

COLGATE UNIVERSITY
Policy of Investigator Financial Conflict of Interest

Introduction and Application

Colgate University has adopted this policy to insure the appropriate management of actual or potential financial conflicts of interest. This policy is also the basis for specific certifications the National Science Foundation, the Public Health Service, and other governmental agencies require from those seeking grant support.

The policy applies to all Colgate University faculty and staff. It also applies to Investigators carrying out externally-funded research for subgrantees or contractors.

Policy

It is the policy of Colgate University that each Investigator disclose any significant financial interests (including those of the Investigator's spouse and dependent children) that would reasonably appear to be affected by research or educational activities funded or proposed for funding by an external agency; or any interest in entities whose financial interests would reasonably appear to be directly and significantly affected by such activities.

Conflicts of interest frequently are matters of degree and judgment, and Colgate University expects faculty and staff to be alert to the possible effect of outside activities on the integrity of decisions and on the ability to fulfill obligations to the institution or to funding agencies. As potential or actual conflicts of interest arise, the Dean of Faculty and Provost will determine which conditions or restrictions might be required to manage, reduce or eliminate actual or potential conflicts of interest. These may include one or more of the following:

- Making public disclosure of significant financial interest;
- Monitoring of the research activities by independent reviewers;
- Modifying the research plan;
- Disqualifying the Investigator(s) from participation in the portion of the funded research that would be affected by the significant financial interests;
- Securing the divesture of the significant financial interests; or
- Severing the relationships that create actual or potential conflicts.

The Dean of the Faculty and Provost will balance the potential negative impact of the conflict of interest against the public purpose to be served by the research. If the Dean of the Faculty and Provost determines that imposing conditions or restrictions would have an unwarranted impact on the interest of scientific progress, technology transfer, or the public health and welfare, he or she may allow the research to go forward with other condition or restriction.

The Dean of the Faculty and Provost will be responsible for seeing that all faculty and staff are aware of the University's investigator financial conflict of interest policy.

Definitions

1. Conflict of Interest

A conflict of interest may take various forms, but arises when a significant financial interest may affect the design, conduct, or reporting of research, or when an Investigator is or may be in a position to influence the business of the college, research, or other decisions in ways that could lead to any form of personal gain for the Investigator, or for any member of the Investigator's family (spouse and/or dependent child).

2. Investigator

"Investigator" means the principal Investigator, co-principal Investigators and any other person who is responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding by an external agency.

3. Significant Financial Interest

"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 interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights).

The term may apply when:

- a. The faculty member or a member of his or her immediate family (spouse and dependent children) is an officer, director, partner, trustee, employee, advisory board member, or agent of an external organization or corporation funding a sponsored project, providing goods and services under a sponsored project in which the faculty member is participating in any capacity, or whose financial interests would reasonably appear to be affected by the sponsored project.
- b. The faculty member or a member of his or her immediate family (together or separately) is the actual or beneficial owner or more than five percent (5%) of the voting stock or controlling interest of such organization or corporation.
- c. The faculty member or a member of his or her immediate family (together or separately) has dealings with such organization or corporation from which he or she derives income or more than \$10,000 per year, exclusive of dividends and interest.

The term does not include:

- a. income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- b. income from service on advisory committees or review panels for public or nonprofit entities;
or

- c. financial interests in business enterprises or entities if the value of such interests does not exceed \$10,000 or does not represent more than a 5% ownership interest for any one enterprise or entity, for the Investigator and the Investigator's spouse and dependent children together.

Procedures for Conflict of Interest Review

1. Faculty* Seeking External Funding

Any faculty or staff member seeking to submit an external proposal must make the financial disclosures required by this policy by the time the proposal is submitted to the external agency. These disclosures can be made using the financial disclosure form available in the Office of Corporate, Foundation, and Government Relations. This form requires individual faculty members to certify that they have read and understood this conflict of interest policy, that they have made all required disclosures, and that they agree to comply with any conditions or restrictions imposed by Colgate University to manage an actual or potential conflict of interest. Faculty should submit the form to the Associate Provost. It is the responsibility of the faculty member to see that the form signed by the Associate Provost is received by the Office of Corporate, Foundation, and Government Relations in time to complete the regular processing of external applications.

Investigators performing research for subgrantees or contractors of the University may comply with this policy either by following the procedure outlines for faculty and staff, or by providing the University with an appropriate assurance from their employer.

2. Initial Review by the Associate Provost

All disclosure statements will be reviewed initially by the Associate Provost. The purpose of this review is to determine whether or not a potential conflict is being reported, and then to gain a better understanding of the nature and extent of the conflict, and explore options for managing it. A list of sample questions the Associate Provost may pursue in making his or her determination is included here as Appendix A.

If the Associate Provost finds there is a possible conflict of interest at the time of application, he or she may include a recommendation for elimination or mitigation of the conflict with the disclosure form, and forward it to the Dean of the Faculty and Provost. However, if necessary for timely submission of a proposal, the dean may postpone his or her recommendation for up to one month to allow time for consultation with the faculty member. In this case, the dean will indicate the possibility of conflict and forward the disclosure form immediately to the Dean of the Faculty and Provost. The dean will be responsible for submitting a plan for elimination or mitigation of the apparent conflict within the following 30 days.

* In the section "Procedures for Conflict of Interest Review," the term "faculty" applies to faculty members and/or any other employee who is applying for or serving on a federal grant as a PI or project director. – *Office of Corporate, Foundation, and Government Relations, 5/2010.*

3. Second Level Review by the Dean of the Faculty and Provost

The Dean of the Faculty and Provost will make the final determination as to which financial conflicts can be managed in a way that protects the integrity of the science and of the University, and which cannot. A list of sample questions the Dean of the Faculty and Provost may pursue in reaching this decision is included here for illustration as Appendix B.

The Dean of the Faculty and Provost will review all disclosure statements which indicate the possibility of a conflict of interest, and will make the final determination as to whether or not a conflict of interest could directly and significantly affect the design, conduct, or reporting of the research. He or she will be responsible for approving all plans for the elimination or mitigation of a possible conflict, including specification of the conditions under which the award can be accepted. In the case where an apparent conflict exists, no grant funds will be expended until the Dean of the Faculty and Provost has approved a plan for eliminating or managing the conflict.

4. Appeal Process

Any Investigator who disagrees with the Dean of the Faculty and Provost's finding of a significant conflict of interest, or with the Dean of the Faculty and Provost's recommendation for managing, reducing, or eliminating the conflict, may appeal the decision using the established University Grievance procedure.

5. Non-Compliance

If an Investigator violates this policy, the Associate Provost will recommend to the Dean of the Faculty and Provost sanctions which range from a public letter or reprimand to dismissal. The Dean of the Faculty and Provost will make the final decision as to the sanctions to be invoked, following established procedures outlined in the Faculty Handbook.

In addition, the University will follow Federal regulations regarding the notification of the sponsoring agency in the event an Investigator has failed to comply with this policy. The sponsor may take its own action as it deems appropriate, including the suspension of funding for the Investigator until the matter is resolved.

If the conflict arises in connection with clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, the University will require disclosure of the conflicting interest in each public presentation of the results of the research.

6. Post-award Provisions

- a. Prior to the expenditure of any funds granted by divisions of the Public Health Service, the Dean of the Faculty and Provost will report the existence (but not the nature) of any conflict of interest, and an assurance that the conflict has been managed, reduced, or eliminated, to the awarding agency.
- b. Once he or she has received an award, a faculty member who obtains a new significant financial interest is responsible for reporting this fact to the Dean of the Faculty and Provost within 30 days of acquiring the interest.

- c. If the University determines that a conflict of interest exists after the grant period of a PHS award has begun, the Dean of the Faculty and Provost will report the existence (but not the nature) of the conflict and an assurance that it has been managed, reduced, or eliminated to the PHS, within 60 days identification of the conflict.
- d. If the University finds that it is unable to satisfactorily manage an actual or potential conflict of interest, the Dean of the Faculty and Provost will be responsible for keeping NSF or other awarding agencies appropriately informed.
- e. The University will retain records of all disclosures and actions taken to resolve actual or potential conflicts interest for at least three years after the completion of the relevant award, or the resolution of any government action involving the records, whichever is later.

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Appendix A Sample Questions for Initial Review

1. Has all relevant information concerning the faculty member's activities been acquired (i.e., has there been full disclosure)?
2. Do the faculty member's relevant financial interests exceed predetermined thresholds of acceptability, where specified?
3. Do the faculty member's reported external commitments exceed permissible levels?
4. Is there any indication the research results have not been faithfully and accurately reported?
5. Is there any indication that the faculty member in his or her professional role has improperly favored any outside entity or appears to have incentive to do so?
6. Has the faculty member inappropriately represented the institution to outside entities?
7. Does the faculty member appear to be subject to incentives that might lead to inappropriate bias?
8. Is there any indication that obligations to the university are not being met?
9. Could the faculty member's circumstances represent any possible violation of federal, state, or local laws and requirements?
10. Do the current engagements of the faculty member present any conflicts between outside interests (e.g., working on projects simultaneously for competing business entities)?

Appendix B:
Sample Questions for Second-Level Review

1. Will the negotiation of relevant research affiliations or other contracts be handled by truly disinterested representatives of the institution?
2. Will the research work plan receive independent peer review prior to its initiation?
3. Are there mechanisms in place to prevent the introduction of bias into research projects (i.e., Is the protocol double-blinded? Are research subjects randomly selected?)?
4. Will the project be supervised by someone with authority and no conflicting interest?
5. Are there means to verify research results (e.g., independent corroboration in another lab, FDA review)?
6. Will data and materials be shared openly with independent researchers? If not, who determines accessibility to such resources?
7. Will the product of the collaborative effort with an outside party be published in the peer-reviewed scientific literature?
8. Will the sponsorship and relevant interests receive acknowledgment in public presentations of the research results?