



Division of Research Policy

SUBJECT: Financial Conflict of Interest in Research	Effective Date: September 30, 2015	Policy Number: 10.1.2				
	Supersedes: August 24, 2012 June 10, 2015	<table border="1"> <tr> <td>Page</td> <td>Of</td> </tr> <tr> <td>1</td> <td>7</td> </tr> </table>	Page	Of	1	7
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Responsible Authorities: Vice President for Research						

- I. 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 of their research activities; b) protecting the welfare of research participants; or c) developing intellectual property.
- II. General Statement
 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.
- 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 and their family members' financial interests. 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, federal regulations.
- IV. Terms and Definitions

Investigator 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.

Family Member means spouse and/or dependent child of any investigator.

Associated Entity means any trust, organization, or enterprise over which an investigator or a family member of the investigator, individually or collectively, exercises a controlling interest.

Financial Conflict of Interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of the research.

Significant Financial Interest (SFI) is defined as:

- 1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the investigator's institutional responsibilities:
 - i) With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
 - ii) With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
 - iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- 2) 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. The Institution's FCOI policy will 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. In accordance with the FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

Significant Financial Interest does NOT include:

- a. Remuneration from FAU (salary, royalties, honoraria, expense reimbursement or any other remuneration);
- b. Remuneration paid to an Investigator's Family by any entity that would not reasonably appear to be related to the Investigator's Institutional Responsibilities;
- c. Remuneration from authorship of academic or scholarly works, regardless of the source;
- d. 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); U.S. research institutes affiliated with institutes of higher education, academic teaching hospitals, and medical centers; and
- e. 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 (COI) is defined when a significant financial interest (as defined herein) of an investigator, a 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.

V. Procedures

- a) Each Investigator participating in a funded research project must disclose to FAU the Investigator's Significant Financial Interest (as defined above) at the time of submission of a proposal for a sponsored research project to Sponsored Programs. All applications for funding from an external agency may not be submitted to Sponsored Programs until all investigators have completed and submitted, the required disclosure forms. Disclosure forms must be completed even if no relevant significant financial interest exists. Investigators can find the disclosure forms at the following link:
[http://fau.edu/research/docs/policies/research-integrity/FCOI Live Form.pdf](http://fau.edu/research/docs/policies/research-integrity/FCOI_Live_Form.pdf)

For as long as the research is ongoing, disclosures under this provision relating to the ongoing research 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.

Positive disclosures indicating a significant financial interest submitted to Sponsored Programs as required by this provision will be forwarded to Research Integrity to process once an indication is received by Sponsored Programs of imminent funding. 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.

- b) Disclosures of significant financial interest must be submitted using the standard form and submitted to Sponsored Programs along with the investigator's grant submission. Link to form:
[www.fau.edu/research/docs/policies/research-integrity/FCOI Live Form.pdf](http://www.fau.edu/research/docs/policies/research-integrity/FCOI_Live_Form.pdf)

- c) 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 researchers. FAU uses the Collaborative Institutional Training Initiative (CITI) Conflict of Interest training module to fulfill this mandatory requirement. <http://www.citiprogram.org>.

The Division of Research requests researchers complete training within 30 days of a proposal submission. Effective January 1, 2016, account set up for all funded awards, regardless of funding source, will not proceed without completion of the required training component.

Financial Conflict of Interest in Research Committee (FCOIC)

Membership

- a) The FCOIC members will be appointed by the President and report to the VPR. The President 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 President from recommendations submitted by the VPR.
- 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.

Responsibilities

- a) The FCOIC provides assistance on matters involving financial conflicts of interest and disclosures of significant financial interests in research as defined by this policy.
- b) The FCOIC makes recommendations on courses of action designed to manage, reduce or eliminate the conflict.
- c) The FCOIC will be assisted in compliance oversight activities by the Research Integrity Office in the Division of Research.
- d) Research Integrity on behalf of the FCOIC shall maintain documentation of all cases reviewed with final decisions, management plans, progress reports and necessary documentation as well as agendas and minutes of all meetings.

Review

Positive significant financial interest disclosure forms shall be promptly reviewed by the Research Integrity (RI) office once forwarded from Sponsored Programs. Designated RI staff will coordinate with the FCOIC Chair for the purpose of determining if a relevant significant financial interest is disclosed. If the review of the disclosure statement reveals that NO relevant significant financial interest exists, the disclosure statement shall immediately be forwarded to Sponsored Programs and no further action is required.

If the review of the disclosure statement reveals that an actual or perceived significant financial interest does exist, the following actions must be completed prior to expenditure of any funds under the award, prior to approval by the IRB and / or prior to the submission of intellectual property for registration:

- a) The FCOIC Chair shall consult with the investigator(s) and the parties shall jointly review the disclosure statement. If a potential or actual conflict of interest is eliminated by agreement of the parties (e.g. through the divestiture of interest, severance of relationships), the FCOIC Chair will provide written detailed confirmation of the agreement of the parties to the VPR and forward the disclosure statement to Sponsored Programs. No further action is required.
- b) If elimination of the conflict or potential conflict is not possible, the FCOI committee shall develop a course of action to manage or reasonably reduce the conflict. The Division of Research may also be consulted for guidance and development of the management plan. The FCOIC Chair, and / or full committee, shall review and approve, or reject, the management plan proposed. For research involving human subjects, special attention must be paid to assure that the plan is designed so that the financial interest does not alter the risk to or welfare of research participants.
 - i. The FCOIC shall review all material provided. 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: public disclosure of significant financial interests, independent reviewer monitoring of the research, modifications of the management plan, disqualifications of members from participation in all or portions of the research, 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
 - ii. 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.
 - iii. If the research involves human subjects, a copy of the final accepted report and recommendations of the FCOIC shall be forwarded to the IRB.
 - iv. The plan recommended by the FCOIC and accepted by the VPR shall require an annual reporting from the investigator to the FCOIC with a final end of project

report. The annual report to the FCOIC must include the status of the management plan, explaining whether the financial conflict is still being managed or why the financial conflict no longer exists and a description of any changes to the management plan since the last FCOI report was submitted. Reports shall be submitted to the FCOIC and the investigator must document the actions taken to implement the conditions outlined in the plan.

VII. Management of Financial Conflict of Interest

The key elements of a management plan include the following:

- a. The 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.

The management plan must confirm that five activities will not occur. The prohibited activities include:

1. 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.
2. 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 his or her family or his or her business associate, separately or in the aggregate, has a controlling ownership interest.
3. Assignment of students to research projects sponsored by a business or entity in which the employee or a member of his or her family or his or her business associate, separately or in the aggregate, has a substantial ownership interest.
4. 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.
5. 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 private company, business or entity.

VIII. Accountability

The Vice President for Research will be responsible for:

- 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:

- 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.
- 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.
- Following all investigator responsibilities as set forth in this policy.

IX. 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.

X. Policy Renewal Date
08/23/13
12/17/16

XI. References
42 CFR 50 Subpart F
45 CFR 94

POLICY APPROVAL

Initiating Authority

Signature: _____



Date: 10-6-15

Name: Dr. Daniel C. Flynn, Vice President for Research

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