



## **Guideline for the Management of Financial Conflict of Interest for Research Funded by the U.S. Public Health Service Requirements (including NIH)**

### **1. Introduction**

This guideline is according to the Pontificia Universidad Javeriana (PUJ) Conflict of Interest Management Manual (Resolution No. 695, issued April 15, 2021). which establishes that the principal investigator, at the time of submitting the project to the faculty's Research and Ethics Committee, must formally state, whether he or she, as well as his or her work team, are involved in a possible conflict of interest in developing the project. Besides, the Faculty Research and Ethics Committees, as part of the feasibility study of the project, must evaluate and examine whether there is a situation among the team members executing the project that could lead to a conflict of interest. If such a situation is identified, they must bring it to light and urge the Principal Investigator to take appropriate measures within the team.

In any case where the Investigator themselves may be involved in a potential conflict of interest, the project approval will be suspended until the Principal Investigator's superior is informed of the case and takes necessary measures to manage the potential conflict. Furthermore, PUJ also requires that investigators, who are seeking for external funding, comply with disclosure policies regarding of external funding agencies, including the U.S. Public Health Service (PHS) and Awarding Components, such as the U.S. National Institutes of Health (NIH), which have specific requirements regarding disclosure and management of FCOI. This guideline is established to fulfill such requirements.

### **2. Purpose**

This document serves to establish the Guidelines to manage Financial Conflict of Interest (FCOI) in research projects at Pontificia Universidad Javeriana (PUJ). The primary goal is to ensure adherence to the 2011 FCOI regulation, which advocates for objectivity in research (42 CFR Part 50 Subpart F).



### 3. Key Definitions

The following definitions are provided as a reference and are considered key definitions to this document in understanding the federal regulations of FCOI. For more information, see: [42 CFR 50.603](#).

**Designated Official** means the individual at the University appointed by the Vice President for Research. If an SFI is deemed to be an FCO disclosures of Significant Financial Interests concerning the Investigator's Institutional Responsibilities, specifically in relation to projects funded by the Public Health Service (PHS) this individual is entrusted with the responsibility of reviewing.

The designated official's role includes assessing whether a financial conflict of interest (FCOI) exists and, if confirmed, ensuring that in accordance with the University's Conflict of Interest Manual, the line manager or ethics committee and the disposition of the conflict will be made in accordance with chapter XI of the Conflict of Interest Manual of the Javeriana University.

Any identified FCOIs are reported to the PHS in accordance with these guidelines and in compliance with PHS regulations.

**Disclosure of significant financial interests** means an Investigator's disclosure of significant financial interests to an Institution.

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

**FCOI report** means an Institution's report of a financial conflict of interest to a PHS Awarding Component.

**Financial interest** means anything of monetary value, whether or not the value is readily ascertainable.

**HHS** means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

**Institutional responsibilities** means an Investigator's professional responsibilities on behalf of the Institution, namely teaching, research and services. These responsibilities encompass various activities such as consulting, continuing education, community outreach, clinical



service, academic administration, and participation in committees, councils, and working groups. **Investigator** means 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. In **U.S. Public Health Service Requirements (including NIH)** it is also called. **PD/PI**

**Manage** means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest or prohibit the conduct, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias. **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 involved may be delegated, including the National Institutes of Health (NIH).

**PHS Awarding Component** means the organizational unit of the PHS that funds the research.

**Public Health Service Act or PHS Act** means the statute codified at 42 U.S.C. 201 et seq. Research means a systematic investigation, study or experiment designed to develop or 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). the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

**Senior/key personnel** mean the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under this subpart.

**Significant Financial Interest (SFI)** means:

(1) **A financial interest** consisting of one or more of the following interests **of the Investigator (and those of the Investigator's spouse and dependent children under 25 years)** that reasonably appears to be related to the Investigator's institutional responsibilities:

(i) **With regard to any publicly traded entity**, a **SFI** exists if the value of any remuneration received from the entity in the twelve months preceding the



**disclosure** and the value of any equity interest in the entity as of the date of disclosure, **when aggregated, exceeds USD \$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;

(ii) **With regard to any non-publicly traded entity**, a **SFI** exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, **when aggregated, exceeds USD \$5,000**, or when the Investigator (**or the Investigator's spouse or dependent children**) holds any equity interest (e.g., stock, stock option, or other ownership interest).

**Note:** Salary, royalties, or other remuneration paid by the University to the Investigator **are not classed as SFI**, if the Investigator is currently employed or otherwise appointed by the University.

(iii) Intellectual property rights (e.g., patents, copyrights), upon receipt of income related to such rights

**Note:** Income related to intellectual property rights assigned to the University and agreements to share in royalties related to such rights **are not classed as SFI**, if the Investigator is currently employed or otherwise appointed by the University

(2) **Any reimbursed or sponsored travel** (i.e. that which is reimbursed to or paid on behalf of the Investigator, the Investigator's spouse/civil partner or dependent children) exceeding USD \$5,000 **related to the Investigator's Institutional Responsibilities**. This disclosure requirement does not apply to travel that is reimbursed or sponsored by a United States federal, state, or local government agency, a United States 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 a United States Institution of Higher Education. The details of this disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration

This provision does not apply to travel which an Investigator books through the University's designated travel provider or claims through the University's expenses system.

(3) The term **SFI** does not include the following types of financial interests:

(i) 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;

(ii) 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;

(iii) 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;

(iv) 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.

#### **4. Scope**

This guideline applies to every Investigator, as defined above, who intends to participate in or is currently involved in research funded by the Public Health Service included NIH.

#### **5. Procedure**

##### **5.1. Training**

All investigators intending to participate in or already involved in PHS-funded research must comply with PUJ's FCOI guidelines Federal regulation 42 CFR Part 50 Subpart F, and their obligation to disclose significant financial interests per the guidelines.

Each Investigator must complete FCOI training. Training must be completed prior to engaging in PHS-funded research and updated at least every four years. To comply with FCOI training, Investigators must complete the Conflicts of Interest module in the CITI Program (<https://citiprogram.org>).

Additionally, training must be also completed when: (i) PUJ revises its FCOI guidelines affecting requirements of Investigators, (ii) An Investigator is new to PUJ, and (iii) An Investigator is not in compliance with this guidelines or management plan.

##### **5.2. Disclosure, Review, and Monitoring Requirements:**



a) The Investigator must comply with the procedure established in the PUJ's Conflict of Interest Management Manual and fill out the disclose **PUJ's Significant Financial Interest Form**. This form has to be submitted in three moments:

- At the time of the project evaluation by the Research and Ethics Committee (REC) and no later than the application for PHS-funded research.
- Annually during the award period.
- Within 30 days of discovering or acquiring a new SFI.

b) Following the PUJ's Conflict of Interest Management Manual, SFIs (and those of the Investigator's spouse and dependent children under 25 years) related to an Investigator's institutional responsibilities will be reviewed by the correspondence instance who will determine if the SFIs constitute FCOIs, based on the following elements:

- An SFI is considered related to PHS-funded research if the SFI could be affected by the research or is in an entity whose financial interest could be affected by the research.
- An Investigator may assist in determining the relationship between an SFI and PHS funded research.
- An FCOI exists if the Research and Ethics Committee Chairman reasonably determines the SFI could directly and significantly affect the research's design, conduct, or reporting.

c) If an SFI is deemed to be an FCOI, the corresponding instance will report the Designated Official appointed by the Vice President for Research.

d) All FCOI identified that are specifically related to PHS funded research are managed prior to expenditure of PHS funds.

e) Prior to expending PHS funds, the Designated Official must:

- Review all Investigator SFI disclosures deemed to be FCOI.
- Determine if any SFIs are related to PHS-funded research.
- Determine if an FCOI exists, and if so,
- Develop and implement a management plan along with the corresponding instance as per PUJ's Conflict of Interest Management Manual

f) If a new Investigator joins or an existing one discloses a new SFI, the Designated Official will review the disclosures within 60 days and implement a management plan if needed plan along with the corresponding instance as outlined PUJ's Conflict of Interest Management Manual



g) If an undisclosed or unreviewed SFI is identified by the REC during ongoing PHS-funded research, the REC Chairman must report to the Designated Official, who will review the disclosure within 60 days and develop a management plan for future action.

h) PUJ will manage FCOIs of all Investigators. For subrecipient Investigators, PUJ will ensure compliance if applicable.

## **6. Reporting Requirements to NIH**

a) PUJ must submit initial, annual, and revised FCOI reports, if applicable, including all necessary information: (i) Project number; (ii) Project title; (iii) PD/PI or contact PD/PI if a multiple PD/PI model is used; (iv) Name of the Investigator with the FCOI; (v) Name of the entity with which the Investigator has a financial conflict of interest; (vi) Reason(s) for the retrospective review; (vii) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed); (viii) Findings of the review; and (ix) Conclusions of the review (defined in [42 CFR 50.605\(b\)\(3\)](#) or *NIH's FAQ H.5*), to the NIH via the eRA Commons FCOI Module for the Institution and its subrecipients if applicable. The reporting will be presented as required by the regulation and statement below:

- Prior to the expenditure of funds.
- Within 60 days of new or newly identified FCOIs for new or existing Investigators.
- Annually, coinciding with the submission of the annual progress report. The report will detail FCOI status and any changes to the management plan until project completion.
- After a retrospective review to update a previously submitted report if new information arises post-review.

b) PUJ must promptly notify NIH of any bias found in the research's design, conduct, or reporting. A Mitigation Report outlining actions taken will be submitted in compliance with [42 CFR Part 50.605\(a\)\(3\)\(iii\)](#).

c) PUJ must promptly inform NIH if an Investigator fails to comply with the Guidelines for the Management of FCOI or if an FCOI management plan appears to bias the research.

## **7. Maintenance of Records**

The Faculty and the Designated Official will maintain records relating to all Investigators' disclosures of SFIs, as well as reviews of and response to such disclosures, and all actions related to complying with these guidelines, for at least three years from the date the final expenditures report is submitted to the PHS, or, when applicable, from other dates specified in PHS regulations, (for more information, see: [45 CFR 75.361](#)).



Furthermore, as per PUJ Conflict of Interest Management Manual (section V) all decisions made in the handling of FCOI, will be forwarded by Designated Official handling them to the General Secretary.

## **8. Enforcement Mechanisms, Remedies, and Noncompliance**

In cases of Investigator noncompliance with PUJ's Guidelines for the Management of FCOI or management plan, Designated Official appears to have biased the design, conduct, or reporting of PHS-funded research, must notify promptly the PHS Awarding Component regarding the correcting action (or sanction) taken or to be taken, including those described in the Faculty Regulations (*Reglamento del Profesorado*), Internal Work Regulations (*Reglamento Interno de Trabajo*) and the PUJ Conflict of Interest Management Manual (*Manual de Conflicto de Interés*).

Whenever a Financial Conflict of Interest is not identified or managed in a timely manner, including:

- a) Failure by the Investigator to disclose a SFI that is determined by the Institution to constitute a Financial Conflict of Interest;
- b) Failure by the Institution to review or manage such a Financial Conflict of Interest; or
- c) Failure by the Investigator to comply with a Financial Conflict of Interest management plan;

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 retrospective review shall include at a minimum the key elements as indicated by [42 CFR 50.605\(a\)\(3\)\(ii\)\(B\)](#)

In a case in which the Department of Health and Human Services determines that a PHS-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by the Institution as required by the regulation, the Institution shall require the Investigator involved to: a) Disclose the FCOI in each public presentation of the results of the research, and; b) To request an addendum to previously published presentations as defined by [42 CFR 50.606\(c\)](#).





## **9. Subrecipient Requirements**

PUJ will include as part of a written agreement with the subrecipient, (i) a statement that the subrecipient's FCOI policy is in compliance with this PHS policy, (2) all subrecipient's Investigators must comply with the subrecipient's FCOI policy, and (3) there is a specified time period for the subrecipient to report all identified conflicts of interest to PUJ, where this time period is sufficient to enable PUJ to report to the PHS as required (e.g., prior to the expenditure of funds under the subaward, within 60 days of identifying a new SFI, and on an annual basis. Subrecipients will certify that their FCOI policy complies with the regulation.

## **10. Public Access**

This Guideline is available on a publicly accessible website and has been made available to PHS via its NIH eRA Commons.

Information concerning FCOIs held by senior/key personnel is made publicly accessible by a written response to any requester within five business days of a request or as required by law. To submit a request, please write to: [viceinv@javeriana.edu.co](mailto:viceinv@javeriana.edu.co). The information provided will include: the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest (in pre-specified dollar ranges), or a statement that a value cannot be readily determined.