

Financial Conflict of Interest Policy (FCOI) related to PHS-funded research at the Erasmus MC

By applying for or participating in United States Public Health Service (PHS) research funding activities, the Erasmus MC, on behalf of the investigator involved, is subject to [PHS regulation 42 CFR 50 Subpart F “Promoting objectivity in research”](#). The obligations of the researcher and the institution are set-out in this document. The following table offers a summary of the main obligations.

Summary table of responsibilities

When	Investigator*	Designated Institutional Officials*
Before submission of project	<ul style="list-style-type: none"> Inform the NIH liaison/coordinator at the Research Development Office (RDO) when applying for PHS-sponsored research funding Discloses significant financial interests (SFI) using form 	-
When project is awarded	<ul style="list-style-type: none"> Executes the management plan if an FCOI was identified 	<ul style="list-style-type: none"> Project can only start if no FCOI exists or if FCOIs are properly managed
During project	<ul style="list-style-type: none"> Completes FCOI training every 4 years after last training. Discloses significant financial interests (SFI) using form: <ul style="list-style-type: none"> ✓ Annually ✓ Within 30 days after new SFI arises ✓ When new to the project Executes the management plan if an FCOI was identified 	<ul style="list-style-type: none"> Review disclosure of SFI Identify FCOI Design and implement management plan Report within 60 days of identification of the FCOI and afterwards annually on the FCOI to the PHS Awarding Component
During project, if FCOI was not timely identified or managed	<ul style="list-style-type: none"> Discloses significant financial interests (SFI) using form: Executes the management plan 	<ul style="list-style-type: none"> Complete a retrospective review within 120 days of identifying noncompliance to determine any bias in the PHS-funded research conducted Review the Investigator's activities and the PHS-funded research project to identify any bias in the conducted research Design and implement management plan Report within 60 days of identification of the FCOI and afterwards annually on the FCOI to the PHS Awarding Component
After project	-	<ul style="list-style-type: none"> Maintain records for at least three years from the date the final expenditures report is submitted to the PHS or, where applicable, from the dates specified in 45 CFR 75.361 for different situations

*See definitions at end of document

Financial Conflict of Interest (FCOI)

This policy is predicated on the expectation that Investigators should conduct their affairs so as to avoid or minimize FCOI, and must respond appropriately when financial conflicts of interest arise. To that end, this policy informs Investigators participating in PHS-sponsored research about situations that generate financial conflicts of interest related to research, provides mechanisms for Investigators and the Erasmus MC to manage those financial conflicts of interest that arise, and describes situations that are prohibited. Every Investigator participating in PHS-sponsored research has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raises questions related to these financial conflict of interest regulatory and policy requirements, an Investigator should discuss the situation with the appropriate Institutional Official.

Disclosure of financial interests

Dutch and Erasmus MC local regulations applicable to all employees, including those working on PHS-funded projects

Collective labor agreement

The Erasmus MC maintains a policy on Outside activities, as defined in the Article 9.3. of the Collective Labor Agreement for University Medical Centres (CAO UMC) in the Netherlands. The CAO UMC is formally a public-law employment status regulation.

In addition to the CAO UMC, the Erasmus MC has a Research Code in place describing all aspects of research integrity including dependency of commercial or financial considerations. Chapter 2.8 on Codes of conduct in relationships with third parties highlights the aforementioned framework and the procedures for reporting on outside activities.

IRB review of financial arrangements

The Institutional Review Board (known as the Medical Research Ethics Committee, MREC) offers its opinion on the remunerations offered to researchers and research subjects, and the corresponding amounts, as well as on the relevant parts of every contract between the sponsor and the site (EU Directive 2001/20/EC Article 6-j). Any type of reward or possible conflict of interest must be reported to the MREC. This is in accordance with the International Ethical Guidelines for Health-related Research involving Humans from the Council for International Organizations of Medical Sciences (CIOMS) and World Health Organization (WHO) (2016). In its review of sponsored research, the MREC assesses the financial interests in conjunction with other aspects of the research.

PHS regulations for researchers involved in PHS-funded research (e.g., NIH)

Every Investigator¹ at Erasmus MC, applying for or participating in PHS-funded research, is subject to the PHS FCOI regulation (42 CFR Part 50 Subpart F).

Annual and ad hoc disclosures

All Investigators involved in PHS-funded research are required to disclose their outside Significant Financial Interests² (SFI) to Erasmus MC (a) prior to submitting an application to a PHS-component agency, such as the United States National Institutes of Health (NIH), or prior to commencing work on PHS-funded research, (b) on an annual basis, and (c) on an ad hoc basis (see below). This should be done using the applicable form provided by Erasmus MC (queries can be directed to research@erasmusmc.nl). The Institutional Official³ is responsible for the distribution, receipt, processing, review and retention of disclosure forms. All Investigators must submit to the Institutional official an ad hoc disclosure of any SFI they acquire or discover during the course of the year as soon as possible and in any case within thirty (30) days of discovering or acquiring the SFI.

Travel

Investigators must also disclose reimbursed or sponsored travel valued at more than USD5,000 during a 12-month period and related to their institutional responsibilities, as defined in the definition of Financial Interest and SFI. 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 represented. The Institutional Official will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes a FCOI with the Investigator's research.

Training

Investigators are required to take a web-based NIH tutorial on FCOI prior to project submission or beginning a project, and at least every four years thereafter: [NIH tutorial \(http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm\)](http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm). An electronic copy of the tutorial's certificate must be stored by the Investigator and made available on request. Investigators 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, if the Investigator is new to the institution or to a PHS-funded project, or if it is determined that the Investigator has not complied with this policy or with a management plan related to their activities.

¹ See definitions at end of document

² See definitions at end of document

³ See definitions at end of document

Investigator non-compliance

Dutch regulations applicable to all employees, including those working on PHS-funded projects

Disciplinary actions

If a FCOI is identified, proper measures will be taken to mitigate the conflict of interest. These measures may include disciplinary action, if deemed appropriate, as described in the CAO UMC (specifically Chapter 11), until the matter is resolved.

An Executive Board or Institutional 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 Institutional official, will be described in a written explanation of the decision to the Investigator and will notify the individual of the right to appeal the decision. The Erasmus MC will promptly notify the PHS Awarding Component of the action taken or to be taken.

Additional regulations for researchers involved in PHS-funded research

Managing a FCOI

If the disclosure form reveals an SFI, it will be reviewed promptly by the Institutional Official or designee to determine whether it constitutes a FCOI⁴. If a FCOI exists, the Institutional Official will take action to manage the FCOI including the reduction or elimination of the conflict, as appropriate.

A FCOI will exist when the Institutional Official or designee determines that an SFI could directly and significantly affect the design, conduct, or reporting of PHS-sponsored research. If the Institutional Official determines that there is a FCOI that can be managed, he or she must develop and implement a written management plan. The written plan will require that the Investigator take certain steps that might include the following:

- Disclosure of the FCOI to lab personnel and collaborators.
- Disclosure of the FCOI directly to human subject research participants.
- Disclosure of the FCOI in publications, journals, and posters, etc.
- Disclosure of the FCOI to audiences at conferences and seminars.
- Monitoring of research, proposals and data by independent peer reviewers.
- Modification of the research plan.
- Removal of an affected Investigator from participation in all or a portion of the research affected by the SFI.
- Divestiture of the SFI by the affected Investigator.
- Limiting the dollar value of fees received and/or stock ownership.
- Severance of the relationship creating the conflict.

⁴ See definitions at end of document

The affected Investigator must formally agree to the proposed management strategies and sign the written management plan before any related PHS-sponsored research resumes.

The Institutional 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.

Reporting to PHS

The Institutional Official will report FCOI or non-compliance to PHS in accordance with PHS regulations. FCOI will be reported using the standard forms available, prior to the expenditure of any funds at the start of the project and within 60 days of the identification of any new FCOI during the project. If the funding for the Research is made available from a prime PHS awardee not being an Erasmus MC employee (if the research is being conducted as a sub-award), Investigators shall disclose their SFI directly to the prime awardee according to the terms of the sub-award contract, so that the prime awardee may fulfill their reporting obligations to the PHS. Subrecipient institutions for which Erasmus MC is the prime awardee will be required to report their FCOI according to the same procedure and deadlines, in order for Erasmus MC to report to PHS.

Retrospective review

In addition, 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, an ad hoc committee appointed by the Institutional Official will complete a retrospective review of the Investigator's activities and the PHS-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 Institutional Official will update any previously submitted report to the PHS, 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 PHS regulations. If bias is found, the Erasmus MC will promptly notify the PHS Awarding Component and submit a mitigation report in accordance with the PHS 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.

Record retention

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, unless any litigation, claim, financial management review, or audit is started before the expiration of the three-year period. In that case, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

Confidentiality

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the Erasmus MC may be required to make such information available to the PHS Awarding Component and/or the United States Department of Health and Human Services (HHS) or to a requestor of information concerning financial conflict of interest related to PHS funding (see section "Public Accessibility"), if requested or required. If the Erasmus MC 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 such disclosure being made.

Public accessibility

Prior to the expenditure of funds, the Erasmus MC will respond to any requestor within five (5) 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 and key personnel;
- A determination has been made that the SFI is related to the PHS-funded research; and
- A determination has been made that the SFI is a FCOI.

The information to be made available shall be consistent with the requirements of the PHS regulation.

Regulatory authority

This policy implements the requirements of 42 CFR 50 Subpart F 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, specifically, any dependent children and spouse.

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 other than those directly related to the employment within Erasmus MC (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works from or by third parties); 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.

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 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 U.S. institutions of higher education, U.S. academic teaching hospitals, and U.S. medical centers.

Financial Interest does NOT include:

- a. salary, royalties, or other remuneration from the Institution (i.e. Erasmus MC);
- 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 U.S. institutions of higher education, U.S. academic teaching hospitals, and U.S. 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.

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 USD5,000; 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 USD5,000; 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 USD5,000 related to intellectual property rights and interests not reimbursed through the Institution, or
- e. is reimbursed or sponsored travel related to their institutional responsibilities, when exceeding USD5,000 during the 12-month period preceding the disclosure.

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 Erasmus MC reasonably determines could directly and significantly affect the design, conduct or reporting of PHS-sponsored research.

Institutional Official means the individual within the Erasmus MC 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 institutional responsibilities. For the purposes of this policy, the Institutional Official is designated as the Chair of the Department within the Erasmus MC where the Research funded by the United States PHS takes place, or, in case the Chair of the Department is the prime Investigator, the Executive Board of the Erasmus MC.

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

Investigator means any individual who is responsible for the design, conduct, and/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 postdoctoral associates, senior scientists, or graduate students. The definition may also include collaborators or consultants as appropriate.

MREC means an accredited Medical Research Ethics Committee reviewing medical scientific research involving human subjects (an Institutional Review Board).

Executive Board means a group of directors elected or appointed to act on behalf of, and with the powers granted to them by the Institution (i.e. Erasmus MC).

Public Health Service or 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 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).

Further information

- [NIH Grants and Funding: Financial Conflict of Interest](#)
- [NIH Grants and Funding: Financial Conflict of Interest: Frequently Asked Questions](#)
- [Training \(for research administrators\)](#)
- [CAO UMC 2018-2020](#) (English)
- [Erasmus MC information on Outside activities](#) (available through Intranet)
- Erasmus MC Research Code (available via research@erasmusmc.nl)