



POLITECNICO
MILANO 1863

Financial Conflict Of Interest (FCOI) Policy for Public Health Service (PHS) Funding

(in accordance with 42 CFR Part 50- Subpart F, and 45 CFR Part 9.)

I. PURPOSE & SCOPE

This Policy implements the 2011 Public Health Service (PHS) regulations on Promoting Objectivity in Research. The Policy is applicable to all PHS Research Activities with an award issue date of August 24, 2012, or later, and to proposals for research activities submitted to PHS on or after August 24, 2012. PHS Research Activities that are ongoing as of August 24, 2012 will become subject to this policy as additional funds are requested through submission of a progress report, competing renewal application, or proposal for supplemental funding. This Policy applies to the Principal Investigator and all other Investigators (regardless of position or title) who are responsible for the design, conduct or reporting of a PHS Research Activity. The Policy is applicable to all research activities supported by a PHS funder, most notably the National Institutes of Health (NIH), through a grant or cooperative agreement (either directly or via another institution as a sub-awardee), and by other sponsors and programs that specifically request review consistent with the PHS regulations on objectivity in research.

II. KEY DEFINITIONS

PHS means the Public Health Service of the United States Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health.

Investigator is defined as the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants. To ensure personnel are correctly identified for the purpose of policy compliance, consider the role of those involved rather than their title and the degree of independence with which they work.

Institutional Responsibilities are defined as an Investigator's professional responsibilities on behalf of the institution, e.g. research, research consultancy, teaching, professional practice, University committee memberships, service on panels such as ethical review boards.

A **Financial Conflict of Interest (FCOI)** exists when the institution, through its Designated Official (see below) reasonably determines that an Investigator's Significant Financial Interest is related to a PHS-funded research project and could directly and significantly affect the design, conduct or reporting of the PHS-funded research.

A **Significant Financial Interest (SFI)** is anything of monetary value that:

- meets the PHS thresholds (see Section IV below) for reporting received by the Investigator and, except for travel, received by the Investigator's spouse or registered domestic partner and dependent children for the following categories; and
- reasonably appears to be related to or is in the same field of expertise as the Investigator's Institutional Responsibilities.

Examples of SFIs include:

- Income or honoraria received for activities such as providing expert testimony or consulting services; serving on a board of directors, scientific advisory board, committee, panel or commission sponsored by a for-profit or non-profit organization, including professional or scholarly societies; acting in an editorial capacity for a professional journal, reviewing journal manuscripts, book manuscripts, or grant or contract proposals for a for-profit or non-profit organization; or salary received outside of the Politecnico di Milano.
- Any equity interest in a company that is developing, manufacturing or selling products or providing services used in an Investigator's clinical practice, teaching, research, administrative or committee responsibilities.
- Receipt of income from any organization other than the Politecnico di Milano for use or sale of patented or copyrighted intellectual property, such as software, textbooks, or other scholarly works for which royalties or licensing fees are received, including income from previous employers and other universities.
- The occurrence of travel by the Investigator which is reimbursed or sponsored by a for-profit or non-profit entity, *excluding* 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 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.

PHS means the Public Health Service of the United States Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health.

III. KEY STAFF INVOLVED

Key staff required to administer the policy are:

- All **Investigators**
- Each Investigator's **Head of Department (HoD)**

- The **General Director (GD)** of Politecnico di Milano
- The **Research Office (RO)**

IV. INVESTIGATOR RESPONSIBILITIES

Each Investigator must disclose to his or her Head of Department any Significant Financial Interests (and those of his/her spouse and dependent children) that reasonably appear to be related to the Investigator's Institutional Responsibilities. Disclosures must be made [using the disclosure form](#) prior to applying for PHS-funded research, within 30 days of discovering or acquiring (e.g. through purchase, marriage, or inheritance) a new Significant Financial Interest, and at least annually during the period of the award.

Investigators disclose SFIs that meet the following thresholds:

1. For a *publicly traded entity*: Income or other payment for services including salary, and any payment for services not otherwise identified as salary, including but not limited to, consulting payments, honoraria, paid authorship, or any other payments or consideration of value, including payments made to a health sciences compensation plan, received during the prior 12 months *and* the value of any equity interest (including stock, stock options or other ownership interests, as determined by public prices or other reasonable measure of fair market value) in the entity as of the date of disclosure, which when aggregated, exceeds \$5,000.
[Investigators are not required to disclose SFI in mutual funds or other investment vehicles such as retirement funds as long as the Investigator does not directly control the investment decisions made for these investment vehicles]
2. For a *non-publicly traded entity*: Income or other payment for services including salary, and any payment for services not otherwise identified as salary, including but not limited to, consulting payments, honoraria, paid authorship, any other payments or consideration of value, including payments made to a health sciences compensation plan, received during the prior 12 months that exceeds \$5,000, *or* equity interest of any amount, including, but not limited to stock, stock options, or ownership interest in the entity.
[Investigators are not required to disclose (a) payments made by Politecnico di Milano, including salary, stipends, royalty payments, honoraria, reimbursement of expenses, or any other remuneration; or (b) income for seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by 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]
3. *Intellectual property rights and interests*: Income received during the previous 12 months that exceeds \$5,000 for such rights and interests.
[SFIs do not include royalties received from Politecnico di Milano related to patents or copyrights]
4. *Travel*: The occurrence of any sponsored or reimbursed travel must be disclosed whether payment is made to the Investigator directly or expenses are paid on behalf of the Investigator by a for-profit or non-profit organization:
 - a. Either prospectively, by listing all travel that the Investigator anticipates will be sponsored or reimbursed during the next 12 months, or
 - b. Within 30 days of the occurrence if the trip wasn't reported prospectively.*[Investigators are not required to disclose travel that is reimbursed or sponsored by 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]

Investigators must cooperate in a timely manner with the Head of Department and Departmental Administrator in developing a management plan for any SFI deemed to be an FCOI and complying with such plan.

Each Investigator, including sub-recipient Investigator(s), must complete training prior to engaging in PHS-funded research and at least every four years, and immediately under certain circumstances (see http://grants.nih.gov/grants/policy/coi/coi_faqs.htm#L, Section L, 1). NIH training is available through an online module - <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>, as well as through familiarisation with the information provided on the ROO web pages.

V. DISCLOSURES BY COLLABORATORS

Collaborators from other institutions who share responsibility for the design, conduct or reporting of research results, and who will be conducting research under a subaward from Politecnico di Milano are expected to comply with the policies and procedures of the organization at which they are employed. Subawards issued by Politecnico di Milano will indicate that the subrecipient organization is responsible for reviewing SFI disclosures and, if FCOI are identified, for sending to Politecnico di Milano a notification of their ability to manage the identified conflicts, in accordance with PHS reporting requirements.

VI. REVIEWS AND REPORTING

The Head of Department must review all SFI's disclosed by Investigators to determine whether any are related to research funded through a U.S. Public Health Service funder and if so, whether they constitute a Financial Conflict of Interest.

If an SFI is determined to be an FCOI, the Head of Department together with the General Director will set out a plan to manage, reduce or eliminate the conflict.

Management plan

The management plan could include the following actions:

- Public disclosure of financial conflicts of interests (e.g. when presenting or publishing the research; to staff members working on the project, to relevant ethics committees);
- For research projects involving human subjects, disclosure of financial conflicts of interest 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);
- Severance of relationships that create financial conflicts.

The management plan should also include the following details:

- 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;
- Other information as needed.

Submission of reports

Unless the conflict is eliminable, the plan must be submitted to the PHS funder; in the case of the NIH this will be via the electronic Research Administration (eRA) Commons FCOI Module. The Head of Department and General Director are responsible for ensuring that reports are submitted on time (via the RO) as and when required. The Research Office Manager has authorized access to submit forms through the eRA Commons Financial Conflict of Interest Module and hence will submit the Conflict of Interest disclosure report.

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

Reports must be submitted prior to any expenditure of funds under a PHS-funded project. Note that reports need only be made if the Head of Department determines that an SFI constitutes an FCOI. But reports must also be submitted if an Investigator does not disclose an SFI in the timeframe required or the University does not review a disclosure but later determines that an FCOI exists.

For new Investigators who join the project, for any SFI disclosed which is judged to be an FCOI, the FCOI report must be submitted within 60 days.

For a new SFI that is deemed to be an FCOI, an FCOI report must be submitted within 60 days of disclosure.

For any FCOI previously reported, the University must provide an annual FCOI report to address the status of the financial interest and any changes to the management plan. The plan must specify whether the FCOI is still being managed or explain why the FCOI no longer exists. Annual reports must be submitted via eRA Commons for the duration of the project period (including extensions with or without funds) at the same time as submitting the annual progress report.

All FCOI reports must include sufficient information to enable the PHS-funder to understand the nature and extent of the FCOI and to assess the appropriateness of the management plan. The regulation provides key elements that must be included in the FCOI report to NIH. These include but are not necessarily limited to the following:

- Project number;
- Programme Director (PD)/PI or Contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the Financial Conflict of Interest;
- Name of the entity with which the Investigator has a Financial Conflict of Interest;
- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- Value of the financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000- \$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
- A description of how the financial interest relates to the NIH-funded research and why the Institution determined that the financial interest conflicts with such research.

NOTE THAT THERE IS NO REQUIREMENT TO SUBMIT A REPORT IF THE UNIVERSITY DETERMINES THAT NO DISCLOSURE OF AN SFI CONSTITUTES AN FCOI.

Failure to comply

If an Investigator fails to comply with the policy or a management plan subsequently put in place, the University must, within 120 days, undertake a retrospective review of the research project to determine if any bias in the design, conduct or reporting of the research. If a bias is found, the PHS funder must be notified and provided with a mitigation plan and thereafter report annually as normal, unless the University decides further interim measures are necessary. The funder is entitled to suspend or terminate the award.

VII. RECORDS ACCESS AND RETENTION

PHS regulations require that Politecnico di Milano respond within 5 business days to any request for information about SFIs held by Key Personnel when Politecnico di Milano has determined that the disclosed SFIs are related to PHS Research Activities and constitute FCOIs.

Records relating to unfunded projects need not be retained. All records of all Investigator disclosures of financial interests and the University's review, or response to, such disclosure (whether or not a disclosure resulted in determination of an FCOI), and all actions under our own policies or retrospective review, must be retained for at least 3 years from the date of submission of the final expenditures report (or other dates as specified in the regulations (see http://grants.nih.gov/grants/policy/coi/coi_faqs.htm#3160, Section A, 9).