

HARVEY MUDD COLLEGE FINANCIAL CONFLICT OF INTEREST POLICY

A. INTRODUCTION

Harvey Mudd College (hereinafter called “College”) is committed to ensuring that academic freedom is preserved for its entire faculty. The intent of the Conflict of Interest (COI) Policy is to ensure that research, consulting and other professional work (“scholarly activity”) are performed with the highest ethical standards and that the interests of the College are protected as this work is pursued. Faculty are expected to be involved in legitimate private and public external activities. It is imperative for the College and its faculty members that the scholarly work that is carried out be free from any conflict of interest, whether real or perceived. The concern with COI reflects the complexity of our society, relations with each other and outside institutions, legal obligations and developments, and the significance of the issue to the public. This policy requires faculty to disclose possible conflicts of interest when they exist and to allow them to be assessed on a yearly basis or as needed basis if necessary. In this way the greatest possible freedom for academic work will be maintained, while preserving the College’s financial health and academic integrity. The Financial COI serves as a supplement to the Faculty Conflict of Interest Policy dated March 24, 2011. This supplement has been issued to address and comply with specific federal agency requirements listed below.

The financial COI policy is intended to be consistent with federal and state law. Where there is a discrepancy, the applicable federal or state law or rule of the funding agency will take precedence, unless the law or rule is less restrictive than the College’s institutional policies.

This policy governing financial COI applies to all sponsored Investigators of the College. The College Official is responsible for ensuring implementation of this policy and may suspend all relevant activities until the financial COI is resolved or other action deemed appropriate by the College Official is implemented. Violation of any part of these policies may also constitute cause for disciplinary or other administrative action pursuant to the College policy.

B. DEFINITIONS

Financial Conflict of Interest: A financial interest that could directly and significantly affect the design, conduct or reporting of funded research, or the performance of duties and responsibilities on behalf the College A financial COI can exist in a variety of situations, including the following examples:

- i. *Research:* A financial interest that could directly and significantly affect the design, conduct, or reporting of research. Financial COI is present in a situation in which a primary interest or responsibility is affected, perhaps unduly, by a secondary interest or responsibility. This means that a subjective component of a primary interest (e.g. research) is affected, or potentially affected, by a financial secondary interest, either ongoing (e.g. consulting) or where there is the potential for increased valuation (of stock or an option). Financial COI is present when the outcome of the research could affect future income or the value of an asset (including an option for equity).

- ii. *Education*: A financial interest that could directly and significantly affect a mentoring relationship or educational presentations. Examples of such presentations are lectures, web-based teaching, and review articles.
- iii. *Purchasing*: A financial interest that could directly and significantly affect a purchasing decision. Examples of such decisions are purchases of equipment, supplies, and services.

Investigator: Any person who is independently responsible for making decisions regarding research, education, purchasing, clinical care, or administrative responsibilities. For any one investigator, the policy includes a financial interest of any immediate family member or relative as if any financial interest of that family member or relative were one of the investigators. 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.

Family Member: The family or relative of a faculty member includes his or her spouse/registered domestic partner, ancestors, siblings (whether whole or half-blood), descendants (meaning for this purpose children (whether natural or adopted), and grandchildren), and spouses/registered domestic partners of such siblings and descendants, in-laws, and other persons living in the faculty member's household. The term also includes any other relative if the latter resides in the same household as the faculty member.

Research: Means a systematic investigation designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research and product development.

Business: Means any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint stock company, receivership, business or real estate trust, or any other legal entity organized for profit or charitable purposes and in which the College is not an equity owner or beneficiary.

Financial Interest: Means anything of monetary value received or held by an Investigator or an Investigator's Family or relative, 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 college 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: means a Financial Interest that reasonably appears to be related to the Investigator's College 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 College, or
- e) is reimbursed or sponsored travel related to their college responsibilities.

College Official: Means the individual within the College 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 College responsibilities. For the purposes of this policy, the College Official is designated as the Dean of Faculty.

College Responsibilities: Means the Investigator's professional responsibilities associated with his or her College appointment or position, such as research, teaching, clinical activities, administration, and institutional, internal and external professional committee service.

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.

C. 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 Investigators about situations that generate conflicts of interest related to research, provides mechanisms for Investigators and the College 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 College official.

1. DISCLOSURE OF FINANCIAL INTERESTS

All Investigators are required to disclose their outside financial interests as defined above to the College on an annual and on an as needed basis, as described below. The College official is responsible for the distribution, receipt, processing, review and retention of disclosure forms.

a. Annual Disclosures

All Investigators must disclose their Significant Financial Interests that are related to the investigator's college responsibilities to the College, through the College Official, on an annual basis. All annual disclosures should be submitted to the College Official.

b. Unscheduled Disclosures

In addition to annual disclosure, certain situations require an unscheduled disclosure. All Investigators must disclose their Significant Financial Interests to the College, through the College Official, within 30 days of their initial appointment or employment.

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

Prior to entering into a sponsored projects or applications for sponsored projects, where the Investigator has a Significant Financial Interest, the Investigator must certify the accuracy of the annual disclosure or submit to the College Official an updated disclosure of his or her Significant Financial Interests with the outside entity. The certification is required to be submitted by all Investigators to the Dean of Faculty on the Harvey Mudd College External Grants and Contracts Approval Form. The College will not submit a research proposal unless the Investigator(s) have submitted such certification or unscheduled disclosures.

It is the responsibility of the Investigator to ensure that each Investigator working under his or her direction on a research project or receiving support from his or her grant or contract makes the appropriate certification and/or disclosure and submits disclosure forms as required by this policy.

If a research project involves subgrantees, sub-recipients, contractors or collaborators, the subgrantee, subcontractor or collaborating institution must provide written assurances that a financial conflict of interest policy is in effect at that institution that is consistent with the requirements of any applicable federal regulations. If the contracting party cannot so certify, the agreement must state that the researchers are subject to this policy as covered individuals.

c. Travel

Investigators must also disclose reimbursed or sponsored travel related to their college responsibilities, as defined above in the definition of Financial Interest and Significant 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 College 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 College Official or designee for a determination of whether it constitutes a Financial Conflict of Interest. If a Financial Conflict of Interest exists, the College Official will take action to manage the financial conflict of interest including the reduction or elimination of the conflict, as appropriate.

A Financial Conflict of Interest will exist when the College Official or designee determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of sponsored research. If the College 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 sponsored research goes forward.

The College 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.

3. REPORTING TO FEDERAL AGENCIES

The College Official will report financial conflicts of interest or non-compliance to the federal awarding agency in accordance with agency regulations. Reports shall be made prior to the expenditure of any funds and within 60 days of any subsequently identified financial conflict of interest such that the College may fulfill their reporting obligations to the federal awarding agency.

4. INVESTIGATOR NON-COMPLIANCE

a) Disciplinary Action

In the event of an Investigator's failure to comply with this Policy, the College official may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the College official is implemented.

A College Official'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 College 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. The Investigator may pursue an appeal through the Research Committee. The College will promptly notify the federal awarding agency of the action taken or to be taken.

b) Retrospective Review

In addition, if the College 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, the Research Committee will complete a retrospective review of the Investigator's activities and the sponsored 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 College official will update any previously submitted report to the granting agency specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. This retrospective review will be completed in the manner and within the time frame established in the granting agency's regulations. If bias is found, the College will promptly notify the granting agency and submit a mitigation report in accordance with the agency regulations. The mitigation report will identify elements documented in the retrospective review, 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, the investigator's responsibilities regarding disclosure and the granting agency regulations prior to engaging in research funded by the agency, and at least every four years thereafter. They must also complete training within a reasonable period of time as determined by the College Official in the event that this Policy is substantively amended in a manner that affects the requirements of Investigators, if the investigator is new to the institution, 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 College Official 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 granting agency unless any litigation, claim, financial management review, or audit is started before the expiration of the three year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

7. CONFIDENTIALITY

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the College may be required to make such information available to the granting agency concerning financial conflict of interest related to agency funding if requested or required. If the College 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 College will publish on a publicly-accessible website or respond to any 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 senior and key personnel;
- b. A determination has been made that the Significant Financial Interest is related to the agency 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 granting agency's regulation.

9. REGULATORY AUTHORITY

This policy implements the requirements of [42 C.F.R. §50 Subpart F](#) Promoting Objectivity in Research and [45 C.F.R. §94](#) Responsible Prospective Contractors; where there are substantive differences between this policy and the requirements, the requirements shall take precedence.