

Significant Financial Conflict of Interest (FCOI) Policy

Overview

To mitigate potential Financial Conflicts of Interest (FCOI), Claremont McKenna College (“Institution”) has implemented an FCOI policy, as mandated by the Department of Health and Human Services (DHHS) and the National Science Foundation (NSF). This policy supplements the Institution’s general Conflict of Interest (COI) policy and is applicable to the Principal Investigator and/or any other individual who is responsible for the design, conduct, or reporting of federal sponsored research (“Investigator”).

As outlined in CFR 42 Part 50, Subpart F, Investigators involved in federally funded research must disclose all foreign and domestic Significant Financial Interests (SFIs), which means: A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's family) that reasonably appear to be related to the Investigator's institutional responsibilities:

- With regard to any publicly traded entity, an SFI exists if the value of any remuneration received from the entity in the 12 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;
- With regard to any non-publicly traded entity, an SFI exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's family, e.g., spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest);
- Intellectual property rights and interests (e.g., patents, copyrights) that exceed \$5,000 upon receipt of income related to such rights and interests;
- All foreign financial interests—which includes income from seminars, lectures, or teaching engagements; income from service on advisory committees or review panels; and reimbursed or sponsored travel received from any foreign entity, including foreign institutions of higher education or foreign governments (including local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of \$5,000).

Investigators also must disclose the occurrence of any reimbursed or sponsored travel in excess of \$5,000 (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 located in the United States, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher

education.

The term SFI 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 located in the United States, a United States Institution of higher education an academic teaching hospital, a medical center, or a research institute that is affiliated with a US institution of higher education; or
- Income from service on advisory committees or review panels for a Federal, state, or local government agency located in the United States, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. Institution of higher education.

The Institution will determine whether these SFIs represent a FCOI as defined by the U.S. Government Code of Federal Regulations (CFR) 42 CFR Part 50 Subpart F, applicable to Public Health Service grants and cooperative agreements.

Procedures and Guidance

Prior to submitting a federal grant application, within 30 days of discovering or acquiring a new SFI, and on an annual basis, each Investigator involved in federally funded research must complete the Institution's SFI Disclosure Form.

The Institution's Sponsored Research Officer with support from an Institutional Official from the Treasurer's Office ("Designated Institutional Officials") will review each disclosure and will determine whether the SFI could be affected by the research or is in an entity whose financial interest could be affected by the research and could be an FCOI. An FCOI exists when the Institution, through its Designated Institutional Officials, reasonably determines that an Investigator's SFI is related to a federally-funded research project (i.e., the SFI could be affected by the research or the SFI in an entity whose financial interest could be affected by the research) and could directly and significantly affect the design, conduct, or reporting of the federally-funded research.

If it is determined that an FCOI exists, the Institution will work with the Investigator to develop and implement a management plan to mitigate the effects prior to the Institution's expenditure of NIH funds authorized under the award (i.e., after the Notice of Award is issued and before the specific amount is charged to an NIH award.)

The mitigation plan will contain a description of the key elements of the Institution's management plan and will include the following:

- The role and principal duties of the conflicted Investigator in the research project;
- Conditions of the management plan;
- How the management plan is designed to safeguard objectivity in the research project;
- Confirmation of the Investigator's agreement to the management plan;
- How the management plan will be monitored to ensure Investigator compliance; and
- Other information as needed

Updated or annual FCOI reports will include the status of the management plan (i.e., whether the financial conflict is still being managed or explain why the financial conflict no longer exists) and a description of any changes to the management plan since the last FCOI report was submitted to the NIH.

The Institution will document the Investigator's agreement to comply with the management plan and will monitor the Investigator's compliance throughout the duration of the project. Conditions or restrictions that might be imposed to manage an Investigator's FCOI may include, but are not limited to:

- Public disclosure of FCOIs (e.g., when presenting or publishing the research; to staff members working on the project; to the Institution's Institutional Review Board(s), Institutional Animal Care and Use Committee(s), etc.;
- For research projects involving human subjects research, disclosure of FCOIs directly to participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- Severance of relationships that create financial conflicts

The Designated Institutional Officials will provide to the funding agency details of each FCOI as required, including the name(s) of the involved parties, the specific nature of the FCOI, the means by which the FCOI was determined, and a detailed account of the management plan. The Designated Institutional Officials will also provide periodic reports per funding agency guidelines, indicating that the Institution is monitoring the implementation of and compliance to the management plan. For all federal awards received, an annual FCOI report must be filed in addition to the agency-mandated progress reports. For NIH awards, the Institution will report the required information via the eRA Commons FCOI Module and will provide the information required by the regulation as stated in NIH's [FAQ H.5](#).

In situations of Investigator non-compliance, the Institution may, among other actions, suspend all relevant activities. The Institution may take additional disciplinary measures until the matter

is resolved or other action deemed appropriate by the Institution is implemented.

Additionally, if the Designated Institutional Officials determine that 1) an Investigator failed to disclose an SFI that is determined to be a FCOI, 2) an Investigator is not complying with a management plan for a FCOI, and/or 3) the Institution failed to review/manage an FCOI, the Institution shall within 120 days of the Institution's determination of noncompliance, complete a "retrospective review" of the Investigator's activities and the NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such research. The Institution shall document the retrospective review, which must include at least the following key elements:

- Project number;
- Project title;
- PD/PI or contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has a financial conflict of interest
- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.);
- Findings of the review; and
- Conclusions of the review

If bias is found, the Institution will notify NIH promptly and submit a mitigation report. If the FCOI was previously reported to the NIH, the mitigation report will be submitted as a "Revised FCOI Report." The mitigation report will include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias (i.e., impact on the research project, extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, the Institution will submit FCOI reports annually as prescribed by the regulation.

In addition to reviewing this policy with the Designated Institutional Officials prior to engaging in federally funded research, each Investigator must complete FCOI training within a reasonable period of time as determined by the Designated Institutional Officials and at least every four years thereafter. They must also complete training. Details regarding FCOI training will be provided to the investigator prior to grant submission. If a grant is funded, FCOI training will be further discussed during the pre-award meeting with the Designated Institutional Officials. FCOI training on the regulation and disclosure requirements will be completed through the [PHS FCOI tutorial](#).

The Designated Institutional Officials will retain all records of all Investigator disclosures of SFIs and the Institution's review of, or response to, such disclosure (whether or not a disclosure resulted in the Institution's determination of a FCOI), and all actions under the Institution's policy or retrospective review, if applicable, for at least three years from the date of submission

of the final expenditures report or, where applicable, from other dates specified in [45 C.F.R. 75.361](#) for different situations.

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 a federal agency that is funding the faculty member's research, to a requestor of information concerning FCOI related to federal 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.

Prior to the expenditure of funds, the Institution will respond to any requestor within five business days of the request, information concerning any SFI that meets the following criteria:

- The SFI was disclosed and is still held by the senior/key personnel;
- Determination has been made that the SFI is related to the federally funded research; and
- Determination has been made that the SFI is a FCOI

The information to be made available shall be consistent with the requirements of federal policy.

This policy implements the requirements of [CFR 42 Part 50, Subpart F](#) and [CFR 45 Part 94, Subchapter A](#); where there are substantive differences between this policy and the requirements, the requirements shall take precedence.

Definitions

Family means the Investigator's spouse and dependent children.

Financial Conflict of Interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of federally-funded research.

Investigator means any individual who is responsible for the design, conduct, or reporting of federal 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 means a Financial Interest that reasonably appears to be related to the Investigator's Institutional Responsibilities, and:

- 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
- 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
- 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
- Is income related to intellectual property rights and interests not reimbursed through the Institution.
- All foreign financial interests—which includes income from seminars, lectures, or teaching engagements; income from service on advisory committees or review panels; and reimbursed or sponsored travel received from any foreign entity, including foreign institutions of higher education or foreign governments (including local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of \$5,000).
- Any reimbursed or sponsored travel in excess of \$5,000 (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 located in the United States, a U.S. institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education.

