



SUBJECT: Financial Conflict of Interest in Research:	Effective Date: November 27, 2023	Policy Number: 10.1.2	
	Supersedes: April 11, 2017	Page 1	Of 10
	Responsible Authorities: Vice President for Research		

I. Background

Florida Atlantic University (FAU) is committed to ensuring the quality and integrity of its research and to compliance with state and federal guidelines and regulations as well as the requirements of sponsor organizations with regard to financial conflicts of interest. As a recipient of Federal funding, FAU is required to maintain an up-to-date written, and enforced policy on financial conflicts that complies with 42 CFR Part 50 Subpart F. The Financial Conflict of Interest Committee has been delegated the authority to set University policy with regards to the review, management, and reporting of potential financial conflicts of interest.

II. Purpose

The purpose of this policy is to ensure that the personal financial interests of FAU employees do not compromise their objectivity in

- a. designing, conducting, or reporting their research activities;
- b. protecting the welfare of research participants; or
- c. developing intellectual property.

This policy applies to all faculty, staff and students involved in sponsored research and related activities as well as the disclosure and subsequent development of intellectual property. Exemptions exist for Phase I SBIR/STTR applicants and recipients.

Policy Number:	
10.1.2	
Page	Of
2	10

III. Policy

Florida Atlantic University and its employees are committed to conducting themselves and their research activities in accordance with the highest standards. The University recognizes that actual or perceived conflicts of interest may occur in the normal conduct of research and other activities. It is essential that investigators disclose their relevant financial interests and those of their immediate family. Only after disclosure of a significant financial interest, can the University make an informed determination about a particular activity and require the appropriate oversight, limitations or prohibitions in accordance with this policy and, if applicable, state and federal regulations.

All key personnel for any sponsored research project will disclose any relevant financial interests as described below. These disclosures will be reviewed by the Financial Conflict of Interest Committee (FCOIC), a faculty led committee created for this purpose, and a determination will be made as to whether the potential for a financial conflict of interest exists.

IV. Terms and Definitions

Investigator

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, and which may include for example, collaborators or consultants

Key Personnel

The Investigator as well as any other person identified as senior or key personnel in any documentation related to a sponsored project

Immediate Family

Any spouse or dependent children of the Investigator or Key Personnel

Associated Entity

Any trust, organization, or enterprise over which an investigator or a family member of the investigator, individually or collectively, exercises a controlling interest

Outside Interest

Any organization or enterprise in which an Investigator or their immediate family holds a Significant Financial Interest

Ownership Interest

An ownership, managerial, or supervisory role with any outside entity that allows the personnel to exert control over the actions of that entity

Policy Number:	
10.1.2	
Page	Of
3	10

Financial Conflict of Interest

A significant financial interest that could directly and significantly affect the design, conduct, or reporting of a funded research project

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 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.

Significant Financial Interest does NOT include:

- i. remuneration from FAU (salary, royalties, honoraria, expense reimbursement or any other remuneration);
- ii. remuneration paid to an Investigator's Family by any entity that would not reasonably appear to be related to the Investigator's Institutional Responsibilities;
- iii. remuneration from authorship of academic or scholarly works, regardless of the source;
- iv. remuneration from seminars, lectures, or teaching engagements sponsored by, or from advisory committees or review panels for, U.S. Federal, state, or local governmental agencies; U.S. institutes of higher education as defined at 20 U.S.C. 1001(a);

Policy Number:	
10.1.2	
Page	Of
4	10

U.S. research institutes affiliated with institutes of higher education, academic teaching hospitals, and medical centers; and

- v. investment by a mutual fund, pension fund or other investment fund over which the investigator or his/her immediate family member does not exercise management of fund investment.

Conflict of Interest

when a significant financial interest (as defined herein) of an investigator, an immediate family member of the investigator, or an associated entity, would reasonably appear to be affected by the research activities of the investigator or the development of intellectual property.

Significant Financial Interest (SFI) Disclosure

A disclosure made annually and updated as needed by Investigators and Key Personnel describing all Significant Financial Interests as described in this document as well as all sponsored or reimbursed travel.

Project Specific Disclosure (PSD)

A disclosure made by Investigators and Key Personnel at the time of funding for a sponsored research project outlining the specific relationship between Significant Financial Interests and funded research projects

Travel Disclosure

Investigators also must disclose the occurrence of any reimbursed or sponsored travel over \$5,000 (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; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or 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. This disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The Financial Conflict of Interest Committee will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a financial conflict of interest with funded research.

Policy Number:	
10.1.2	
Page	Of
5	10

V. Procedures

1. Each Investigator participating in a funded research project must disclose to FAU the Investigator's Significant Financial Interests (as defined above) in a Significant Financial Interest (SFI) Disclosure at the time of submission of a proposal for a sponsored research project to Sponsored Programs. Applications for funding from an external agency may not be submitted to Sponsored Programs until all Investigators have completed and submitted, the required SFI disclosures. Disclosures must be completed even if no relevant significant financial interest exists.

For as long as the research is ongoing, SFI disclosures must be updated annually or at any time a relevant significant financial interest, not originally disclosed, develops or is acquired. Disclosures under this provision related to intellectual property shall be updated prior to the execution of any contract, license, or other transaction involving the intellectual property. The Vice President for Research (VPR) may also require an investigator to update a disclosure at any time.

2. Disclosures indicating a Significant Financial Interest will be forwarded to Research Integrity for pre-review once an indication is received by Sponsored Programs of imminent funding. At this time, any key personnel who have disclosed a relevant Outside Interest in their SFI Disclosure will complete a Project Specific Disclosure (PSD). In any instance where the required disclosure form is not submitted with the proposal submission to Sponsored Programs, the disclosure form shall be solicited directly from the Investigator.
3. Research Integrity will work with the Financial Conflict of Interest Committee, the Committee Chair, and the Investigator to ensure that the committee has enough information to make a determination as to the existence of a potential conflict of interest. This may include asking for more information from the discloser or inviting the discloser to attend an FCOIC meeting. If review of the disclosures reveals that no relevant significant financial interest exists, Sponsored Programs will be notified that no further action is required.
4. The SFI and PSD will be reviewed by the full FCOIC, or a subset of the full committee in the case of disclosures that are substantially similar to disclosures already reviewed by the committee. Any review can be referred to the full committee at any time. Once the review is complete, the committee (or subcommittee) will determine if a potential conflict exists.
5. If it is determined that a potential conflict exists, the committee will work with the PI and the Investigator to alleviate the potential for conflict. The investigator may

Policy Number:	
10.1.2	
Page	Of
6	10

eliminate a potential conflict by divesting themselves of an investment, severing a relationship with an outside entity, changing their role in the sponsored research project, or any other course of action deemed appropriate and agreed to by the FCOIC, the Investigator, and the PI.

6. If a potential conflict exists that cannot be easily eliminated, the FCOIC will work with the Investigator and the PI to develop a plan for managing and reducing the potential for conflict. The committee, or a designated subcommittee, will review and approve any proposed management plan. For research involving human subjects, the primary focus of the management plan should be to ensure that outside financial interests in no way affect the welfare of research participants. In this case, a copy of the final management plan will be sent to the IRB.
7. Some funding organizations have their own regulations regarding the disclosure, review, management, and reporting of financial conflicts of interest. In addition, some federal, state, or local regulations regarding conflicts of interest may apply. Any relevant regulations will be taken into account at each step in the review process and the FCOIC will ensure that the University and PI take steps to comply with them and to keep all parties informed of potential conflicts as required or appropriate.
8. Some funding organizations require that award subrecipients certify as part of their agreement that they have an FCOI policy in place that complies with the funding organization's policies, or that they will be subject to the FCOI policy of the primary recipient. The Office of Sponsored Programs will ensure that agreements with subrecipients meet this requirement.

An Investigator may not engage in research activities in which a potential or actual conflict exists, unless authorized in writing by the FCOI committee and endorsed by the VPR and conducted in full accord with conditions and restrictions imposed by the FCOI Committee and endorsed by the VPR.

VI. Training

Several federal agencies including the National Institutes of Health (NIH) and the National Science Foundation (NSF) require mandatory Conflict of Interest (COI) training. FAU has implemented this training for all investigators. FAU uses the Collaborative Institutional Training Initiative (CITI) Conflict of Interest training module to fulfill this mandatory requirement. Account set up for all funded awards, regardless of funding source, will not proceed without completion of the required training.

VII. The Financial Conflict of Interest Committee (FCOIC)

Policy Number:	
10.1.2	
Page	Of
7	10

Financial conflict of interest disclosures will be reviewed by the Financial Conflict of Interest Committee, a faculty led committee created for this purpose.

Membership

- a. The FCOIC members will report to and be appointed by the VPR as designated by the President. The VPR shall designate, in writing, the Chair and all other members of the committee.
- b. In addition to the Chair of the FCOIC, the FCOIC shall be composed of at least four (4) other voting members selected by the VPR from recommended nominations of members.
- c. The majority of the membership shall consist of faculty employees holding academic tenure, without administrative appointments. The remaining appointments may be comprised of faculty employees with administrative appointments and research experience (e.g., assistant deans, associate deans, deans, academic unit directors, and center or institute directors).
- d. The ex-officio members are non-voting members and should be executive staff within the Division of Research representing key areas such as Sponsored Programs, Technology Development, Research Integrity and General Counsel.
- e. The FCOIC members, other than those with ex-officio status, shall have a minimum of three (3)-year appointments.

VIII. Financial Conflict of Interest Management

If necessary, the FCOIC will work with the Investigator and PI to develop a management plan. This plan should, at a minimum, include:

- a. A description of the role and principal duties of the conflicted Investigator in the research project as well as the potential for conflict created by their Outside Interests;
- b. The specific conditions of the management plan, outlining how the plan will safeguard objectivity in the research project;
- c. Confirmation of the Investigator's agreement to the management plan;
- d. Provisions for monitoring the management plan to ensure Investigator compliance;

The management plan should pro-actively prevent:

- a. Outside activities and/or relationships in which the faculty or staff member diverts to external businesses or entities or other institutions, opportunities for research support that could have been obtained by the institution.
- b. Participation in institutional research which is funded by a grant or contract from a business or entity in which the employee, or a member of their family, or a business

Policy Number:	
10.1.2	
Page	Of
8	10

- associate, separately or in the aggregate, has a controlling ownership interest.
- c. Assignment of students to research projects sponsored by a business or entity in which the employee, a member of their family, or a business associate, separately or in the aggregate, has a substantial ownership interest.
 - d. Outside activities in which an institution's student or employee is directly or indirectly supervised by the individual seeking the exemption or if the individual in any way supervises or evaluates the student or employee as part of his or her institutional duties.
 - e. Direct supervision of any student or employee in one's capacity as a university employee and in one's capacity as an official, employee or agent of the outside company, business or entity.

The FCOIC can recommend, and the VPR impose, conditions or restrictions on investigators in formulating courses of action designed to deal with potential or actual conflict of interest. Such restrictions include, but are not limited to:

- a. public disclosure of significant financial interests,
- b. independent review of the research,
- c. disqualification of members from participation in all or portions of the research,
- d. divestiture of the significant financial interest and/or severance of relationships creating the actual or potential conflict of interest.

The FCOIC may conclude that the potential or actual conflict is sufficiently remote or unrelated to the research or intellectual property so that no action, other than the disclosure and annual reporting requirements, is required.

The VPR may accept the report and recommendations of the FCOIC or return the matter to the FCOIC with stated concerns or suggestions. The VPR shall render the final decision and notify the investigator and the FCOIC of any terms and conditions that shall be employed to manage, reduce or eliminate the conflict.

If the research involves human subjects, a copy of the final accepted report and recommendations of the FCOIC shall be forwarded to the IRB. Funding agencies may also require a reporting of potential, or managed conflicts of interest.

The plan recommended by the FCOIC and accepted by the VPR shall require annual reporting from the Investigator to the FCOIC as well as a final end of project report. The annual report to the FCOIC must include the status of the management plan, including a description of how the financial conflict is being managed or an explanation of why financial conflict no longer exists and a description of any changes to the implementation of the management plan since the last FCOI report was submitted.

Policy Number: 10.1.2	
Page	Of
9	10

IX. Accountability

The Vice President for Research will be responsible for:

1. Authorizing (in writing) an investigator to engage in research activities in which a potential or actual financial conflict exists. Such activities will be conducted in full accord with conditions and restrictions set forth in the management plan developed and endorsed by the FCOIC, the VPR, the PI and the Dean of the PI's College.

The Principal Investigator will be responsible for:

1. Disclosing all requested information needed for an appropriate review of potential or actual financial conflict of interest and ensuring that all disclosure of such information is complete, accurate and honest.
2. Completing required CITI Conflict of Interest Training Submission of the completed disclosure forms with the submission of a proposal to Sponsored Programs, and any subsequent information requested by the RI office or FCOIC and ensuring such information is provided in a timely manner.
3. Following all investigator responsibilities as set forth in this policy

The Financial Conflict of Interest Committee will be responsible for:

1. Reviewing all disclosures related to relevant outside interests and making a determination as to the existence of the potential for financial conflict of interest.
2. Reviewing and approving policies regarding financial conflict of interest disclosure and review.
3. Working with Investigators to develop Management Plans when needed

Research Integrity will be responsible for:

1. Working with the FCOIC and Investigators to ensure that all required disclosures are made correctly, and with sufficient information.
2. Working with the FCOIC and Investigators to to develop appropriate Management Plans when needed.
3. Maintaining meeting agendas, minutes, and records, as well as disclosures and any other relevant documentation.

The Office of Sponsored Programs will be responsible for:

1. Referring Investigators to the FCOI to submit Project Specific Disclosures at the time of award.
2. Ensuring that subrecipient agreements meet sponsor organization requirements.

Policy Number:	
10.1.2	
Page	Of
10	10

X. Enforcement

A violation of this policy is grounds for the discipline of an investigator or other employee. Sanctions that may be imposed for such a violation include, but are not limited to, any one or more of the following: involuntary termination of employment, non-renewal of appointment, suspension, letter of admonition, public disaffirmation of research, notification to regulatory bodies, notification to actual or potential funding agencies, decline sponsored research agreements or decline to submit or further process of intellectual property. All disciplinary proceedings initiated under this policy will be in accordance with the University governing and administrative regulations, human resources policy and procedures.

XI. References

42 CFR 50 Subpart F
45 CFR 94

POLICY APPROVAL

Initiating Authority

Signature: Gregg Fields

Date: 11/27/2023

Name: Gregg B. Fields, Ph.D, Interim Vice President for Research

Executed signature pages are available in the Initiating Authority Office(s)