealthCare System are <u>not</u> 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 Research Project or a product being investigated for clinical use at or by Carolinas HealthCare System, 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.

U) "Institutional Responsibilities" means an Investigator's professional responsibilities on behalf of the Institution, including, but not limited to, activities such as Research, Research consultation, teaching, professional practice, patient care, institutional committee memberships, and service on panels.

V) "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 Research Project. All Investigators are Covered Individuals.

W) "IACUC" is the Carolinas HealthCare System Institutional Animal Care and Use Committee.

X) "IRB" is the Carolinas HealthCare System Institutional Review Board, inclusive of a designated external IRB contracted by CHS to perform those services.

Y) "OGC" is the Carolinas HealthCare System Office of General Counsel.

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

(1) Designing or directing a CHS Research Project;
(2) Serving as the principal investigator, co-investigator, or sub-investigator;
(3) Enrolling Research subjects (including obtaining Human Subjects' informed consent, if applicable);
(4) Making decisions related to eligibility to Research subjects' enrollment in a CHS Research Project;
(5) Analyzing or reporting CHS Research Project data, and/or
(6) Submitting manuscripts concerning the CHS Research Project for publication as a primary author or co-author.

AA) "PHS" is the Public Health Service, which is an agency 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).

BB) "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.

CC) "Research" means a systematic investigation, including Research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

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

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

FF) "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.

GG) "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 Institution, including:

(1) 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.

(2) Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.

(3) 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.

HH) "Sponsor" of a Covered Clinical Study means a party financially supporting a study.

II) "Spouse" includes a person to whom a Covered Individual is married or with whom the Covered Individual lives together in the same residence, shares responsibility for each other's welfare and shares financial obligations.

POLICIES AND PROCEDURES

I. Research-related Conflicts of Interest

A. <u>Policy</u>

Without the prior approval of the Assistant Vice President ("AVP") Research Compliance, in consultation with the Vice President ("VP") Research and VP Corporate Compliance, a Covered Individual may not participate in any CHS Research Project if the Covered Individual or his or her Family has a Significant Financial Interest ("SFI") or Disclosable Financial Interest ("DFI") related to the Covered Individual's Institutional responsibilities.

Assessment

The AVP Research Compliance, or his or her designee, as set forth by the Chief Compliance Officer, is the designated institutional official responsible for soliciting and reviewing Disclosures of SFIs and DFIs of Covered Individuals participating in any CHS Research Project. In consultation with the VP Research and VP Corporate Compliance, the AVP Research Compliance also must approve any CHS Research Project in which CHS has an Institutional Financial Interest in the sponsor of the CHS Research Project or any other Financially Interested Company. The AVP Research Compliance may appoint a designee for the VP Research and/or VP Corporate Compliance, if circumstances warrant such action.

Compelling Circumstances

The AVP Research Compliance, in consultation with the VP Research and VP Corporate Compliance, is responsible for determining whether Compelling Circumstances exist. If Compelling Circumstances are found to exist, the CHS Research Project may be conducted and/or the Covered Individual may participate in the CHS Research Project. If such determination is made, a management plan documenting the Compelling Circumstances, approval by the Research COI Committee and, where applicable, ratification by the IACUC or IRB.

B. Procedure

1. *Disclosure*

   All Covered Individuals must complete a Conflict of Interest Disclosure Form on an annual basis, which is reviewed and maintained by the Corporate Compliance Department. The Conflict of Interest Disclosure Form and information contained within shall be considered confidential and treated as such by the Corporate Compliance Department and only disclosed to those individuals with a need to know. Investigators are subject to additional disclosure requirements as set forth below.

   a. Investigators must disclose SFIs and DFIs at the time of application for any CHS Research Project by updating the Conflict of Interest Disclosure Form. Any additional updates must be submitted within 30 days of discovering or acquiring a new SFI or DFI including, but not limited to, the consideration of a new CHS Research 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 1 thru 6 must be resolved as an Investigator also must disclose members of his or her Family, if the Investigator is aware 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;

2. The occurrence of any reimbursed or sponsored travel (i.e. paid on behalf of the Investigator and not reimbursed to Investigator).

Review

The Carolinas HealthCare System AVP Research Compliance, or his/her designee, will review each Conflict of Interest Disclosure Form that contains a potential SFI or DFI in consultation with other Carolinas HealthCare System officials, as appropriate. As a result the AVP Research Compliance, in consultation with the VP Research and VP Corporate Compliance, as necessary, may:

a. Take no action, if the Disclosure is not an SFI or DFI;
b. Determine a management plan acknowledging the presence of a FCOI exists and CHS is aware of such FCOI, or
c. Refer the Disclosure to the Research COI Committee for further evaluation.

3. *Research COI Committee*

a. The composition and responsibilities of the Research COI Committee are set forth in the by-laws in Appendix I.
b. When the AVP Research Compliance, in consultation with the VP Research and VP Corporate Compliance as warranted, determine additional review of an FCOI is necessary, the Research COI Committee shall convene to review the FCOI and determine what, if any, steps shall be taken to mitigate the conflict.
c. In addition, 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.

4. Reporting Requirements for PHS-funded Research

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

Additionally, the Form FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators Statement must be completed for each Investigator who, or whose Family, has or had DFI and/or arrangements with any Sponsor of a Covered Clinical Study.

5. Management, Reduction and Elimination of Conflicts of Interest in Research

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

If, upon review of Disclosures of SFIs and DFIs, it is determined by the AVP Research Compliance that a management plan is necessary to manage a Financial Conflict of Interest (FCOI), such management plan will be implemented which specifically details the actions that have been, and will be, taken to manage such FCOI. In some instances, the management plan may simply acknowledge and document the FCOI and require no further action.

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 Research 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 Research Project;
g. Severance of relationships that create actual or potential Conflicts of Interest.

Management plans shall be drafted by Corporate Compliance and sent to the Investigator and his/her Responsible Administrator or other supervisor for signature.

The Institution shall complete a retrospective review of any Investigator's activities and his or her CHS Research Project if it is determined that a FCOI 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 management plan, and the design, conduct, or reporting of a CHS Research Project appears to have been biased, the Institution will immediately notify and submit a mitigation report to the Awarding Component detailing the corrective actions taken or planned to be taken by the institution.

The Institution is required to permit an onsite review of all records relating to compliance of any Investigator Disclosure of SFI or DFI by the applicable granting institution, HHS or the Awarding Component at any time before, during or after award.

6. Retention

All FCOI records, including Conflict of Interest 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.

7. Subrecipient Requirements

If a CHS Research 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 Carolinas HealthCare System and the subrecipient site.

8. Education Requirements

All Covered Individuals participating in a CHS Research Project will be informed of this policy and their responsibilities regarding Disclosure of SFIs and DFIs. 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 thereafter by regulatory, CHS and/or other requirements.

Prior to engaging in any CHS Research Project, all Investigators and Research Staff must complete CITI Training Modules, as required by CHS.

CITI Training must be repeated periodically as required by CHS and immediately under the following circumstances:

- Policy revisions as to affect the Investigator's current obligations,
- Or, if the Investigator has been found in violation of this policy or an applicable management plan set forth by the Institution.

9. Public Accessibility

This Research-Related COI Policy is accessible on the external Carolinas HealthCare System website. If this policy is unavailable due to website maintenance, then the policy will be made available within five (5) business days of a request.
The Institution will make available to the public upon request, information concerning any SFI or DFI disclosed to the Institution that meets the following three criteria:

- The SFI or DFI is held by the senior/key personnel of the active PHS projects;
- The Institution determines that the SFI or DFI is related to PHS funded Research; and
- The Institution determines that the SFI or DFI is a FCOI.

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.

II. Compliance

All Covered Individuals are expected to comply fully and promptly with all requirements of this policy. 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 Carolinas HealthCare System administration. The VP Research, AVP Research Compliance and VP Corporate Compliance, in coordination with the Chief Compliance Officer are responsible for investigating instances of noncompliance and determining whether to impose sanctions and what sanctions will be applied. In making these determinations, they may consult with the Responsible Administrator, the Research COI Committee, OGC, human resources and/or other appropriate individuals. A Covered Individual who is the subject of a disciplinary action may appeal such action in accordance with established Carolinas HealthCare System grievance and/or disciplinary procedures.

APPROVALS

Policy Coordinator	Genevieve deLemos, AVP Research Compliance
Policy Approver	Sara Mikus, Senior Vice President & Chief Compliance Officer

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

The Research COI Committee will include the following members or their designees: Vice President Research (Chair), Chief Compliance Officer, Chair of IRB, a member of OGC, Assistant Vice President Research Compliance, 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 and Disclosable Financial Interest in Research;
- Recommend policies and procedures to address research-related Conflicts of Interest within Carolinas HealthCare System;
- Review Conflict of Interest Disclosures Forms to determine if Investigators have Conflicts of Interest, Significant Financial Interests or Disclosable Financial Interests that might compromise, or appear to compromise, the protection of Human Subjects, the integrity of CHS Research Projects, or otherwise inhibits objectivity in the conduct of a CHS Research Project;
- Recommend if and how conflicts, SFIs or DFIs 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 Carolinas HealthCare System Corporate Compliance Office for at least three (3) years after the termination or completion of the CHS Research Project to which those records relate or until resolution of any government activity related to those records.