



Inter American University of Puerto Rico

NORMS AND PROCEDURES FOR THE DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS IN RESEARCH PROJECTS

NORMATIVE DOCUMENT A-0423-070

Introduction

Inter American University of Puerto Rico (IAUPR) promotes transparency and ethical values in all its functions, including those in research projects. The Institution, as well as the members of the Institutional community that collaborate in research projects, have the obligation of ensuring that research projects are not a cause of conflict about financial interest. This implies that the researchers and their family members or the persons who work in these projects cannot have financial interests related to the project that could affect or predispose their judgment in the design and execution of the tasks they must perform to achieve project goals.

I. Legal Base

This normative document is established by virtue of the authority conferred to the President of IAUPR by the Board of Trustees in the Bylaws of the Institution and is in harmony with institutional policies and norms and with the applicable federal and state regulations. This document also complies with the prescribed requirements of the National Institutes of Health (NIH), the National Science Foundation (NSF), and any other regulatory agency.

II. Purpose

This document establishes the norms and procedures to ensure that those significant financial conflict of interest (SFI) from investigators, that are determined to be a financial conflict of interest (FCOI) be identified, managed, and reported to National Institutes of Health (NIH) or any other local or federal agency.

III. Applicability

The provisions of this document apply to investigators working on research projects supported by the Public Health Service (e.g., NIH), research projects supported by other federal and state agencies, and research projects with no external funding.

IV. Definitions

1. Agency or Sponsoring Entity: Organization to which a proposal or request for external funds is made.
2. Company or Business (Outside Organization): means organization, independent of its legal form, in which, through the administration of its resources, capital and work, goods or services are produced to satisfy people's needs. This term does not include the Institution or any of its auxiliary enterprises.
3. Designated Institutional Official: means the person appointed by the President to oversee the compliance with conflict-of-interest regulations and policies.
4. Disclosure of Significant Financial Interests: means an Investigator's disclosure of significant financial interests that are related to the Investigator's institutional responsibilities (e.g., research, research consultation, teaching, clinical, etc.) to the Institution.
5. Family Member: means an Investigator's spouse or dependent children.
6. Federal Funds: Research funding by means of a grant or cooperative agreement from the Federal Government of the United States of America, either received directly from the federal agencies (e.g., NIH) or pass thru from an agency or public corporation of the Commonwealth of Puerto Rico.
7. FCOI Report: means the Institution's report of a financial conflict of interest to an external agency or sponsoring entity awarding component.
8. Financial Conflict of Interest: A significant financial interest that could directly and significantly affect the design, conduct or reporting of funded research.
9. Financial Interest: means anything of monetary value, whether the value is readily ascertainable.
10. Institution: means Inter American University of Puerto Rico (IAUPR) and any of its academic units or auxiliary enterprises.
11. Institutional Official: means the President of the Institution.
12. Institutional Research Funds: means money from an institutional fund destined to subsidize research projects.
13. Investigator (Researcher): 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 funded research, or proposed for such funding, which may include, for example, collaborators or consultants.
14. Significant Financial Interest means:
 - a. 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 university (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 12 months preceding the disclosure and the value of any equity interest or fixed asset value of the entity as of the date of disclosure, when aggregated, equals or exceeds \$5,000;
 - ii. with regard to any non-publically traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, equals or exceeds \$5,000 or when the investigator (or the

- investigator's spouse and dependent children) holds any equity interest (e.g., stock, stock options, or other ownership interest); or
 - iii. intellectual property rights and interests (e.g., patents, copyrights, trademarks), upon receipt of income related to such rights and interests, that equals or exceeds \$5,000;
 - iv. Clinical trial intellectual property rights (and royalties or other remuneration, if any, paid with respect to such rights).
- b. The disclosure of the Investigators 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), related to their institutional responsibilities, that equals or exceeds \$5,000.
- i. This disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government located in the United States, a United States institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States institution of higher education.
- c. The term *significant financial interest* 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;
 - ii. rights in intellectual property assigned to the Institution, including the right to participate in the Institution's royalties;
 - iii. equity in or income from investment vehicles, such as mutual funds and retirement accounts, if the Investigator does not directly control the investment decisions made in these vehicles; or
 - iv. income from seminars, lectures, or teaching engagements sponsored by, or income from service on advisory committees or review panels.
16. Proposal: Document prepared in response to a Request for Proposal (RFP) from a program or sponsoring organization to obtain funding.
17. 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).
18. Subrecipient: means a nonfederal entity that receives a subaward from a pass-through entity to carry out a federal program but does not include an individual that is a beneficiary of such program.
19. Subsidy or External Funding: Economic aid granted by a sponsoring organization to achieve determined objectives, and activities for which responsibilities and results are required, in return.

V. General Provisions

1. Investigators who work in research projects must submit the “Financial Conflict of Interest Annual Disclosure Form” (Supplement I) properly completed in agreement with the instructions provided. This form must be submitted: (a) with each proposal request, (b) with each acceptance of project funds even though no proposal has been submitted, and (c) once a year on the date designated by the Institution. The submission of this document is required prior to participation in any research project.
2. When the research proposal entails the review and authorization of some regulatory committee (including, but not limited to protection of human or animal subjects, and biosafety) it must include the proper form along with the documents that will be submitted for evaluation and authorization of the appropriate committee and the final determination of said committee.

VI. Institutional Responsibilities

The Institution is responsible for:

1. Providing the regulatory framework and resources to effectively implement the financial conflict of interest norms and procedures.
2. Informing and providing investigators financial conflict of interest training as required by federal entities:
 - a. Institution policies and procedures
 - b. NIH conflict of interest training module for NIH funded research grants
 - c. Other federal entities training requirement, if applicable
3. Provide adequate guidelines to the Designated Institutional Official to determine whether an Investigator's SFI is related to PHS/NIH-funded research or any other agency, and, if so related, whether the SFI is an FCOI. (See Section 7.6)
4. Designate an Institutional official(s) to solicit and review Investigator SFI disclosures and those of the Investigator's spouse and dependent children related to an Investigator's institutional responsibilities for a determination of FCOI.
5. Send initial, annual (i.e., ongoing) and revised FCOI reports for the Institution's Investigators and those of its subrecipients, if applicable, including all required information defined in the regulation (e.g., 42 C.F.R. 50.605) via the means (e.g., eRA Commons FCOI Module), as required by such regulation.
6. Maintain all FCOI-related records, for at least three (3) years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 C.F.R. 75.361, for different situations, of:
 - a. Investigator disclosures of financial interests
 - b. Institution's review of, and response to, such disclosures (whether a disclosure resulted in the Institution's determination of a financial conflict of interest) of all actions under the Institution's policy or retrospective review, if applicable,

7. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator's compliance (e.g., letters of reprimand, restriction on the use of funds, etc.).
8. For clinical research where an FCOI was not managed or reported by the Institution, as required by the regulations, the Institution shall require the Investigator to:
 - a. Disclose the FCOI in each public presentation of the results of the research, and
 - b. Request an addendum to previously published presentations.
9. Subrecipient will follow their FCOI policy if IAUPR determines the subrecipient has a compliant FCOI policy.
10. Make the Institution's FCOI policy, as well as required information concerning identified significant FCOI held by senior/key personnel in PHS funded research, or research projects from other agency, publicly accessible upon request within five (5) business days.

VII. Distribution of Responsibilities and Procedures

1. The Assistant Vice-presidency for External Resources has the responsibility of:
 - a. Requiring the submission of the "Financial Conflict of Interest Annual Disclosure Form" (Supplement I) as part of the documents for submission of proposals.
 - b. Inform the researchers about the existence of institutional norms and policies regarding their responsibilities to disclose all foreign and domestic significant financial interests (SFI).
2. The Office of Institutional Academic Research has the responsibility of:
 - a. Provide training to researchers about institutional norms and policies related to significant financial conflict of interest.
 - b. Make available training resources to researchers (e.g. NIH modules for NIH funded research at <https://grants.nih.gov/grants/policy/coi/fcoi-training.htm>, CITI program and any other available training).
 - c. Assist the Designated Institutional Official with the review of the FCOI reports prior to submission.
3. The Investigator (researcher) has the responsibility to:
 - a. Complete FCOI training prior to engaging in research related to NIH, NSF, and any other regulatory agency, at least every four (4) years, when the Institution revises its FCOI policy that affects requirements of Investigators, when the Investigator is new to an Institution, or when the researcher is not in compliance with the policy or management plan.
 - b. Know and understand the federal and state laws, as well as the institutional norms and policies applicable to the research project.
 - c. Disclose their foreign and domestic Significant Financial Interests (SFIs) and those of the Investigator's spouse and dependent children, if applicable, including but not limited to research, research consultation,

teaching, and professional practice, no later than at the time of application for funded research, at least annually during the period of the award, or within thirty (30) days of discovering or acquiring a new SFI.

- d. Submit, as part of the proposal package, the “Financial Conflict of Interest Annual Disclosure Form” (Supplement I) as established in the institutional norms and policies.
 - i. In case a significant financial conflict of interest is declared, the researcher must provide information for each organization (source) where such conflict of interest was declared.
 - e. When the research proposal requires the authorization of an ethics regulatory committee (IRB, IACUC, IBC), submit the conflict-of-interest form, properly filled out and signed along with all necessary documents for the evaluation and authorization of the appropriate committee.
 - f. When disclosing travel expenditures, the Investigator must specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration, for the Designated Institutional Official to determine if further information is needed to determine whether the travel constitutes an FCOI with the funded research.
 - g. For clinical research where an FCOI was not managed or reported by the Institution, as required by the regulations, the Institution shall require the Investigator to: Disclose the FCOI in each public presentation of the results of the research and request an addendum to previously published presentations.
4. The Designated academic unit official has the responsibility to:
- a. Review the proposal package, including the FCOI documentation to make recommendation to the Chief Executive of the academic unit, prior to proposal submission.
5. The Chief Executive or the designated official of the academic unit has the responsibility to:
- a. Review proposal package considering the recommendations of the Designated academic unit official.
 - b. Submit the FCOI documentation to the Designated Institutional Official for its review and the proposal package to the Assistant Vice-Presidency of External Resources.
 - c. As instructed by the Designated Institutional Official, ensure the execution of the implementation of the conflict-of-interest management plan as recommended.
6. The Designated Institutional Official has the responsibility to:
Reasonably determines that an Investigator’s Significant Financial Interest is related to a research project (e.g., NIH funded or another agency) when: (a) the Significant Financial Interest affects the research; or (b) the Significant Financial Interest in an

entity whose financial interest could be affected by the research; and, (c) could directly and significantly affect the design, conduct or reporting of the NIH-funded research.

- a. Review the Investigator's SFI disclosures and those of the Investigator's spouse and dependent children, related to an Investigator's institutional responsibilities to determine if conflict exists or not, within the following timeframes:
 - i. Prior to the expenditure of funds under a new award;
 - ii. Within 60 days if an Investigator is new to participating in the research project or when an existing Investigator discloses a new SFI.
- b. If it is determined that significant financial conflict of interest exists:
 - i. Notify the Chief Executive of the academic unit about the finding.
 - ii. Develop and implement a conflict-of-interest management plan to take care of and manage conflicts.
 - iii. Inform all interested parties: Chief Executive of the academic unit, the Dean of Academic Affairs, the Investigator.
 - iv. This plan may include, but is not limited to:
 1. Inform all interested parties regarding the conflict of interest when the researcher is going to publish or present results.
 2. Require the Investigator to disclose the FCOI to research personnel working on the study.
 3. Inform the Institutional Academic Research Office, as well as the participants, about the conflict when the project involves human subjects.
 4. Inform the Auxiliary Vice-Presidency of External Resources if the Investigator is associated with a funded grant.
 5. Name an independent monitor that has the responsibility to take measures to design strategies that protect the design, and the way of reporting the results of the research.
 6. Require the Investigator to modify the research plan.
 7. Require changes or the substitution of project personnel.
 8. Require the researcher to somehow reduce his conflict of interest in the project.
- c. Develop and implement, within the established timeframes, at least on an interim basis, a management plan that specifies the actions that have been, and will be taken to manage the FCOI, when the Institution identifies an SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Institution during ongoing funded research project.
- d. Manage FCOIs, including any financial conflicts of a subrecipient Investigator, if applicable, and monitor Investigator compliance with management plans until completion of the project.
- e. If it is determined that there should be participation of the researcher's peers in the supervision of the implementation of the conflict-of-interest

management plan, one or more of the researcher's peers, who are not from the same academic unit, will be appointed for this task.

- f. Together, with the appointed peers, if any:
 - i. Supervise the implementation of the conflict-of-interest management plan for the project under consideration.
 - ii. Ensure that the academic unit involved complies with the implementation of the conflict-of-interest management plan of the indicated project.
 - iii. Maintain the Chief Executive of the academic unit and the Designated Academic Unit Official, informed about the implementation of the conflict-of-interest management plan.
 - iv. If required, submit to the funding agency a report indicating the steps that have been taken to significantly reduce or eliminate the financial conflict of interest.
- g. Prepare and send initial, annual (i.e., ongoing) and revised FCOI reports for the Institution's Investigators and those of its subrecipients, if applicable, including all required information defined in the regulation via the means required by each agency (e.g., eRA Commons FCOI Module), as follows:
 - i. Initial report – Prior to the institution's expenditure on any funded research project (e.g., NIH).
 1. This also applies for non-funded research projects.
 - ii. Initial FCOI reports during an ongoing research project (e.g., NIH-funded):
 1. Sixty (60) days after its determination that an FCOI exists for an Investigator who is newly participating in the project or for an existing Investigator who discloses a new Significant Financial Interest to the Institution during the period of award.
 2. Within sixty (60) after de Designated Institutional Official review a previously existing Significant Financial Interest that was not disclosed by the Investigator
 3. Within 120 days of the Institution's determination of noncompliance, as described in Section of this document.
 - iii. Annual report – Two months prior to the start date or 45 days prior to the start date of the noncompeting continuation award, at the same time as when the Institution is required to submit the annual progress report.
- h. When required, if bias is found, submit to NIH or other applicable entities, a Mitigation Report based on the results of a retrospective review.
- i. Notify the agency if an Investigator (or subrecipient Investigator) fails to comply with the Institution's FCOI policy or noncompliance with a FCOI management plan.

- j. Apply the established mechanisms and employee sanctions or other administrative actions to ensure Investigator compliance (e.g., letters of reprimand, restriction on the use of funds, etc.).
- k. Complete a retrospective review within 120 days of the Institution's determination of noncompliance when an SFI is not disclosed timely or previously reviewed or whenever an FCOI is not identified or managed in a timely manner, including:
 - i. Failure by the Investigator to disclose an SFI that is determined by the Institution to constitute a financial conflict of interest;
 - ii. Failure by the Institution to review or manage such a financial conflict of interest;
 - iii. Failure by the Investigator to comply with the financial conflict of interest management plan.
- l. Document and report the retrospective review, including the minimum key elements as established by NIH or other entities, as applicable. For NIH funded research projects, the review will include at least the following key elements:
 - 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, etc.);
 - viii. Findings of the review; and
 - ix. Conclusions of the review.
- m. For clinical research where an FCOI was not managed or reported by the Institution, as required by the regulations, the Investigator shall:
 - i. Disclose the FCOI in each public presentation of the results of the research; and
 - ii. Request an addendum to previously published presentations.
- n. Ensuring subrecipient's compliance with the regulation and reporting identified financial conflicts of interests for subrecipient Investigators to the NIH or other applicable entities.
 - i. Require subrecipients to certify that they have an FCOI policy and that it complies with applicable regulations.
- o. If the subrecipient does not have or cannot certify that they have a compliant FCOI policy, the subrecipient shall comply with the Institution's FCOI policy.
- p. Appoint ad hoc committees' members to collaborate in the implementation of any of the responsibilities within this section.

VIII. Severability

If any part of this document is declared null by a competent authority, such a decision will not affect the rest of the document.

IX. Repeal or Amendments

This normative document revokes the normative document A-0811-039R *Norms and Procedures for the Disclosure of Significant Financial Interests or Obligations in Projects Subsidized with External and Institutional Funds* and any other directives in conflict with the provisions established herein. This document may be amended or repealed by the President of the University.

X. Effective Date

This document will go into effect upon the approval and signature of the President.

XI. Approval

Signed by President on

April 2, 2024

Rafael Ramírez Rivera, Ed.D.

Date

President

Supplements



Inter American University of Puerto Rico

Supplement I (Investigator)

**INVESTIGATOR FCOI DISCLOSURE FORM
To Be Completed and Signed by the Investigator**

Investigator Information	Sponsor Information (NIH, NSF, Other)
Investigator Name: _____	Sponsoring Agency: _____
IAUPR Campus and Department: _____	Project Title: _____
Email: _____	Project Start Date: _____
Phone: _____	Project End Date: _____
	Grant Number for the Project: _____

SIGNIFICANT FINANCIAL INTERESTS

For you the investigator, your spouse/partner and dependent children, identify significant financial interests (SFI) that are reasonably related to your institutional responsibilities (e.g., research, research consultation, teaching, clinical, etc.) performed on behalf of IAUPR, and meet any of the following criteria: (A) any remuneration received from an external entity at present or in the 12 months preceding the disclosure that totals or exceeds \$5,000 (the \$5,000 threshold applies to salary, royalties, and other payments aggregated for the individual, one's spouse/ partner and dependent children); (B) publicly-traded equity if the value of the equity (plus any remuneration) meets or exceeds \$5,000; (C) any level of ownership of privately-held equity regardless of the dollar value. You do not need to disclose any financial interests from your employer or income received from seminar lectures, or teaching engagements sponsored by or income from service on advisory committee or review panels for a U.S. Federal, state or local government agency, a U.S. institution of higher education, a U.S. academic teaching hospital, medical center, or a U.S. research institute affiliated with a U.S. Institution of higher education. Refer to the full definition in the following page for additional information

I do not have any SFI (proceed to and complete certification section below)

I disclose the following SFI (complete the table below and complete certification section below)

Name: _____		Mail Address: _____			
Institution: _____		Telephone Number: _____			
		Email Address: _____			
			Approximate value of the financial interest		
Identify the source of the SFI	Identify the Recipient (Investigator, Spouse/Partner,	Identify the SFI Type (e.g., salary, royalty, equity,	\$5,000 - \$19,999 increments of \$5,000 (e.g.	\$20,000 - \$100,000 Increments of \$20,000	\$100,000 and above by increments of \$50,000

	Dependent Child, or combination)	stocks, consulting fees, honoraria, etc.)	\$5,000 to \$10,000)		

SPONSORED/REIMBURSED TRAVEL
Provide the Following Fields Below (refer to the FAQs on the following page for additional information)

Sponsor	Destination	Start / End Date	Purpose

Prior to submitting this form, please review your entries for accuracy then sign and date the form.

Certification: By signing this form, as the investigator, I certify that the above entries are true and complete to the best of my knowledge and belief, and that I have reviewed IAUPR FOIC policy and have completed the CITI training and/or the NIH FCOI Training, as applicable. I understand and agree that it is my responsibility to update this information promptly if my personal or financial interests related to this study's research activities change and at least annually during the period of the award. I understand and agree with the sponsored travel requirement as outlined in the documents. I will report qualified sponsored travel to IAUPR within 30 days of the conclusion of the trip.

Name (Please Print)

Signature

Date (MM/DD/YYYY)

SIGNIFICANT FINANCIAL INTEREST (SFI)

Significant Financial Interest:

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 university (institutional) responsibilities.

- with regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure and the value of any equity interest or fixed asset value of the entity as of the date of disclosure, when aggregated, equals or exceeds \$5,000;
- 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 12 months preceding the disclosure, when aggregated, equals or exceeds \$5,000 or when the investigator (or the investigator's spouse and dependent children) holds any equity interest (e.g., stock, stock options, or other ownership interest); or
- intellectual property rights and interests (e.g., patents, copyrights, trademarks), upon receipt of income related to such rights and interests, that equals or exceeds \$5,000;
- Clinical trial intellectual property rights (and royalties or other remuneration, if any, paid with respect to such rights).

Significant Financial Interest does NOT include:

- Financial interests or activities that do not relate to your academic or professional work at your employer organization;
- Salary support received through your organization or salary support through your organization's administered sponsored awards;
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as you do not directly control the investment decisions made in these vehicles;
- Income from seminars, lectures and teaching engagements sponsored by U.S. Federal, state or local government agencies; U.S. Institutions of higher education or U.S. research institutes; U.S. academic teaching hospitals or U.S. medical centers that are affiliated with U.S. Institutions of higher education;
- Income from service on advisory committees or review panels for U.S. Federal, state or local government agencies; U.S. Institutions of higher education or U.S. research institutes; U.S. academic teaching hospitals or U.S. medical centers that are affiliated with U.S. Institutions of higher education.

SPONSORED TRAVEL

The disclosure of the Investigators 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), related to their institutional responsibilities, that equals or exceeds \$5,000.

This disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government located in the United States, a United States institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States institution of higher education.

This reporting requirement does not apply to NSF awards.

You must disclose third party paid travel related to your institutional responsibilities if you ARE responsible for the design, conduct or reporting of research funded by the PHS (or other agencies/sponsors that have adopted the PHS regulations):

Third party paid travel means:

- Third party directly pays in whole or in part for travel on your behalf;
- You pay for travel and third party reimburses you in whole or in part;
- Your institution pays in whole or in part for travel and the third party reimburses your institution;
- PHS regulations require you to disclose travel paid by:
- Paid for by external professional organizations and societies, academic journals, and publishing companies; and
- ANY travel reimbursed or sponsored by a foreign institution of higher education or the government of another country.

PHS regulations exclude travel paid by:

- Your institution or funded by a sponsored award to your institution;
- U.S. Federal, state or local government agencies;
- U.S. Institutions of higher education or U.S. research institutes; and
- U.S. academic teaching hospitals or U.S. medical centers that are affiliated with U.S. Institutions of higher education.

Additional examples are provided in the following chart:

Travel paid for by industry (directly paid to the individual, not through your own institution)	Yes
Travel paid for by a non-profit foundation	Yes
Travel paid for by a professional society (e.g. American Cancer Society, European Society for Pediatric Infectious Diseases)	Yes
Travel to a university paid for by the United States university to give a lecture	No
Travel funds received from a foreign government or foreign institution of higher education, etc. requires disclosures if such income exceeds the threshold for disclosure.	Yes
Travel to a board meeting in another state paid for by the American Heart Association	Yes
Travel to an advisory board meeting for a nonprofit for which you are reimbursed	Yes
Travel paid for by the American Cancer Society to an academic meeting to present NIH grant-funded research	Yes
Travel to another university to give a seminar where the university reimburses you, but the university received funding for the seminar from a pharmaceutical company	No, if the reimbursement came from a United States university
Travel that combines a trip to an advisory board paid for by the company and a family vacation for which I am paying for myself	The vacation part of the trip must be paid for by personal funds and not by the company that is paying for the business trip. (Only need to disclose the duration of the business portion of the trip)



Inter American University of Puerto Rico

Supplement II (Subrecipients)

**SUBRECIPIENT FCOI DISCLOSURE FORM
To Be Completed and Signed by the Subrecipient**

The Inter American University of Puerto Rico (IAUPR), determine if a subrecipient

Subrecipient Information	Sponsor (NIH, NSF, Other) & IAUPR Information
Subrecipient's Legal Name: _____	Sponsoring Agency: _____
Address: _____ _____	Project Title: _____
Name of Investigator: _____	Sponsor's Identification Number for the Project: _____
	Name of IAUPR PI: _____

institution representing an "investigator" has a compliant financial conflict of interest (FCOI) policy, and requires the subrecipient to disclose information should a FCOI be present. These sponsors include the United States Public Health Service (PHS), which includes the National Institutes of Health (NIH) and other agencies, the National Science Foundation (NSF), and others (for a current list of non-PHS Agencies adhering to PHS's FCOI policy go to: http://sites.nationalacademies.org/PGA/fdp/PGA_070596). The term "investigator" means any person on behalf of the subrecipient who is responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding by that sponsor, including a consultant or collaborator, as applicable. The following information is requested to ensure compliance with the requirements.

CONFLICT OF INTEREST (CHECK APPLICABLE BOX)

Subrecipient hereby certifies it has implemented and is enforcing a written policy of financial conflict of interest compliant with the Public Health Service (PHS) provisions of 42 CFR Part 50, Subpart F and 45 CFR Part 94. The investigator responsible for the design, conduct or reporting of research for the proposal has made the required disclosures in accordance with the subrecipient's policy. Subrecipient shall report any financial conflict of interest to IAUPR's Designated Institutional Official. Such report shall be made before expenditure of funds authorized by the sponsor and within 40 days of any subsequently identified financial conflict of interest. Submit a copy of your FCOI Policy.

Subrecipient **HAS NOT** implemented a written policy of financial conflict of interest compliant with PHS provisions of 42 CFR Part 50, Subpart F and 45 CFR Part 94 or NSF's requirement, as applicable. Subrecipient Investigators will complete the attached

IAUPR Financial Conflict of Interest Disclosure Form and return them to the appropriate office at the following times:

- No later than at the time of application for funded research and before funds can be released;
- Within 30 days of discovering or acquiring a new Significant Financial Interest;
- At least annually during the period of the award.

DEBARMENT AND SUSPENSION

Is the investigator proposed to participate in this project debarred, suspended, or otherwise excluded from or ineligible for participation in federal dept., agency, assistance programs or activities?

Yes (If "Yes", explain in below) No

Signature of Subrecipient: _____ Date: _____

Name: _____ Title: _____

Return the completed form(s) to _____

All investigators must complete training on Financial Conflicts of Interest. This training is provided by CITI, and can be taken online by registering at the following website: <https://www.citiprogram.org/>

For NIH funded grants, complete the NIH Conflict of Interest Module available at:

SUBRECIPIENT FCOI DISCLOSURE FORM
To Be Completed and Signed by the Subrecipient

SIGNIFICANT FINANCIAL INTERESTS

For you the investigator, your spouse/partner and dependent children, identify significant financial interests (SFI) that are reasonably related to your institutional responsibilities (research, research consultation, teaching, clinical) performed on behalf of your institution, and meet any of the following criteria: (A) any remuneration received from an external entity at present or in the 12 months preceding the disclosure that totals or exceeds \$5,000 (the \$5,000 threshold applies to salary, royalties, and other payments aggregated for the individual, one's spouse/ partner and dependent children); (B) publicly-traded equity if the value of the equity (plus any remuneration) meets or exceeds \$5,000; (C) any level of ownership of privately-held equity regardless of the dollar value. You do not need to disclose any financial interests from your employer or income received from seminar lectures, or teaching engagements sponsored by or income from service on advisory committee or review panels for a U.S. Federal, state or local government agency, a U.S. institution of higher education, a U.S. academic teaching hospital, medical center, or a U.S. research institute affiliated with a U.S. Institution of higher education. Refer to the full definition in the following page for additional information

I do not have any SFI (proceed to and complete certification section below)

I disclose the following SFI (complete the table below and complete certification section below)

Name: _____	Mail Address: _____
Institution: _____	Telephone Number: _____
	Email Address: _____

		Approximate value of the financial interest _____			
	Identify the Recipient (Investigator, Spouse/Partner, Dependent Child, or combination)	Identify the SFI Type (e.g., salary, royalty, equity, stocks, consulting fees, honoraria, etc.)	\$5,000 - \$19,999 increments of \$5,000 (e.g. \$5,000 to \$10,000)	\$20,000 - \$100,000 Increments of \$20,000	\$100,000 and above by increments of \$50,000

SPONSORED/REIMBURSED TRAVEL

Provide the Following Fields Below (refer to the FAQs on the following page for additional information)

Sponsor	Destination	Start / End Date	Purpose

Prior to submitting this form, please review your entries for accuracy then sign and date the form.

Certification: By signing this form, as the investigator, I certify that the above entries are true and complete to the best of my knowledge and belief, and that I have reviewed IAUPR FOIC policy and have completed the CITI training and/or the NIH FCOI Training,

as applicable. I understand and agree that it is my responsibility to update this information promptly if my personal or financial interests related to this study's research activities change and at least annually during the period of the award. I understand and agree with the sponsored travel requirement as outlined in the documents. I will report qualified sponsored travel to IAUPR within 30 days of the conclusion of the trip.

Name (Please Print)

Signature

Date (MM/DD/YYYY)

SIGNIFICANT FINANCIAL INTEREST (SFI)

Significant Financial Interest:

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 university (institutional) responsibilities.

- with regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure and the value of any equity interest or fixed asset value of the entity as of the date of disclosure, when aggregated, equals or exceeds \$5,000;
- 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 12 months preceding the disclosure, when aggregated, equals or exceeds \$5,000 or when the investigator (or the investigator's spouse and dependent children) holds any equity interest (e.g., stock, stock options, or other ownership interest); or
- intellectual property rights and interests (e.g., patents, copyrights, trademarks), upon receipt of income related to such rights and interests, that equals or exceeds \$5,000;
- Clinical trial intellectual property rights (and royalties or other remuneration, if any, paid with respect to such rights).

Significant Financial Interest does NOT include:

- Financial interests or activities that do not relate to your academic or professional work at your employer organization;
- Salary support received through your organization or salary support through your organization's administered sponsored awards;
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as you do not directly control the investment decisions made in these vehicles;
- Income from seminars, lectures and teaching engagements sponsored by U.S. Federal, state or local government agencies; U.S. Institutions of higher education or U.S. research institutes; U.S. academic teaching hospitals or U.S. medical centers that are affiliated with U.S. Institutions of higher education;
- Income from service on advisory committees or review panels for U.S. Federal, state or local government agencies; U.S. Institutions of higher education or U.S. research institutes; U.S. academic teaching hospitals or U.S. medical centers that are affiliated with U.S. Institutions of higher education.

SPONSORED TRAVEL

The disclosure of the Investigators 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), related to their institutional responsibilities, that equals or exceeds \$5,000.

This disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government located in the United States, a United States institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States institution of higher education.

This reporting requirement does not apply to NSF awards.

Third party paid travel means:

- Third party directly pays in whole or in part for travel on your behalf;
- You pay for travel and third party reimburses you in whole or in part;
- Your institution pays in whole or in part for travel and the third party reimburses your institution;
- PHS regulations require you to disclose travel paid by:
- Paid for by external professional organizations and societies, academic journals, and publishing companies; and
- ANY travel reimbursed or sponsored by a foreign institution of higher education or the government of another country.

PHS regulations exclude travel paid by:

- Your institution or funded by a sponsored award to your institution;
- U.S. Federal, state or local government agencies;
- U.S. Institutions of higher education or U.S. research institutes; and
- U.S. academic teaching hospitals or U.S. medical centers that are affiliated with U.S. Institutions of higher education.

Additional examples are provided in the following chart:

Travel paid for by industry (directly paid to the individual, not through your own institution)	Yes
Travel paid for by a non-profit foundation	Yes
Travel paid for by a professional society (e.g. American Cancer Society, European Society for Pediatric Infectious Diseases)	Yes
Travel to a university paid for by the United States university to give a lecture	No
Travel funds received from a foreign government or foreign institution of higher education, etc. requires disclosures if such income exceeds the threshold for disclosure.	Yes
Travel to a board meeting in another state paid for by the American Heart Association	Yes
Travel to an advisory board meeting for a nonprofit for which you are reimbursed	Yes
Travel paid for by the American Cancer Society to an academic meeting to present NIH grant-funded research	Yes
Travel to another university to give a seminar where the university reimburses you, but the university received funding for the seminar from a pharmaceutical company	No, if the reimbursement came from a United States university
Travel that combines a trip to an advisory board paid for by the company and a family vacation for which I am paying for myself	The vacation part of the trip must be paid for by personal funds and not by the company that is paying for the business trip. (only need to disclose the duration of the business portion of the trip)