



JACKSON STATE UNIVERSITY
FINANCIAL CONFLICT OF INTEREST POLICY (FCOI)
RELATED TO FEDERAL PHS-FUNDED RESEARCH

I. PURPOSE

The University is committed to ensuring that research is conducted in a manner that ensures the integrity of the research process, free from financial conflicts of interest that might compromise, or give the appearance of compromising, the sound professional judgment of its Investigators; and minimizing the adverse affects of financial conflicts of interest in research by mitigating, managing, or if necessary, eliminating those conflicts. To that end, the purpose of this Policy is to:

- a. implement the requirements of the federal regulations set forth in 42 CFR Part 50 (the “federal regulations”) governing the University’s and each Investigator’s responsibilities for promoting objectivity in Public Health Service (“PHS”) funded research; and
- b. publish and disseminate standards that provide a reasonable expectation that the design, conduct, and reporting of research under PHS-funded grants, sub grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

II. SCOPE OF POLICY

This policy:

- a. applies to all persons at the University who meet the definition of Investigator and applies to all University activities meeting the definition of Research where the activity is funded by the PHS;
- b. is supplemental to the University’s ethics and conflict of interest policies, except that this policy supersedes all prior and existing policies on matters specifically related to financial conflicts of interest in PHS-funded research; and
- c. shall be construed in accordance with the federal regulations cited herein and shall be deemed to include any requirements set forth in such regulations that are not expressly set forth below.

III. DEFINITIONS

As used in this Policy:

Designated Institutional Official (“DIO”) means the administrator designated by the University to solicit and review disclosures of SFIs of the Investigator (and those of the Investigator’s spouse, domestic partner, and dependent children) related to an Investigator’s institutional responsibilities.

Disclosure of significant financial interests means an Investigator's disclosure of significant financial interests to the University.

Financial conflict of interest (“FCOI”) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

FCOI report means the University’s report of a financial conflict of interest to a PHS Awarding Component.

Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

Institutional responsibilities means an Investigator's professional responsibilities on behalf of the University, and as defined in this policy, which may include for example: 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.

Investigator means the project director (PD) or principal Investigator (PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of PHS-funded research, or proposed for such funding, which may include, for example, collaborators or consultants.

Office of Sponsored Research and Programs (“ORSP” or “ORSP staff”) means the University’s administrative unit charged with monitoring compliance with FCOI management plans.

Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). As used in this policy, the term includes any such activity for which research funding is available from the PHS through a grant or cooperative agreement, including 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 means the PD/PI and any other person identified as senior/key personnel by the University in the grant application, progress report, or any other report submitted to the

PHS by the University under Title 42, Subpart F (Promoting Objectivity in Research) of the Code of Federal Regulations.

Significant financial interest (“SFI” or “SFIs”) means:

1. A financial interest consisting of one or more of the following interests of the Investigator (*and those of the Investigator's spouse, domestic partner, and dependent children*) that reasonably appears to be related to the Investigator's Institutional Responsibilities:
 - a. 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.
 - b. 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).
 - c. Intellectual property rights and interests (e.g., patents, copyrights) upon receipt of income related to such rights and interests.
 - d. Reimbursed or sponsored travel (*i.e.*, that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities.
2. Exceptions: “Significant financial interest” **does not** include the following type of financial interests:
 - a. Salary, royalties, or other remuneration paid by the University to the Investigator if the Investigator is currently employed or otherwise appointed by the University;
 - b. Intellectual property rights assigned to the University and agreements to share in royalties related to such rights;
 - c. Income from seminars, lectures, or teaching engagements 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;

d. 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 these vehicles;

e. Income from service on advisory committees or review panels for 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; or

f. 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.

University means Jackson State University.

IV. POLICY IMPLEMENTATION

A. Training Requirements

As of August 24, 2012, all PHS-supported Investigators are required to complete mandatory FCOI training at the following times:

- a. prior to engaging in PHS-funded research and at least once every four years thereafter;
- b. when this policy is revised in any manner that affects the requirements of Investigators;
- c. when an Investigator is new to JSU; and
- d. when an Investigator is not in compliance with this FCOI policy or a management plan, as determined by the Designated Official.

The Investigator is required to complete the online certification training tutorial and print a certificate for filing with other FCOI disclosure documentation. The training tutorial is available online at <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>.

B. Disclosure of Significant Financial Interest “SFI”),

Each Investigator must submit a FCOI Disclosure Statement form (together with the funding application) to the Designated Institutional Official (“DIO”) specifically identified in section “C” below, reflecting all of the Investigator’s SFI (and those of the Investigator’s spouse,

domestic partner, and dependent children), that the Investigator determines to be reasonably related to the Investigator's institutional responsibilities. The disclosure form is available online at <http://2.jsucdn.com/research/files/2013/01/SubcontractorDisclosure.pdf> . Investigator disclosures are required as follows:

1. Upon Application. Each Investigator who is planning to participate in PHS-funded research must disclose SFI to the DIO not later than the time of application or submission of a formal proposal for the PHS-funded research.
2. Annually. Each Investigator who is participating in PHS-funded research must submit an updated disclosure of SFI at least annually to the DIO during the period of the award. Such disclosure shall include any information that was not disclosed initially to the University pursuant to paragraph "1" above, or in any subsequent disclosure of SFI (e.g., any financial conflict of interest identified on a PHS-funded project that was transferred from another Institution), and shall include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).
3. New SFI. Each Investigator who is participating in PHS-funded research must submit a disclosure of SFI within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.
4. With respect to SFI of reimbursed or sponsored travel, disclosures will include, at minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

C. Process for Reviewing Investigator Significant Financial Interests

1. Designated Institutional Official ("DIO")

The Vice President of Research and Federal Relations is the University's Designated Institutional Official to solicit and review disclosures of SFI of the Investigator (and those of the Investigator's spouse, domestic partner, and dependent children) related to an Investigator's institutional responsibilities.

2. Initial Review and Action

Prior to the Investigator's expenditure of and before the University disburses any funds for a PHS-funded research project, the DIO will do the following:

- a. *Solicit and review* Investigator SFI disclosures and any other information deemed relevant (e.g. research proposal summary). In connection with this review, the DIO may require the Investigator to provide additional information.

b. *Determination of SFI.* The DIO will determine whether an Investigator's SFI is related to the PHS-funded research project. An Investigator's SFI is related to PHS-funded research when the University, through its DIO, reasonably determines that the SFI: (i) could be affected by the PHS-funded research; or (ii) is in an entity whose financial interest could be affected by the research. The DIO may involve the Investigator in the DIO's determination of whether a SFI is related to the PHS-funded research. The DIO will be guided by the following practices and apply them as may be appropriate in determining whether the SFI is related to the PHS-funded research project.

i) Consider the nature and extent of the financial interest in the relationship of the investigator/family member and the external organization.

ii) Give special consideration to the terms and conditions of sponsored project agreements that may mitigate or complicate the given situation.

iii) Consult with and obtain additional information from the Investigator/family member as either the DIO or the Investigator/family member may feel to be helpful in resolving actual or potential conflicts.

iv) Act in a timely manner so as to not delay unduly the conduct of the sponsored project.

c. *Determination of FCOI.* Upon determining that the disclosed financial interest is a SFI, the DIO will review the SFI to determine whether a FCOI exists and thus whether further review and management is required. An FCOI exists when the University, through its DIO, reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

D. Management of FCOI

1. Management Plans. When the DIO has determined that a FCOI exists, the DIO will develop and recommend for implementation to the Vice President for Research & Federal Relations a management plan that specifies the actions that have been and/or will be taken to manage the FCOI. The University reserves the right to reject the PHS-funded research project in lieu of developing and implementing a management plan.

2. Conditions or Restrictions. Should the University choose to accept the PHS-funded research project and develop and implement a plan to manage the FCOI, examples of conditions or restrictions that might be imposed to manage the FCOI include, but are not limited to:

a. Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);

- b. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
 - c. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
 - d. Modification of the research plan;
 - e. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
 - f. Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
 - g. Severance of relationships that create financial conflicts.
3. Monitoring Compliance with the Management Plan. OSRP Staff shall conduct random monitoring on an ongoing basis of FCOI Management Plans until completion of the PHS-funded research project.

E. New SFIs during ongoing PHS-funded research

Whenever, in the course of an ongoing PHS-funded research project, an Investigator who is new to participating in the research project discloses a SFI or an existing Investigator discloses a new SFI to the University, the DIO shall, within sixty (60) days of such disclosure:

- a. review the disclosure of the SFI;
- b. determine whether the SFI is related to PHS-funded research;
- c. determine whether a FCOI exists; and,
- d. if an FCOI exists, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such FCOI. Depending on the nature of the significant financial interest, the University may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date of disclosure and the completion of the University's review.

F. Review of Existing SFI

Whenever the University identifies a SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the University during an ongoing PHS-

funded research project (e.g., was not timely reviewed or reported by a subrecipient), the DIO shall, within sixty (60) days of the identification:

- a. review the SFI;
- b. determine whether it is related to the PHS-funded research project;
- c. determine whether a FCOI exists; and, if so:
- d. implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such FCOI going forward.

G. Retrospective Review

1. Noncompliance. Whenever a FCOI is not identified or managed in a timely manner including failure by the Investigator to disclose a SFI that is determined by the University to constitute a FCOI; failure by the University to review or manage such a FCOI; or failure by the Investigator to comply with a FCOI management plan, the University shall, within 120 days of the University's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

2. Review documentation. Under the federal regulation, the University is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:

- a. Project number;
- b. Project title;
- c. PD/PI or contact PD/PI if a multiple PD/PI model is used;
- d. Name of the Investigator with the FCOI;
- e. Name of the entity with which the Investigator has a financial conflict of interest;
- f. Reason(s) for the retrospective review;
- g. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- h. Findings of the review; and

- i. Conclusions of the review.
3. Update FCOI Report.
 - a. Based on the results of the retrospective review, if appropriate, the University shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward.
 - b. If bias is found, the University is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.
 - c. *Mitigation Report.* 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 the University'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).
 - d. *Annual reporting.* Following submission of the Mitigation Report, the University will submit FCOI reports annually, as specified in this policy.
 - e. *Additional interim measures.* Depending on the nature of the FCOI, the University 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 the University's retrospective review.

H. Subrecipient Requirements

If the University carries out the PHS-funded research through a subrecipient (e.g., subcontractors or consortium members), the University shall take reasonable steps to ensure that any subrecipient Investigator complies with this policy:

1. Incorporating as part of a written agreement with the subrecipient terms that establish whether the University's FCOI policy or that of the subrecipient will apply to the subrecipient's Investigators.
 - a. If the subrecipient's Investigators must comply with the subrecipient's FCOI, the subrecipient shall certify as part of the agreement referenced above that its policy complies with the University's FCOI policy. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the University's FCOI policy for disclosing SFI that are directly related to the subrecipient's work for the University.

b. If the subrecipient's Investigators must comply with the subrecipient's FCOI, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified FCOI to the University. Such time period(s) shall be sufficient to enable the University to provide timely FCOI reports, as necessary, to the PHS as required by this policy;

c. Alternatively, if the subrecipient's Investigators must comply with the University's FCOI policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of SFI to the University. Such time period(s) shall be sufficient to enable the University to comply timely with its review, management, and reporting obligations under this policy and the federal regulations.

2. Providing FCOI reports to the PHS Awarding Component regarding all FCOI of all subrecipient Investigators consistent with this policy, *i.e.*, prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

I. Reporting Requirements to NIH

1. Prior to the University's expenditure of any funds under a PHS-funded research project, the University shall provide to the PHS Awarding Component an FCOI report regarding any Investigator's FCOI.

2. In cases in which the University identifies a FCOI and eliminates it prior to the expenditure of PHS-awarded funds, the University shall not submit an FCOI report to the PHS Awarding Component.

3. For any FCOI that the University identifies subsequent to the University's initial FCOI Report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), the University shall provide to the PHS Awarding Component, within sixty (60) days, an FCOI Report regarding the FCOI.

4. If bias is found during a retroactive view conducted pursuant to Section "G" of this policy, the University shall notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.

5. Any FCOI Report required under paragraphs (1) – (4) of this section 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 the Institution's management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:

(i) Project number;

(ii) PD/PI or Contact PD/PI if a multiple PD/PI model is used;

- (iii) Name of the Investigator with the financial conflict of interest;
- (iv) Name of the entity with which the Investigator has a financial conflict of interest;
- (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 the University’s determination that the financial interest conflicts with such research; and
- (viii) A description of the key elements of the University’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.

6. For any FCOI previously reported by the University with regard to an ongoing PHS-funded research project, the University shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of the FCOI and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the FCOI is still being managed or explain why the FCOI no longer exists. The University shall provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

J. Maintenance of Records

1. The University policy for maintaining FCOI files is for at least 3 years from the date the final expenditures report is submitted to the PHS Awarding Component and,

where applicable, from other dates specified in 45CFR 74.53(b) and 92.42(b), relating to records retention.

2. The Division of Research and Federal Relations shall maintain the records pertaining to each disclosure in strict confidence. Access to such records will be limited to the investigator/family member, ORSP Staff, the Vice President for Research & Federal Relations, Provost/Vice President for Academic Affairs and others who have a legal right to review the records. Certain sponsors, particularly federal agencies, may have requirements that differ from this policy with regard to the timing and frequency of disclosures and other provisions as well. In the case of such discrepancies, the federal requirements will generally prevail.

K. Enforcement Mechanisms and Remedies for Noncompliance

1. Failure to file a complete and truthful disclosure as required by this policy or to comply with the conditions or restrictions imposed in the resolution, management, or elimination of FCOI constitutes a violation of this policy and may violate state and/or federal law. In such cases, the Investigator will be subject to appropriate sanctions consistent with University policies relating to faculty, staff, or other applicable disciplinary policies. In addition, the University may suspend an ongoing research project, halt the expenditure of funds, or suspend technology transfer activity to prevent continued violation of this policy. In any case in which the Investigator does not comply with any applicable conditions or restrictions imposed pursuant to this policy, the University reserves the right to withdraw any affected applications/proposals for funding if the project cannot otherwise be completed without the services of the Investigator.

2. The ORSP or designee(s) will review allegations of violations and will make recommendations regarding the imposition of sanctions to the Vice President for Research & Federal Relations.

3. The Vice President for Research & Federal Relations shall make recommendations to the Provost/Vice President of Academic Affairs regarding sanctions, who in turn, makes a recommendation to the President. The decision of the President is final.

L. Public Accessibility Requirements

The FCOI policy shall be posted on the University's public website at <http://www.jsums.edu/research/compliance-unit/fcoi/>. Also, information will be made available concerning FCOI held by senior/key personnel and publicly accessible prior to the expenditure of funds. Website information shall be managed and updated as follows:

- a. The information that the University posts shall be updated at least annually.

- b. The Web site shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within 60 days of the University's identification of a new FCOI.
- c. Update the Web site within 60 days of the University's receipt or identification of information concerning any additional SFI of the senior/key personnel for the PHS-funded research project that was not previously disclosed.
- d. If the University responds to written requests for the purposes of this complying with the public accessibility requirements, the University will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the University's identification of a new FCOI, which should be requested subsequently by the requestor.
- e. Remain available for three years from the date the information was most recently updated.