Policy on Conflicts of Interest in Public Health Service Sponsored Programs

State University of New York and The Research Foundation for The State University of New York

I. Reason for Policy

The State University of New York ("SUNY") and The Research Foundation for The State University of New York ("RF") have an agreement providing that applications made by faculty or staff at SUNY who are seeking support for sponsored programs shall be made by SUNY through RF, and all funds awarded by sponsors in support of such sponsored programs shall be paid to and administered by RF in accordance with the terms and conditions of the grants.

As institutions that receive U.S. Public Health Services ("PHS") funding, SUNY and RF and their faculty, research staff and administrators are committed to meeting the highest ethical standards and to preserving the public trust by promoting objectivity in their teaching, research and public service missions. As part of this commitment, SUNY and RF share an obligation to protect their missions and reputations from being compromised by private interests and to operate in compliance with policies of various federal funding agencies.

This policy addresses the requirements under the revised regulation on *Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors*, published in Federal Register, vol. 76, No. 165, on August 25, 2011. This policy does not replace or supersede disclosure requirements under NY Public Officers Law, §73-a, or ethical standards under NY Public Officers Law, §§ 73 and 74.

II. Statement of Policy

SUNY and RF Investigators may not have any interest or engage in any outside activity which results in unmanaged Financial Conflict of Interest. To this end, SUNY and RF Investigators must disclose their interests and outside activities, and those of a Related Party, which may affect their independent and objective performance of their PHS-funded project(s). Financial Conflict of Interest shall be subject to management plans, and compliance with such management plans shall be monitored.

III. Applicability

This policy applies to all Investigators who apply for, receive, plan to participate in or are participating in PHS grants or cooperative agreements for research. This includes SBIR/STTR Phase II applicants/awardees (but not Phase I SBIR/STTRs, which are exempt from this policy).

A Campus may promulgate a policy and procedure that is more stringent than this policy or applies to conflicts in addition to FCOIs in PHS-sponsored programs, provided that such policy and procedure complies with the requirements of this policy, the PHS Regulations, and collective bargaining requirements, as determined and approved by the SUNY Vice Chancellor for Research. Until a Campus policy and procedure is so approved, this policy shall apply.

IV. Definitions

1. **Campus:**

One of the several colleges or universities or other operating locations or administratively separate units of which SUNY is comprised (e.g. University at Albany).

2. **PHS:**

The Public Health Service of the U.S. Department of Health and Human Services and its component agencies, including the National Institutes of Health.

3. **Designated Institutional Official ("DIO")**:

The DIO for each Campus will be appointed by the SUNY Vice Chancellor for Research who is also the President of RF on the recommendation of the respective campus president, and may be the Vice President for Research, RF Operations Manager, another individual, or a committee. The DIO shall:

1. Solicit and review disclosures of Significant Financial Interest from each Investigator who is planning to participate in, or is participating in, PHS-funded research;

2. Provide guidelines to determine whether an Investigator's Significant Financial Interest is related to the proposed or PHS -funded research (that is, whether the SFI could be affected by the PHS-funded research or is an interest in an entity whose financial interest could be affected by the research), and to determine whether such Significant Financial Interest constitutes a Financial Conflict of Interest;

3. Develop management plans that specify the actions that have been, and shall be, taken to manage Financial Conflict of Interest; and

4. Perform such other functions required of a DIO as set forth in this policy and the PHS Regulations.

4. **Investigator:**

A SUNY or RF employee who is the project director or principal investigator and any other person, including a student or post-doctoral fellow, regardless of title or position, who is responsible for the design, conduct or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

5. **Institutional Responsibilities:**

Investigator's professional responsibilities on behalf of SUNY and/or RF, which may include activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

6. **Related Party:**

An Investigator's spouse and dependent children.

7. Significant Financial Interest ("SFI"):

A financial interest of the Investigator (or ofa Related Party) that reasonably appears to be related to the Investigator's Institutional Responsibilities and that consists of one or more of the following:

a. With regard to any publicly traded entity, a SFI exists if:

i. the value of any remuneration[1] received from the entity in the twelve months preceding the disclosure; and

ii. the value of any equity interest[2] in the entity as of the date of disclosure, when aggregated, exceeds $5,000.

b. With regard to any non-publicly traded entity, a SFI exists if:

i. the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or
ii. the Investigator (or a Related Party) holds any equity interest (e.g., stock, stock option, or other ownership interest);

c. Intellectual property rights and interests (e.g., patents, copyrights), and royalties from such rights, upon receipt of income related to such rights and interests; or
d. reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator, and not reimbursed to the Investigator so that the exact monetary value may not be known by the Investigator), related to the Investigator's Institutional Responsibilities, in an amount or estimated amount in excess of $500. Excluded from this requirement is travel that is reimbursed or sponsored by a federal, state or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

SFI Exclusions

1. Salary, royalties, or other remuneration paid by SUNY or RF to the Investigator if the Investigator is currently employed or otherwise appointed by SUNY or the RF;
2. Intellectual property rights assigned to SUNY or RF and agreements to share in royalties related to such rights;
3. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator or a Related Party does not directly control the investment decisions made in these vehicles;
4. Income from seminars, lectures, or teaching engagements sponsored by a federal, state or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center,

[1] Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship).
[2] Equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

or a research institute that is affiliated with an institution of higher education; or

5. Income from service on advisory committees or review panels for a federal, state or local government agency, institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

8. Financial Conflict of Interest ("FCOI"):

A Financial Conflict of Interest exists when an SFI could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

9. Senior/Key personnel:

Project Director/Principal Investigator and any other person identified as senior/key personnel in the grant application, progress report, or any other report submitted to the PHS by SUNY or RF, per PHS Regulations.

10. PHS Regulations:

42 CFR Parts 50 and 94.

V. Procedure

A. Disclosure and Management Plans

(1) Investigators shall disclose all SFIs to the DIO (see Appendix E for PHS Significant Financial Interest Disclosure Form):

a) At the time of application for PHS funds,
b) Annually thereafter during the period of the PHS-funded award, and
c) Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

(2) Upon receipt of a PHS proposal for processing, the DIO will confirm that updated disclosures for all Investigators have been made.

(3) Awards involving subrecipients must comply with the PHS Regulations by incorporating, as part of the written agreement with the subrecipient, terms establishing whether this policy or that of the subrecipient will apply to the subrecipient's investigators. If the subrecipient's policy applies, the subrecipient shall certify in the written agreement that its policy complies with PHS Regulations. If subrecipient cannot make such certification, then the written agreement shall provide that this policy will apply for disclosing investigator SFIs that are directly related to subrecipient's work for SUNY or RF. The written agreement shall also include time periods for subrecipient to provide to the DIO all necessary information for evaluation of subrecipient investigator disclosures and reporting of FCOI to the sponsor.

(4) The DIO will review the disclosures of SFIs and determine if a FCOI exists. In determining whether a FCOI exists, the DIO will determine if the SFI is related to the PHS-funded research, and, if so, could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

(5) For all identified FCOIs, the DIO will develop and implement a management plan (which may include the reduction or elimination of the SFI). Examples of conditions or restrictions that a management plan might include are:

a) Public disclosure of FCOIs;
b) Monitoring of research by independent reviewers;
c) Modification of the research plan;
d) Disqualification from participation in the portion of the research that could be affected by the FCOIs;
e) Divesture of SFIs;
f) Severance of relationships that create actual or potential conflicts;
g) Removal of Investigator as Principal Investigator/Project Director; and
h) Additional remedies specific to the conduct of research involving human subjects, including but not limited to, disclosure in the consent process of the Investigator's FCOI, and removal of the Investigator's ability to recruit research subjects.

(6) The Investigator must agree to comply with the management plan in written or recorded form.

(7) The FCOI and the management plan will be reported to PHS (see Appendix A for content of report):

a) prior to expenditure of any funds under the award;
b) within 60 days of identifying a new FCOI for an existing Investigator, during the period of the award (FCOI must be determined, and management plan implemented within those 60 days); or
c) within 60 days of identifying an FCOI for an Investigator who is newly participating in the project.

In addition, for any FCOI previously reported with respect to an ongoing PHS-funded research project, the DIO shall annually report on the status of the FCOI and any material changes in the management plan.

(8) For all identified FCOI's, the DIO will monitor compliance with the applicable management plan. Such monitoring will be documented and maintained in accordance with the PHS Regulations.

(9) In any case in which PHS determines 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 whose FCOI was not managed or reported as required by this policy or the PHS regulations, the Investigator involved will disclose the FCOI in each public presentation of the results of the research and will request an addendum to previously published presentations.

B. Required Investigator Training

Each Investigator must complete FCOI training:

1. prior to engaging in research related to any PHS-funded grant and at least every four years, and
2. immediately under the following circumstances:

a) FCOI policies change in a manner that materially affects Investigator requirements,
b) An Investigator is new to RF or SUNY, or
c) The DIO finds an Investigator noncompliant with PHS Regulations, this policy or a related management plan.

C. Public Disclosure of FCOI's

The DIO will make information concerning FCOIs held by Senior/Key personnel available via a written response to any requestor within five business days of a request, and update such information as specified in the PHS Regulations. In response to such request, the Institution will provide, at a minimum, the information outlined in Appendix B. Requests for information concerning FCOIs held by Investigators other than Senior/Key personnel will be governed by the provisions of the New York's Freedom of Information Law (NY Public Officers Law, Art. 6).

D. Retrospective Review

When a FCOI is not identified or managed in a timely manner or when an Investigator fails to comply with a management plan, the DIO, within 120 days of a determination of non-compliance, must complete a retrospective review of the Investigator's activities and the PHS Award to determine if there was bias in the design, conduct, or reporting of such research. The information that must be documented in the retrospective review is outlined in Appendix C.

If bias is found through a retrospective review, the DIO will notify the PHS Awarding Component promptly and submit a mitigation report containing the information outlined in Appendix D.

Thereafter, the DIO will submit FCOI reports annually as described in Appendix A.

E. Documentation

The DIO will maintain records of all Investigator disclosures of financial interests and the DIO's review of, and response to, such disclosures (whether or not a disclosure resulted in the DIO's determination of FCOI) and all actions under this policy, including retrospective review, if applicable, for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR §74.53(b) and §92.42 (b) for different situations.

F. Other Requirements

1. RF and SUNY will maintain this policy and make it publicly available on their respective websites.

2. Violators of this policy are subject to the respective disciplinary policies of RF and SUNY.

Appendix A

FCOI Reports to PHS will consist of:

1. Grant number;
2. PD/PI or contact PD/PI;
3. Name of Investigator with the FCOI;
4. Name of the entity with which the Investigator has an FCOI;
5. Nature of FCOI (e.g., equity, consulting fees, travel reimbursement, honoraria);
6. Value of the financial interest $0-4,999; $5K-9,999; $10K-19,999; amounts between $20K-100K by increments of $20K; amounts above $100K by increments of $50K or a statement that a value cannot be readily determined;
7. A description how the Significant Financial Interest relates to PHS-funded research and the basis for the DIO's determination that the Significant Financial Interestis a FCOI; and
8. Key elements of the related management plan, including:
    a) Role and principal duties of the conflicted Investigator in the research project;
    b) Conditions of the management plan;
    c) How the management plan is designed to safeguard objectivity in the research project;
    d) Confirmation of the Investigator's agreement to the management plan;
    e) How the management plan will be monitored to ensure Investigator compliance; and
    f) Other information as needed.

Appendix B

The following information regarding an SFI will be made publicly available prior to expenditure of any PHS Award funds if it is determined that an Investigator still holds the SFI and that the SFI is a FCOI and is related to the PHS Award.

1. Investigator's name;
2. Investigator's title and role with respect to the research project;
3. Name of the entity in which the SFI is held;
4. Nature of the SFI; and
5. Approximate dollar value of the SFI (dollar ranges will be provided, e.g., $0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000), or a statement that the interest is one whose value cannot be readily determined through references to public prices or other reasonable measures of fair market value.

Appendix C

The following must be documented in the retrospective review:

1. Project number;
2. Project title;
3. PD/PI or contact PD/PI if a multiple PD/PI model is used;
4. Name of the Investigator with the FCOI;
5. Name of the entity with which the Investigator has an FCOI;
6. Reason(s) for the retrospective review;
7. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
8. Findings and conclusions of the review.
9. If results of the retrospective review warrant, update previously submitted FCOI report

Appendix D

The following will be documented in mitigation report:

1. Key elements documented in retrospective review;
2. Description of the impact of the bias on the research project;
3. Plan of action(s) to eliminate or mitigate the effect of the bias; and
4. Extent of harm done including supporting data, if any.

Appendix E

PHS Significant Financial Interest Disclosure Form

Name of Investigator	
Title	**Campus**
Department	
Project(s) / Proposal(s)	

1. List the names of all **publicly traded entities** from which you or a Related Party[1] receive remuneration[2] or in which you or a Related Party hold an equity interest[3]. Report only those entities from which the aggregate of remuneration received in the preceeding 12 months and the current value of equity interests exceeds $5,000.

Name (self/Related Party	Relationship	Entity	Nature	Amount

2. List the names of all **non-publicly traded entities** from which you or a Related Party receive remuneration. Report only those entities from which remunerations received over the preceeding 12 months exceed $5,000.

Name (self/Related Party)	Relationship	Entity	Nature

[1] A Related Party is your spouse or dependent child.
[2] Remunerations include, salaries, consulting fees, honoraria, or paid authorship.
[3] Equity interests include, stock, stock options, or other ownership interests.

3. List the names of all **non-publicly traded companies** in which you or a Related Party hold an equity interest. .

Name (self/Related Party)	Relationship	Entity	Nature

4. List and describe intellectual property rights or interests (e.g., patents, copyrights) held by you or a Related Party, royalties from such rights, and/or agreements to share in royalties related to such rights . Do not include intellectual property rights assigned to SUNY or the Research Foundation, or agreements to share in royalties related to such rights.

Name (self/Related Party)	Relationship	Nature	Income Received (Y/N)

5. List and describe any reimbursed or sponsored[4] travel related to your institutional responsibilities. You do not need to disclose travel that was reimbursed or sponsored by

[4] That which is paid on your behalf but not reimbursed whether you know the exact monetary value.

a federal, state, or local government agency, an Institution of higher education[5], an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Date	Purpose of Trip	Sponsor/Organizer	Destination	Duration Estimated Amount

6. If you believe the interests indicated above are not related to you institutional responsibilities, explain the reasons for your belief.

7. Describe whether, and how, the financial interests described in items 2-5 above may be affected by the Project or is an interest in an entity whose financial interest could be affected by the Project.

For all of the above, please use additional pages if necessary.

By signing below, Investigator (1) certifies that this form provides an accurate report of the Investigator's t Significant Financial Interests, and (2) acknowledges responsibility to provide a complete disclosure of all Significant Financial Interests reasonably related to the Investigators' Institutional Responsibilities prior to PHS award receipt, as those interests change, and on an annual basis during the project award period.

_____ _____

Investigator Date

[5] *See* definition in 20 U.S.C. § 1001(a). The definition includes SUNY Campuses.