

Governors State University

Financial Conflict of Interest (FCOI) in Externally Sponsored Research and Educational Activities

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I. Statement of Need & Purpose

The purpose of this policy is to promote objectivity in externally funded research and educational activities by ensuring that the design, conduct, and reporting of research and educational activities funded under external grants or cooperative agreements will be free from bias resulting from the investigator (and/or the investigator's spouse and/or dependent children) having significant financial conflicts of interest.

A significant financial conflict of interest (FCOI) means a significant financial interest (SFI) that could directly and significantly affect the design, conduct, or reporting of research or educational activities. Faculty and staff of the University have an obligation to maintain the

objectivity of their research and educational activities by avoiding any financial conflict of interest. Governors State University developed this policy to protect the integrity of externally sponsored research and educational activities and to comply with federal regulations.

II. Investigator Requirements

Any Investigator responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding by external sources is required to:

- A. Disclose, prior to applying for external funding, all “significant financial interests” over the previous twelve-month period (and those of his/her spouse, or dependent children) related to his or her institutional responsibilities.
- B. Complete an annual disclosure form at the beginning of each academic year during the period of an award.
- C. Update the disclosure within 30 days of discovery or acquisition (e.g. through purchase, marriage, or inheritance) of a new significant financial interest (including those of the investigator’s spouse and dependent children), and at least annually throughout the life of a sponsored agreement.
- D. Comply with FCOI management plans instituted by Governors State University.
- E. Complete FCOI training via the method/curriculum approved by Governors State University as described on the Office of Sponsored Programs and Research (OSPR) webpage:
 1. prior to engaging in the externally sponsored research or educational activities funded by external sources.
 2. at least every 4 years during the award period.
 3. any time an investigator is new to the institution and plans to participate in externally funded research or educational activities
 4. in the event an investigator has been found to be non-compliant with this policy or a management plan instituted by Governors State University.
- F. Disclose the occurrence of any 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 to the project sponsor and/or university) related to the Investigator’s institutional responsibilities including:
 1. the purpose of the trip
 2. the identity of the sponsor/organizer
 3. the destination
 4. the duration

Project directors/principal investigators must ensure that all individuals who are responsible for the design, conduct, or reporting of externally funded research and educational activities disclose all significant financial interests related to their institutional responsibilities (see Section XIV. B. for definition of institutional responsibilities). This includes individuals who come to work on an established project through reallocation of effort, hiring, transfer, promotion, etc., and who thereby take on a responsible position in a project. New disclosures regarding ongoing projects shall be made by contacting OSPR.

III. Applicability

- A. **General Applicability:** This policy applies to each Investigator who is planning to participate in, or is participating in, externally sponsored research and/or educational activities, regardless of sponsor or sponsor type. The policy also includes the

Investigator's immediate family, which is defined as his/her spouse and dependent children.

This policy does not apply to Small Business Innovation Research (SBIR) applications.

- B. Subrecipients (ONLY APPLIES TO PHS FUNDED PROPOSALS AND AWARDS):
Subrecipients: The responsibility to identify, manage, and report significant financial conflicts of interests only applies to subrecipients when funds flow down from or through an awardee Institution to another individual or entity and the subrecipient will be conducting a substantive portion of the work funded by the Public Health Service (PHS) of the U.S. Department of Health and Human Services, including the National Institutes of Health (NIH). No other subrecipients funded by external funds are included under this policy. Subrecipient agreements for PHS externally funded awards issued by Governors State University shall contain language documenting whether the subrecipient organization will be subject to Governors State University's FCOI policy or the FCOI policy of the subrecipient's own institution.

When the subrecipient will be following his/her own institutional FCOI policy, Governors State University will obtain a written certification from the subrecipient organization that its FCOI policy complies with the applicable sponsoring agency regulations regarding the identification, management, and reporting of FCOIs. Additionally, the subrecipient agreement will require the subrecipient organization to report identified FCOIs for its investigators to Governors State University, and will specify an acceptable time-frame for this reporting that will allow Governors State University to in turn report these FCOIs to the sponsoring agency as required.

If a subrecipient cannot certify that their FCOI policy and procedures meet sponsoring agency regulations, then the subrecipient organization will be required to adhere to the Governors State University policy and procedures, and to submit subrecipient Investigator disclosures to Governors State University. The timeframe for submitting disclosures will be specified, consistent with federal requirements. In addition, the subrecipient investigator(s) must complete training prior to engaging in PHS funded research at least every four years during the award period, and immediately under the designated circumstances:

1. Institutional Financial Conflict of Interest policies change in a manner that affects Investigator requirements
 2. An Investigator is new to an Institution
 3. An Institution finds that an Investigator is not in compliance with the Institution's Financial Conflict of Interest policy or management plan.
- C. Policy Implementation Schedule: This policy was required as of August 24, 2012 for entities with PHS funding.

IV. What is a *Significant Financial Interest*?

A financial interest that consists of one or more of the following interests of the Investigator (and/or those of the Investigator's spouse and and/or dependent children) and reasonably appears to be related to the Investigator's institutional responsibilities is considered a "significant financial interest" and must be disclosed:

- A. Interests in Publicly Traded Entities: 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 any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this policy, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship). Equity interest includes stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
- B. Interests in Non-publicly Traded Entities: With regard to any non-publicly traded entity, a significant financial interest exists if the value of the total remuneration received from the entity in the twelve months preceding the disclosure 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), regardless of dollar value associated with that equity 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: Investigators also must disclose the occurrence of any 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 to the project sponsor and/or university), related to their institutional responsibilities. The items that would have to be disclosed are the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.
- E. Other: An Investigator should disclose any other financial or related interest that might present an actual, potential, or perceived conflict of interest.

V. Exclusions

Financial interests that are excluded from this policy and which need not be disclosed include:

- A. Salary, royalties, remuneration paid by Governors State University.
- B. Income from seminars, lectures, or teaching engagements sponsored by:
 1. A federal, state, or local government agency
 2. An institution of higher education
 3. An academic teaching hospital
 4. A medical center that is affiliated with an institution of higher education
 5. A research institute that is affiliated with an institution of higher education
- C. Income from service on advisory committees or review panels sponsored by:
 1. A federal, state, or local government agency
 2. An institution of higher education
 3. An academic teaching hospital
 4. A medical center that is affiliated with an institution of higher education
 5. A research institute that is affiliated with an institution of higher education
- D. Travel reimbursed or sponsored by:
 1. A federal, state, or local government agency

2. An institution of higher education
3. An academic teaching hospital
4. A medical center that is affiliated with an institution of higher education
5. A research institute that is affiliated with an institution of higher education
6. Intellectual property rights that the Investigator has assigned to Governors State University or instances where an agreement exists to share royalties to such property rights with the University. Unlicensed intellectual property that does not generate income is excluded.
7. Income from investment vehicles or retirement accounts unless the Investigator directly controls the investment decisions for these vehicles.

VI. Disclosure Process

Each Investigator applying for external funding for research and educational activities must disclose all significant financial interests (and those of his/her spouse, and dependent children) by completing a Governors State University FCOI Screening and Disclosure Form, in keeping with the following disclosure requirements:

- A. All significant financial interests must be disclosed prior to the time a proposal for external funding is submitted. The initial disclosure process will coincide with the normal proposal routing/approval process used by OSPR. No proposal will be submitted by OSPR until each Investigator (e.g., any individual responsible for the design, conduct, or reporting of the proposed project, regardless of title) submits the FCOI Screening and Disclosure Form.
- B. During the period of the sponsored agreement, all financial disclosures must be updated by Investigators within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.
- C. All financial disclosures must be updated by Investigators at least annually on September 1 of each year during the period of the award. Such disclosure shall include any information that was not disclosed initially to Governors State University at the time of submission.
- D. Investigators newly hired or otherwise advancing to a role of responsibility in the design, conduct, and reporting of externally sponsored research or educational activities must ensure that they complete a FCOI Screening and Disclosure Form and notify the Office of Sponsored Programs and Research to disclose significant financial interests (SFIs) and complete the required training.
- E. Individuals should contact OSPR to update disclosures for ongoing sponsored projects.

Disclosures made to OSPR will be forwarded to Governors State University's authorized signing official for grants (or designee) for review.

VII. Review Process

The authorized signing official for grants (or designee) is responsible for reviewing FCOI Screening and Disclosure forms in which significant financial interests have been disclosed in order to determine whether the interests could reasonably be expected to affect the design, conduct, or reporting of the activities funded or proposed for funding. The authorized signing official for grants (or designee) may request additional clarifying information from the Investigator as necessary to complete their review.

In the case of initial awards, the authorized official for grants or designee will conduct the review of disclosures and work with the Dean of the College where the individual will be

employed to develop a management plan, if necessary, prior to the expenditure of funds. In the case of disclosures of new financial interests throughout the life of an on-going project, the authorized signing official for grants or designee will conduct the review of disclosures and work with the Dean of the College where the individual resides to develop a management plan, if necessary, within 60 days of receiving the disclosure.

VIII. Management/Monitoring Process for Identified Conflicts of Interest

The Dean of the College where the individual is employed is responsible for developing a management plan for any identified conflicts of interest to ensure that any conflict is managed, reduced, or eliminated. The Dean may include the Investigator in the development of this plan. In all cases, resolution of the conflict or establishment of an acceptable conflict management plan must be achieved before expenditure of any funds under an award.

A. Management plans may include, but are not limited to, the following conditions or restrictions:

1. Public disclosure of significant financial interests;
2. Monitoring of the research by independent reviewers;
3. Modification of the planned activities (possibly subject to sponsor approval);
4. Disqualification from participation in all or part of the project;
5. Reduction or elimination of the significant financial interests (e.g., sale of an equity interest);
6. Severance of relationships creating financial conflict.

B. Management plans will include at a minimum the following elements:

1. Role and principal duties of the conflicted investigator in the research project.
2. Conditions of the management plan.
3. How the management plan is designed to safeguard the objectivity in the research project.
4. Confirmation of the Investigator's agreement to the management plan.
5. How the management plan will be monitored to ensure investigator compliance.
6. Other information as needed.

In completing the FCOI Screening and Disclosure form, each Investigator must certify that if the authorized signing official for grants (or designee) determines a conflict exists, the Investigator will adhere to all conditions or restrictions imposed upon the project and will cooperate fully with the individual(s) assigned to monitor compliance throughout the life of the funded project.

IX. Retrospective Review Process and Remedies

In instances where any of the following has occurred, the authorized signing official for grants or designee will complete within 120 days a retrospective review of the research project to determine whether bias has occurred in the research:

- A. A financial conflict of interest was not identified or managed in a timely manner, including instances where an investigator failed to disclose a significant interest that is determined by the authorized signing official for grants or designee to be a financial conflict of interest;
- B. The institution has failed to review or manage a financial conflict of interest;

- C. An Investigator has failed to comply with the conflict of interest management plan proscribed by the Dean of the College where the individual is employed.

If it is determined through retrospective review that the research has been biased by the Investigator's financial interests, then the authorized signing official for grants or designee and the Dean of the College where the individual is employed will specify an appropriate set of remedies to eliminate or mitigate the bias.

Depending on the nature of the financial conflict of interest, the authorized signing official for grants or designee may determine that additional measures are necessary with regard to the Investigator's participation in the funded research project during the period of the retrospective review.

X. Maintenance of Records

OSPR will maintain records of all disclosures, reviews, and associated actions. All records will be maintained for three years following the letter of termination or completion of the project or resolution of any government action involving the records.

All FCOI Screening and Disclosure forms and related documents are considered sensitive information, and only those persons involved in the implementation of this policy will routinely have access to such records. However, all FCOI and SFI information (including institutional reviews and determinations) will be made available to the sponsoring agency upon request, or as required by this policy's reporting requirements. Additionally, there may be circumstances in which FCOI related information is made public in accordance with sponsor regulations and the public accessibility requirements of this policy (see Reporting Process and Public Accessibility sections below).

XI. Reporting Process

Governors State University recognizes its obligation to report information originating from the University's FCOI process to sponsoring agencies, and will provide the necessary information to those agencies in a manner, format, and level of detail consistent with the sponsor's requirements for such reporting. OSPR will review the sponsoring agency's reporting requirements to ensure the appropriate information is submitted.

- A. Reporting to PHS Awarding Components: Management plan reports to PHS awarding components will include at a minimum the following elements:
 1. Sponsor Project Number or identifier
 2. Project Director/Principal Investigator (PD/PI) or contact PD/PI
 3. Name of Investigator with the financial conflict of interest
 4. Name of entity with which the Investigator has a financial conflict of interest
 5. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium)
 6. Value of the financial interest (utilizing the categories below is permissible):
 - ___ \$0-4,999
 - ___ \$5,000 - \$9,999
 - ___ \$10,000 - \$19,999
 - ___ \$20,000 - \$39,999
 - ___ \$40,000 - \$59,999

- ___ \$60,000 - \$79,999
- ___ \$80,000 - \$100,000
- ___ Over \$100,000 (document in increments of \$50K)
- \$ _____
- ___ Value cannot be readily determined

7. A description of how the financial interest relates to the funded research, and the basis for the institution's determination that the financial interest conflicts with such research.
8. A description of the key elements of the 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 the 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.
 - f. Other information as needed.

B. Retrospective Review and Mitigation Reports to PHS Awarding Components: In the event that the failure of an Investigator to comply with this policy or with a financial conflict of interest management plan, OSPR will notify the sponsoring agency of the corrective action taken, including the outcome of the retrospective review, and the mitigation plan.

Retrospective Review and Mitigation Reports to PHS awarding components will include, at minimum, the following elements:

1. Project Number;
2. Project Title;
3. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
4. Name of Investigator with the FCOI;
5. Name of the entity with which the Investigator has a financial conflict of interest;
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;
9. Conclusions of the review; and
10. Description of the impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias.

XII. Public Accessibility for PHS Awarding Components (ONLY APPLIES TO PHS FUNDED PROPOSALS AND AWARDS)

Governors State University recognizes the importance of transparency, and that PHS requires information about FCOIs to be made accessible to the public. Governors State University maintains an FCOI Public Accessibility webpage to fulfill this obligation regarding PHS Awarding Components. In instances where a financial conflict of interest of senior/key personnel has been managed (rather than eliminated) the following information will be made available to the public prior to expenditure of funds:

- A. Name of Investigator with the financial conflict of interest
- B. Title and role with respect to the research project
- C. Name of entity in which the significant financial interest is held
- D. Nature of the significant financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium)
- E. Value of the financial interest (utilizing the categories below is permissible):
 - ___ \$0-4,999
 - ___ \$5,000 - \$9,999
 - ___ \$10,000 - \$19,999
 - ___ \$20,000 - \$39,999
 - ___ \$40,000 - \$59,999
 - ___ \$60,000 - \$79,999
 - ___ \$80,000 - \$100,000
 - ___ Over \$100,000 (document in increments of \$50K)
 - \$_____
 - ___ Value cannot be readily determined

Additionally, this information will be updated annually throughout the life of the funded project, and within 60 days of any new disclosure determined to be a financial conflict of interest. The information will remain available for 3 years from the date of the most recent update of the information.

XIII. Enforcement Mechanisms, Remedies, and Noncompliance

Failure to properly disclose relevant financial interests or to adhere to conditions or restrictions imposed by the authorized signing official for grants or designee or the Dean of the College where the individual with conflict of interest is employed will be considered a violation of this policy.

Alleged violations of this policy will be investigated by the authorized signing official for grants or designee, who will provide a written report of findings to the Provost. Breaches of policy include failure to file the necessary disclosure statements; knowingly filing incomplete, erroneous, or misleading disclosure forms; or failure to comply with procedures prescribed by the authorized signing official for grants or designee.

If the Provost determines that this policy has been violated, he/she may impose sanctions consistent with the rights of faculty and staff members under the Ethics Act (5 ILCS 430/State Officials and Employees Ethics Act), subject to applicable collective bargaining agreements. These sanctions may include, but are not limited to: notification of sponsor and possible termination of award; formal admonition; a letter to the Investigator's personnel file; suspension of the privilege to apply for external funding and/or to seek IRB/IACUC approval; and other remedies necessary to eliminate or mitigate the impact of any potential bias.

If the allegations and review suggest a possible violation of the GSU Board of Trustees regulations regarding the "provisions to ensure that persons engaged in grant or contract funded activities do not have conflicts of interest that could compromise the integrity of the activities and the university," then a concurrent report to GSU Internal Audit will be made.

See http://www.govst.edu/AboutGSU/t_AboutGSU.aspx?id=9410 for the regulations issued July 12, 1996 in Section III. Academic Affairs Subsection D. Grants and Contracts.

XIV. Appendix

A. Definitions

Disclosure of significant financial interests: an Investigator's disclosure of significant financial interests to an Institution.

Financial conflict of interest (FCOI): a significant financial interest that could directly and significantly affect the design, conduct, or reporting of externally funded research or educational activity.

FCOI report: an Institution's report of a financial conflict of interest to the external sponsor, including the awarding component within PHS for PHS funded research.

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

Institutional Responsibilities: an individual's professional responsibilities on behalf of Governors State University, which include: research, teaching, institutional committee memberships, and service on panels such as the Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), or other monitoring boards.

Investigator: any project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research; this may include collaborators or consultants.

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.

PD/PI: a project director or principal Investigator of a funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator.

PHS: the Public Health Service of the US 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: an organizational unit within PHS that funds research.

Research and/or Educational Activities: a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research (e.g., for a published article, book, or book chapter), product development (e.g., for a diagnostic test or drug), and artistic or creative works. As used in this policy, the term includes any such activity for which funding is available for research and/or educational activities through a grant (sponsored project) or cooperative agreement.

Significant Financial Interest: a financial conflict of interest that could directly and significantly affect the design, conduct, or reporting of externally funded research. (See section “What is a Significant Financial Interest?”)

Senior/key personnel: the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under this subpart

Small Business Innovation Research (SBIR) Program: the extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Pub. L. 97-219, the Small Business Innovation Development Act, as amended. For purposes of this policy, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Pub. L. 102-56

B. Governors State University Institutional Responsibilities

As an institution that receives external funding for sponsored programs, research, or educational activities, Governors State University must:

1. Establish standards that provide a reasonable expectation that the design, conduct, and reporting of externally funded research and educational activities will be free from bias resulting from Investigator financial conflicts of interest.
2. Maintain an up to date, written, enforced policy that complies with federal FCOI regulations and make this policy available via a publicly accessible website.
3. Inform each Investigator of this policy and their responsibilities regarding disclosure.
4. Require each Investigator to complete training regarding this policy prior to engaging in externally funded research and educational activities, at least every 4 years during the course of the project, and immediately when any of the following circumstances apply:
 - a. The policy is revised.
 - b. The Investigator is new to Governors State University.
 - c. An Investigator is found to be out of compliance with the policy or an FCOI management plan.
5. Take reasonable steps to ensure any PHS funded subrecipient complies with either this policy or their own institutional policy which must meet the external sponsor's FCOI requirements.
6. Designate an institutional official or officials to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, funded research.
7. Require that each Investigator disclose to the designated official(s) the Investigator's significant financial interests, and those of the Investigator's spouse and dependent children prior to submission of a proposal for external funding for research or educational activities.
8. Require that the Investigator involved in externally funded research and educational activities submit an updated disclosure of significant financial interest at least annually.
9. Require that the Investigator involved in the externally funded research and educational activities submit an updated disclosure of significant financial interest within 30 days of discovering or acquiring (through purchase, marriage, or inheritance) a new significant financial interest.

10. Provide guidelines for the designated officials to determine whether a significant financial interest is related to funded research, and if so related, whether it is a financial conflict of interest.
11. Take such actions as necessary to manage a financial conflict of interest, including any financial conflict of interest of a PHS funded subrecipient Investigator that is complying with our institution's policy. Management of an identified FCOI requires development and implementation of a management plan, and, if necessary, a retrospective review and mitigation report.
12. Provide initial and ongoing reports as required by the sponsoring agency.
13. Maintain records of all Investigator disclosures of Investigator financial interests and the institution's review of and response to such disclosures (whether or not a disclosure resulted in the institution's determination of FCOI) and all actions under the institution's FCOI policy or retrospective review if applicable. These records shall be maintained for at least 3 years from the date of submission of the final expenditures report, or as specified by the funding agency.
14. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance, as appropriate.
15. Provide certifications regarding the University's FCOI process in each application for funding when such certifications are required by the sponsor.
16. Disclose information about FCOIs currently being managed in relation to the institution's sponsored agreements via a publicly accessible website (when required to do so by the sponsoring agency).

C. Informing the Campus Community of this Policy

As a matter of process, Investigators will be informed of these requirements through multiple means and at several key time-points, including (but not limited to) some or all of the methods listed below. This list is not meant to be exhaustive or proscriptive, but rather is meant to convey the institution's commitment to establishing a culture of compliance with this policy by utilizing multiple and varied communication strategies.

1. Campus-wide communications/reminders regarding Governors State University sponsored programs and research policies.
2. Publication of this policy on the OSPR website.
3. During the Governors State University proposal routing process.
4. New award communications sent to the principal Investigator during the award set-up phase, and prior to expenditure of funds.

Effective as Interim August 2012
Revised 6/13/13