

 <p>SOUTHEAST MISSOURI STATE UNIVERSITY · 1873</p>	<p align="center">BUSINESS POLICY AND PROCEDURE MANUAL</p>	Date Issued: 12/15	Revision Date: 08/17	Page: 1 of 9
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GENERAL STATEMENT OF POLICY

This policy provides a framework to manage, reduce or eliminate Conflicts of Interest in research, education, and service activities and protects the credibility and integrity of faculty and staff, so that public trust and confidence in the sponsored activities are ensured.

Externally sponsored research and educational activities are a vital part of Southeast Missouri State University's mission. When accepting external funds for these projects, the University has a responsibility to promote objectivity in research and other sponsored programs by establishing standards to ensure that there is no reasonable expectation that the design, conduct, or reporting of research and project activities under grants and cooperative agreements will be biased by any conflicting financial interest of an investigator.

A potential Conflict of Interest occurs when there is a divergence between an individual's personal interests and his or her professional obligations to the University, such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise. A potential Conflict of Interest or the appearance of a Conflict of Interest may be complex and can include both ethical and financial considerations. Federal and other regulations also address the roles of the spouse, dependent children, and other close relatives as potential sources of Conflict of Interest. Even when the behavior itself is exemplary, the appearance or perception of a Conflict of Interest should be avoided.

The Public Health Service (PHS), the National Science Foundation (NSF), and other Federal agencies have promulgated regulations that apply to institutions and individual investigators who seek Federal grants and contracts. Institutions are required to enforce such rules through written policies and procedures. Investigators are required to comply with these rules as a condition when seeking and administering Federal grants and contracts, including funds that pass through other organizations. The rules can be found at Title 42 Code of Federal Regulations (CFR) Part 40 Subpart F, within the NSF Grant Policy Manual, and within other Federal agencies' regulations. As a recipient of Federal grants and contracts, the University must maintain standards for employees engaged in the award and administration of contracts in order to prevent Conflict of Interest.

Further, Federal regulations require Southeast Missouri State University to manage, reduce, or eliminate any actual or potential Conflicts of Interest that may be presented by a financial interest of an investigator (i.e., principal investigator, project director, and other persons responsible for the design, conduct, or reporting of a sponsored project). Accordingly, the University must require that investigators disclose any significant financial interest that may present an actual or potential Conflict of Interest in a sponsored project.

The regulations require that such disclosure occur prior to the submission of a sponsored project proposal. Investigators are also required to disclose a significant financial interest to the University as soon as it comes into existence if one develops after proposal submission or issuance of award. Additionally, projects funded by NSF, a PHS agency, or other sponsor with specific requirements will be required to disclose at least annually during the project period covered by the grant. Investigators are also required to comply with any conditions or restrictions determined by the University, including the retention of documentation to demonstrate compliance with a management plan, if needed.

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I. DEFINITIONS:

Conflict of Interest (COI): A significant interest, outside activity or commitment, financial or otherwise, that could directly and significantly affect the design, conduct, or reporting of externally funded research or educational activities.

Disclosure: An Investigator’s disclosure of Significant Financial Interests to the University.

Financial Interest: Anything of monetary value, whether or not the value is readily ascertainable. This includes, but is not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); or intellectual property rights (e.g., patents, copyrights, or royalties from such rights).

Institution: Southeast Missouri State University, or the “University.”

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

Key Personnel: Individuals who contribute to the scientific development or execution of a project in a substantive, measurable way.

Management Plan: A plan developed by an Investigator and his/her academic dean or Division executive, and approved by the University Reviewer, which outlines the steps that must occur by the Investigator and/or the University to manage or eliminate a potential Conflict of Interest.

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.

Potential Conflict of Interest: Any outside activity, commitment, or interest that may reasonably give the appearance of adversely affecting, compromising, or being incompatible with the University obligations of the Investigator.

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 and product development. 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), contract or cooperative agreement.

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Significant Financial Interest: A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’s spouse and dependent children) that reasonably appears to be related to the Investigator’s institutional responsibilities:

- 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.
- 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).
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- 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; *however, this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.* This disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

The term Significant Financial Interest does **not** include the following types of financial interests:

- Salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights.
- Any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization.
- 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.
- 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

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academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

- 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.

Small Business Innovation Research (SBIR): 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.

University: Southeast Missouri State University

University Reviewer: The Vice President for Finance and Administration and/or his/her designee(s). A committee may perform this function at the discretion of the Vice President for Finance and Administration. The University Reviewer, in consultation with the appropriate Division executive, will determine whether a Significant Financial Interest could potentially directly and significantly affect the design, conduct or reporting of the proposed sponsored project. The University Reviewer and appropriate Division executive will also determine what conditions or restrictions, if any, should be imposed by the University to manage actual or potential Conflicts of Interest arising from disclosed Significant Financial Interests.

II. Institutional and Investigator Responsibilities

A. University Applicability

This policy is intended to carry out the University's responsibilities for externally sponsored research and educational activities. It applies to all principal investigators, project directors, and other persons, regardless of title or position, who are responsible for the design, conduct, or reporting of research or educational activities (funded or proposed). It also applies to the interests of the investigator's spouse or domestic partner and dependent children. All University employees are required to comply with this policy and the procedures and guidance established for disclosure, review, and management of Conflicts of Interest.

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

B. Institutional Certifications

The University's Authorized Organizational Representative must certify on each proposal that

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- The University has in effect a written and enforced process to identify and manage, reduce or eliminate conflicting interests, consistent with the provisions of the appropriate agency regulations;
- To the best of his/her knowledge and belief, all financial disclosures required by the Conflict of Interest policy have been made; and
- All identified Conflicts of Interest will have been satisfactorily managed, reduced, or eliminated prior to the expenditures of funds under the award, in accordance with the policy.

C. Investigator Disclosure

Each investigator named in a proposal is required to report, on the PI or co-PI Proposal Certification Forms, whether there is any Significant Financial Interest/ potential Conflict of Interest (including those of his/her spouse, domestic partner, or dependent children) that may impact the proposed project prior to submission of the proposal to the funding agency. Additionally, some agencies may require other key personnel to identify and disclose potential Conflicts of Interest as well. If a potential Conflict of Interest exists, the Investigator(s) must complete a Disclosure Form and return it to the Office of Research and Sponsored Programs prior to the proposal being submitted.

The Office of Research and Sponsored Programs will be responsible for obtaining such disclosures as part of the sponsored project proposal review and routing process. The Co-Investigator Certification form must also be completed by other Key Personnel for NSF, PHS, or other sponsors as required by the sponsor. It is the responsibility of the principal investigator to identify other individuals involved in the design, conduct, supervision, or reporting of the research to be funded by Federal agencies that require Key Personnel to provide the documentation referred to in this policy.

Financial disclosures for sponsored projects must be updated during the period of an award on an annual basis, or within 30 days of discovering or acquiring a new reportable Significant Financial Interest.

D. Subrecipient/Consultant/Collaborator Applicability

The responsibility to identify, manage, and report Conflicts of Interest extends to collaborating Investigators and consultants who are responsible for the design, conduct, or reporting of the project. This includes all collaborators, subrecipients and consultants. Agreements with collaborators, subrecipients and consultants will contain language documenting whether the collaborators, subrecipients and consultants will be subject to the Southeast Missouri State University Conflict of Interest Policy (this policy) or the financial Conflict of Interest policy of their own institution.

When the collaborator, subrecipient, or consultant will be following its own institutional Conflict of Interest policy, the University will obtain a written certification from the organization that its Conflict of Interest policy complies with the applicable sponsoring agency regulations regarding the

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identification, management, and reporting of Financial Conflicts of Interest. Additionally, the agreement will require the organization to report identified Conflicts of Interest for its investigators to the University, and will specify an acceptable timeframe for this reporting that will allow the University to in turn report these Conflicts of Interest to the sponsoring agency as required.

If a collaborator, subrecipient, or consultant cannot certify that their Financial Conflict of Interest policy and procedures meet sponsoring agency regulations, then the agreement will require the collaborator, subrecipient, or consultant to adhere to the Southeast Missouri State University policy and procedures, and to submit Investigator disclosures to the University. The timeframe for submitting disclosures will be specified so as to allow the University to comply in a timely manner with its review, management, and reporting obligations under this policy.

E. Reports to US Department of Health and Human Services (DHHS) (for awards from DHHS only)

The 2011 revised regulation promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research performed under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest. Prior to expending any funds under a DHHS award, the University will report to the DHHS awarding component the existence of a Conflict of Interest and assure that it has been managed, reduced, or eliminated, and for any interest identified as conflicting subsequent to the University’s initial acceptance of the award, a report will be made and the Conflict of Interest will be managed, reduced, or eliminated, at least on an interim basis, within 60 days. Upon request, the University will make information available to DHHS regarding all Conflicts of Interest, indicating how those interests have been managed, reduced, or eliminated.

F. Retention of Records

Conflict of Interest Disclosures and Management Plans prepared to manage actual or potential Conflicts of Interest must be maintained by the University for at least three years from the date of submission of the final expenditures report or other dates as specified in 45 CFR 74.53(b) or sponsor requirements, or the resolution of any government action involving those records.

Information regarding disclosure of Significant Financial Interests is considered sensitive; only those persons involved in the implementation of this policy will routinely have access to such records. All Financial Conflict of Interest and Significant Financial Interest will, however, be made available to the sponsoring agency upon request or as necessitated by agency reporting requirements. Additionally, there may be circumstances in which Financial Conflict of Interest is made public in accordance with sponsor regulations and public accessibility requirements.

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III. Review of Disclosure Forms

A. University Reviewer

The Vice President for Finance and Administration and/or his/her designee(s) will serve as the University Reviewer charged with determining the existence of conflicting interests and taking actions to ensure that they will be managed, reduced or eliminated.

B. Review and Reporting

The University Reviewer is responsible for reviewing Conflict of Interest Disclosure Forms to determine whether the financial interests could reasonably be expected to directly and significantly affect the design, conduct, or reporting of the activities funded or proposed for funding. The University Reviewer may request additional information from the Investigator as necessary to complete the review. The University Reviewer will consult with the appropriate Vice President or Division executive to determine whether the project should proceed and whether any conditions or restrictions should be placed on the project to manage, reduce or eliminate the potential Conflict of Interest.

The University reserves the right to not process a grant proposal or application if all required disclosures are not completed.

The Office of Research and Sponsored Programs will report all significant financial interest disclosures to the relevant sponsoring agency and its subrecipients prior to the issuance of an award. For new and existing Investigators, if a new or newly identified significant financial Conflict of Interest is identified, the sponsoring agency and its subrecipients will be notified within 60 days of identification. Until the completion of the project, the Office of Research and Sponsored Programs will notify the sponsoring agency and its subrecipients as required, at least annually and/or at the time of an extension, of the status of the financial Conflict of Interest and any changes to the management plan.

IV. Management/Monitoring of Identified Conflicts of Interest

The Investigator, in cooperation with the academic dean of the college or Division executive, as needed, will develop and present to the University Reviewer a Conflict of Interest Management Plan that details proposed steps that will be taken to manage, reduce, or eliminate any actual or potential Conflict of Interest presented by a Significant Financial Interest. The University Reviewer will approve or request modifications to the plan as needed.

Management plans will include, at a minimum, the following elements:

- Role and principal duties of the Investigator with the conflict in the research project.
- Conditions of the Management Plan
- How the Management plan is expected to safeguard objectivity in the research project.

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- Confirmation of the Investigator’s agreement with the Management Plan.
- How the Management Plan will be monitored to ensure Investigator compliance.
- Other information as needed.

Conditions or restrictions that may be instituted include, but are not limited to:

- Public disclosure of significant financial interests.
- Review and/or monitoring of research protocol/research by independent reviewers, who will be required to sign a confidentiality agreement.
- Modification of the research plan.
- Disqualification from participation in all or a portion of the research funded.
- Reduction or elimination of the Significant Financial Interest.
- Severance of relationships that create actual or potential conflicts of interest.

As part of the screening and disclosure process, each Investigator must certify that if the University Reviewer determines that a Conflict of Interest exists, the Investigator will adhere to all conditions and restrictions imposed on the project and will cooperate fully with the individual(s) assigned to monitor compliance throughout the life of the funded project.

If the Investigator cannot fulfill the recommendations outlined in the Management Plan, it is the responsibility of the Investigator to notify the University Reviewer. The Office of Research and Sponsored Programs will be responsible for notifying the sponsor if it finds the University is unable to satisfactorily manage, reduce or eliminate a Conflict of Interest.

V. Non-Compliance

In the event that an Investigator is found to have violated this policy or the terms of a Management Plan for Potential Conflict of Interest, the University Reviewer will make recommendations for sanctions to the President. Those recommendations may include disciplinary action in accordance with University policies.

If a PHS-funded project of clinical research, whose purpose was to evaluate the safety or effectiveness of a drug, medical device, or treatment was designed, conducted, or reported by an Investigator with a conflicting interest that was not disclosed or managed, the Institution must require the Investigator(s) to disclose the conflicting interest in each public presentation of the results of the research.

The Office of Research and Sponsored Programs will promptly notify the funding agency if an investigator fails to comply with the University's Conflict of Interest Policy, as required by the sponsor’s policy.

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Sponsors may suspend or terminate the award and/or debar an Investigator from receiving future awards in the event of failure to comply with applicable Federal regulations on disclosure and review of Significant Financial Interests related to sponsored projects.

The Vice President for Finance and Administration shall be responsible for developing operating procedures to implement this policy.