

SUFFOLK COUNTY COMMUNITY COLLEGE

RESEARCH CONFLICT OF INTEREST POLICY

INTRODUCTION

This policy governs disclosure and management of financial conflicts of interest with respect to research sponsored by the U.S. Department of Health and Human Services, Public Health Service (PHS) and other agencies and conducted at Suffolk County Community College (“College”). The Institutional Official, as defined below, is responsible for ensuring implementation of this policy and may suspend all relevant activities until the financial conflict of interest is resolved or other action deemed appropriate is implemented. Violation of any part of this policy may also constitute cause for disciplinary or other administrative action pursuant to College policy and any applicable collective bargaining agreement.

DEFINITIONS

Family means the Investigator’s spouse, domestic or civil union partner, and all dependent children.

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

Financial Interest does NOT include:

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

For Investigators, *Financial Interest* also includes any reimbursed or sponsored travel undertaken by the Investigator and related to his/her institutional responsibilities. This includes travel that is paid on behalf of the Investigator, as well as travel that is reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

Significant Financial Interest means a Financial Interest that reasonably appears to be related to the Investigator’s Institutional Responsibilities, and:

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

- value of any equity interest during the 12-month period preceding or as of the date of disclosure, exceeds \$5,000; or
- b) if with a non-publicly-traded company, is an equity interest of any value during the 12-month period preceding or as of the date of disclosure; or
 - c) is income exceeding \$5,000 related to intellectual property rights and interests not reimbursed through the Institution, or
 - d) is reimbursed or sponsored travel related to their institutional responsibilities.

Financial Conflict of Interest means a Significant Financial Interest that the College reasonably determines could directly and significantly affect the design, conduct or reporting of sponsored research.

Institutional Official means the individual within the Institution that is responsible for the solicitation and review of disclosures of significant financial interests, including those of the Investigator's family related to the Investigator's institutional responsibilities. For the purposes of this policy, the Institutional Official is designated as the College Assistant Dean of Grants Development.

Institutional responsibilities means the Investigator's professional responsibilities associated with his or her Institutional appointment or position, such as teaching, administration, and institutional, internal and external professional committee service.

Investigator means any individual who is responsible for the design, conduct, or reporting of sponsored research, or proposals for such funding. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal and may also include collaborators or consultants, as appropriate.

Public Health Service or *PHS* means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration.

Research means a systematic investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research.

CONFLICT OF INTEREST

This policy is predicated on the expectation that Investigators should conduct their affairs so as to avoid or minimize conflicts of interest, and must respond appropriately when conflicts of interest arise. To that end, this policy informs Investigators about situations that generate conflicts of interest related to research, provides mechanisms for Investigators and the College to manage those conflicts of interest that arise, and describes situations that are prohibited. Every Investigator has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raising questions of conflict of interest arises, an Investigator should discuss the situation with the Institutional Official.

1) DISCLOSURE OF FINANCIAL INTERESTS

All Investigators are required to disclose their outside financial interests as defined above to the Institution on an annual and on an *ad hoc* basis, as described below. The Institutional official is responsible for the distribution, receipt, processing, review and retention of disclosure forms.

a) Annual Disclosures

All Investigators must disclose their Significant Financial Interests that are related to the investigator's institutional responsibilities to the Institution, through the Institutional Official, on an annual basis.

b) Ad hoc Disclosures

In addition to annual disclosure, certain situations require *ad hoc* disclosure. All Investigators must disclose their Significant Financial Interests to the College, through the Institutional Official in a timely manner, as determined by the Institutional Official.

Prior to entering into sponsored projects or applications for sponsored projects, where the Investigator has a Significant Financial Interest, the Investigator must affirm the currency of the annual disclosure or submit to the Institutional Official an *ad hoc* updated disclosure of his or her Significant Financial Interests with the outside entity. The Institution will not submit a research proposal unless the Investigator(s) have submitted such *ad hoc* disclosures.

In addition, all Investigators must submit to the Institutional official an *ad hoc* disclosure of any Significant Financial Interest they acquire or discover during the course of the year.

c) Travel

Investigators must also disclose reimbursed or sponsored travel related to their institutional responsibilities, as defined above, in the definition of Financial Interest and Significant Financial Interest. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value.

2) REVIEW AND DECISION OF THE INSTITUTIONAL OFFICIAL

If the disclosure form reveals a Significant Financial Interest, it will be reviewed promptly by the Institutional Official or designee for a determination of whether it constitutes a Financial Conflict of Interest. If a Financial Conflict of Interest exists, the Institutional Official will take action to manage the financial conflict of interest including the reduction or elimination of the conflict, as appropriate.

A Financial Conflict of Interest will exist when the Institutional Official or designee determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of sponsored research. If the Institutional Official determines that there is a Financial Conflict of Interest that can be managed, he or she must develop and implement a written

management plan. The affected Investigator must formally agree to the proposed management strategies before any related sponsored research goes forward.

The Institutional Official will periodically review the ongoing activity to monitor compliance with the management plan.

3) REPORTING TO PHS

The Institutional Official will report financial conflicts of interest or non-compliance to PHS in accordance with PHS regulations. If the funding for the Research is made available from a prime PHS-awardee, such reports shall be made to the prime awardee prior to the expenditure of any funds and within sixty (60) days of any subsequently identified financial conflict of interest such that the prime awardee may fulfill their reporting obligations to the PHS.

4) INVESTIGATOR NON-COMPLIANCE

a) Disciplinary Action

In the event of an Investigator's failure to comply with this Policy, the Institutional Official may suspend all relevant activities or refer the matter to the Office of Human Resources, for appropriate action. The institution will promptly notify the PHS Awarding Component of the action taken or to be taken. If the funding for the research is made available from a prime PHS awardee, such notification shall be made promptly to the prime awardee for reporting to PHS.

b) Retrospective Review

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

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

The Institutional Official will update any previously submitted report to the PHS or the prime PHS-awardee relating to the research, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. This retrospective review will be completed in the manner and within the time frame established in PHS regulations. If bias is found, the College will promptly notify the PHS Awarding Component and submit a mitigation report in accordance with the PHS regulations. The mitigation report will identify elements

documented in the retrospective review, a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

5) TRAINING

Each Investigator must complete training on this Policy, the Investigator's responsibilities regarding disclosure and the regulations prior to engaging in research, and at least every four years thereafter. They must also complete training within a reasonable period of time as determined by the Institutional Official in the event that this Policy is substantively amended in a manner that affects the requirements of Investigators, if the Investigator is new to the College, or if it is determined that the Investigator has not complied with this policy or with a management plan related to his/her activities.

6) RECORD RETENTION

The Institutional Official will retain all disclosure forms, conflict management plans, and related documents for a period of three years from the date the final expenditure report is submitted to the PHS or to the prime PHS awardee, unless any litigation, claim, financial management review, or audit is started before the expiration of the three year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

7) CONFIDENTIALITY

To the extent permitted by law, including, but not limited to, the New York Freedom of Information Law (Public Officers Law, Article 6), all disclosure forms, conflict management plans, and related information will be deemed confidential. However, the Institution may be required to make such information available to the PHS Awarding Component and/or HHS, to a requestor of information concerning financial conflict of interest related to PHS funding or to the primary entity who made the funding available to the College, if requested or required. If the Institution is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

8) PUBLIC ACCESSIBILITY

The College will respond to any request for public records maintained by the College, in accordance with the New York Freedom of Information Law (Public Officers Law, Article 6) or any other applicable law, rule or regulation.

9) REGULATORY AUTHORITY

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

**Approved by Cabinet
March 14, 2016**