



Conflict of Interest in Research # 2370.005

INITIAL EFFECTIVE DATE:	LAST REVISION DATE:	RESPONSIBLE UNIVERSITY DIVISION/DEPARTMENT
November 3, 2008	August 18, 2021	Office of Research Integrity

POLICY STATEMENT

Florida International University promotes objectivity in research by establishing and maintaining standards that require the design, conduct, and reporting of research conducted at the University, or on its behalf, be free from bias due to any Financial Conflict of Interest as defined herein. To this end, all Investigators, as defined herein, on proposed or existing research projects must disclose to the University all financial interests, including those as defined as Significant Financial Interests (as defined herein) in relation to the Investigators' University responsibilities and the University will approve and manage or disapprove any Financial Conflict(s) of Interest in accordance with this policy.

Additionally, all University employees engaging in research overseen by ORED consent to University policies, the regulations of the Florida Board of Governors, and the laws of the State of Florida. All University employees engaged in the design, conduct, or reporting of research are required to disclose to the University and receive a determination from the University that their outside activity or financial interest does not affect the integrity of the University. An employee who has failed to disclose any outside activity or financial interest as required by Florida Statute Section 1012.977 and this policy shall be suspended without pay pending the outcome of an investigation which shall not exceed sixty (60) days. Upon conclusion of the investigation, the University may terminate the employee.

This policy implements the disclosure and review requirements of outside activities and financial interests applicable to research, which requirements stem from federal and State of Florida laws and regulations. FIU employees are also required to disclose their outside activities and financial interests pursuant to the State of Florida Code of Ethics for Public Officers and Employees, Part III, Chapter 112, Florida Statutes and FIU policies implementing the Florida Code of Ethics, policies #140.105, Ethics in Purchasing and Gift Policy, and #140.110, Fraud Prevention and Mitigation/University Responsibility and Response.

All University employee disclosures of outside activities, financial interests or other conflicts of interest (whether required under this policy or under any other FIU conflict of interest policy) shall be done via the Division of Human Resources' "Report of Outside Activity/Conflict of Interest" Employee Portal. The questions on the Employee Portal prompt FIU employees to make the necessary disclosures.



If there is any new outside activity or financial interest, including any new Significant Financial Interest or material change in a previously disclosed outside activity or financial interest, including any Significant Financial Interests, the employee must disclose the same within thirty (30) days of discovering or acquiring the new outside activity or financial interest. In addition, annually, the employee must submit a report of outside activity or financial interest on the Employee Portal regardless of whether he/she has any outside activity or financial interest; thus, the employee must certify either that he/she has no outside activity or financial interest or disclose those that he/she has on the Employee Portal. The employee may not engage in the activity until approved whether the disclosure is part of the annual reporting or a new reporting because of a material change.

SCOPE

This policy applies to all University faculty, staff and students engaged in all proposed or existing University research and collaborators in proposed or existing University research.

REASON FOR POLICY

To establish a disclosure and review process that ensures that conflicts of interest in research projects are reviewed and managed in accordance with applicable laws and regulations.

DEFINITIONS

TERM	DEFINITIONS
Designated Official	the Vice President for Research or his/her designee.
Disclosure of significant financial interests	an Investigator's disclosure of significant financial interests to the University.
Engaged in Research	participating in a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge.
Financial Conflict of Interest (FCOI)	a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
FCOI report	the University's report of a financial conflict of interest to a PHS Awarding Component.
Financial interest	anything of value, other than that provided directly by the University, whether or not the value is readily ascertainable.
HHS	the U.S. Department of Health and Human Services.
Human Subjects Research	all research meeting the definition of "research" involving "human subjects" as defined in the Federal Common Rule (45 CFR Part 46 and 21 CFR Part 56), regardless of the source of research funding or whether the research is otherwise subject to federal regulation.

<p>Institutional responsibilities</p>	<p>an employee’s professional responsibilities on behalf of the University, which includes: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.</p>
<p>Intellectual Property</p>	<p>inventions, discoveries, processes, methods, compositions, formulae, procedures, protocols, techniques, results of experimentation and testing, information and data, whether patentable or not, patents, designs (whether registered or unregistered and including semi-conductor topographies), utility models, copyright and database right, trademarks and service marks (whether registered or unregistered), trade names and domain names, trade secrets rights in goodwill, rights in unpatented know-how, rights of confidence and any other intellectual or industrial property rights of any nature including without limitation all rights to the grant of and applications for the same and all renewals, reissues, extensions, divisions and continuations of them, together with all similar and analogous rights throughout the world for their full term.</p>
<p>Investigator</p>	<p>the principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research or of proposed research, which may include, for example, collaborators or consultants. For purposes of this definition:</p> <p><i>“Conduct of research”</i> means the supervision or management of a study's execution. This is typically done by the principal investigator (PI) and co-investigators, but also may be performed by postdoctoral fellows and graduate students who have significant supervisory roles for junior researchers or technicians who are part of the study. For studies involving human subjects, this includes anyone who is responsible for explaining the study, risk-benefit, and/or alternatives to potential participants, is listed on the Form FDA 1572 or device agreement, and/or must complete a sponsor's conflict of interest form.</p> <p><i>“Design of research”</i> means the planning of the scientific strategy to test a research proposal.</p> <p><i>“Reporting of research”</i> means the authorship of: publications to journals or otherwise, reports to the research sponsor, or presentation at conferences or</p>



	scientific meetings related to the research.
Manage	taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
ORED	Office of Research and Economic Development, Florida International University.
Outside Activity	includes anything a University employee does for an organization or an individual other than the University that is related to the employee's expertise and/or is not part of the employee's assigned duties.
PHS	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	the organizational unit of the PHS that funds the research that is subject to this subpart.
Principal Investigator or (PI)	the University employee listed on the Electronic Proposal Routing Approval Form (ePRAF) as having primary responsibility for the overall conduct of the sponsored project, or if the research is not externally funded, the University employee having primary responsibility for the overall research project. The PI is a senior/key personnel and an Investigator.
Research	a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. 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 or other sponsor through a grant or cooperative agreement or contract, 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	the PI and any other person identified as senior/key personnel on a grant application, progress report, or any other report submitted to the project sponsor.
Significant Financial Interest (SFI)	a financial interest of the Investigator (and those of the Investigator's spouse and dependent children) that are set forth in the federal regulation and which reasonably appear to be related



	to the Investigator's institutional responsibilities. The entire definition of Significant Financial Interest is contained in section I(A)(2) of the Procedures below.
University	Florida International University.

RELATED RESOURCES

FIU Human Resources Conflict of Interest/Outside Activity Policy including FIU Policy #140.105, Ethics in Purchasing and Gift Policy

FIU Policy No. 140.110, Fraud Prevention and Mitigation/University Responsibility and Response

45 CFR 74.42

45 CFR Part 94

State of Florida Code of Ethics for Public Officers and Employees, Chapter 112, Part III, Florida Statutes

Florida Statute Section 1012.977

CONTACTS

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HISTORY

Initial Effective Date: November 3, 2008

Review Dates (*review performed, no updates*): January 12, 2024

Revision Dates (*updates made to document*): August 24, 2012 and October 4, 2012. [October 4th 2012 revision was non-substantive in nature: all references to the “Internal Clearance Form” in the policy document were revised to reflect that the form is now known as the “Electronic Proposal Routing Approval Form (ePRAF)”]. November 30, 2020. [This last revision was made to comply with the requirements of Florida Statute Section 1012.977 which became effective on July 1, 2020.]; November 30, 2020; August 18, 2021; April 4, 2023 (procedure only).



Conflict of Interest in Research # 2370.005a

INITIAL EFFECTIVE DATE:	LAST REVISION DATE:	RESPONSIBLE UNIVERSITY DIVISION/DEPARTMENT
November 3, 2008	April 4, 2023	Office of Research Integrity

PROCEDURE STATEMENT

I. Reporting Obligations

A. Federal Reporting Requirements

1. Who must report, when and how?

Each Investigator who is planning to participate, or who is participating in a research project, must disclose to FIU the Investigator's Significant Financial Interests (and those of the Investigator's spouse and dependent children):

- a. no later than the time a proposal for a sponsored research project is submitted to the Office of Research and Economic Development for review;
- b. an updated disclosure of Significant Financial Interests annually by the University's due date for all conflict of interest disclosures
 - which shall include any new Significant Financial Interests and also updated information regarding any previously disclosed Significant Financial Interest (e.g., the updated value of a previously disclosed equity interest); and
- c. an updated disclosure of Significant Financial Interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest.

An "Investigator" is the Principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of the research (including collaborators or consultants).

The above required disclosures are to be done via the Division of Human Resources' "Report of Outside Activity/Conflict of Interest" webpage, with Investigators who are University employees disclosing electronically on the "Employee Portal" (the "OA/COI Electronic Portal") and Investigators who are not University employees (e.g., students, subcontractors, consultants or collaborators) disclosing using the paper form available on that same webpage.

2. What must be reported?

The items that must be disclosed are Significant Financial Interests (SFI) which are defined as the following interests of the Investigator and the Investigator's spouse and

dependent children that reasonably appear to be related to the Investigator's Institutional responsibilities:

- a. Interest in publicly traded entities if the following interests, when aggregated among the Investigator and the Investigator's spouse and dependent children, exceed \$5,000:
 - i) any remuneration (e.g., salary and any payment for services not otherwise identified as salary such as consulting fees, honoraria, paid authorship) received from the publicly traded entity by the Investigator and/or the Investigator's spouse and dependent children in the twelve months preceding the disclosure plus
 - ii) the value of any equity interest (including stock, stock options, or other ownership interest) in the publicly traded entity as of the date of the conflict disclosure.
- b. Interest in non-publicly traded entities if:
 - i) the aggregated value of any remuneration received from any non-publicly traded entity by the Investigator and/or the Investigator's spouse and dependent children in the twelve months preceding the conflict disclosure exceeds \$5,000 **OR**
 - ii) when the Investigator (or the Investigator's spouse or dependent children) holds *any* equity interest in the non-publicly traded entity.
- c. Intellectual Property rights and interests. Disclosure is required upon receipt of income related to such rights and interests except for royalties received from intellectual property assigned to the University as described below.
- d. Travel must be disclosed as follows:
 - i) If it is reimbursed or sponsored travel related to the Investigator's Institutional responsibilities and
 - ii) The travel is sponsored or reimbursed from an entity that is not one of the following **United States** entities:
 - (1) a Federal, state, or local government agency;
 - (2) an institution of higher education;
 - (3) an academic teaching hospital;
 - (4) a medical center; or
 - (5) a research institute that is affiliated with an institution of higher education.
 - iii) Disclosure is required both when the amount of reimbursement or payment for the travel is known and when the travel is paid on behalf of the Investigator and the exact monetary value is not known.
 - iv) The details of travel disclosure must include, at a minimum:
 - (1) the purpose of the trip;
 - (2) the identity of the sponsor/organizer;
 - (3) the destination;

(4) the duration; and

(5) additional information may be required (including a determination or disclosure of monetary value) if the Designated Official determines that the information is needed to determine whether the travel constitutes a FCOI.

The following types of financial interests are not deemed to be SFI under the federal regulations and therefore need not be disclosed in connection with this policy:

1. salary, royalties, or other remuneration paid by the University to the Investigator if the Investigator is currently employed or otherwise appointed by the University, including intellectual property rights assigned to the University and agreements to share in royalties related to such rights;
2. 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 those vehicles;
3. income from seminars, lectures, or teaching engagements sponsored by one of the following **United States** entities: a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or
4. income from service on advisory committees or review panels for one of the following **United States** entities: a Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

B. All Employees Engaged in Sponsored Research

Florida law requires that all University employees engaged in the design, conduct or reporting of sponsored research on behalf of FIU must report his/her financial interests (i.e., anything of value other than that provided directly by the University) and his/her outside activities (i.e., anything the University employee does for an organization or an individual other than the University that is related to the employee's expertise and/or is not part of the employee's assigned duties). Therefore, to the extent that a University employee has a financial interest or an outside activity that is not already reported pursuant to section 1.A above, the University employee must report those outside activities and financial interests on the "Report of Outside Activity/Conflict of Interest" Employee Portal.

C. Electronic Proposal Routing Approval Form (ePRAF) Conflict of Interest Questions

In addition to the reporting noted above, if the research project is or seeks to be externally funded, the Principal Investigator must respond to the conflict of interest questions on the ORED ePRAF. If a Significant Financial Interest, outside activity or financial interest arises after the proposal was submitted to an external sponsor, then the same must be reported by the employee on the Employee Portal and also to ORED by the PI submitting an amended response to ORED to the ePRAF questions as soon as the PI becomes aware of the new Significant Financial Interest, outside activity or financial interest. At time of award setup or

award action continuation ORED will follow up with the PI to ensure that all employees engaged in research activities in said project have met the disclosure requirements of this policy.

II. University Review and Reporting of Conflict of Interest Disclosure

A. Determination if Financial Conflict of Interest (FCOI) Exists and Development of Management Plan

A research project (regardless of funding source) may not commence unless the review of the disclosed Significant Financial Interests, outside activities and financial interests is finalized and the research has been approved to continue as set forth below. If a Significant Financial Interest, outside activities or financial interests is disclosed on a currently existing research project that is sponsored by any sponsor other than the PHS, the University shall review the same and impose actions regarding them (e.g., updating an existing management plan) using the same processes as set forth in this Section II. The PHS imposes additional requirements for Financial Conflicts of Interest discovered on existing PHS-funded research projects and those are set forth below in Section III. To the extent that any sponsor in addition to the PHS adopts the PHS FCOI requirements, the

University shall apply the PHS requirements set forth in this policy to such sponsor's proposals and awards.

Prior to FIU's commencement of any research project or the expenditure of any funds on any sponsored research project, or if a Significant Financial Interest, outside activity or financial interest is disclosed on an existing project that is not funded by the PHS, the Designated Official shall review the disclosures to determine whether any is related to the research and, if so, whether the disclosure(s) is/are a Financial Conflict of Interest. An Investigator's Significant Financial Interest and/or an employee's financial interest or outside activity is related to the research when the Designated Official reasonably determines that the Significant Financial Interest, outside activity or financial interest could be affected by the research; or is in an entity whose financial interest could be affected by the research. The Designated Official may contact the Investigator or University employee for additional information, as needed, and may involve the Investigator or the employee in the Designated Official's determination of whether a Significant Financial Interest, financial interest or outside activity is related to the research. The Designated Official may refer the matter to a research conflict of interest committee (the "Committee") for review and recommendation. A FCOI exists when the Designated Official or the Committee reasonably determines that the Significant Financial Interest, outside activity or financial interest could directly and significantly affect the design, conduct, or reporting of the research.

If an FCOI exists, the Designated Official or Committee may determine that the FCOI is such that the research project may not proceed or that the research project may proceed upon conditions imposed to manage the FCOI. Such conditions shall be set forth in a management plan. If the FCOI matter is submitted to the Committee, the Committee shall provide its written findings and recommendations to the Designated Official, together with a draft recommended management plan, if such a plan was deemed appropriate, for the Designated

Officials' final determination of the FCOI matter. The Designated Official may (1) accept or reject some or all of the Committee's recommendations; and/or (2) revise the draft management plan to be implemented, if applicable; and/or (3) return the matter to the Committee with instructions for further review, in which case the Committee shall, after completion of the further review, submit to the Designated Official its updated findings, recommendations and recommended draft management plan, if applicable, for final determination.

The management plan shall specify the actions that have been, and shall be, taken to manage the FCOI. Examples of conditions or restrictions that might be imposed to manage a FCOI include, but are not limited to:

- (i) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- (ii) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- (iii) 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;
- (iv) Modification of the research plan;
- (v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- (vi) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- (vii) Severance of relationships that create financial conflicts.

FIU shall monitor compliance with the management plan on an ongoing basis until the completion of the research project.

B. Reporting to the Project Sponsor

1. PHS-Funded Research

Prior to FIU's expenditure of any funds under a PHS-funded research project, FIU shall provide to the PHS Awarding Component a FCOI report regarding any Investigator's Significant Financial Interest found by FIU to be conflicting and ensure that FIU has implemented a management plan. If FIU identifies an FCOI and eliminates it prior to the expenditure of PHS-awarded funds, FIU shall not submit an FCOI report to the PHS Awarding Component.

The FCOI report shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of FIU's management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:

- (i) Project number;
- (ii) PI or Contact PI if a multiple PI model is used;
- (iii) Name of the Investigator with the FCOI;
- (iv) Name of the entity with which the Investigator has an FCOI;

(v) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);

(vi) Value of the 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;

(vii) A description of how the financial interest relates to the PHS-funded research and the basis for FIU's determination that the financial interest conflicts with such research; and

(viii) A description of the key elements of FIU's management plan, including:

(A) Role and principal duties of the conflicted Investigator in the research project;

(B) Conditions of the management plan;

(C) How the management plan is designed to safeguard objectivity in the research project;

(D) Confirmation of the Investigator's agreement to the management plan;

(E) How the management plan will be monitored to ensure Investigator compliance; and

(F) Other information as needed.

For any FCOI previously reported by FIU with regard to an ongoing PHS-funded research project, FIU shall provide to the PHS Awarding Component an annual FCOI report, concurrently with the annual progress report, that addresses the status of the FCOI and any changes to the management plan for the duration of the PHS-funded research project, including extensions with or without funds. The annual FCOI report shall specify whether the FCOI is still being managed or explain why it no longer exists.

2. NSF-funded Research

For projects funded by the NSF, the University must inform the NSF's Office of the General Counsel if the University finds that it is unable to satisfactorily manage an actual or potential FCOI. The University's notification must be submitted electronically via the NSF FastLane system.

3. Other Funded Research

The University shall report any FCOI to the sponsors on projects other than PHS or NSF funded projects as required by applicable sponsor regulations and the sponsor award document.

III. Additional Requirements for PHS-Funded Research

A. Review of a New SFI Disclosure in an Ongoing PHS-funded Research Project

If, in the course of an ongoing PHS-funded research project, an Investigator who is new to participating in the research project discloses a Significant Financial Interest or an existing

Investigator discloses a new Significant Financial Interest to FIU, the Designated Official shall, within sixty days of receipt of the disclosure: review the disclosure to determine whether it is related to ongoing research, whether a FCOI exists and, if so, implement, on at least an interim basis, a management plan (as described in section II above). Depending on the nature of the Significant Financial Interest, the Designated Official may determine that additional interim measures are necessary with regard to the Investigator's participation in the ongoing research project between the date of the disclosure and the completion of FIU's review.

If a FCOI is found, FIU shall provide an updated FCOI report to the PHS Awarding Component within sixty days of, as applicable, the identification of the FCOI for the Investigator who is newly participating in the project or the identification of the new FCOI for an existing Investigator. The content of the FCOI report is set forth in section II above.

B. Review of an Untimely SFI Disclosure in an Ongoing PHS-Funded Research Project

If FIU identifies a Significant Financial Interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by FIU during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the Designated Official shall, within sixty days of learning of the failure of the disclosure or review of the SFI: review the Significant Financial Interest, determine whether it is related to the research, determine whether a FCOI exists and, if so: implement, on at least an interim basis, a management plan (as described in section II above) that shall specify the actions that have been, and will be, taken to manage such FCOI going forward.

In addition, whenever a FCOI on a PHS-funded project 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 Designated Official to constitute a FCOI; failure by FIU to review or manage such a FCOI; or failure by the Investigator to comply with a Management Plan, the Designated Official shall, within 120 days of FIU's determination of noncompliance, complete a retrospective review of the Investigator's activities and the research project to determine whether any research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research. FIU shall document such review, including but not necessarily limited to, all of the following key elements:

- (1) Project number;
- (2) Project title;
- (3) PI or contact PI if a multiple PI model is used;
- (4) Name of the Investigator with the FCOI;
- (5) Name of the entity with which the Investigator has an FCOI;
- (6) Reason(s) for the retrospective review;
- (7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- (8) Findings of the review; and
- (9) Conclusions of the review.

Based on the results of the retrospective review, if appropriate, FIU shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, FIU will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and FIU's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, FIU will submit FCOI reports to PHS annually. Depending on the nature of the FCOI, FIU may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the FCOI or the Investigator's noncompliance is determined and the completion of FIU's retrospective review.

C. Public Disclosure of Financial Conflicts of Interest

Prior to FIU's expenditure of any funds under a PHS-funded research project, if requested, FIU shall make available within five business days of the University Designated Official's receipt of the written request, the following information regarding any FCOI of senior/key personnel on the research project: 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 (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. This information shall remain available, for responses to written requests, for at least three years from the date that the information was most recently updated. Written requests for such information must be made via email to the Vice President for Research at vpr@fiu.edu.

D. Training

Each Investigator must complete training on this policy and the Investigator's responsibilities regarding disclosure of SFI and PHS regulations regarding financial conflicts of interest:

- (1) prior to engaging in any PHS-funded research and
- (2) at least every four years thereafter; and
- (3) immediately when any of the following circumstances apply:
 - a. the Investigator requirements of this policy are revised;
 - b. an Investigator is new to an Institution; or
 - c. FIU finds that an Investigator is not in compliance with this policy or a management plan.

IV. Subawards on Sponsored Projects

Sponsored projects may require the University to enter into subcontracts or consulting agreements (“subawards”) with outside entities or persons. In those situations, the Principal Investigator must disclose to Pre-Award, any SFI in relation to proposed subaward, regardless of the project sponsor, before the subaward is executed. If the SFI arises after the subaward is executed, the PI shall disclose to Pre-Award, the SFI as soon as the Principal Investigator learns of it.

The above disclosures are done by the PI completing the Subcontract Agreement/ Amendment Request Form or the Consulting Agreement/ Amendment Request Form, as applicable, which are available on the Office of Research and Economic Development website. Any question regarding the disclosure required should be addressed to the Pre-Award representative for the project.

V. Non-Compliance

An Investigator’s failure to report SFI as required by this policy or to follow any conditions imposed pursuant to the University’s review of such SFI may be grounds for disciplinary action, up to and including termination.

If the failure of an Investigator to comply with this policy or a management plan appears to have biased the design, conduct, or reporting of PHS-funded research, FIU shall promptly notify the PHS Awarding Component of the corrective action taken or to be taken.

In any case in which the HHS determines that a PHS-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 FCOI that was not managed or reported by FIU, FIU shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

Additionally, Florida law provides that an employee who fails to disclose any outside activity or financial interest as required by Florida law, as set forth in these Procedures, shall be suspended without pay pending the outcome of an investigation which shall not exceed sixty (60) days. Thus, if the University learns of information indicating that an employee may have failed to report information required by Florida law, the University shall conduct a review to determine if an investigation is warranted. In accordance with the requirements of FS. 1012.977, the employee will be suspended without pay during the conduct of the investigation which shall not exceed sixty (60) days from the date of commencement of the investigation. During the investigation, the University may request additional information, including from the employee, to determine if the employee, in fact, failed to disclose. After the investigation is concluded, the University may terminate the employee if it is found that the employee did not disclose information as required by Florida law.



VI. Records Retention

Records relating to all Investigator disclosures of SFI, all employee disclosures of outside activities and financial interests and FIU's review of, and response to, such disclosures (whether or not a disclosure resulted in FIU's determination of a FCOI) and all actions undertaken by FIU shall be maintained for the longer of: (a) three years from the date the final expenditures report on the research project is submitted to the sponsor or; (b) final resolution of any litigation, claim, financial management review, or audit relating to the research project or any record related thereto.