

Chapter 23

DISCLOSURE OF FINANCIAL INTERESTS RELATED TO SPONSORED RESEARCH

A. Intent

This policy requires the disclosure of financial interests related to sponsored research and sets forth a mechanism for investigating and managing any conflicts of interest that may arise from such financial interests. The CAMC Health Education and Research Institute, Inc. (Institute) serves as the sponsored projects applicant and recipient institution on behalf of those conducting research at the CAMC Health System and will provide administrative oversight for this policy. The intent of this policy is to ensure the highest level of integrity in the conduct of scientific research conducted at the CAMC Health System.

B. Policy

It is the policy of the Institute to make every effort to ensure there are no biases in the design, conduct, or reporting of research receiving funding from federal, state, local, industry or other sponsors that may be related to conflicting financial interests or relationships of an Investigator with a sponsor.

C. Definition of Research

For the purpose of this policy, “research” means a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences research. The term encompasses basic and applied research and product development.

D. Definition of Conflict of Interest

For the purpose of this policy, a conflict of interest will exist when it is reasonably determined that an Investigator’s financial interest or relationship with the research sponsor could directly and significantly affect the design, conduct or reporting of the funded research.

E. Applicability

This policy is applicable to all Investigators conducting sponsored research at any CAMC Health System facilities and to all sponsored research conducted under the auspices of the CAMC/WVU Institutional Review Board (IRB). For the purposes of this policy, “Investigator” means any person who is responsible for the design, conduct, or reporting of research funded or to be funded by a federal, state, local, industry or other sponsor (“sponsored research”) and shall also include the Investigator’s spouse and dependent children. For purposes of this policy, the “CAMC Health System” shall mean CAMC, Inc., Charleston Area Medical Center, Inc., Strategic Health Services, Inc., Charleston Area Medical Center Foundation, Inc., Charleston Area Health Plan, Inc. (Carelink), Integrated Health Care Providers, Inc., Braxton County Memorial Hospital, Inc., Oak Hill Hospital, Inc., WomenCare, Inc., and Health Plus Professionals, Inc., and any other entity which controls, is controlled by, or is under common control with CAMC, Inc.

F. Disclosure Process

1. Completion of Disclosure of Financial Interest Statement

Each Investigator conducting research at any CAMC Health System facility or under the auspices of the CAMC/WVU Institutional Review Board must complete and submit a “Disclosure of Financial Interest Statement” (“Disclosure Statement”) which shall be included as part of the research approval form set provided by the Office of Research and Grants Administration. All information provided by an Investigator in connection with the Disclosure Statement shall be confidential, and shall not be disclosed to anyone other than Institute employees and agents who have a need to know the information except as necessary to implement this policy or as otherwise required by law.

2. Information Requiring Disclosure

A. Financial Interest Disclosure:

The Investigator shall set forth on the Disclosure Statement anything of monetary value received by the Investigator, his or her spouse or dependent children from a granting agency or sponsor, including but not limited to salary or other payments for services (e.g. consulting fees or honoraria); equity interests in the granting agency or sponsor (e.g. stock, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties) from the granting agency or sponsor, including but not limited to:

- (1). Any income paid or to be paid to the Investigator, or his or her spouse or dependent children including salary, consulting payments, honoraria, royalty payments, or any other thing of value received from the granting agency or sponsor during the previous twelve months or projected to be received during the succeeding twelve months; or
- (2). Equity in the form of stock, stock options, real estate, or any other investment or ownership interest exceeding either \$10,000 (current market value if publicly traded; otherwise, amount of investment), or a 5% ownership interest in the sponsor when aggregated for an Investigator, his or her spouse and dependent children.

B. Disclosure of Other Financial Influences that may Impart Bias in Research:

In addition to the above requirements, an Investigator shall disclose any financial or other interest that could present an actual conflict of interest or be perceived to present a conflict of interest. Situations that may impart bias in research and potential conflict of interests include but are not limited to:

- (1). Accepting gratuities or special favors from granting agencies or research sponsors.
- (2). Undertaking research when the Investigator, his/her spouse or any dependent child is on the governing body of a granting agency or sponsoring organization or has a business, financial, managerial, or other relationship with the granting agency or sponsor or in the company producing a drug or device being evaluated by the sponsor.

- (3). An Investigator's influence or attempt to influence the purchase of resources for the CAMC Health System (such as equipment, supplies, and facilities) in support of a sponsor with which the Investigator may have a financial interest or other relationship.
- (4). The Investigator's influence or attempt to influence negotiations of contracts between the CAMC Health System and the granting agency or sponsor with which an Investigator has a financial interest or other relationship.

C. Interests Not Requiring Disclosure Include:

- (1). Salary, fees or other remuneration from the sponsor for sponsored research when such salaries, fees or other remuneration will be in the form of reimbursement paid to the Institute rather than to the investigator(s);
- (2). Salary, fees or other remuneration from the CAMC Health System;
- (3). Any ownership interests in the CAMC Health System;
- (4). Income from seminars, lectures or teaching engagements sponsored by public or nonprofit entities other than the sponsor;
- (5). Income from service or advisory committees or review panels for public or nonprofit entities other than the sponsor;
- (6). An interest in a pooled fund such as diversified mutual fund. (Such an interest has been determined to be sufficiently remote and will not be expected to create a conflict of interest for the Investigator and therefore such interests are exempt from disclosure by the Investigator on that basis unless there is significant evidence otherwise);and
- (7). Service on boards and committees of public or private organizations other than the sponsor.

3. *Levels of Review by the Institute*

Based upon an objective and confidential evaluation of the Disclosure Statement and the nature of the proposed research, the Institute may require that certain action be taken by the Investigator or certain modifications be made to the research to minimize the possibility that any financial interest in or relationship with the sponsor may directly affect the design, conduct or reporting of research. The Investigator shall be notified in writing if the Institute's review results in a determination that such action or modification shall be required with respect to the research.

A. Director of Review (Financial Interests Involving < \$50,000)

The Director of Research and Grants Administration ("Director") is responsible by signature for assuring the Institute that a Disclosure Statement is received from all Investigators at the time that the forms packet related to the research proposal is submitted to the RESEARCH AND GRANTS ADMINISTRATION....

If the Director's review of a Disclosure Statement results in a determination that the Investigator has no financial interest or relationship with the sponsor, or that the financial interest or relationship is not likely to directly affect the design, conduct or reporting of the research, this determination will be recorded and the original Disclosure Statement filed in the RESEARCH AND GRANTS ADMINISTRATION. Office.

If the Director's review of a Disclosure Statement results in a determination that there may be an actual or potential conflict of interest, this determination will be recorded by

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the Director and the original Disclosure Statement and any related information will be forwarded to the Institute's Conflict of Interest Review Committee (COIC).

B. COIC Review

Any financial interest of \$50,000 or more, or any potential conflict of interest as determined by the Director, will be forwarded directly to the COIC whose composition and authority is the following:

Composition:

The members of the COIC will be appointed by the Institutional Research Officer and shall include (but not be limited to) a member of the Institute's Board of Directors, one attorney (member of CAMC in-house legal staff), the Director of Research and Grants Administration, a representative of the CAMC/WVU Institutional Review Board (IRB); a representative of the CAMC Ethics Committee, and the appropriate medical department chief/chair or administrator of the department to which the investigator belongs.

Authority:

The Conflict of Interest Review Committee will:

Review all Disclosure Statements that reveal financial interests of \$50,000 or more;

Review Disclosure Statements and recommendations of the Director in the event the Director determines there is a potential conflict of interest;

Seek such additional information as may be necessary to determine whether a conflict of interest exists or require that the Investigator take such action it deems necessary to eliminate or manage an Investigator's conflict of interest; and

Take appropriate disciplinary action against an Investigator who has failed to take such action as may be required by the COIC to eliminate or manage a conflict of interest.

Confidentiality:

The COIC will exercise every precaution to assure the objectivity and confidentiality of its proceedings.

Procedures to Eliminate or Manage a Conflict of Interest:

In the event the COIC determines there is a potential conflict of interest, the COIC will determine whether further action by the Institute or the Investigator may be necessary or desirable to manage or eliminate the conflict of interest. Such actions may include, but shall not be limited to:

- Disclosure of the Investigator's financial interest(s) in each public presentation of the results of the research;
- Appointment of independent reviewers to monitor the research;
- Modification of the research plan;
- Disqualification of the Investigator from participating in all or a portion of the research;
- Divestiture of the financial interests; or

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- Severance of relationships that create actual or potential conflicts or interest.

Grant or award funds will not be expended by the Institute until any conflicts of interest have been managed or eliminated in the manner set forth in this policy.

G. Appeal

If the Investigator is dissatisfied with the decision of the COIC, the Investigator may appeal to the Institutional Research Officer who will consult with the COIC, the Investigator, the sponsor or other individuals as may be necessary or appropriate to the particular circumstance. The decision made by the Institutional Research Officer will be final.

H. Reporting Requirements

As required by law, the Institute shall, within 60 days of any grant award notice, report to the PHS the existence of *ANY* conflict of interest of the Investigator (but not the nature of the interest or other details) and assure the PHS that the conflict has been managed or eliminated in accordance with PHS regulation.

I. Failure to Disclose

If the Investigator fails to comply with this Financial Disclosure Policy and it is later determined by the Institute, the PHS, or other federal regulatory authority that any funded research has been designed, conducted, or reported by an Investigator with a conflict of interest that was not disclosed or managed as required by this Policy, the Investigator's conflict must be disclosed to the PHS and must also be disclosed in each public presentation of the results of the research. The PHS will consider the situation and may take such further action, or direct the Institute to take such further action against the Investigator as it deems appropriate.

J. Retention of Records

Disclosure Statements, Director determinations, COIC actions, and results of any appeals shall be retained for three years beyond the termination or completion of a sponsored research project, or until resolution of any action by the sponsor involving the records, whichever is longer.