

Financial Conflict of Interest Policy in U.S. Public Health Service (PHS) and National Science Foundation (NSF)-Funded Research

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# I. <u>Purpose & Scope</u>

To establish Skidmore College's policy regarding financial conflicts of interest in research funded by the U.S. Public Health Service (PHS) and the National Science Foundation (NSF).

In addition to <u>Skidmore's Conflict of Interest Policy</u>, Skidmore College has instituted this Financial Conflict of Interest (FCOI) Policy to satisfy the requirements of the U.S. Department of Health and Human Services (HHS) FCOI Regulation for PHS-funded research (42 CFR Part 50 and 45 CFR Part 94) and the National Science Foundation (NSF Award and Administration Guide, Chapter IV).

Consistent with 42 CFR 50.601, the PHS FCOI regulation was established to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under NIH grants or cooperative agreements will be free from bias resulting from any conflicting financial interest of an Investigator.

Skidmore College is required to create and maintain a written and enforced policy stating the procedures for implementing the PHS FCOI regulation and to inform each Investigator of the regulation, of the College's FCOI policy, and of the Investigator's disclosure responsibilities under the regulation and the policy. Skidmore College is also responsible for managing, reducing, or eliminating identified conflicts, and reporting identified conflicts to the Public Health Service (PHS) Awarding Component.

Investigators are responsible for complying with Skidmore College's written FCOI policy and for disclosing their Significant Financial Interests to Skidmore College.

This policy applies to all PHS Research Activities with an award issue date of August 24, 2012 or later, and to proposals for research activities submitted to PHS on or after August 24, 2012. PHS research activities that are ongoing as of August 24, 2012 will become subject to this policy as additional funds are requested through submission of a progress report, competing renewal application, proposal for supplemental funding, or through approval of a no-cost time extension. The PHS FCOI regulation does not apply to Phase I Small Business Innovative Research or Small Business Technology Transfer applications.

This policy also applies to research or educational activities funded or proposed for funding by the National Science Foundation. To the extent that other funding agencies or organizations (whether governmental or private) have adopted financial conflict of interest policies and procedures, Skidmore College will comply with such policies and procedures when applicable.

**Sections II through X** of this Policy apply <u>only</u> to <u>PHS</u>-funded research.

**Section XI** of this Policy applies <u>only</u> to <u>NSF</u>-proposed or funded research and educational activities.

Section XII of this Policy applies to research funded by either PHS or NSF.

Skidmore College will certify in each application for PHS funding that Skidmore College:

- has in effect an up-to-date written and enforced administrative process to identify and manage FCOIs related to all PHS research projects;
- will promote and enforce Investigator compliance with the PHS FCOI regulation pertaining to disclosure of Significant Financial Interests; and
- will manage FCOIs and provide initial and ongoing FCOI reports to PHS

Skidmore College designates the Director of the Office of Sponsored Research to administer this policy. The Office of the Dean of the Faculty has overall responsibility for this policy. It is the obligation of any Investigator with concerns or questions about this policy to seek guidance from Skidmore College. E-mails with concerns or questions relating to this policy should be sent to: mhoehn@skidmore.edu.

# II. Definitions Applicable to PHS-Funded Research

As stated in 42 CFR 50.603:

**Disclosure of significant financial interests** means an Investigator's disclosure of significant financial interests to an Institution.

*Financial Conflict of Interest (FCOI)* is a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

*FCOI report* means an Institution's report of a financial conflict of interest to a PHS Awarding Component.

*Financial interest* means anything of monetary value, whether or not the value is readily ascertainable.

*HHS* means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

*Institution* means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding.

*Institutional responsibilities* means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: 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.

*Investigator* means 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 the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

*Manage* means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

**PD/PI** means a Project Director or Principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of Senior / Key personnel and Investigator under this subpart.

**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 involved may be delegated, including the National Institutes of Health (NIH).

**PHS Awarding Component** means the organizational unit of the PHS that funds the research that is subject to this subpart.

Public Health Service Act or PHS Act means the statute codified at 42 U.S.C. 201 et seq.

**Research** means a systematic investigation, study or experiment 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 (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). As used in this subpart, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

**Senior / Key personnel** means the PD/PI 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 by the Institution under this subpart.

### Significant Financial Interest (SFI) is defined as:

- 1. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
  - (i) With regard to any **publicly traded entity**, a *significant financial interest* 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 disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes 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, as determined through reference to public prices or other reasonable measures of fair market value;
  - (ii) With regard to any **non-publicly traded entity**, a *significant financial interest* 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) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
  - (iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

- 2. Investigators also must disclose the occurrence of any **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 their institutional responsibilities; provided, however, that this disclosure requirement does not apply to 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.
- 3. The term *significant financial interest* does **NOT** include the following types of financial interests:
  - salary, royalties, or other remuneration paid by Skidmore College to the Investigator if the Investigator is currently employed or otherwise appointed by Skidmore College, including intellectual property rights assigned to Skidmore College and agreements to share in royalties related to such rights;
  - any ownership interest in Skidmore College held by the Investigator, if the Institution is a commercial or for-profit organization;
  - income from investment vehicles, such as mutual funds and 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; and
  - 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.

# III. Training Requirements

Each Investigator, including subrecipient Investigator(s), must complete FCOI training before engaging in research related to any PHS-funded grant or contract, and at least every four years. Investigators must also complete FCOI training immediately under the following circumstances:

- Skidmore College's FCOI policies change in a manner that affects Investigator requirements;
- An Investigator is new to Skidmore College; or
- Skidmore College finds an Investigator to be noncompliant with Skidmore College's FCOI policy or management plan.

# IV. Investigators' Disclosure Requirements

Investigators are required to disclose to Skidmore College all of their Significant Financial Interests (and those of the Investigator's spouse and dependent children) that reasonably appear to be related to their institutional responsibilities:

- 1. at the time of application for PHS-funded research;
- 2. no later than thirty days from the date of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest; and
- 3. at least annually during the period of award.

The definition of "Significant Financial Interest" is above in the "Definitions" section of this document.

Investigators also must disclose any reimbursed or sponsored travel (that which is paid on behalf of the Investigator and not reimbursed to the Investigator) related to their Institutional responsibilities. This disclosure requirement does not apply to 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.

The disclosure of reimbursed or sponsored travel must include:

- the purpose of the trip;
- the identity of the sponsor / organizer;
- the destination; and
- the duration of the trip.

Skidmore College will determine if further information is needed, including a determination or disclosure of monetary value, to determine whether the travel constitutes an FCOI with PHS-funded research.

### V. <u>Subrecipients and Other Collaborators</u>

### A. Skidmore College subrecipients:

Where Skidmore College carries out PHS-funded research through subgrantees / contractors / subcontractors / collaborators, Skidmore College will take reasonable steps to ensure that Investigators working for such entities comply with the FCOI regulation. For PHS-funded research, Skidmore College will incorporate in a written agreement with any subrecipient terms that establish whether Skidmore College's FCOI policy or the subrecipient's FCOI policy will apply to subrecipient Investigators, and will include time periods to meet disclosure and/or FCOI reporting requirements. If the subrecipient's Investigators must comply with the subrecipient is FCOI policy, the subrecipient must certify as part of the agreement with Skidmore College that its FCOI policy complies with the PHS FCOI regulation. If the subrecipient will state that subrecipient Investigators are subject to Skidmore College is FCOI policy for disclosing Significant Financial Interests that are directly related to the subrecipient's work for Skidmore College. Please see 42 CFR Section 50.604(a) for grants and cooperative agreements and 45 CFR Part 94.4(a) for contracts. With respect to grants or cooperative agreements, this arrangement should be defined in a formal written agreement with each consortium participant.

# B. Skidmore College Investigators who receive PHS subawards:

If Skidmore College will be a subrecipient / subcontractor to another entity on a PHS award / contract, a Skidmore College Investigator or department may receive a form from the prime grantee / contractor asking Skidmore College to certify whether Skidmore College will use its own FCOI policy or whether Skidmore College will use the prime recipient / contractor's policy. The answer is always that Skidmore College uses its own FCOI policy. Skidmore College does not agree to use or follow any other entity's FCOI policy, forms, or procedures.

# VI. <u>Reporting of Financial Conflicts of Interest to PHS Awarding Components</u>

For PHS awarded grants and cooperative agreements, Skidmore College will submit all required FCOI reports to the PHS Awarding Component through the electronic Research Administration (eRA) Commons FCOI Module.

**Submission of Initial FCOI Reports**: Before Skidmore College's expenditure of any funds under a PHS-funded research project, Skidmore College will provide to the PHS Awarding Component an FCOI report and ensure that Skidmore College has implemented a management plan for any FCOI. If Skidmore College identifies an FCOI and eliminates it prior to the expenditure of PHS-awarded funds, Skidmore College is not required to submit an FCOI report to the PHS Awarding Component.

**Submission of FCOI Reports during ongoing PHS-funded Research**: For any FCOI that Skidmore College identifies during an ongoing PHS-funded research project (such as, upon participation of an Investigator who is new to the project, or for newly identified FCOIs for existing Investigators), Skidmore College will provide to the PHS Awarding Component, within 60 days, an FCOI report regarding the FCOI and ensure that a management plan has been implemented.

**Annual FCOI report:** For any FCOI previously reported by Skidmore College, Skidmore College will provide an annual FCOI report that addresses the status of the financial interest and any changes to the management plan. Annual FCOI reports will specify whether the FCOI is still being managed or explain why the FCOI no longer exists. Annual FCOI reports must be submitted to the NIH (e.g., through the eRA Commons for grants and cooperative agreements) for the duration of the project period (including extensions with or without funds) at the same time as when Skidmore College is required to submit the annual progress report (i.e., two months prior to the start date or 45 days prior to the start date of the noncompeting continuation award), including a multi-year funded progress report, or at the time of the extension (e.g., submission of an extension notification in the eRA Commons or submission of a NIH prior approval request, whichever is applicable). The annual FCOI report is not to be submitted as part of the annual progress report. The annual FCOI report is submitted separately through the eRA Commons FCOI Module.

All FCOI reports must include the following information:

- Grant/Contract Number;
- Project Director/Principal Investigator (PD/PI) or Contact PD/PI;
- Name of Investigator with FCOI;
- Whether FCOI was managed, reduced or eliminated;
- Name of the entity with which the Investigator has a FCOI;
- Nature of FCOI (e.g., equity, consulting fees, travel reimbursement, honoraria);
- 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
- A description of how the financial interest relates to PHS-funded research and the basis for Skidmore College's determination that the financial interest conflicts with such research;
- Key elements of the Skidmore College management plan; and
- An FCOI report for any FCOIs identified for subrecipient Investigators.

### VII. Management Plans for Financial Conflicts of Interest

Prior to Skidmore College's expenditure of any funds under a PHS-funded research project, the Skidmore College designated official(s) will review all Investigator disclosures of Significant Financial Interests; determine whether any SFIs relate to PHS-funded research; determine whether an FCOI exists; and, if so, develop a management plan that specifies the actions that have been and will be taken to manage the FCOI.

The key elements of the management plan include:

- The role and principal duties of the conflicted Investigator in the research 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
- Examples of conditions or restrictions that might be imposed to manage an FCOI include, but are not limited to:
  - Public disclosure of financial conflicts of interest (e.g., when presenting or publishing research);
  - For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
  - Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias, resulting from the FCOI;
  - Modification of the research plan;
  - Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
  - Reduction or elimination of the financial interest (e.g., sale of an equity interest); and
  - Severance of relationships that create financial conflicts.

Updated or annual FCOI reports must include the status of the management plan (i.e., whether the financial conflict is still being managed or explain why the financial conflict no longer exists) and a description of any changes to the management plan since the last FCOI report was submitted to the PHS Awarding Component.

The NIH may, at any time, request additional information regarding all conflicting interests identified by Skidmore College and how those interests have been managed, reduced or eliminated to protect the research from bias and may inquire into Skidmore College's procedures and actions regarding FCOIs in research funded by NIH, including a requirement for submission, or review on site, of all records pertinent to compliance with the regulation.

## VIII. <u>Retrospective Review and Mitigation Reports</u>

Whenever an FCOI is not identified or managed in a timely manner, including:

- Failure by the Investigator to disclose a Significant Financial Interest that is determined by the Institution to constitute an FCOI;
- Failure by the Institution to review or manage such an FCOI; or
- Failure by the Investigator to comply with an FCOI management plan.

Skidmore College will, within 120 days of Skidmore College'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.

Skidmore College will document the retrospective review, which will include at least 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 an FCOI;
- 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, etc.);
- Findings of the review; and
- Conclusions of the review.

If bias is found, Skidmore College will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report will include, at a minimum, the key elements documented in the retrospective review above, a description of the impact of the bias on the research project, and Skidmore College's plan of action or actions taken to eliminate or mitigate the effect of the bias (i.e., 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, Skidmore College will submit FCOI reports annually as prescribed by the regulation.

# IX. Public Accessibility of FCOI Policy and FCOI Information

Skidmore College makes its policy on Financial Conflict of Interest in PHS-Funded Research publicly available via this web site:

http://www.skidmore.edu/sponsored\_research/policiesandprocedures/financialconflictofinterest\_ph s.php Skidmore College will make information available concerning identified FCOIs by Senior / Key personnel by a written response to any requestor within 5 business days of a request made to <u>mhoehn@skidmore.edu</u>. Skidmore College will update such information as specified by the HHS rules. This information will include:

- The name of the Investigator;
- 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 or a statement that the interest is one whose value cannot be readily determined through reference to public process or other reasonable measures of fair market value.

In situations where Skidmore College is working with a subrecipient, it is Skidmore College's responsibility to make FCOI information publicly accessible. However, when the subrecipient Investigator is required to comply with the subrecipient's FCOI policy, the subrecipient Institution will also make FCOI information publicly accessible. In these situations, Skidmore College can consider including the requirement for the subrecipient Institution to make FCOI information publicly available as part of the subaward agreement.

## X. Implementation of Financial Conflict of Interest Requirements for PHS-Funded Research

Skidmore College will:

- Solicit and review SFI disclosure statements from each Investigator who is planning to participate in, or is participating in, PHS-funded research, no later than at the time of application;
- Provide guidelines to the designated official(s) to identify FCOIs;
- Establish a process to review all SFI, determine if they relate to PHS-funded research and determine if an FCOI exists, prior to Skidmore College's expenditure of funds;
- Inform each Investigator of Skidmore College's Policy as well as the PHS FCOI regulation;
- Inform each Investigator of his/her disclosure responsibilities and procedures for doing so;
- Provide guidelines for enforcement mechanisms and sanctions where appropriate;
- Proceed with appropriate actions to manage, reduce, or eliminate any FCOIs. Management of an FCOI requires development and implementation of a management plan;
- Complete and document a retrospective review, as necessary, and, if bias is found, develop and submit a monitoring plan and a mitigation report, pursuant to 50.605(a) and 50.605(b)(2);
- Maintain records of all financial disclosures and all actions taken by Skidmore College with respect to each FCOI as follows:

- in the case of grants or cooperative agreements, 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) for different situations; and
- 2. in the case of research contracts, for three years after final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7.
- Establish adequate enforcement mechanisms and provide for sanctions where appropriate;
- Certify, in each application for funding to which the regulation applies, that the Institution has a written and enforced administrative process to identify and manage, reduce, or eliminate conflicting interests with respect to all research projects for which funding is sought from the PHS;
- Prior to the time of application, require that each Investigator who is planning to participate in the research has submitted to the Institutional designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children) 1) that would reasonably appear to be affected by the research for which funding is sought; and 2) in entities whose financial interest would reasonably appear to be affected by the research;
- Report the existence of any FCOI to the PHS Awarding Component accurately and in a timely manner as required by the regulation;
- Prior to the Institution's expenditure of any funds under the award must report to the PHS Awarding Component the existence of an FCOI (but not the nature of the interest or other details) found by Skidmore College and ensure that the conflicting interest has been managed, reduced, or eliminated;
- For any FCOI that Skidmore College identifies subsequent to the Skidmore College's initial report under the award, Skidmore College must report the FCOI and manage, reduce, or eliminate it, at least on an interim basis, within 60 days of that identification; and
- Make information available upon request to the NIH regarding all FCOIs identified by Skidmore College and how those conflicting interests have been managed, reduced, or eliminated.

### XI. <u>Requirements for Reporting and Managing FCOIs in Research funded by NSF</u>

For research funded or proposed for funding by the National Science Foundation (NSF), the term "investigator" means the Principal Investigator, co-Principal Investigators, and any other person at Skidmore College who is responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding by NSF.

For NSF-funded research, Skidmore College has chosen to apply the definition of "Significant Financial Interest" as used in the PHS FCOI regulation, as it relates to remuneration and equity interests in publicly-traded and non-publicly traded entities, and as it relates to intellectual property rights and interests. However, unlike for PHS-funded projects, Skidmore College is not requiring Investigators on NSF-funded projects to report reimbursed or sponsored travel. See Section II of this Policy for the definition of "Significant Financial Interest."

Each Skidmore College Investigator must disclose to Skidmore College 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.

Investigators must disclose to Skidmore College their Significant Financial Interests (SFIs) (and those of their Spouse and Dependent Children):

- 1. at the time a proposal is submitted to the National Science Foundation;
- 2. as new reportable SFIs are obtained; and
- 3. at least annually during the period of award.

A conflict of interest exists when the designated Skidmore College official reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of NSF-funded research or educational activities.

The designated Skidmore College official will review Investigator's financial disclosures, determine whether a conflict of interest exists, and determine what conditions or restrictions, if any, should be imposed by Skidmore College to manage, reduce, or eliminate the conflict of interest. If the designated Skidmore College official 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 interest of scientific progress, technology transfer, or the public health and welfare, then the Skidmore College official may allow the research to go forward without imposing such conditions or restrictions.

Skidmore College will take reasonable steps to ensure that subawardees, contractors, or collaborators on Skidmore College research projects have their own FCOI policies in place that meet NSF's COI policy standards or that Investigators working at those entities follow Skidmore College's FCOI policy.

Skidmore College Investigators who receive NSF subawards: If Skidmore College will be a subrecipient/subcontractor to another entity on an NSF award/contract, a Skidmore College Investigator or department may receive a form from the prime grantee/contractor asking Skidmore College to certify whether Skidmore College will use its own FCOI policy or whether Skidmore College will use the prime recipient/contractor's policy. The answer is always that Skidmore College uses its own FCOI policy. Skidmore College does not agree to use or follow any other entity's FCOI policy, forms, or procedures.

Skidmore College will use the NSF FastLane System to notify NSF of any conflict of interest that cannot be managed, reduced or eliminated.

Skidmore College will keep NSF's Office of the General Counsel appropriately informed if Skidmore College finds that it is unable to satisfactorily manage a conflict of interest.

Skidmore College will maintain records of all financial disclosures and of all actions taken to resolve conflicts of interest for at least 3 years beyond the termination or completion of the grant to which they relate, or until the resolution of any NSF action involving those records, whichever is longer.

## XII. Sanctions

Note: this section pertains to research funded by both the Public Health Service and the National Science Foundation

Failure by an individual to comply with the terms of this policy, to file a complete and truthful financial disclosure for pending proposals, or when a new financial interest is obtained, or failure to comply with any conditions or restrictions directed or imposed, including failure to cooperate with appointed project monitoring bodies, will be grounds for discipline. Agreements with consultants who either fail to file a complete disclosure or fail to comply with any conditions or restrictions imposed may be terminated. Similarly, agreements with subrecipient organizations may be terminated if that organization fails to comply with its obligations under the PHS regulations.

In any case in which the U.S. Department of Health and Human Services determines that a PHSfunded research 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 Skidmore College as required by the PHS regulation, Skidmore College will require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and request an addendum to previously published presentations.

## Effective date of this policy: August 24, 2012