



Significant Financial Conflict of Interest (FCOI) Policy Claremont McKenna College

(Applicable to all Federally Sponsored Research Proposals)

To mitigate potential Financial Conflicts of Interest (FCOI), Claremont McKenna College (CMC) has implemented a revised FCOI policy, as mandated by the Department of Health and Human Services. This policy supplements the general Conflict of Interest (COI) policies in the CMC Faculty Handbook, Section 10.2, (http://www.cmc.edu/dof/policies/Faculty_Handbook_July_2010.pdf) and the Keck Science Faculty Handbook, Section 4.2 (available in the Keck Science Department Office). This revised policy is applicable to investigators applying for or participating in federally funded research projects. The College requires all federal grant applicants and recipients, irrespective of funding agency, to be in compliance with the regulations below. Investigators are required to report all significant financial interests prior to the submission of a proposal. The College will determine whether these interests represent a conflict of interest as defined by the US Government Code of Federal Regulations (CFR). This document details compliance requirements effective August 24, 2012.

This policy document consists of three sections:

- **Section A** provides the relevant portion of the above-mentioned CFR. The CFR is the codification of the general and permanent rules published in the Federal Register by the executive departments and the agencies of the federal government.
- **Section B** explains what this policy means to faculty participating in federally funded research.
- **Glossary of Terms.**

A. From 42 CFR Part 50, Subpart F

Significant financial interest means:

(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. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

(3) The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution 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; or 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.

B. What does this mean to faculty at CMC?

1. The definition of “investigator” has been expanded to include the principal investigator, project director and “any other person, regardless of title or position, who is responsible for the design, conduct, and reporting of research,” which can include “collaborators or consultants.” CMC will review the financial interests of *all* research personnel including those not employed by CMC. Each person must sign CMC’s significant financial interest disclosure form or, if a subrecipient of a grant managed by another institution, must provide written assurance that his/her home institution certifies that they have a compliant FCOI policy and, furthermore, that the investigators will comply with that policy. All assurances must be received *prior* to the submission of a proposal.

Investigators must disclose their Significant Financial Interests to CMC on an annual basis. The FCOI form must be submitted annually.

2. The threshold values for significant financial interests have changed. Remuneration greater than \$5,000 from an entity and/or equity in a publicly traded entity must be disclosed. (The old threshold was \$10,000.) Additionally, *any* equity in a non-publicly traded entity must be disclosed. For the first time, travel sponsored or reimbursed by an outside entity must also be disclosed as a significant financial interest. (This excludes travel that is sponsored or reimbursed by federal, state, or local government agencies; research institutes affiliated with institutions of higher education; or certain academic medical centers.)
3. A CMC Sponsored Research Officer will review each disclosure to will determine whether the proposed research could affect the value of the significant financial interest or the value of the organization involved. Additionally, CMC will determine whether the SFI “could directly and significantly affect the design, conduct or reporting” of the research project. If it is determined that a financial conflict of interest exists, the institution will work with the PI to develop and implement a management plan to mitigate the effects within 60 days. CMC will document the investigators’ agreement to comply with the management plan and will monitor the investigators’ compliance throughout the duration of the project.
4. CMC will provide to the funding agency details of each FCOI as required, including the name of the involved party, the specific nature of the FCOI, the means by which the FCOI was determined and a detailed account of the management plan. CMC will also provide periodic reports per funding agency guidelines, indicating that the College is monitoring the implementation of and compliance to the management plan. For grants received from the Department of Health and Human Services, including the National Institutes of Health, annual FCOI reports must be filed in addition to the agency-mandated progress reports.
5. In situations of potential non-compliance, research-related misconduct will be handled through due process protection for faculty, in a matter consistent with the Faculty Handbook. If due process indicates that non-compliance exists, CMC may, among other actions, suspend all relevant activities. CMC may take additional disciplinary measures until the matter is resolved or other action deemed appropriate by CMC is implemented.

Additionally, 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, CMC 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, within 120 days.

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 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.

6. 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. Details regarding FCOI training will be provided to the investigator prior to grant submission. If a grant is funded, FOCI training will be further discussed during the pre-award meeting with the Sponsored Research Officer.
7. The Institutional 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 PHS or to the prime PHS awardee.
8. 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.
9. Prior to the expenditure of funds, the Institution 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:

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

10. 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.

DEFINITIONS

Family means any member of the Investigator's immediate family. As defined by the US Office of Personnel Management (75 FR 33491), this includes:

1. Spouse, and parents thereof;
2. Sons and daughters, and spouses thereof;
3. Parents, and spouses thereof;
4. Brothers and sisters, and spouses thereof;
5. Grandparents and grandchildren, and spouses thereof;
6. Domestic partner and parents thereof, including domestic partners of any individual in 2 through 5 of this definition; and
7. Any individual related by blood or affinity whose close association with the employee is the equivalent of a family relationship

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 Institution;
- 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. 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. This responsibility will reside in the Office of Sponsored Research.

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

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 senior scientists, postdoctoral associates, or 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 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).

Significant Financial Interest Disclosure

(Applicable to all Federally Sponsored Research Proposals)

Name/Title/Institution: _____

Address: _____

Phone: _____ Email: _____

Grant Proposal Title: _____

Role on the Grant (i.e., PI, Co-PI, post-doc, student, consultant, etc.): _____

I have received training from an authorized Sponsored Research Officer regarding all aspects of Claremont McKenna College's financial conflict of interest policy. I have also reviewed the NIH Office of Extramural Research online FCOI tutorial. <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>

I am disclosing the following significant financial interests as defined in 42 CFR Part 50, Subpart F. I am attaching supporting documentation that identifies the business enterprise or entity involved and the nature and amount of the interest:

- Salary or other payment for services (e.g., consulting fees or honoraria).
- Equity interests (e.g., stocks, stock options, or other ownership interests).
- Intellectual property rights (e.g., patents, copyrights, and royalties from such rights).
- Travel that is sponsored or reimbursed by an outside entity.
- Other significant financial interest of the investigator that possibly could affect or be perceived to affect the results of the research or educational activities funded or proposed for funding.
- I have no significant financial interests associated with this project.

Further I agree:

- I will comply with all aspects of CMC's FCOI policy.
- I will be notified if disclosure information is requested or required by any outside entity, including, but not limited to government agencies, auditors or funding agencies.
- To update this disclosure during the period of the award, either on an annual basis, or as new reportable significant financial interests are obtained. In the case of travel, the disclosure will occur no more than 30 days after the date of travel.
- To cooperate in the development of a plan to resolve any conflicts of interest.
- To comply with any conditions or restrictions imposed by the College to manage, reduce, or eliminate actual or potential conflicts of interests or to forfeit the award.

Signed: _____

Date: _____

(A "per" signature is not acceptable.)

Endorsements:

I have reviewed the significant financial interest disclosure and believe that it will be possible to mitigate any actual or potential financial conflicts of interest; and, therefore, I recommend that that proposal be submitted to the agency at this time.

Authorized Organizational Representative: _____

Signed

Date