

FFM's Financial Conflict of Interest Policy



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1 - INTRODUCTION

Fundação Faculdade de Medicina (“FFM”), which is part of the FM/HCFMUSP System, is a non-profit organization, created in 1986, which actively supports the teaching, research and assistance activities of the Faculdade de Medicina da Universidade de São Paulo (“FMUSP”) and the Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo (“HCFMUSP”).

In a shared action with HCFMUSP, FMUSP and other partners, FFM manages relevant projects and research, mainly focused on the prevention and treatment of diseases that affect the health of the Brazilian population, generating hundreds of publications published in indexed journals and have been gaining global reach and visibility.

FFM's activities are in unison with the decisions of its Trustees and Advisory Boards, HCFMUSP's Deliberative Council and FMUSP's Congregation.

FFM is subject to the legal and regulatory structures applicable to non-profit philanthropic entities, framed within the Brazilian legislation and/or the relevant spheres, mainly the Curatorship of Foundations of the Public Prosecutor's Office of the State of São Paulo, in addition to being subject to specific legislation and rules according to the type of funds/resources managed. In this context, FFM has internal rules and regulations in line with the applicable legislation, and principles observed continuously by the governance, in order to guarantee the correct fulfillment of the legal dictates. FFM is also regularly checked by external audits and inspections, both general and specific for funds, programs and projects, always amassing favorable opinions.

All FFM and FM/HCFMUSP System's professionals, including those involved in projects and research, are supposed to carry out their functions in a way that promotes and preserves public trust, proper administration and confidence in the integrity of FFM and the FM/HCFMUSP System.

The purpose of this **FFM's Financial Conflict of Interest Policy** (“this Policy”), formally approved by the FFM Board of Trustees, is to ensure the identification and management of conflicts of interest between the professional and their personal financial interests through a process of disclosure and review.

The requirements of this Policy are intended to complement, rather than replace, existing obligations and processes; therefore, this Policy should be read in conjunction with the **Policy for Conflict of Interest in Clinical Research from FMUSP-HC System** and the **Compliance Professional Conduct - FMUSP/HC/FZ/FFM**, which provide general instructions on prevention, recognition and mitigation of conflicts of interest.

2. DEFINITIONS

Board of Trustees is FFM's highest body, which holds a normative, deliberative and management control function.

Co-responsible is the professional linked to the FM/HCFMUSP System who takes on responsibility, not only for the Management Center (MC) to be opened by the FFM for the financial management of the project, but also for its continuity in the event of impediment of the External Principal Coordinator.

External Principal Coordinator is the Principal Investigator or the Project Coordinator who has no employment relationship with the FM/HCFMUSP System and, therefore, needs a Co-Responsible to enable the development of their research or project.

Family member is the spouse, partner or relatives, consanguineous or similar, in a straight or collateral line (e.g., father, mother, children, grandparents, grandchildren, nephews, cousins, uncles, parents-in-law and siblings-in-law).

Financial Conflict Management Plan (FCOI Management Plan) means a plan developed in accordance with this Policy for the management, reduction or elimination of an identified Significant Financial Conflict of Interest.

Financial Conflict of Interest (FCOI) means a Significant Financial Interest that can directly and significantly affect the proper development of the Project/Research.

Financial Conflicts of Interest Committee (FCOI Committee) is the committee appointed to review and provide recommendations for the management of Significant Financial Interests in accordance with this Policy. The FCOI Committee will be composed of a representative of FFM's Financial Superintendence, a representative of FFM's General Management of Projects and Research and a representative of the Clinical Research Office of the HCFMUSP (EpeClin).

Financial Conflict of Interest Report (FCOI Report) means the report on a Significant Conflict of Interest identified to be forwarded by the Institutional Officer to the Granting Organization.

FM/HCFMUSP System is a Health System, which involves assistance, teaching and research. It develops Brazilian projects and research in the areas of health and biomedical sciences. The highest levels of the System are the FMUSP's Congregation and the HCFMUSP's Deliberative Council, both chaired by FMUSP's Dean.

HCFMUSP Clinical Research Office (EpeClin) is the area linked to the HCFMUSP Clinical Directorate which aims to support researchers, adapt procedures and advise areas of the FM/HCFMUSP System that carry out scientific research processes involving human beings.

Institutional Officer is the FFM representative designated as responsible for the management of this Policy, including requesting and reviewing disclosures of Significant Financial Interests, providing guidance to Technical Officers and retaining records and sending reports to the Granting Organizations. These functions are performed by the FFM Financial Superintendent.

Project means a temporary activity that aims at a single result and has limited resources. A project can be labeled as social, institutional, assistance, as well as innovation or research-related.

Research means a systematic investigation, study or experiment designed to contribute to knowledge widely associated with public health. The term covers basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or medication).

Significant Financial Interest (SFI) consists of the financial interest of the Technical Manager and other professionals involved (including that of their family members) with the Granting Organization, in the situations listed below:

- a) If they occupy any position of influence or if they are shareholders in the Subsidiary Organization;
- b) If, in the twelve months preceding the formalization of the Project/Research, they have received any remuneration from the Granting Organization. Remuneration includes salary and any payment for services not identified as salary (e.g., scholarships, consultancy fees, services, etc.);

- c) If, with respect to intellectual property rights (e.g., patents, copyrights), the revenue related to such rights and interests is received;
- d) If any trip has been reimbursed or sponsored directly by the Subsidizing Organization (i.e., one that is paid on behalf of the Technical Manager and/or their family members), excluding trips paid for by the FM/HCFMUSP System and/or FFM or trips reimbursed or sponsored exclusively for the Technical Manager by public bodies (national and international), development agencies, higher education institutions (national and international), for academic, assistance and research purposes, in the interest of the FM/HCFMUSP System.

The term Significant Financial Interest does not include the salary or other remuneration paid by the FM/HCFMUSP System to the Technical Manager who is currently employed or otherwise appointed by the FM/HCFMUSP System, including intellectual property rights attributed to the FM/HCFMUSP System in formal agreements, to share royalties related to such rights.

Subsidizing Organization means a source of funding, coming from public or private, national or international organizations.

Technical Manager is the Principal Investigator; Project Coordinator; research or project team member; and/or other individuals that the Principal Investigator or the Project Coordinator identifies as responsible for independent and substantial decision-making with respect to the Research or Project, including collaborators or consultants.

3. SCOPE OF APPLICATION

This Policy is applicable to all Technical Managers, External Principal Coordinators, Co-responsibles, regardless of the Granting Organization, also including all professionals, scholarship holders, graduate students, visiting scientists and researchers, as well as any subcontractors belonging to other institutions, who conduct research or projects on behalf of the FM/HCFMUSP System.

4. RESPONSIBILITIES

a) The Institutional Officer, or their appointed delegate, must communicate to the Technical Managers the need to become aware of this Policy, understand its content and commit to fully comply with its provisions.

b) The Institutional Officer will be responsible for providing all clarifications and resolving any doubts regarding any Financial Conflict of Interest or this Policy.

c) All Technical Managers covered by this Policy must become familiar with and comply with its provisions, being obliged to disclose to the other professionals involved the Financial Interests that may affect or be affected by the activities they are developing or intending to develop.

d) Any individual involved with the activities to be developed must report, to the Institutional Officer, suspicions of Financial Conflict of Interest or violations of this Policy.

e) FFM shall review and manage, together with the FCOI Committee, any Significant Financial Interests and determine a FCOI Management Plan designed to minimize or eliminate them, in order to ensure that the activities to be carried out are free from bias resulting from the financial interests of the Technical Manager.

5. DISCLOSURE PROCEDURES

a) When submitting the Project or Research to the FFM, the Institutional Officer, or their appointed delegate, must inform the Technical Manager of the obligation to become aware of this Policy and to state that they understand its content and that they commit to fully comply with its provisions, through the “Certification Declaration” (which is part of this Policy as “Appendix 1”).

b) The Institutional Officer, or their appointed delegate, will communicate to the Technical Manager that they also have a continuous obligation to update changes or additions to Significant Financial Interests, and must disclose them, within 30 (thirty) days of their appearance, through the “**Significant Financial Interest Disclosure Form**” (“SFI Disclosure Form”), which is part of this Policy as “Appendix 2”).

c) It will be the responsibility of the Institutional Officer to provide all clarifications, in order to resolve any doubts regarding Financial Conflicts of Interest or this Policy.

6. REVIEW, MANAGEMENT AND REPORTING PROCEDURES

a) The Institutional Officer, or their appointed delegate, will conduct a preliminary investigation of any SFI Disclosure Form that identifies a Significant Financial Interest.

b) The Institutional Officer shall forward to the **Financial Conflicts of Interest Committee** (“FCOI Committee”), for review, all SFI Disclosure Forms that reveal a Significant Financial Interest, together with its recommendations on which significant financial interests deserve further investigation, in order to determine if there is a Financial Conflict of Interest.

c) The FCOI committee is responsible for investigating Significant Financial Interests, as necessary, and determining whether there is a Financial Conflict of Interest. There will be a Financial Conflict of Interest if the FCOI Committee determines that it can directly and significantly affect the activities to be developed or being developed. The FCOI committee, with the support of the Institutional Officer, will decide on the appropriate action to be taken to manage, reduce or eliminate any Financial Conflict of Interest.

d) If it is found that there is a Financial Conflict of Interest, the Institutional Officer will inform the Subsidiary Organization, through the **“Financial Conflict of Interest Report”** (“FCOI Report”), which is part of this Policy as **“Annex 3”**).

7. FINANCIAL CONFLICT OF INTEREST MANAGEMENT PLAN

FFM will review and manage, minimize or eliminate Significant Financial Interests to ensure that the Research or Project is free from bias resulting from the Technical Manager's financial interests. By determining a FCOI Management Plan, FFM will endeavor to achieve the following goals:

- Protect the integrity of the FM/HCFMUSP System research programs or projects;
- Ensure that projects or research are objective and impartial in their planning, development and completion;
- Report the identified financial conflicts of interest to the Granting Organization;
- Ensure that all Technical Managers comply with this Policy and any other applicable regulations regarding Financial Conflicts of Interest.

8. SANCTIONS

In the event of Significant Financial Interest that, in addition to affecting the execution of the activities, may impair the suitability of the FM/HCMUSP and/or FFM System, it will be incumbent upon the FCOI committee, together with the higher bodies of the FM/HCMUSP System, to define the appropriate administrative and legal sanctions.

9. REFERENCES

This Policy was drafted in accordance with the following documents:

- [Compliance Professional Conduct - FMUSP/HC/FZ/FFM](#) ;
- [Policy for Conflict of Interest in Clinical Research from FMUSP-HC System](#) ;
- [Internal Rules of Fundação Faculdade de Medicina](#) ;
- [Internal Rule of Procedure No. 01/2016 for the Issuance of a Contract with a Legal Entity](#) .

ANNEX 1

FFM's Financial Conflict of Interest Policy

CERTIFICATION STATEMENT

I declare that I have received a copy of the **FFM's Financial Conflict of Interest Policy**, understood its content and pledge to fully comply with its provisions.

I declare that I have not received, in the twelve months prior to the formalization of the Project/Research now submitted and identified below, any remuneration from the Granting Organization.

Technical Manager Name:	
Project/Research Title:	
Granting Organization:	
Expected duration:	
Grant amount:	

I declare that the information above is true and I undertake to provide any additional data and promptly notify if there is any change.

Signature: _____ Date: _____

ANNEX 2

FFM's Financial Conflict of Interest Policy

SIGNIFICANT FINANCIAL INTEREST DISCLOSURE FORM

Name of the Technical Manager with a Financial Conflict of Interest	
Name of the entity with which the Technical Manager has a Financial Conflict of Interest	
Type of Financial Interest	
Amount of the Financial Interest	
Description of how the Financial Conflict of Interest relates to the research funded by the Granting Organization and why the institution determined that the financial interest is in conflict with such research	

Signature: _____ Date: _____

ANNEX 3

FFM's Financial Conflict of Interest Policy

FINANCIAL CONFLICT OF INTEREST REPORT

Project Number	
Name of the Technical Manager with a Financial Conflict of Interest	
Name of the entity with which the Technical Manager has a Financial Conflict of Interest	
Type of Financial Interest	
Amount of the Financial Interest	
Description of how the Financial Interest relates to research funded by the Granting Organization and why the institution determined that the financial interest is in conflict with such research	
Description of the main elements of the FCOI Management Plan, including: <ul style="list-style-type: none"> a. Role and main duties of the Technical Manager in conflict in the research project; b. Conditions of the FCOI Management Plan; c. How the FCOI Management Plan is designed to safeguard objectivity in the Research project; d. Confirmation of the Technical Manager's compliance with the FCOI Management Plan; e. How the FCOI Management Plan will be monitored to ensure compliance by the Technical Manager; and f. Other information that may be necessary and/or requested by the Granting Organization. 	

Signature: _____ Date: _____