



POLICY ON THE MANAGEMENT OF FINANCIAL CONFLICT OF INTEREST (FCOI) AT UNIVERSIDAD NACIONAL (UNA), COSTA RICA FUNDED BY THE NATIONAL INSTITUTES OF HEALTH (NIH) OF THE UNITED STATES OF AMERICA

1. Policy Statement

As a higher education institution, Universidad Nacional (UNA), Costa Rica is committed to protecting the integrity and objectivity of its research activities by establishing standards to ensure that the design, conduct, and reporting of Public Health Service (PHS, which includes NIH) funded research, grants or cooperative agreements will not be biased or appear to be biased by FCOI (of the investigator, and/or of the Investigator's spouse and/or dependent children).

UNA acknowledges that investigators, and their families and dependents, have the right to acquire, retain and accumulate personal financial assets (including personal income from the transfer of technology or intellectual property subject to University policy) and to establish financial relationships with outside private entities. Investigators also have the responsibility to manage their financial affairs and relationships in a manner that does not interfere with, or improperly influence the performance of, their duties and responsibilities. UNA will exercise oversight and care in eliminating or managing FCOIs that do or may arise because of an investigator's Financial Interest in University activities or research activities.

2. Purpose

This policy has been developed to identify, manage, reduce, neutralize, or eliminate actual, apparent, and potential FCOI, as a requirement of Federal government to entities receiving federal funding. The policy was written to be in conformance with the specific federal agency requirements as defined in the 2011 Revised Financial Conflict of Interest Regulation, Promoting Objectivity in Research (42 CFR part 50 subpart F).

These regulations describe the actions an individual and an organization must take to promote objectivity in research. The regulations apply to investigators participating in, or planning to participate in, all PHS funded grants, cooperative agreements, research contracts (but not Phase 1 Small Business Innovation Research or Small Business Technology Transfer program grants), and subawards where the originating sponsor is PHS. An electronic version of the regulation is found at <https://www.federalregister.gov/documents/2011/08/25/2011-21633/responsibility-of-applicants-for-promoting-objectivity-in-research-for-which-public-health-service>

3. Acronyms

- 3.1 *DO: Designated Official*
- 3.2 *eRA: electronic Research Administration*
- 3.3 *FCOI: Financial Conflict of Interest*
- 3.4 *HHS: U.S. Department of Health and Human Services*
- 3.5 *NIH: National Institutes of Health*

- 3.6 *PD/PI*: Project Director or Principal Investigator
- 3.7 *PHS*: Public Health Service
- 3.8 *SFI*: Significant Financial Interest
- 3.9 *UNA*: Universidad Nacional, Costa Rica

4. Key definitions

The following definitions are provided as a reference and are considered key definitions to this document only with no implied or intended institution-wide use, in understanding the federal regulations of FCOI. A complete list of official definitions can be found at 42 CFR 50.603.

- 4.1 Designated Official: According to the provisions of Articles 3, paragraph h), 11, 14 and 15 of the Regulations on impediments, excuses and recusals of the UNA, the corresponding hierarchical superior is the competent body to resolve situations that prevent an official from performing his/her duties due to an ethical conflict.
- 4.2 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.
- 4.3 Financial conflict of interest (FCOI): A significant financial interest (SFI) that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
- 4.4 Institutional responsibilities: an Investigator's professional activities on behalf of UNA (e.g., teaching, administration, research, or clinical care). Specifically, these include -but is not limited to-:
 - Externally sponsored research or scholarly activities (includes activities such as proposing, conducting, and analyzing research and disseminating results);
 - Research (includes participation in study sections, peer review of manuscripts, or effort on non-sponsored research);
 - Instruction/University Supported Academic activities (including preparation for and presentations of formal and informal courses to students/trainee groups, mentoring students and trainees, and participation in resident training);
 - Administrative activities including serving as Department Chair, Program Director, or service on institutional committees, participation in department activities or faculty advisory boards, etc.; or
 - Special Service activities on behalf of UNA including institutional community service.
- 4.5 Investigator: a Project Director or Principal Investigator (PD/PI) and any other person, regardless of title or position, who is or will be responsible for the design, conduct, or reporting of research or proposed research for funding by the PHS/NIH, which may include, for example, subgrantees, contractors, subcontractors, collaborators or consultants.
- 4.6 PHS: the U.S. Public Health Service, an operating division of the U.S. Department of Health and Human Services (HHS), and any components of the PHS to which the authority involved may be delegated, including the NIH.

- 4.7 PHS Awarding Component: Organizational unit of the PHS that funds the research that is subject to 42 CFR 50 subpart F.
- 4.8 Project Director (PD)/Principal Investigator (PI): is the individual designated by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program to be supported by the award. Multiple individuals may be designated as program directors/principal investigators who share the authority and responsibility for leading and directing the project, intellectually and logistically.
- 4.9 Reimbursed or sponsored travel: travel which is paid on behalf of the Investigator and not reimbursed to the Investigator related to the Investigator's institutional responsibilities so that the exact monetary value may not be readily available.
- 4.10 Remuneration: includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship).
- 4.11 Research: 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). As used in 42 CFR 50 subpart F, 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.
- 4.12 Senior/Key Personnel: 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 the regulation 42 CFR part 50 subpart F.
- 4.13 Significant Financial Interest (SFI):
- (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) that reasonably appears to be related to the Investigator's institutional responsibilities:
 - (i) With regard to any publicly traded entity, a significant financial interest 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 \$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 significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$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); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests when exceeds \$5,000.

(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available) when exceeds \$5,000, related to their institutional responsibilities. Investigators, including subrecipient Investigators, must disclose all financial interests received from a foreign Institution of higher education or the government of another country (which includes local, provincial, or equivalent governments of another country). The disclosure will include:

(i) The purpose of the trip

(ii) The identity of the sponsor/ organizer

(iii) The destination of the trip

(iv) The duration of the trip

(v) Other information that is needed according to the institutional official(s) opinion, as a but not limited to, disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

(3) The term SFI 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.

4.14 Subrecipient: An entity that receives a subaward from the awardee Institution to carry out part of the PHS-funded research and is accountable to the awardee institution for programmatic outcomes and compliance matters. The term includes consortium participants. For ensuring any subrecipient's compliance with the regulation and reporting identified FCOI for subrecipient Investigators to the NIH, the awardee institution will incorporate as part of a written agreement with a subrecipient the terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient will apply to subrecipient Investigators and the requirements related to disclosure of FCOI.

5. Procedure:

5.1 Responsibilities

5.1.1 PD/PI:

The PD/PI must comply with all Investigator Responsibilities and in addition provide a list of individuals who meet the definition of “investigator” within the required disclosure timeline.

5.1.2 Investigators:

- a. Completing all required training and education.
- b. Disclose any and all identified SFI.
- c. Assist with the development of a management plan for any identified SFI.
- d. Comply with this procedure and with any management plan developed to manage any identified FCOIs.
- e. Disclose a new SFI within 30 days of acquiring or discovering a new SFI.
- f. Completing the annual disclosure form even if they have no financial interests to report.
- g. Submit to the DO all the records relating to implementation of this procedure.

5.1.3 Institutional

- a. Provide annual and ad hoc FCOI reports to PHS/NIH;
- b. Maintain central records relating to all Investigator disclosures of financial interests and review of and actions taken related to such disclosures;
- c. Address non-compliance in accordance with this procedure;
- d. Take relevant corrective actions;
- e. Receive, review and register changes to FCOIs;
- f. Receive from investigators new SFIs disclosed within 30 days and reporting to NIH within 60 days of identifying an FCOI
- g. Provide Institutional-level monitoring and assurance;
- h. Record completion of training by all Investigators;
- i. Ensure that all University Investigators involved in the PHS/NIH project are aware of, comply with and make any disclosures required under this procedure; and
- j. Ensuring that annual updates and disclosures of new or increased financial interests are disclosed.

5.2 SFI Disclosure

5.2.1 Persons Required to Disclose an SFI

The PD/PI and all other investigators must complete and submit to UNA’s DO a fully completed SFI Disclosure Form (this requirement also applies to investigators who are or who work for subgrantees, subcontractors, or collaborators on PHS-funded research), for each NIH funded project at the following times SFI must be disclosed to the Institutional designated official(s) by the time an application is submitted to the NIH for funding, within thirty (30) days of discovering or acquiring a new Significant Financial Interest, and on an annual basis.

5.2.2 *Annual Reporting and After-Acquired SFIs:* all Investigators shall notify the DO:

- annual SFI Disclosure reports;
- an updated disclosure of SFI within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI; or
- SFI Disclosure when joining an ongoing PHS-funded project as soon as possible.

5.3 **Determination of FCOI**

- 5.3.1 DO determines, on behalf of the University, whether an FCOI exists for the purposes of the NIH policy.
- 5.3.2 The DO must determine whether the SFI declared by the Investigator may reasonably be said to be related to the PHS/NIH research by assessing whether the SFI:
- a. could be affected by the PHS/NIH research; or
 - b. is in an entity whose financial interest could be affected by the PHS/NIH research.
- 5.3.3 If the SFI is determined by the DO to be related to the PHS/NIH research, the DO must determine whether the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH research.
- 5.3.4 If the SFI is determined by the DO to both: (a) relate to the NIH research; and (b) affect the design, conduct or reporting of the PHS/NIH research, it is an FCOI, and must be managed (see below).

5.4 **Disclosure review**

Upon receipt of a completed SFI Disclosure, UNA's DO will review the form. If necessary, additional information shall be requested from the investigator and other individuals to help determine whether the SFI disclosed is related to a proposed or existing sponsored project or program. The review will determine whether financial relationships present a source of potential conflict with PHS-sponsored research. If it is determined that there:

- is not a FCOI, the "disclosure forms" will be filed in the SFI binder.
- is a potential, creates a FCOI related to that research subaward, submit an FCOI report to PHS/NIH and implement a management plan within 60 days of disclosure.

All FCOI reports shall be submitted to the NIH through the electronic Research Administration (eRA) commons.

5.5 **Reporting**

The University, through its DO, must provide initial and ongoing FCOI reports to NIH. As outlined in the NIH Regulation, FCOI reports must include sufficient information to enable NIH to understand the nature and extent of the financial conflict and to assess the appropriateness of the UNA's management plan.

UNA will provide to the PHS/NIH a FCOI report as outlined in the regulations:

- Initial Report: Prior to expenditure of any funds under the NIH-funded research project, the Institution will provide a FCOI report regarding any SFI found to be a FCOI.

- UNA will also provide a FCOI report within 60 calendar days from the date of a new SFI disclosure determined to be a FCOI, a new Investigator with an identified FCOI becomes engaged in the project or when the Institution identifies a FCOI not previously disclosed.
- Annual FCOI reports (or revised reports as a result of retrospective reviews), will include the status of financial conflict, i.e., whether the financial conflict is still being managed or explains why the financial conflict no longer exists. These FCOI reports will also include a description of any changes to the management plan since the last FCOI report.

5.6 **Management of FCOI**

Where a FCOI is identified, the DO must develop and implement a management plan on a case by case basis within 60 days of the FCOI being identified that specifies the actions that have been, and shall be, taken to manage such FCOI. The Investigator is required to comply with the management plan prescribed by the DO. On behalf of the UNA, the DO must appropriately monitor compliance at the local level with any management plan until the completion of the PHS/NIH project.

Such a plan will include some or all of the following as deemed appropriate:

- a. Public disclosure of FCOI (e.g., when presenting or publishing the research to staff members working on the project; to the Institution's Institutional Review Board(s), etc;) if appropriate.
- b. Disclosure of SFI directly to subjects involved in human research.
- c. 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;
- d. Modification of the research plan;
- e. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- f. Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- g. Severance of relationships that create the actual or potential conflict of interest.

5.7 **Non-compliance**

- 5.7.1. In the event that an incidence of non-compliance or suspected non-compliance is identified, PD/PI and/or Investigators must immediately:
 - a. report the non-compliance or suspected non-compliance to the DO; and
 - b. take all necessary steps to retrospectively comply with this procedure relating to disclosure, determination and management of SFIs.
- 5.7.2. In any case in which the HHS determines that an NIH-funded 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 a conflicting interest that was not managed or reported by the Institution as required by the regulation, the Institution must require the Investigator(s) involved to disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations. Institution's Financial Conflict of Interest policy may have additional requirements.

- 5.7.3. Whenever a Financial Conflict of Interest is not identified or managed in a timely manner, including:
- Failure by the Investigator to disclose a Significant Financial Interest that is determined by the Institution to constitute a Financial Conflict of Interest;
 - Failure by the Institution to review or manage such a Financial Conflict of Interest; or
 - 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.
- 5.7.4. Where non-compliance relates to PHS/NIH research investigating the safety or effectiveness of a drug or device, the University may require the Investigators to disclose the FCOI in each public presentation and request an addendum to previously published outcomes relating to the research, and the Investigators must comply with this requirement.
- 5.7.5. In the event of non-compliance with any requirements under this procedure, the University may take corrective actions in accordance with applicable University and NIH policies and procedures, including withholding access to NIH funds and/or suspending project activity.

5.8 **Training requirements**

PHS-funded Investigators must complete FCOI training prior to engaging in research related to any PHS-funded grant or contract or as deemed necessary by the University due to:

- An investigator is new to the institution research under a subaward issued under a PHS prime award.
- Changes in the FCOI policy in a manner that effects PHS-funded Investigator disclosure or compliance requirements (training is to be completed within the timeframe specified in communications announcing such changes).
- An investigator is new to a subrecipient and will be working on PHS funded research.
- Non-compliance of the Investigator with the FCOI Policy or an FCOI Management Plan (training is to be completed within 30 days in the manner specified by the DO).

At least, the FCOI training shall be taken every four years thereafter. Upon completion of the training, a certificate of completion must be turned into the DO. All investigators must print the certification and retain it for audit purposes. NIH web-based training will be used. The course is accessible at https://grants.nih.gov/grants/policy/coin/tutorial2018/story_html5.html

5.9 **Sub-recipient**

Sub-award recipients (involves subcontractors, subgrantees or subawardees) must comply with this policy or provide certification that their organization is in compliance with the Federal policy, *2011 Revised Financial Conflict of Interest Regulation, Promoting Objectivity in Research (42 CFR part 50 subpart F)* and that their portion of the research project, as detailed in their sub-award agreement (all matters necessary to implement 42 CFR 50.604), is in compliance with their institutional policies. If a SFI is identified by the sub-award recipient, they are required to:

- a. notify UNA's DO of the existence of the conflicting interest within 30 days of the identification of the interest.
- b. submit all requisite details of FCOIs to the DO
 - i. prior to the expenditure of funds; and
 - ii. within 30 days of any subsequently identified FCOI;
- c. promptly notify the University of any management plan and suspected non-compliance; and
- d. provide a declaration that all FCOIs have been identified, disclosed, managed, reduced or eliminated in accordance with NIH requirements.

5.10 **Records**

Records of Investigator SFI Disclosure forms and the Institution's review of, or response to, such disclosure (whether or not a disclosure resulted in the Institution's determination of a Financial Conflict of Interest), and all actions under the Institution's policy or retrospective review, shall be store and retain by the DO for three (3) years from the date the final expenditure report is submitted to the NIH (in accordance with NIH and University requirements) or, where applicable, from other dates specified in 45 C.F.R. 75.361 for different situations.

5.11 **Public Accessibility**

1. As required by PHS regulation, the UNA FCOI policy will be publicly available via the UNA web site: <https://www.aice.una.ac.cr/index.php/documentos-de-interes>
2. For PHS-Funded Research, DO shall make information concerning SFI that meet the criteria below available to the public, upon written request for such information:
 - a. SFI was disclosed and is still held by Senior/Key Personnel (as defined in this policy);
 - b. DO determined the SFI is related to a PHS-Funded Research project;
 - c. DO determined the SFI constitutes an FCOI.
3. The above information made available shall consist of the minimum elements as required by 42 CFR Part 50, Subpart F and shall be provided by written response to the requestor including, at least, following:
 - Investigator's name;
 - Investigator's title and role with respect to the research project;
 - Name of the entity in which the Significant Financial Interest is held;
 - Nature of the Significant Financial Interest; and
 - Approximate dollar value of the Significant 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.

4. The above information shall remain available for public request for at least three years from the date that the information was most recently updated.