



Institutional Conflict of Interest #150.200

INITIAL EFFECTIVE DATE:	LAST REVISION DATE:	RESPONSIBLE UNIVERSITY DIVISION/DEPARTMENT
January 3, 2022	February 9, 2024	Office of University Compliance and Integrity

POLICY STATEMENT

It is critical to the mission and reputation of Florida International University to maintain the public's trust that the University's endeavors are done in a manner that is not, and is not perceived as, biased or compromised by Institutional Officials' financial or business considerations. An Institutional Conflict of Interest occurs when there may be a reasonable perception that the decision of an Institutional Official in relation to a University transaction may be unduly influenced by his/her personal interests or those of his/her Family Member or those of the University instead of being made in an unbiased manner. Institutional Conflicts of Interest are not inherently unethical; however, they may introduce risks to the integrity of Institution. Because of the many and complex relationships that the University has with public and private entities, the University must be aware of any relationships involving financial gain that may compromise or appear to compromise the University's integrity. This policy implements the disclosure and review requirements of the private interests of Institutional Officials and their Family Members, so that the University may review, manage, reduce or eliminate any Institutional Conflicts of Interest.

This policy does not address the personal conflicts of interest that may arise when a University faculty member or other University employee stands to benefit financially from the results of his/her own Research because those situations are covered by other University policies, including the Conflict of Interest in Research policy #2370.005. Additionally, there are other University policies that require disclosures of employees' personal financial interests and approval of outside activities. This policy does not change or supplant the disclosures or processes required by those other University policies or procedures, and University faculty and staff are reminded that they are obliged to comply with all such applicable University policies and procedures.

SCOPE

This policy applies to the Institutional Officials.



REASON FOR POLICY

To establish a disclosure and review process that ensures that Institutional Conflicts of Interest are properly reviewed, managed, reduced or eliminated in order to avoid bias, or the appearance of bias, in University transactions.

DEFINITIONS

TERM	DEFINITIONS
Board of Trustees	Florida International University's Board of Trustees
Committee or ICOI Committee	Institutional Conflict of Interest Committee
Days	References to days in the policy and procedures shall refer to University business days unless otherwise stated
Family Member	An Institutional Officials spouse and/or dependent children
Fiduciary Role	One's legal and/or ethical obligation to act in the best interests (e.g., the financial and/or operating success) of another person or entity, other than the University or other University entity, whether such role is compensated or uncompensated. Examples of Fiduciary Roles include but are not limited to membership on a board of directors or board of advisors or a management role in a company or other entity (e.g., as corporate officer, LLC member, general partner, and governing board member of a professional association).
Human Subjects Research	This term is used as defined by the Department of Health and Human Services (HHS) and the Office for Human Research Protections (OHRP) in applicable federal laws and regulations as amended from time to time (including, without limitation, 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.
Institutional Conflict of Interest (ICOI)	when the financial or Fiduciary Roles of Institutional Officials or of the University influence or may reasonably appear to influence business or administrative decisions made by Institutional Officials on behalf of the University.
Institutional Official	an individual with direct authority over the allocation of University resources, including without limitation to assignments of University personnel and graduate students, trainees, funding, space allocation, salary, or promotion or other employment decisions for faculty who are conducting Research or performing



	<p>other services or functions on behalf of the University. For purposes of this policy, Institutional Officials include:</p> <ul style="list-style-type: none">• University President;• Executive Committee;• Athletic Director;• University Provost;• University Vice Presidents;• Deans; and• Other senior administrators, as determined by the University Compliance Officer in consultation with the University President.
Research	<p>Any organized program of scientific inquiry that involves a systematic investigation designed to develop or contribute to generalizable knowledge that is performed at, or under the auspices of, the University, and includes the design, development, testing, evaluation, conduct, reporting, review, or oversight of such program of scientific inquiry. Research includes, but is not limited to, basic and applied research, clinical research, research fellowships and training programs, and research-related activities in undergraduate and graduate education. Research also includes testing of products or research results by the University recharge centers or via auxiliary agreements.</p>

ROLES AND RESPONSIBILITIES

Institutional Officials are responsible to report their and their Family Member's financial interests and Fiduciary Roles within the timeframes set forth in this policy. The Chief Compliance Officer has the responsibility for chairing the Committee when convened.

RELATED RESOURCES

Conflict of Interest, Policy #1710.075

Conflict of Interest in Research, Policy # 2370.005

Ethics in Purchasing for Research and Intellectual Property Contracts Under Florida Law, Procedures #140.105(a)

Fraud Prevention and Mitigation/University Responsibility and Response, Policy #140.110



CONTACTS

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HISTORY

Initial Effective Date: January 3, 2022

Review Dates (*review performed, no updates*): N/A

Revision Dates (*updates made to document*): January 3, 2022; February 9, 2024 (procedure only)



Institutional Conflict of Interest #150.200a

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PROCEDURE STATEMENT

I. Reporting Institutional Officials' and their Family Members' Interests

On an annual basis, the Institutional Officials must report their and their Family Members' financial interests and/or Fiduciary Roles on the University's Human Resources Report of Outside Activity/Conflict of Interest (ROA/COI) so that ICOIs are identified and addressed in accordance with this policy. Additionally, the Institutional Officials must update their reports within twenty (20) business days of any change in their or their Family Members' financial interests and/or Fiduciary Roles. The reporting shall address the following financial interests and/or Fiduciary Roles held by the Institutional Officials and/or their Family Members:

- Equity and/or ownership interests in publicly traded for-profit entities of an amount exceeding \$10,000 in the value of its stock. Not included are: 1) equity or ownership interests in mutual funds; and 2) equity or stock holdings for which the Institutional Official or his/her Family Members do not have a role or influence over trading decisions;
- Equity (including stock, options, warrants, and the like), ownership, or founders' interests in non-publicly traded companies;
- Any Fiduciary Roles, other than to the University or other University entity, including but not limited to membership on a board of directors or board of advisors, or a management role in a company or other entity (e.g., as corporate officer, LLC member, general partner, and governing board member of a professional association); and
- Income, including royalty, equity, consulting fees, payment for travel, or other payments from for-profit entities that, in the aggregate, exceeds \$10,000 per year from each entity.
- Income in any amount from any foreign university or other foreign entity or foreign government, including any involvement in any talent programs (e.g., programs in which you have been recruited by a foreign university, entity or government).

II. Institutional Conflict of Interest Committee

The Institutional Conflict of Interest Committee (the Committee) will be comprised of individuals with sufficient independence, knowledge, and seniority. The Committee is appointed by the University President and consists of at least five (5), but no more than seven (7), voting members, comprised of representatives from University Internal Audit, the Office of Research and Economic Development, the Office of the Provost, the Office of Finance and Administration, the Office of University Compliance and Integrity, and up to two (2) voting members which may be appointed by the President. The Office of the General Counsel shall be a non-voting *ex officio* member. The Chair of the Committee will be the representative from the Office of University Compliance and Integrity. The Chair of the Committee may include additional non-voting members to the Committee on an *ad hoc* basis, as needed.

III. University Review of ICOI

The section of the ROA/COI completed by the Institutional Officials as required by this Policy will be routed to the Compliance Officer or designee for review. The Compliance Officer or designee will route to the Office of Research and Economic Development (ORED) for review and comment. The Compliance Officer will review and provide a recommendation for how to proceed in regard to each ROA/COI and, if necessary, convene the ICOI Committee to review and to provide a recommendation for how to proceed in regard to each ROA/COI.

Any subject University transaction which is, or may reasonably be viewed as being, affected by an ICOI may not be executed or commenced unless there has been a determination as set forth in this policy that there is no ICOI or that compelling circumstances warrant proceeding with the transaction despite the presence of an ICOI, provided that the transaction proceeds in accordance with the requirements imposed by a management plan to reduce, manage or eliminate the ICOI.

In reviewing a potential ICOI, the Compliance Officer and/or ICOI Committee shall consider, at a minimum, the following factors: (1) the nature of the transaction sought to be pursued at the University; (2) the nature of the financial interests or Fiduciary Roles involved; (3) how closely related are the financial interests or the Fiduciary Roles to the transaction; (4) the degree to which the financial interests or Fiduciary Roles can affect the transaction; (5) the degree of risk that the ICOI poses to the integrity or reasonable appearance of integrity of the transaction; and (6) the degree to which the ICOI can be effectively managed, reduced or eliminated. The standards and evaluation criteria do not vary by funding or regulatory oversight; additionally, the same standards apply to reviews of the financial interests of the Institution and of the financial interests and/or Fiduciary Roles held by Institutional Officials.

The Compliance Officer and/or Committee shall make its recommendations to the University President when the ICOI situation does not involve any financial interest or Fiduciary Roles of the President or the President's Family Members. The University President shall determine

how to proceed with regard to the pending transaction and the President or the President's designee shall communicate the determination, in writing, to: 1) the University employee(s) and unit(s) affected; 2) the Chair of the ICOI Committee; and 3) the Office of the Institutional Review Board (IRB) and the Chair of the IRB, if applicable. All recommendations of the Compliance Officer and/or the ICOI Committee, which involve any financial interest or Fiduciary Role of the President or the President's Family Members, will be presented to the University Board of Trustees for determination. The Chair of the University Board of Trustees shall communicate the Board of Trustees' determination, in writing, to: 1) the University President and any other University employee(s) and unit(s) affected; 2) the Chair of the ICOI Committee; and 3) the Office of the IRB and the Chair of the IRB, if applicable. In all cases where Human Subjects Research is involved, the IRB of record will have final authority to decide whether the interest and its management, if any, allows the Human Subjects Research to be approved.

The Compliance Officer and/or ICOI Committee's recommendation to the President or the University Board of Trustees, as applicable, shall be one of the following:

- No ICOI. The arrangement does not represent a significant actual, potential, or perceived ICOI that needs to be managed;
- Manageable ICOI. The arrangement can be managed with required changes. In such cases, the Committee will prepare a management plan setting forth the recommended management measures. These may include, but are not limited to: 1) effective recusal from decision-making regarding the proposed arrangement by the financially interested or fiduciary impacted Institutional Official and disclosure of the recusal to the appropriate individuals implementing the recusal; 2) reduction in the magnitude of the financial interest and/or Fiduciary Roles (generally to below the thresholds outlined above); 3) disclosure of the financial interest or Fiduciary Role in relevant publications, presentations, human subject consent forms, clinical procedure or other consent forms, educational material, etc.; 4) oversight by a disinterested University senior official or committee; and/or 5) other measures as deemed appropriate; or
- Unmanageable ICOI. The arrangement is not manageable and either the activity may not proceed or the financial interest or Fiduciary Roles must be eliminated or reduced. In cases judged to be unmanageable, eliminating or reducing the financial interest or Fiduciary Roles is preferable to prohibiting the proposed activity. The reviewing bodies and the University should generally give precedence to activities that carry out University missions over conflicting financial interests.

In all cases reviewed, the Compliance Officer and ICOI Committee must retain documentation of the review in accordance with established University requirements.

IV. ICOI That Involve Human Subjects Research

All reviews of ICOIs related to Human Subjects Research must consider whether the financial interests and/or Fiduciary Roles reported in accordance with this policy have the potential to, or may appear to, affect any of the following:

- Safety of human research subjects;
- Safety of patients; and
- Integrity of research.

The standards and evaluation criteria do not vary by funding or regulatory oversight; additionally, the same standards apply to reviews of the financial interests of the Institution and of the financial interests and/or Fiduciary Roles held by Institutional Officials.

In reviewing ICOIs that relate to Human Subjects Research, the protection of the safety and welfare of the human subjects participating in the Research is of utmost concern. Therefore, the Committee will apply, at a minimum, the following criteria in its evaluation. The Committee may determine that additional considerations are necessary on a case-by-case basis.

1. Each ICOI that is related to Human Subjects Research that involves more than minimal risk to the human subjects, requires strict scrutiny by the Committee. In such cases, the Committee, in coordination with the University's Office of Research Integrity, will invite the appropriate Institutional Review Board ("IRB") Chair, Co-Chair or member in light of the Human Subjects Research involved, to participate in the Committee's review, in an advisory role.
2. In its review of the ICOI, the Committee shall apply a rebuttable presumption that absent compelling circumstances, the Research to which the ICOI is related should not be conducted at or under the auspices of the University.
3. The rebuttable presumption may be challenged and overturned if the Committee determines that compelling circumstances exist and a management plan is developed to effectively manage or eliminate the ICOI. All reviews must consider whether the financial interests and/or Fiduciary Roles reported in accordance with this policy have the potential to appear to affect the safety of human research subjects, the safety of patients or the integrity of the Research.

V. Philanthropy

Gifts, pledges, and solicitation of gifts to the University are important to its mission. However, no charitable donation is allowed to be contingent upon the outcome of any business transaction or Research conducted at or by the University. The University hereby affirms that it will not solicit or accept gifts that in any way limit the ability of its personnel, investigators or students to conduct and/or report the results of Research in accordance with the highest scientific, medical, professional, and ethical standards. Nor will the University solicit or accept gifts (including gifts to support Research) that are contingent upon any particular business or purchasing decision(s). All gifts to the University must be handled in accordance with the institutional fundraising and gift acceptance guidelines and should be forwarded to the FIU

Foundation, Inc., for processing and record-keeping purposes. Faculty and staff members are accountable for adhering to institutional gift policies.

In some cases, the University may enter into arrangements involving the donation of all or a portion of capital equipment, with the expectation that the equipment will be used for Research or patient care. Such arrangements are appropriate, provided they do not limit the professional independence of faculty, staff or students.

VI. Institutional Investment Assets, including Endowment

The University's endowment includes assets received from philanthropy, investment, and other sources. The University hereby affirms that the individuals charged with managing the investments and endowments of the University will not communicate with Institutional Officials or University researchers concerning the conduct and interpretation of ongoing or planned Research performed at the University for the purpose of influencing investment decisions. Maintaining this robust "firewall" is essential for ensuring that the core activities of the University are not affected, or perceived to be affected, by the University's interest in maximizing the value of the endowments. If an individual becomes aware of a situation in which there appears to be a conflict of interest involving philanthropic gifts, solicitation of gifts, or management of the endowments, the individual must notify the University Compliance Officer who will ensure a review of the arrangement is conducted, and if necessary, refer the matter to the ICOI Committee.

VII. Implementation

The University Compliance Office is responsible for procedures to implement this policy.

VIII. Noncompliance

- A. Noncompliance with Disclosure Requirements. In cases in which the Compliance Office determines that there has been noncompliance with the disclosure requirements of this policy, the Compliance Office will contact the Institutional Official(s) found to be noncompliant to attempt to remedy the noncompliance. After two (2) attempts have been made by the Compliance Office, the matter will be forwarded to the individual's supervisor for appropriate action or, in the case of the President, to the Board of Trustees.
- B. Noncompliance with a Management Plan. In cases in which the ICOI Committee determines that there has been noncompliance with the terms of any management plan issued under this policy, the ICOI Committee will endeavor to work with the individual(s) to find an appropriate remedy. The ICOI Committee may recommend:
 - 1. Revision of the existing management plan to apply more stringent requirements or external monitoring;

2. Revocation of ICOI Committee approval of the conflicted activity, including possible termination of the transaction or the Research or activities related to the ICOI;
3. Removal of noncompliant individual(s) from Research or activities related to the ICOI; and/or
4. Other corrective actions, as appropriate.

C. Noncompliance Remedy Unsuccessful. If the ICOI Committee's attempt to remedy noncompliance is not successful, the ICOI Committee will report the matter to the President, or to the President's designee, or to the Board of Trustees, in the case of noncompliance by the President, for consideration of whether employee sanctions or other administrative actions are appropriate, in accordance with relevant University policies and procedures, and applicable laws and regulations.