

Financial Conflict of Interest (FCOI) Policy

Background: On August 25, 2011, the Department of Health and Human Services amended its regulations related to financial disclosure. These regulations are contained in 42 CFR 50 Subpart F and 45 CFR 94 (2011 Revised FCOI Regulation). All institutions applying for U.S. Public Health Service (PHS) funding for research are required to have a policy that complies with these amended regulations. The guidelines below define Davidson College policy and procedures regarding conflicts of interest in relationship to sponsored projects funded by PHS. The Davidson College policy fulfills the requirements of grantee institutions as put forth in the 2011 Revised FCOI Regulation.

Purpose: In accordance with federal regulations, the College has a responsibility to manage conflicts of interest that arise in the course of projects funded by the U.S. government. The objective of this policy and the federal regulations on which it is based is to promote "objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under [federal grants] will be biased by any conflicting financial interest of an Investigator"(45 CFR 50.601). Further, the policy protects the credibility and integrity of the College's faculty and staff so that public trust and confidence in the College's sponsored activities is ensured.

Policy: The College requires that Investigators disclose Significant Financial Interests when applying for external grant funding as well as during the award period. Each Investigator doing PHS-funded research must complete the College's FCOI training.

This policy applies to all Investigators of the College who are involved with PHS-funded research. The Institutional Official is responsible for ensuring implementation of this policy and may suspend all relevant activities until the Financial Conflict of Interest is resolved or other action deemed appropriate by the Institutional Official is implemented. Violation of any part of these policies may also constitute cause for disciplinary or other administrative action pursuant to College policy.

Definitions

Conflict of Interest Committee (COI Committee) means the College's committee that advises the Institutional Official on conflict of interest matters. The committee consists of: Chair, Human Subjects IRB; Chair, Professional Affairs Committee; Chair, Professional Conduct Committee; General Counsel; Director, Grants and Contracts; Controller.

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

Family means any member of the Investigator's immediate family, specifically, spouse, domestic partner and dependent children.

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

copyrights), upon receipt of royalties or other income related to such intellectual property rights and interests.

Financial Interest does NOT include:

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

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

Significant Financial Interest (SFI) means a Financial Interest that reasonably appears to be related to the Investigator's Institutional Responsibilities, and:

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

Conflict of Interest means there is a divergence between an individual's private interests and his/her professional obligations to the College such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise.

Financial Conflict of Interest (FCOI) means a Significant Financial Interest (or, where the Institutional Official requires disclosure of other Financial Interests, a Financial Interest) that the Institution reasonably determines could directly and significantly affect the design, conduct or reporting of PHS-sponsored research.

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.

Institutional Official means the individual within the Institution that is responsible for the solicitation and review of disclosures of Significant Financial Interests including those of the Investigator's Family related to the Investigator's Institutional Responsibilities. For the purposes of this policy, the

Institutional Official is designated as the Vice President for Academic Affairs/Dean of Faculty acting through the Director of the Office of Grants and Contracts.

Institutional Responsibilities mean an Investigator's professional responsibilities on behalf of Davidson College, and as defined by Davidson College, including, but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as the Institutional Review Board.

Senior/Key Personnel means the Project Director/Principal Investigator (PD/PI) and any other person *identified* as senior/key personnel by Davidson College in the grant application, progress report, or any other report submitted to the funding agency by Davidson College under the regulation.

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

Research means a systematic investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

Investigator Responsibilities

Through implementation of the FCOI regulation by Davidson College, an Investigator is responsible for complying with Davidson's FCOI policy and procedures, completing training on FCOI, and for disclosing the required information to Davidson College whether the Investigator is planning to participate in or is participating in PHS-funded research. Every Investigator has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raising questions of conflict of interest arises, an Investigator should discuss the situation with the Institutional Official.

Training

Each Investigator (including senior/key personnel) on projects funded by or proposed to NIH or other Public Health Service (PHS)-affiliated agencies must complete the College's FCOI training:

- Prior to engaging in research related to any PHS-funded project;
- At least every four years, and
- Immediately when any of the following circumstances apply:
 - The College revises its policy in a manner that affects the Investigator;
 - An Investigator is new to the College; or
 - The College finds an Investigator is not in compliance with the College's policy or management plan.

Disclosure of Financial Interests

To comply with federal law and federal regulations, Investigators must complete and submit the College's Investigator Disclosure of Financial Interests in Research to the Office of Grants and Contracts prior to submission of a PHS-funded research grant application.

What Must Be Reported

The FCOI regulation covers all Financial Interests of monetary value, whether or not the value is readily ascertainable. Investigators seeking external research support must disclose all Significant Financial Interests (SFI) of the Investigator (and those of the Investigator's spouse, domestic partner, and/or dependent children):

- (1) that reasonably appear to be related to the Investigator's institutional responsibilities;
- (2) involving any reimbursed or sponsored travel related to the Investigator's institutional responsibilities as required in the regulation.

When The Form Must Be Completed

- (1) No later than at the time of application for PHS-funded research;
- (2) Within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI; and
- (3) At least annually, in accordance with the specific time period prescribed by Davidson College, during the period of award.

Review and Monitoring Process

If the disclosure form reveals a Significant Financial Interest, it will be reviewed promptly by the Institutional Official or designee for a determination of whether it constitutes a Financial Conflict of Interest. If a Financial Conflict of Interest exists, the Institutional Official will take action to manage the financial conflict of interest including the reduction or elimination of the conflict, as appropriate. The Institutional Official may consult the COI Committee for guidance in specific cases, or in the application of the policy to particular situations.

A Financial Conflict of Interest will exist when the Institutional Official or designee determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS-sponsored research. If the Institutional Official determines that there is a Financial Conflict of Interest that can be managed, he or she must develop and implement a written management plan. The affected Investigator must formally agree to the proposed management strategies and sign the written management plan before any related PHS-sponsored research goes forward.

The Institutional Official will periodically review the ongoing activity, monitor the conduct of the activity (including use of students and postdoctoral appointees), to ensure open and timely dissemination of the research results, and to otherwise oversee compliance with the management plan.

Whenever an FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose an SFI, failure by the College to review or manage an FCOI, or failure to comply with the management plan, the College shall, within 120 days of the determination of noncompliance, complete a retrospective review of the Investigator's activities and the project to determine bias in the design, conduct or reporting of such research. If bias is found, the College will complete a Mitigation report describing the impact of the bias on the research project and the College's plan of action taken to eliminate or mitigate the effect of the bias.

Reporting to PHS

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

Subrecipients

The College is responsible for ensuring all subrecipients' compliance with the applicable federal regulations regarding Financial Conflicts of Interest. To this end, the College shall enter a written agreement with each subrecipient that shall specify whether this policy, or the applicable policy of the subrecipient's institution, will apply to subrecipient Investigators. Said agreement will specify the timing for reporting of FCOIs by subrecipients to Davidson College to enable the timely review and reporting of such FCOIs in compliance with funding agency requirements.

Record Retention

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

Confidentiality

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the Institution may be required to make such information available to PHS, to a requestor of information concerning financial conflict of interest related to PHS funding or to the primary entity who made the funding available to the Institution, if requested or required. If the Institution is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

Public Accessibility

Prior to the expenditure of funds, Davidson College, through the Office of Grants and Contracts, will, via response to requestor within five business days of the request, ensure public accessibility of information about any Significant Financial Interest that meets the following criteria:

- a) The Significant Financial Interest was disclosed and is still held by the Investigator;
- b) A determination has been made that the Significant Financial Interest is related to the PHS-funded research; and
- c) A determination has been made that the Significant Financial Interest is a Financial Conflict of Interest.

The information to be made available shall be consistent with the requirements of the PHS regulation.

Additional resources:

Financial Conflict of Interest (FCOI) regulation 42CFR Part 50 Subpart F - Grants :

<http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=992817854207767214895b1fa023755d&rgn=div5&view=text&node=42:1.0.1.4.23&idno=42#42:1.0.1.4.23.6>

Financial Conflict of Interest (FCOI) regulation 45 CFR Part 94 - Contracts: <http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=992817854207767214895b1fa023755d&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45>

<http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=992817854207767214895b1fa023755d&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45>

Frequently Asked Questions: Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought: <http://grants.nih.gov/grants/policy/loi/>

National Science Foundation Proposal and Award Policies and Procedures Guide (PAPPG), January 2017, [Conflict of Interest Policies](#).

Related Davidson College Policies:

[Responsible Conduct of Research Policy](#)

[Policy on Ethical Conduct in Research and Scholarship](#)

[Human Subjects IRB](#)

[Animal Care and Use in Research](#)

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