

COLGATE UNIVERSITY
PHS/NIH Financial Conflict of Interest Policy

INTRODUCTION

The Department of Health and Human Services amended its regulations related to financial disclosure on 8/25/2011. All institutions applying for funding by the National Institutes of Health (NIH) and other entities of the Public Health Service (PHS) are required to have a policy compliant with these amended regulations. This *PHS/NIH Financial Conflict of Interest Policy* is designed to comply with the federal regulations and hereby incorporates by reference 42 CFR chapter I, subchapter D, part 50.

This policy is adopted in addition to and as a supplement to the Colgate University institutional “Policy of Investigator Conflict of Interest” (adopted April 1996).

These guidelines define general Colgate University policy and procedures regarding conflicts of interest in relationship to sponsored projects funded by the Public Health Service. Their purpose is to protect the credibility and integrity of the University's faculty and staff so that public trust and confidence in the University's PHS-funded sponsored activities is ensured.

This policy applies to all Investigators of the University (as defined by the policy) 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 University policy.

DEFINITIONS

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

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 Colgate University;
- 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; U.S. 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 for Colgate University. This includes travel that is paid on behalf of the Investigator rather than reimbursed, even if the exact monetary value is not readily available. It excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers.

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

- a) if with a publicly traded 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 related to intellectual property rights and interests not reimbursed through the Institution.

Financial Conflict of Interest 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 Institutional research.

Institutional Official means the individual within the Institution that is responsible for the solicitation and review of disclosures of significant financial interests including those of the Investigator's Family related to the Investigator's institutional responsibilities for Colgate University. For the purposes of this policy, the Institutional Official is designated as the Associate Provost.

Institutional responsibilities means the Investigator's responsibilities on behalf of Colgate University, which are defined by the University as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as institutional review boards (IACUC, IBC, and IRB).

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, senior scientists, or graduate students. The definition may also include collaborators or consultants as appropriate.

Public Health Service or PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, the National Institutes of Health and the Centers for Disease Control.

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).

CONFLICT OF INTEREST:

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

1) DISCLOSURE OF FINANCIAL INTERESTS

All Investigators are required to disclose their outside financial interests to the University on an annual and on an ad hoc basis, as described below, using the Significant Financial Interest Disclosure Form. Forms are available on the Corporate, Foundation and Government Relations website.

The Project Director or Principal Investigator (PD/PI) on a proposed PHS/NIH application for funding is responsible for obtaining a PHS/NIH Financial Conflict of Interest Disclosure Form for all participating Investigators.

The Institutional Official is responsible for the receipt, processing, and review of disclosure forms. Completed disclosure forms are retained by the Office of Corporate Foundation and Government Relations.

Regardless of the disclosure requirements, the Investigator, in his or her own best interest, is encouraged to disclose any other financial or related interest that could present an actual conflict of interest or be perceived to present a conflict of interest.

Investigators provide the following information for all Significant Financial Interests: name of the entity, nature of the financial interest, the monetary value of the financial interest or its approximate value, and any supporting documentation needed to make a determination of whether a FCOI exists.

a) Annual Disclosures

All Investigators must disclose their Significant Financial Interests to the University, through the Institutional Official, at least annually during the grant period; normally this must be done within 30 days after the anniversary date of the Notice of Award (NOA).

b) Ad hoc Disclosures

In addition to annual disclosure, certain situations require ad hoc disclosure.

All Investigators involved with PHS-funded research must disclose their Significant Financial Interests to the University, through the Institutional Official, within 30 days of their initial appointment or employment.

Prior to submitting grant proposals for PHS funding or entering into subaward agreements for PHS-funded research, each Investigator must submit to the Institutional Official an ad hoc updated disclosure of his or her Significant Financial Interests. The Institution will not submit a research proposal unless the Investigator(s) have submitted such ad hoc disclosures.

In addition, all Investigators must submit to the Institutional Official an ad hoc disclosure of any Significant Financial Interest they acquire during the course of the year within thirty (30) days of discovering or acquiring the Significant Financial Interest.

c) Travel

Investigators must also disclose reimbursed or sponsored travel related to their institutional responsibilities, as defined above in the definition of Financial Interest. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The Institutional Official will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a Financial Conflict of Interest with the Investigator's research.

2) REVIEW AND DECISION OF THE INSTITUTIONAL OFFICIAL

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

A Financial Conflict of Interest will exist when the Institutional Official or designee determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS-supported research. If the Institutional Official determines that there is a Financial Conflict of Interest that can be managed, he or she must require and approve a written management plan before any related research goes forward. The affected Investigator is responsible for developing and submitting a proposed management plan, in consultation with the Institutional Official.

Examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to: (1) public disclosure of significant financial interests; (2) appointment of independent monitor(s) capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest; (3) modification of the research plan; (4) change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research; (5) reduction or elimination of the financial interest (e.g., sale of an equity interest); or (6) severance of relationships that create financial conflicts.

For all management plans, the University is required to monitor Investigator compliance with

the management plan on an on-going basis until the completion of the PHS-funded research project.

To address complex situations, oversight committees may be established by the Institutional Official to periodically review the ongoing activity, to 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.

3) REPORTING TO PHS

Should any reported conflict or non-compliance require reporting to PHS, the Institutional official or designee will report in accordance with PHS regulations. If the funding for the Research is made available from a prime PHS-awardee, such reporting shall be made available to the prime awardee such that they may fulfill their reporting obligations to the PHS.

Prior to expending any funds under an PHS funded grant, cooperative agreement or contract, or subaward where the prime award is funded by a PHS entity, the University must report to the applicable PHS funding agency (or the prime awarded) the existence of any FCOI (as defined above) and assure that the University has implemented a management plan in accordance with the FCOI Regulations.

If the University identifies a FCOI and eliminates it prior to the expenditure of any PHS-awarded funds, the University is not required to submit a FCOI report to the respective agency.

4) INVESTIGATOR NON-COMPLIANCE

a) Disciplinary Action

In the event of an Investigator's failure to comply with this Policy, the Institutional Official will notify the Provost and Dean of the Faculty who may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Institutional Official is implemented.

The Provost and Dean of the Faculty's decision to impose sanctions on an Investigator because of failure to comply with this Policy, or failure to comply with the decision of the Institutional Official, will be described in a written explanation of the decision to the investigator, and, where applicable, the IRB, and will notify the individual of the right to appeal the decision to the President.

b) Retrospective Review

In addition, if the Institutional Official determines that a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a Significant Financial Interest that is determined to be a Financial Conflict of Interest, or failure by an Investigator to materially comply with a management plan for a Financial Conflict of Interest, a committee appointed by the Institutional Official

will complete a retrospective review of the Investigator's activities and the research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research.

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

The Institutional Official or designee will update any previously submitted report to the PHS or the prime PHS-awardee relating to the research, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. If bias is found, the report will include a mitigation report in accordance with the PHS regulations, including a description of the impact of the bias on the research project and the plan of action to eliminate or mitigate the effect of the bias.

5) TRAINING

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

6) RECORD RETENTION

The Office of Corporate, Foundation and Government Relations 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.

7) CONFIDENTIALITY

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the Institution may make such information available to an agency funding research of the faculty member, 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.

8) PUBLIC ACCESSIBILITY

Prior to the expenditure of funds, the Institution, through the Office of Corporate, Foundation and Government Relations, will ensure public accessibility of information about any FCOI, via response to requestor within five business days of the request, information concerning 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 policy.

9) REGULATORY AUTHORITY

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