

## FIOCRUZ

Potential Financial Conflicts of Interest (FCOI) for Research  
Funded by the Public Health Services (PHS) of the  
United States Department of Health and Human Services (HHS)  
Conflitos de interesse financeiro potenciais (FCOI) em pesquisas  
financiadas pelos Serviços de Saúde Pública (PHS) do  
Departamento de Saúde e Serviços Humanos dos Estados Unidos da América  
(HHS)

### I. Introduction

Academic and scientific research is guided by the precepts of Research Integrity, including all stages of scientific work, from conception to publication. It is essential that research teams act and be perceived as impartial and that they do not allow secondary interests to unduly interfere with the researcher's primary interests. One of the issues involved in Fiocruz's research integrity guidelines refers to potential financial conflicts of interest.

**This policy is applicable to any individual, acting as an investigator linked to Fiocruz who is applying or receiving grant funding from the Public Health System of the US Department of Health and Human Services (HHS) and component organizations of the PHS, including, but not limited to, the National Institutes of Health (NIH).**

### II. Definitions

**Financial conflict of interest (FCOI)** - a financial interest that can directly and significantly affect the design, conduct, or reporting of PHS/NIH-funded research.

**Investigator** - principal investigator (PI), project coordinator and any other person, regardless of title or position, responsible for designing, conducting or reporting research funded by the PHS/NIH or proposed for such funding, which may include, for example, collaborators or consultants.

**Research** - systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge and encompasses basic and applied research (including its "products/results", such as a scientific article, diagnostic test or drug) funded by the PHS/NIH.

**Significant financial interest (SFI)** – it consists of one or more interests of the investigator (and/or the investigator's spouse and/or dependent children) that reasonably appear to be related to or impact the investigator's institutional responsibilities, such as:

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<sup>1</sup> This policy was based on the policies of the University of São Paulo (USP) <https://prp.usp.br/phs-nih-fcoi/>; University of St. Andrews <https://www.st-andrews.ac.uk/policy/research-conduct-and-ethics/financial-conflict-of-interest-us-phs.pdf>; and The University of Manchester <https://documents.manchester.ac.uk/DocuInfo.aspx?DocID=24603>

- aggregate value of any remuneration (salary or other payments for services) and/or equity interest (shares, stock options or other equity interest) of any publicly-held company in the 12 months prior to the statement greater than US\$5,000; or
- aggregate value of any remuneration (salary or other payments for services) of any non-publicly traded entity in the 12 months prior to the statement exceeding US\$5,000 or when the investigator (and/or the investigator's spouse and/or dependent children) holds any equity of interest (stocks, stock options or other equity interest); or
- Intellectual property rights and interests (e.g. patents and copyright) upon receipt of income relating to such rights and interests; or
- Travel reimbursed or sponsored related to institutional liability (including that paid on behalf of the investigator and not reimbursed to the investigator so the exact amount may not be available).

Note that the following financial interests are excluded from classification as a significant financial interest (SFI):

- Travel reimbursed or sponsored by a federal, state or local government agency, higher education institution (HEI), university hospital, medical center or research institute affiliated with an HEI in the United States;
- Salary, royalties or other remuneration paid by the institution employing the researcher;
- Intellectual property rights assigned to the institution and agreements to share royalties of such rights;
- Income from investment instruments (e.g., mutual funds and retirement accounts), provided the investigator does not directly control the investment decision made in these instruments;
- Income from service on advisory committees or review panels for a federal, state or local government agency, higher education institution (HEI), university hospital, medical center or research institute affiliated with an HEI;
- Income from seminars, lectures, scientific recognition awards or teaching commitments sponsored by a federal, state, or local government agency, an institution of higher education (HEI), an academic teaching hospital, medical center or institute of research affiliated with an HEI.

### III. Responsibilities

The **Principal Investigator (PI)** must:

1. Ensure that all investigators and other staff working on the project comply with the FCOI policy and complete the NIH mandatory online FCOI training process. The PI must also inform new researchers about the requirements when working on NIH-funded projects.

The **Investigators** must:

1. Disclose any significant financial interest (SFI)<sup>2</sup> within the timeframe specified by the funder.

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<sup>2</sup>do you need this reference?

2. Complete the NIH online FCOI training process prior to conducting any PHS/NIH-funded research and update it at least every four years.
3. Comply with the Management Plan proposed by the researcher and agreed in the case of any identified FCOI.

**Fiocruz must:**

1. Make public, disseminate among investigators and update the FCOI policy;
2. Review the SFI disclosures and determine whether the SFI constitutes an FCOI.
3. Manage FCOI and, if necessary, establish a management plan to manage any potential conflicts of interest and monitor compliance under institutional supervision.
4. Submit initial and annual FCOI reports to PHS/NIH, with operational support from the units.
5. Maintain records relating to all investigators' SFI disclosures and all actions taken in relation to such disclosures for at least three years from the date the final report is submitted to the NIH or, where applicable, other dates specified in the rules of the PHS/NIH.
6. Take the relevant corrective actions.
7. Receive, review and report FCOI changes.
8. Develop and implement processes at the institutional level to comply with the PHS/NIH policy.
9. Report any FCOI changes to the PHS/NIH.

**IV. Requirements regarding sub-recipients or subcontractors or collaborators**

If Fiocruz is the primary awarded institution, it delegates responsibility for complying with the NIH FCOI policy regarding the identification, disclosure, determination and management of FCOI for each sub-recipient, and it shall specify all necessary matters in any sub-recipient agreement, including that the sub-recipient must:

1. comply with the requirements of the PHS/NIH FCOI policy;
2. send all necessary details of the FCOIs to Fiocruz:
  - (i) before the expenditure of funds; and
  - (ii) within 60 days of any subsequently identified FCOI.
3. immediately notify Fiocruz of any management plan and suspected non-compliance; and
4. provide a statement that all FCOIs have been identified, disclosed and managed in accordance with PHS/NIH requirements.

**V. Training process for investigators**

All investigators must understand their responsibilities regarding the PHS/NIH FCOI policy and must complete the NIH online training process available at:

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<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm> :

1. before engaging in PHS/NIH-funded research;
2. at least once every 4 years; and
3. immediately when any of the following circumstances apply:
  - procedures relating to FCOI policies are revised in a way that affects the investigator's requirements;
  - an investigator is new at Fiocruz; or
  - an investigator is not in compliance with this policy or the FCOI management plan;

When the PHS/NIH online tutorial is completed, the Investigator must save an electronic copy of the certificate generated by the system and provide a copy to the Fiocruz Research Integrity Committee (CIP) linked to the Vice-Presidency of Research and Biological Collections (VPPCB) by e-mail: [integrity.pesquisa@fiocruz.br](mailto:integrity.pesquisa@fiocruz.br)

## **VI. Statement of Significant Financial Interest (SFI)**

When a new investigator joins the PHS/NIH-funded project, they must complete the Significant Financial Conflict Disclosure Form within 30 days of joining the project and return it to the CIP that will review it and take any other appropriate action within 30 days.

Each investigator participating in a PHS/NIH-funded project(s) must update the Significant Financial Interest Disclosure Form annually at the beginning of the US academic year (August 1st) no later than within 30 calendar days from this date.

Each investigator must resubmit a new Significant Financial Interest Disclosure Form if the investigator acquires or discovers a previously undisclosed significant financial interest (e.g., through marriage, purchase, inheritance). Resubmission must be made within 30 calendar days after the change in circumstances.

Fiocruz will report to the PHS/NIH any significant financial interests deemed to conflict with the PHS-funded project prior to the expenditure of funds and implementation of the management plan.

For any FCOI identified by Fiocruz, CIP will provide the PHS/NIH with an annual FCOI Report and its status and any changes to the management plan during the project.

Fiocruz will make relevant details available on the website so that the public can request information about significant financial interests related to the research funded by the PHS/NIH. The website that contains information about significant financial interests will be updated at least annually and within 60 days of any new information about significant conflicts of interest.

## **VII. Identification of Potential Financial Conflict of Interest (FCOI)**

The CIP will review whether an FCOI exists for the purposes of the PHS/NIH regulatory requirements, and whether the significant financial interest declared

by the investigator can be considered related to the PHS/NIH research, evaluating whether the SFI:

1. may affect PHS/NIH research; or
2. relates to an entity whose financial interest may be affected by the PHS/NIH research.

If it is determined that the SFI is related to the PHS/NIH research, and affects the design, conduct or reporting of the PHS/NIH research, the SFI is a potential FCOI and must be managed through a specific plan and included in the electronic PSH/NIH Commons Research Administration (eRA) FCOI Module.<sup>3</sup>

### **VIII. Management of Financial Conflict of Interest**

Unless the potential financial conflict of interest is demonstrably remediable immediately, a plan must be submitted to the PHS/NIH funder via the FCOI Module.

CIP is responsible for ensuring that all documentation and reports are submitted on time and when necessary. FCOI reports must be updated annually, must include the status of the management plan (i.e. whether the potential financial conflict of interest is still being managed or if the financial conflict no longer exists) and a description of any changes to the management plan since the last FCOI report submitted.

Reports must be submitted prior to any expenditure of the installments of the PHS/NIH-funded project. Reports need only to be prepared if the Vice-President of Research and Collections, through the CIP, identifies that an SFI constitutes an FCOI. Reports must also be submitted if an investigator does not disclose an SFI within the required timeframe or if Fiocruz does not review a conflict statement but subsequently determines that an FCOI exists.

All FCOI reports must include sufficient information to allow the PHS/NIH funder to understand the nature and extent of the FCOI and to assess the adequacy of the management plan.

FCOI management plans **may contain the following** reduction or elimination actions or other actions depending on the nature of the conflict:

- Public disclosure of potential financial conflict of interest;
- Disclosure of the financial conflict of interest to participants involved in the research;
- Appointment of an independent monitor capable of taking steps to protect the design, conduct or reporting of the research;
- Modification of the research plan;
- Change of personnel or personnel responsibilities;
- Reduction or elimination of the financial interest (e.g. sale of an equity interest); or
- Disruption of relationships that create financial conflict.

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<sup>3</sup><https://public.era.nih.gov/commonsplus/public/login.era?TARGET=https%3A%2F%2Fpublic.era.nih.gov%3A443%2Fcommons%2FcommonsInit.do>

The FCOI management plan must also include the following details:

- The role and main duties of the conflicting investigator in the research project;
- Conditions of the management plan;
- How the management plan is designed to safeguard the objectivity of the research project;
- Confirmation of the investigator's agreement with the management plan;
- How the management plan will be monitored to ensure compliance by the Investigator;
- Other information deemed necessary by the investigators and/or the CIP.

Whenever Fiocruz implements an FCOI management plan, CIP will continuously monitor compliance until the end of the project. The CIP will maintain records relating to all investigator's disclosures and the institution's analysis, responses and actions in relation to the management of the FCOI for at least three years from the date the final expenses are submitted to the PHS/NIH or according to the individual circumstances of the project.

## **IX. Non-compliance**

If an investigator does not comply with this policy or with an FCOI management plan, Fiocruz must, within 120 days, carry out a retrospective review of the research project to determine if there is any bias in the design, conduct or reporting of the research.

If a bias is found, the PHS/NIH funder must be notified and a mitigation plan agreed between the CIP and the investigator must be provided and subsequently reported in the annual report as mitigated, unless Fiocruz decides that others mitigation measures are needed. The funder has the right to suspend or terminate the award/funding.

## **X. Confidentiality**

To the extent permitted by law, plans for managing potential financial conflicts of interest shall be confidential. However, Fiocruz may have to make information available to a requester for PHS/NIH FCOI information related to funding, if necessary. If Fiocruz is asked to provide disclosure forms, FCOI management plan and related information to an external entity, the investigator will be informed of this action.

Version	Alteration/change performed	Document status	Author of change/position and area	Date

**Annex – SIGNIFICANT FINANCIAL INTEREST STATEMENT FORM**  
(It must be completed by each project investigator)

Investigator's name:  
 Institution's name:  
 Project:  
 Function in the project:  
 Period:

1) In the last and next 12 months, you or, to the best of your knowledge, your spouse/partner or dependent child/children received compensation of any kind from any commercial entity that would appear to be affected by the conduct of the research results?

( ) Yes ( ) No

If NO, skip this section of the questionnaire and go to question 2.

If YES, check all applicable options below:

Options	Investigator	Spouse or partner	Investigator's dependent child	Entity	Amount
Consultancy fees					
Fees for lectures, works, teaching					
Officer/Director salary, fees					
Gifts / gratuities (over US\$100)					
Remuneration for service on the advisory board					
Payment of rights					
Other: _____					

2) Do you or, to the best of your knowledge, your spouse/partner or dependent child/children own types of stock or other forms of ownership in any business entity that appears to be affected by the conduct or results of the research?

( ) Yes ( ) No

If NO, skip this section of the questionnaire and go to question 3.

If yes, check all applicable options below:

	Investigator	Spouse or partner	Investigator's dependent child	Entity	Ownership % value
<b>Publicly-held company</b>					
Shares					
Types of stock					
Other types of ownership					
<b>Privately-held company</b>					
Shares					
Types of stock					
Other types of ownership					

3) Are you or, to the best of your knowledge, your spouse/partner or dependent child/children mentioned as inventors in an issued patent or patent application whose value appears to be affected by the conduct or result of the research?  
 Yes  No

If NO, skip this section of the questionnaire and go to question 4.

If YES, who owns the patent?

- You
- Spouse / partner
- Investigator's dependent child

Please explain:

4) In the last 12 months, any business entity that would appear to be affected by the conduct or result of the research paid or reimbursed you (or spouse/partner or dependent child/children) for any travel (e.g., hotel, transportation)?  
 Yes  No

If NO, skip this section of the questionnaire and go to question 5.

If yes, please explain below:

Entity	Purpose	Destination	Duration	Did the entity pay for your spouse/partner or dependent child to travel with you?

5) Do you have any other financial interests that seem to affect or affect your conduct or the results of the research?  
 Yes  No

If yes, please explain below:

\_\_\_\_\_

I certify that the information provided by me is accurate and complete and I will promptly report any changes.

Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_