



SAINT VINCENT COLLEGE

Financial Conflict of Interest (FCOI) Policy for Federally-funded Research

A. FINANCIAL CONFLICTS OF INTEREST IN RESEARCH POLICY

A-1. Purpose. Federal regulations require institutions to establish and administer a financial conflict of interest and disclosure policy for investigators who conduct research funded by federal grants. Saint Vincent College (“the College”) has adopted an institutional policy to promote objectivity in research and to foster compliance with federal regulations.

The College requires all investigators seeking research funding (including but not limited to grants, cooperative agreements, and contracts) or having obtained research funding from the Public Health Service (PHS), the National Science Foundation (NSF), or other federal agencies to comply with the following policy on the disclosure of significant financial interests and the management and reporting of financial conflicts of interest (FCOI).

A-2. Responsible College Authority: Vice President for Academic Affairs. The Vice President for Academic Affairs (VPAA), or his designee(s), shall be the authority who provides and monitors training of investigators required by federal regulations and/or policy; evaluates all disclosures by investigators made under this policy; solicits disclosures to be made under this policy; determines whether a financial conflict of interest exists; develops and implements a management plan for financial conflicts of interest subject to this policy; performs retrospective review of potential instances of noncompliance with this policy; makes, as required by federal regulation, information on investigator financial conflicts of interest publicly available; and reports, as required by federal regulation, on College determination of the existence of a financial conflict of interest, implementation of management plan for a financial conflict of interest, determination of noncompliance, and the results of any retrospective review.

Circumstances for designation of responsibility include, but are not limited to, obtaining a second opinion on potential conflicts of interest or during retrospective reviews, development of appropriate management plans, training of investigators, as described below, or reporting, as required by federal regulation.

A-3. Informing Investigators. Prior to an Investigator submitting a proposal seeking research funding from NSF or any PHS Awarding Component, the VPAA and/or his designee will deliver a copy of this policy to the Investigator and instruct the Investigator to read this policy and the applicable federal regulations in full. Furthermore, the VPAA and/or his designee will explain to the Investigator what the Investigator’s disclosure responsibilities are under this policy and the applicable federal regulations.

A-4. Disclosure of significant financial interests. All personnel responsible for the design, conduct or reporting of research under the terms of a federal grant, cooperative agreement, or contract (each, an “Investigator”) are required to disclose to the VPAA and/or his designee all Significant Financial Interests of the Investigator and/or the Investigator’s spouse, partner, and dependent children.

The terms of such disclosure, both the timing and the standards for defining Significant Financial Interest (SFI) vary with the source of funding, as described below. When, because of existing funding and/or proposed research, an individual investigator is subject to both the PHS and NSF FCOI requirements, the PHS requirements set forth in Section B shall govern.

A-5. Subawardees and subcontracts. When the College is a subawardee or subcontractor of another institution, the College policy will apply, unless the terms of the subaward or subcontract expressly prohibit it. Conversely, The College requires its subcontractors and subawardees to develop and manage their own federally compliant conflict of interest policies as appropriate to each funding agency.

The standards in Section B apply to PHS-funded research; different standards apply to NSF-funded work, as described in Section C.

B. POLICY APPLICABLE TO PUBLIC HEALTH SERVICE (PHS) / NATIONAL INSTITUTES OF HEALTH (NIH) FUNDING

This policy is intended to comply with substantial changes in Public Health Service regulations on *Promoting Objectivity in Research* (42 C.F.R. 50 and 45 C.F.R. 94) and to fulfill the requirements of grantee institutions as put forth in the National Institutes of Health's guidelines (see <http://grants.nih.gov/grants/policy/coi/index.htm>).

NIH requires grantees and investigators (except Phase I SBIR/STTR applicants and grantees) to comply with the requirements of 42 CFR 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought." A Final Rule amending the 1995 PHS regulation (and the companion regulation at 45 CFR 94, "Responsible Prospective Contractors," imposing similar requirements for research contracts) was published on August 25, 2011 in the Federal Register (<http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>).

The requirements under the 2011 revised regulation promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be free from bias by any conflicting financial interest of an Investigator, defined as the Project Director or Principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding, which may include, for example, collaborators or consultants. These requirements do not apply to Federal employees or Federal agencies. Federal agencies have their own set of rules governing financial conflicts of interest for employees.

Recent changes to the regulations regarding conflict of interest in research funded by the Public Health Service (PHS) affect the definition and inclusiveness of the term "investigator," *de minimis* standards for reporting, public accessibility requirements, management responsibilities, and the requirements for training in conflict of interest.

B-1. Definitions for PHS-funded Research.

These definitions set forth in this subsection are meant to mirror, as applied to the context of the College, the definitions set forth in 42 C.F.R. § 50.603. All persons involved in the administration of a grant from a PHS awarding component must familiarize themselves with the definitions of this subsection as well as the definitions set forth in 42 C.F.R. § 50.603.

Investigator refers to the project director, principal investigator, co-principal investigators, and any other person who is responsible for the design, conduct, or reporting of research funded by the Public

Health Service (PHS). In addition to College faculty members, this definition may apply to staff, postdoctoral fellows, or others with independent responsibility for portions of the design, conduct, or reporting of research of an Investigator's proposed or funded project, or when they seek research funding subject to this policy.

Each project director or principal investigator is responsible for determining all project personnel who meet the above definition of Investigator and therefore who must be trained, must disclose financial interests to the College, and must report when the status of any financial interest changes or when new interests are acquired. In making such determinations, the project director/ PI should consider the role, rather than the title, of those involved in research and the degree of independence with which those individuals work.

Significant Financial Interest (SFI). An SFI means one or more of the following interests of the Investigator (or the Investigator's spouse, partner, or dependent children), if it reasonably appears to be related to the Investigator's institutional responsibilities:

a) With regard to any publicly traded entity, an SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure *and* the value of any equity interest in the entity as of the date of the disclosure, when aggregated, exceeds \$5,000. For the purposes of this definition remuneration includes salary and any payment for services not otherwise identified as salary (e.g. consulting fees, paid authorship, honoraria); 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.

b) With regard to any non-publicly traded entity, an SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, *or* when the Investigator (or the Investigator's spouse or dependent children) owns *any* equity interest, regardless of dollar value.

c) With regard to intellectual property rights and interests (e.g. patents and copyrights) an SFI exists upon receipt of income related to such rights and interests.

d) Any occurrence of 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 readily available) related to the Investigator's institutional responsibilities must also be disclosed, with the exception of any travel 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. The Investigator must disclose the purpose of the trip, the identity of the sponsor and/or organizer, the destination and its duration. Additional information, including the estimated cost of travel, may be required.

e) Exclusions. The term "Significant Financial Interest (SFI)" does not include the following types of financial interests:

- salary, royalties, or other remuneration from the College if the Investigator is currently employed or otherwise appointed by the College, including intellectual property rights assigned to the College and agreements to share in royalties related to such rights;
- income from investment vehicles such as mutual funds or retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
- 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, or a research institute that is affiliated with an Institution of higher education; or

- income from service on advisory committees or review panels for 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.
- **Financial Conflict of Interest** (FCOI) exists when the VPAA and/or his designee reasonably determines that a SFI could directly and significantly affect the design, conduct, or reporting of federally-funded research or educational activities.

B-2. Training for PHS-funded Research.

The College will require each Investigator to complete training prior to engaging in PHS-supported research and at least every four years, and immediately when any of the following circumstances apply:

- The College's Financial Conflict of Interest policies change in a manner that affects Investigator requirements;
- An Investigator is new to the College; or
- The College finds an Investigator noncompliant with the institutional Financial Conflict of Interest policy or management plan.

The nature and extent of the required training will be determined by the VPAA and/or his designee. The VPAA and/or his designee will submit a memorandum to the Investigator setting forth the nature and extent of the required training.

B-3. Disclosure for PHS-funded Research.

Investigators must disclose all SFI at or before the time a proposal is submitted to any component of the PHS, and prior to engaging in any PHS-funded research governed by a Notice of Award (NOA) dated after August 24, 2012. Furthermore, Investigators new to participating in a research project must disclose SFI to the VPAA and/or his designee prior to beginning participation in the project, or if participation has already begun, then such Investigators must disclose SFI to the VPAA and/or his designee immediately.

In addition, Investigators must update those financial disclosures:

- Within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage or inheritance) any new Significant Financial Interest; and
- Annually within the period of the award, beginning with the anniversary date of the original disclosure.

Investigators must provide the following information for all significant financial interests:

- name of the entity with which the Investigator has a financial conflict of interest;
- nature of the financial interest (e.g., consulting fees, honoraria, paid authorship, equity interest, intellectual property rights and interests, and reimbursed or sponsored travel);
- the monetary value of the financial interest or its approximate value;
- a description of how the financial interest relates to the PHS-funded research; and
- any supporting documentation needed to make a determination of whether a FCOI exists.

B-4. Review of Financial Disclosures.

Determination of Financial Conflicts of Interest. Prior to the expenditure of any funds under a PHS-funded research project, VPAA and/or his or her designee shall:

- review each disclosed SFI;
- determine whether such SFI relates to federally-funded research—an Investigator’s SFI is related to PHS-funded research when the VPAA and/or his designee reasonably determines that the SFI could be affected by the PHS-funded research or is in an entity whose financial interest could be affected by the research—and
- if so related, determine whether a FCOI exists; and determine what conditions or restrictions, if any, should be imposed by the institution to manage, reduce, or eliminate such conflict or interest. The VPAA and/or his designee may, depending on the scope of the potential conflict, request that additional staff and/or faculty serve on an *ad hoc* review committee to assist in this review, and they or the VPAA may request additional information from the Investigator who disclosed the SFI.

Management of Financial Conflicts of Interest. If the VPAA and/or his designee determines that a SFI constitutes a FCOI, the VPAA and/or his designee shall determine the conditions or restrictions to be imposed and implemented as part of a formal management plan in order to manage or eliminate the conflict.

The Management Plan may include, but is not limited to, these elements:

- a) public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- b) for research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- c) appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- d) modification of the research plan;
- e) change of personnel or personnel policies, or disqualification from participation in all or a portion of the research;
- f) reduction or elimination of SFI;
- g) severance of relationships that create financial conflicts.

The VPAA and/or his designee shall communicate this determination and the means that he has identified for eliminating or managing the FCOI to the individual Investigator, the relevant Principal Investigator or Project Director (if applicable), the appropriate department chair, and, as necessary, the PHS awarding component.

No expenditures on PHS awards will be permitted until (1) the Investigator has complied with the disclosure and training requirements of this policy; (2) the VPAA and/or his designee has reviewed all Investigator disclosures of SFIs; (3) the VPAA and/or his designee has determined whether any SFIs relate to PHS-funded research; (4) the VPAA and/or his designee, if it is determined that any SFIs relate to PHS-funded research, has developed a management plan that specifies the actions that have been and shall be taken to manage such FCOIs; and (5) the Investigator has agreed, in writing, to comply with any plan(s) determined to be necessary for the management of the FCOI.

Investigators New to Research. In the course of an ongoing PHS-funded research project, if an Investigator who is new to participating in the research project discloses a SFI or an existing Investigator discloses a new SFI, the VPAA and/or his designee shall, within sixty days (1) review the disclosure of the SFI; (2) determine whether the SFI is related to PHS-funded research; (3) determine whether a FCOI exists; and (4) if an FCOI exists, implement, at least on an interim basis, a management plan that shall specify the actions that have been and will be taken to manage such FCOI. Depending on the nature of the SFI, additional interim measures may be necessary regarding the Investigator's participation in the PHS-funded research project between the date of disclosure and the completion of the review.

SFI Not Timely Disclosed Or Not Previously Reviewed. If the College identifies an SFI that was not disclosed timely by an Investigator or an SFI not previously reviewed by the College, the VPAA and/or his designee shall, within 60 days, determine whether the SFI is related to PHS-funded research, determine whether the SFI rises to the level of an FCOI, and if so, implement, at least on 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, and

- In addition whenever an FCOI is not identified or managed in a timely manner including (1) failure by the Investigator to disclose an SFI that the College determines to constitute an FCOI; (2) failure by the College to review or manage such an FCOI; or (3) failure by the Investigator to comply with a financial conflict of interest management plan, the VPAA and/or his designee shall, within 120 days of the Institution's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

- The VPAA and/or his designee shall document the retrospective review; 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 FCOI;
 - 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; and
 - Conclusions of the review

- Based on the results of the retrospective review, if appropriate, the College shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, the VPAA and/or his designee must promptly notify the PHS Awarding Component of this finding and must draft and submit to the PHS Awarding

Component a mitigation report. The mitigation report must include, at a minimum, the following key elements:

- All of the key elements required for a retrospective review as listed above;
 - A description of the impact of the bias on the research project; and
 - The College'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)
- Thereafter, the VPAA and/or his designee must submit FCOI reports annually throughout the duration of the PHS-funded research, as specified elsewhere in this policy and the applicable federal regulations. Depending on the nature of the FCOI, the College may determine that additional interim measures are 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.

Upon the implementation of any management plan for PHS-funded research, the VPAA and/or his designee shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project. The nature and extent of such monitoring shall be determined by the VPAA and/or his designee and shall be set forth in writing. The VPAA and/or his designee may take

In any case in which the HHS 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 with an FCOI that was not managed or reported by the College as required by federal regulations, the Investigator involved must disclose the financial conflict of interest in each public presentation of the results of the research and must request an addendum to previously published presentations.

B-5. Reporting Financial Conflicts of Interest.

The VPAA and/or his designee will follow PHS regulations with regard to reporting FCOIs and non-compliance with disclosure requirements and management plans. This requirement includes reporting FCOIs to the PHS Awarding Component:

- prior to the expenditure of funds;
- within 60 days of identification for an Investigator who is newly participating in a project;
- within 60 days for new, or newly identified, financial conflicts of interest for existing Investigators;
- At least annually (at the same time as when the Institution is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension) to provide the status of a financial conflict of interest and any changes to the management plan, if applicable, until the completion of the project;
- following a retrospective review, as outlined in **B-4**, to update a previously submitted report, if appropriate.
-

Any FCOI report required under this subsection B-5 shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to ass the

appropriateness of the College's management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:

- project number;
- PD/PI or Contact PD/PI if multiple PD/PI is used;
- name of the Investigator with the FCOI
- name of the entity with which the Investigator has a FCOI;
- nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- value of the financial interest (dollar ranges are permissible: \$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 reference to public prices or other reasonable measures of fair market value;
- a description of how the financial interest relates to the PHS-funded research and the basis for the College's determination that the financial interest conflicts with such research; and
- a description of the key elements of the College's management plan, including:
 - role and principal duties of the conflicted Investigator in each project;
 - conditions of the management plan;
 - how the management plan is designed to safeguard objectivity in the research project;
 - confirmation of the Investigator's agreement to the management plan;
 - how the management plan will be monitored to ensure Investigator compliance; and
 - other information as needed.

For any SFI that the College identifies as conflicting subsequent to the College's initial FCOI report during an ongoing PHS-funded research project, the VPAA and/or his designee shall, within sixty days, in addition to providing the PHS Awarding Component with an FCOI report, ensure that the College has implemented a management plan in accordance with federal regulation.

The VPAA and/or his designee will notify the PHS awarding component promptly if bias is found with the design, conduct or reporting of PHS-funded research. The VPAA and/or his designee also will notify the PHS awarding component if an Investigator fails to comply with the College's FCOI policy or a FCOI management plan appears to have biased the design, conduct, or reporting of PHS-funded research. In each notification, the VPAA and/or his designee will include a description of the corrective action taken or to be taken.

The College will not report FCOI to the sponsoring agency if they are identified and eliminated prior to the expenditure of grant funds.

Information on Financial Conflicts of Interest will be made available to members of the public in response to inquiries within 5 business days of receipt of such requests.

B-6 Subrecipient Requirements

If the College carries out PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), and the College is the awardee institution, the College shall take reasonable steps to ensure that any subrecipient Investigator complies with federal regulation by:

- Incorporating as part of a written agreement with the subrecipient terms that establish whether the financial conflicts of interest policy of the College or that of the subrecipient will apply to the subrecipient's Investigators.
 - If the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with federal regulation. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the FCOI policy of the College for disclosing SFI that are directly related to the subrecipient's work for the College;
 - Additionally, if the subrecipient's Investigators must comply with the subrecipient's FCOI policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified FCOI to the College. Such time period(s) shall be sufficient to enable the College to provide timely FCOI reports, as necessary, to the PHS as required by federal regulation and this policy;
 - Alternatively, if the subrecipient's Investigators must comply with the College's FCOI policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of SFI to the College. Such time period(s) shall be sufficient to enable the College to comply timely with its review, management, and reporting obligations under federal regulation and this policy.
- Providing FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators consistent with this policy and federal regulation, i.e., prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.
- Ensure that the written agreement with the subrecipient includes, at a minimum, the requirements set forth in NIH Grants Policy Statement 15.2.1.

B-7 Maintenance of Records.

For the College's requirements regarding maintenance of records, see **§ F. Records** below.

B-8 Public Accessibility

Prior to the College's expenditure of any funds under a PHS-funded research project, the College shall ensure public accessibility via written response to any requestor within five business days of a request, of information concerning any SFI disclosed to the College that meets the following criteria:

- The SFI was disclosed and is still held by the senior/key personnel as defined by federal regulation
- The College determines that the SFI is related to the PHS-funded research; and
- The College determines that the SFI is a FCOI.

The information that the College makes available via written response to any requestor within five business days of a request, shall include, at a minimum, the following:

- the Investigator's name;

- the Investigator’s title and role with respect to the research project;
- the name of the entity in which the SFI is held;
- the nature of the SFI; and
- the approximate dollar value of the SFI (dollar ranges are permissible: \$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 reference to public prices or other reasonable measures of fair market value.

The College will note in all written responses under this subsection that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within sixty days of The College’s identification of a new FCOI, which should be requested subsequently by the requestor.

Information concerning the SFI of an individual subject to this subsection shall remain available for responses to written requests for at least three years from the date that the information was most recently updated.

C. POLICY APPLICABLE TO NATIONAL SCIENCE FOUNDATION (NSF) FUNDING

This policy is intended to comply with the National Science Foundation’s conflict of interest policies

http://www.nsf.gov/pubs/policydocs/pappguide/nsf08_1/nsf081.pdf

http://www.nsf.gov/pubs/policydocs/pappguide/nsf11001/aag_4.jsp

The National Science Foundation requires each Investigator to disclose to a responsible representative of a grantee institution all significant financial interests of the Investigator (including those of the Investigator’s spouse and dependent children) (i) that would reasonably appear to be affected by the research or educational activities funded or proposed for funding by NSF; or (ii) in entities whose financial interests would reasonably appear to be affected by such activities.

C-1. Definitions for NSF-funded Research.

Investigator means the principal investigator/project director, co-principal investigators/co-project directors, and any other person at the institution who is responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding by NSF.

Significant Financial Interest means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interest (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). Such Significant Financial Interests include those that are owned by the Investigator, the Investigator’s spouse, and the Investigator’s dependents.

The term does not include:

- a. salary, royalties or other remuneration from the applicant institution;
- b. any ownership interests in the institution, if the institution is an applicant under the Small Business Innovation Research Program or Small Business Technology Transfer Program;
- c. income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities;
- d. income from service on advisory committees or review panels for public or nonprofit entities;
- e. an equity interest that, when aggregated for the investigator and the investigator’s spouse and dependent children, meets both of the following tests: (i) does not exceed \$10,000 in value as

determined through reference to public prices or other reasonable measures of fair market value; and (ii) does not represent more than a 5% ownership interest in any single entity; or

f. salary, royalties or other payments that, when aggregated for the investigator and the investigator's spouse and dependent children, are not expected to exceed \$10,000 during the twelve-month period.

C-2. Disclosure for NSF-funded Research.

Investigators must disclose to the VPAA and/or his designee all Significant Financial Interests at the time the proposal is submitted to NSF. Any financial disclosures must be updated during the period of the award on an annual basis. The VPAA and/or his designee will determine the date for the scheduled submission of the annual update. In addition to the annual update, investigators must update financial disclosures during the period of the award within 30 days of obtaining new reportable significant financial interests. If the new reportable significant financial interest is obtained 60 or fewer days before the scheduled submission of the annual update, the investigator needs only to include the new reportable significant financial interest on the annual update and must do so if reasonably practicable; however, if including the new reportable significant financial interest on the annual update is not reasonably practicable, the investigator must provide an additional update within 30 days of obtaining the new reportable significant financial interest.

C-3. Review of Financial Disclosures.

The VPAA and/or his designee(s) shall review each financial disclosure, determine whether a conflict of interest exists, and determine what conditions or restrictions, if any, should be imposed by the institution to manage, reduce or eliminate such conflict of interest. A conflict of interest exists when the reviewer(s) reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of NSF-funded research or educational activities.

Examples of conditions or restrictions that might be imposed to manage, reduce or eliminate conflicts of interest include, but are not limited to:

- a. public disclosure of significant financial interests;
- b. monitoring of research by independent reviewers;
- c. modification of the research plan;
- d. disqualification from participation in the portion of the NSF-funded research that would be affected by significant financial interests;
- e. divestiture of significant financial interests; or
- f. severance of relationships that create conflicts.

If the reviewer(s) determines that imposing conditions or restrictions would be either ineffective or inequitable, and that the potential negative impacts that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the reviewer(s) may allow the research to go forward without imposing such conditions or restrictions.

D. OTHER FUNDING SOURCES.

Research by any Investigator (person responsible for the design, conduct, or reporting of research or educational activities) funded or proposed for funding by a federal agency other than NSF or the PHS shall comply with that agency's policies regarding financial conflict of interest.

E. ENFORCEMENT.

The College shall establish appropriate procedures and mechanisms for enforcement of this policy, including sanctions¹ where appropriate. Disciplinary proceedings initiated in connection with this policy shall be conducted in accordance with the Faculty Handbook, the Staff Handbook or the Student Code of Conduct. All relevant regulatory bodies and funding agencies will be promptly informed of disciplinary sanctions. In the case of PHS-funded research, the College will conduct a retrospective review of any failure to comply, as required by federal regulations. In the case of NSF-funded research, the VPAA and/or his designee must also keep NSF's Office of the General Counsel appropriately informed if the College finds that it is unable to satisfactorily manage a conflict of interest.

Conditions that may lead to sanctions include but are not limited to failure to fully and timely disclose all significant financial interests, or required updates to such disclosures; submission of an incomplete, erroneous, or misleading disclosure; or failure to comply with the conditions of a management or mitigation plan.

The funding agency may impose sanctions even if the College chooses not to do so, and sanctions by the College do not preclude additional sanctions imposed by the funding agency.

F. RECORDS.

The VPAA and/or his designee shall maintain all records relating to Investigator disclosures of financial interests and The College's review of, and response to, such disclosures—regardless of whether a disclosure resulted in the College's determination of a financial conflict of interest—and all actions under this policy or retrospective review, if applicable, for

- at least 3 years from the date the final expenditures report is submitted to PHS/NSF or where applicable,
- for awards that are renewed quarterly or annually, at least 3 years from the date of the submission of the quarterly or annual financial report.

If an expenditure report has been waived, the retention period starts on the day the report would have been due.

The only exceptions are the following:

- If any litigation, claim, financial management review, negotiation, audit, or other action involving the records is started before the expiration of the 3-year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken, or until the end of the 3-year period, whichever is later.
- Records for real property and equipment acquired with Federal funds shall be retained for 3 years after final disposition or replacement or transfer at the direction of the awarding agency.
- The maintenance of indirect cost rate computations or proposals, cost allocation plans, and any similar accounting computations of the rate at which a particular group of costs is chargeable (such as computer usage chargeback rates or composite fringe benefit rates) are governed by the following:

¹ Such sanctions may include, but are not limited to, any one or more of the following: Letter of admonition; temporary suspension of access to active research funding, either for a fixed term or pending completion of a remediation plan; temporary suspension of rights to apply for internal and external research funding as a PI, either for a fixed term or pending completion of re-training and remediation; investigation and mitigation of possible research bias resulting from improperly disclosed Significant Financial Interests, and reporting of corrective action to the relevant funding agency/agencies; inquiry into possible research misconduct in accordance with the College's policies and procedures; non-renewal of appointment, as per the terms and procedures outlined in the Faculty Handbook; involuntary termination of employment, as per the terms and procedures outlined in the Faculty Handbook. This passage shall not be construed to contradict or supersede any disciplinary policies and procedures detailed elsewhere in the Faculty Handbook.

- If the recipient submits to the Federal Government or the subrecipient submits to the recipient the proposal, plan, or other computation to form the basis for negotiation of the rate, then the 3-year retention period for its supporting records starts on the date of such submission.
- If the recipient is not required to submit to the Federal Government or the subrecipient is not required to submit to the recipient the proposal, plan, or other computation for negotiation purposes, then the 3-year retention period for the proposal, plan, or other computation and its supporting records starts at the end of the fiscal year (or other accounting period) covered by the proposal, plan, or other computation.
- In some cases, grantees must report income after the period of grant support. Where there is such a requirement, the retention period for the records pertaining to the earning of the income starts from the end of the grantee's fiscal year in which the income is earned.

This section is designed to comply with 42 CFR 50.604(i); 45 CFR 74.53(b); and 45 CFR 92.42(b)–(c). The VPAA must remain informed of these recordkeeping regulations.

G. DISCLOSURE STATEMENTS.

Copies of the College's Disclosure Statement forms are available online. All senior personnel who are submitting proposals to a federal funder must complete this Disclosure Statement. The certification page of a research proposal cannot be signed until disclosure forms for all Investigators have been submitted to the VPAA. By signing this form, the applicant certifies that he/she has read and understood the College Policy on Financial Conflicts of Interest for Federally-funded Research and that he/she either a) does not have potential Financial Conflicts of Interest as defined therein or b) does have potential conflicts that are disclosed in accordance with the policy requirements. In either case, the applicant also declares that he/she will notify the VPAA and/or his designee of any change or discovery requiring modification of the above statement.

Adopted February 27, 2013.

Updated May 27, 2014.