

**SIU School of Medicine
SIU Healthcare
POLICY**

Conflict of Interest and Conflict of Commitment

PURPOSE:

Southern Illinois University (“SIU”) School of Medicine (“SOM”) is committed to protecting the integrity of research and medicine, providing quality care to patients, and ensuring compliance with laws related to conflicts of interest. The purpose of this *Policy* is to promote ethical conduct in clinical care, research, leadership, education, and professional duties at SIU SOM and its affiliated entity SIU Healthcare (SIU HC).

DEFINITIONS:

Conflict of Commitment:

A conflict of commitment is a situation in which an individual is dedicating more time to personal or outside activities than SIU SOM policy permits, and may detract from the individual’s primary responsibility and commitment to SIU SOM.

Conflicts of Interest:

Conflicts of interest exist where there are circumstances that create a risk that a secondary interest may unduly influence professional judgment or actions regarding a primary interest.

Consulting:

Consulting is when a covered person is engaged in providing professional or technical advice or services that are outside the scope of his or her job responsibilities at SIU SOM that may or may not include remuneration. Providing similar services under a SIU SOM Revenue Contract is not included in this definition, as services provided in a Revenue Contract are performed as part of the covered person’s job responsibilities.

Covered Persons:

This *Policy* applies to all employees of SIU SOM and SIU HC, members of the SIU HC Board of Directors, SIU HC officers, and members of committees with board-delegated authority, and others as determined by the SIU SOM Chief Compliance Officer or SIU System President or designee.

Duty of Care:

The duty of care is a fiduciary duty for SIU SOM and SIU HC leadership to exercise good faith and reasonable oversight of SIU SOM to protect the institution and ensure compliance with the law.

Ethics Officer:

The Ethics Officer is responsible for:

1. acting as a liaison between SIU and the EEC (“Executive Ethics Commission”) and OEIG (“Office of Executive Inspector General”);
2. reviewing statements of economic interests and disclosure forms of officers, senior employees, and contract monitors before filing with the Secretary of State; and
3. providing guidance to officers and employees in the interpretation and implementation of the State Officials and Employees Ethics Act.

Executive Ethics Commission (“EEC”):

EEC is a commission in the State of Illinois that oversees compliance with Illinois ethics laws.

Fair Market Value:

Fair market value means the value in an arms-length transaction, consistent with the market value that would result of bona fide bargaining between well-informed buyers and sellers, who are not able to generate business for the other party.

Financial Conflict of Interest (“FCOI”):

A FCOI means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of *research*.

Significant Financial Interest (“SFI”):

SFI means the investigator’s financial interest (and those of the investigator’s spouse and dependent children) appears to be reasonably related to the investigator’s responsibilities to SIU SOM and consists of one or more of the following:

Publicly Traded Entity – a SFI exists if the value of:

1. any remuneration received from the entity in twelve (12) months preceding the disclosure; and
2. the value of any equity interest in the entity as of the date of disclosure—when aggregated—exceeds \$5,000.

Note: Remuneration includes salary and any payment for services not identified as salary, including consulting fees, honoraria, and paid authorship. Equity interest includes stock, stock options, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

Non-Publicly Traded Entity – A SFI exists if:

1. the value of any remuneration received from the entity in the twelve (12) months preceding the disclosure exceeds \$5,000 when aggregated; or
2. the investigator (or the investigator’s spouse or dependent children) holds any equity interest.

Intellectual Property – An investigator has a SFI upon receipt of intellectual property rights or income related to such rights and interests (e.g., patents, copyrights, or royalties).

Travel – investigators must disclose reimbursed or sponsored travel related to their institutional responsibilities. SIU SOM will determine whether reimbursed or sponsored travel constitutes a SFI based on the information the investigator discloses

Financial Interest:

A financial interest includes anything of monetary value, whether or not the value is readily ascertainable. A financial interest is not necessarily a conflict of interest.

Gift:

A gift means any gratuity, discount, entertainment, hospitality, loan, forbearance, or other tangible or intangible item having monetary value including, but not limited to, cash, food and drink, and honoraria for speaking engagements related to or attributable to government employment or the official position of the employee, or officer.

Immediate Family Member:

For the purposes of this *Policy*, immediate family member means husband or wife; birth or adoptive parent, child or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

Institutional Responsibilities:

Institutional Responsibilities include an investigator’s professional responsibilities on behalf of SIU SOM, which may include 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:

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 research (e.g., collaborators or consultants).

Office of Executive Inspector General (“OEIG”):

OEIG is an independent executive branch state agency that functions to ensure accountability in state government and investigate allegations of misconduct.

PHS Awarding Component:

The PHS Awarding Component is the organizational unit of PHS that funds research.

Primary Interests:

Primary interests may include promoting and protecting the integrity of research, the quality of medical education, and the welfare of patients.

Prohibited Source (Per IL Governmental Ethics Act):

A prohibited source may be any person or entity who:

1. is seeking official action by an employee or another representative of SIU SOM;
2. does business or seeks to do business with the employee, SIU SOM, or one of its agents;
3. conducts activities regulated by the employee, SIU SOM, or one of its agents;
4. has interests that may be substantially affected by performance of official duties of the employee, SIU SOM, or one of its agents;
5. registers or should register with the Secretary of State under the Lobbyist Registration Act; or
6. is an agent of, a spouse of, or an immediate family member living with a "prohibited source."

Note: An entity does not become a prohibited source merely because a registered lobbyist is one of its members or serves on its board of directors.

Public Health Service ("PHS"):

PHS is a division of the U.S. Department of Health and Human Services ("HHS") that oversees issues related to public health and oversees funding for clinical research studies.

Relative:

A relative means father; mother; son; daughter; brother; sister; uncle; aunt; great aunt; great uncle; first cousin; nephew; niece; husband; wife; grandfather; grandmother; grandson; granddaughter, father-in-law; mother-in-law; son-in-law; daughter-in-law; brother-in-law; sister-in-law; stepdaughter; stepbrother; stepsister; half-brother; half-sister; and including the father, mother, grandfather, or grandmother of the individual's spouse and individual's fiancé or fiancée.

Remuneration:

Remunerations means any payment, discount, forgiveness of debt, or other benefits made in cash or in kind.

Research:

Research is a systematic investigation designed to develop or contribute to generalizable knowledge, including biomedical, behavioral, social-science research or other scholarly activity.

Secondary Interests:

Secondary interests include financial interests; the pursuit of professional advancement and recognition; and the desire to do favors for friends, family, students, or colleagues.

Significant Financial Conflict of Interest: See Financial Conflict of Interest.

Sponsored Travel:

Sponsored travel is travel for which an entity pays on behalf of an investigator or other covered person, rather than reimbursing the investigator or covered person for the cost of the travel, which mean the exact monetary value may not be readily available.

POLICY:

It is the policy of SIU SOM to require disclosure of actual or perceived conflicts of interest and monitor or manage conflicts of interests appropriately.

SIU SOM encourages faculty, administrators, and staff to engage in professional relationships with others in the healthcare industry and other private entities. Relationships with entities in the healthcare space can often be beneficial to SIU SOM and the patients it serves by achieving technological advances, developing innovative care treatments and delivery models, and bringing new resources and knowledge to the institution.

Although a conflict of interest does not imply misconduct or inappropriate activities, conflicts of interest do require review and management to help SIU SOM ensure that conflicts do not unduly influence professional judgment that would impact clinical care and research at SIU SOM. It is important that faculty, other SIU SOM employees, and contractors working on behalf of or in support of SIU SOM disclose conflicts of interest promptly and thoroughly. Faculty, administrators, and staff must provide complete and accurate disclosures to help SIU SOM effectively evaluate and manage conflicts of interest.

Conflicts of Commitment SIU SOM Responsibilities:

Outside activities and relationships can enhance the mission of SIU SOM and the institution recognizes that conflicts of interest and conflicts of commitment are inevitable. However, SIU SOM employees cannot let outside activities interfere with their obligations to SIU SOM.

All faculty and staff must report any outside research or consulting activities and get written approval from the Office of Compliance before engaging in such activities. Additionally, any outside employment or business activity done in conjunction with other SIU SOM employees or SIU SOM or SIU HC vendors, or other activities that could conflict with, may negatively impact one's ability to perform normal job duties, or occur during normal business hours must also be disclosed. Full-time members of faculty must obtain prior written approval from the SIU System President or President's designee and must annually submit the amount of actual time spent on any outside research or consulting services to the President (or such designee), pursuant to the University Faculty Research and Consulting Act.

Fiduciary Duties and Conflicts of Interest:

SIU SOM expects its faculty, administrators, contractors, and staff to refrain from self-dealing and diverting SIU SOM or SIU HC resources and opportunities for their own personal gain. Members of the SIU HC Board of Directors have a heightened responsibility because they owe a fiduciary duty of loyalty, under corporate law, to always put SIU HC's interests ahead of their own. Directors also have a duty of care to provide oversight and make sure SIU HC has an effective policy and process for evaluating and managing conflicts to protect the mission of SIU HC and ensure compliance with the law.

Gifts and Entertainment:

The acceptance of gifts and business courtesies are a common risk area for conflicts of interest and can lead to liability under healthcare fraud and abuse laws—such as the Anti-Kickback Statute and Stark law—as well as provisions under the Illinois State Officials and Employees Ethics Act, and the Illinois Governmental Ethics Act. Even small gifts can bias, or create the appearance of bias, in professional judgment. This *Policy* prohibits acceptance or solicitation of any remuneration in exchange for improper referrals, orders, purchase, or lease of healthcare items and services, in violation of the Anti-Kickback Statute, Stark Law, or False Claims Act.

This *Policy* also prohibits any officer or employee (and the spouse or immediate family member living with the officer or employee) from intentionally soliciting or accepting any gift in violation of federal or state law or from any prohibited source, unless an exception applies.

Exceptions to the Gifts and Entertainment Policy per IL Governmental Ethics Act

1. Opportunities, benefits, and services that are available to the general public on the same conditions.
2. Anything for which the officer or employee pays the fair market value.
3. A gift from a relative.

4. *De minimus* meals or refreshments available at a business meeting or reception that the employee attends in the course of his or her duties to SIU SOM. This includes meals provided as part of a conference registration fee or otherwise available to the majority of meeting attendees.
5. The cost of registration fees, travel, lodging, or meals that:
 - a. relate to state business or educational activities;
 - b. have a close connection to the recipient officer's or employee's state employment;
 - c. predominantly benefit the public (not the employee or officer); and
 - d. are in a style and manner in character with the conduct of state business.

The prohibited source must make, or arrange, payment or reimbursement of such costs directly to SIU SOM, and the Ethics Officer must provide prior written approval.

6. Food, refreshments, lodging, transportation, and other benefits resulting from outside business or employment activities that are:
 - a. not connected to their official position as a state employee and
 - b. customarily provided to others in similar circumstances.
7. A gift on the basis of a personal friendship (not because of the official position or employment). In determining whether a gift is made on the basis of a personal friendship, the employee shall consider the circumstances under which the individual offered the gift:
 - a. the history of the relationship and previous exchange of gifts;
 - b. whether, to the actual knowledge of the employee, the individual sought a business reimbursement for the gift; and
 - c. whether to the actual knowledge of the member, officer, or employee, the individual gave the same or similar gift to other employees.
8. Bequests, inheritances, and other transfers at death.
 - a. All exceptions to the policy are governed by state or federal law, which may be updated from time to time. Utilization of an exception may be subject to the Executive Order 15-09 Gift Ban Exception Request Form. SIU SOM employees are encouraged to confer with the Office of Compliance when attempting to accept a gift.

Disposition of Gifts

An officer or employee can remedy a violation of the *Gifts and Entertainment Policy* by promptly taking reasonable action to return the prohibited gift to its source or give the gift—or an amount equal to its value—to an appropriate charity that is a 501(c)(3) organization under the Internal Revenue Code. The Ethics Officer in Carbondale will keep a log of donations to resolve violations of the *Gifts and Entertainment Policy*.

Conflicts of Interest in Research:

Most conflicts of interest in research stem from universities conducting industry-funded biomedical research and investigators who have a financial stake in the outcome of a clinical trial. SIU SOM must comply with regulatory requirements specific to research conflicts of interest.

Tech Transfer Conflicts of Interest:

A conflict of interest may exist in a technology transfer agreement when an SIU SOM faculty, official, employee, or contractor has an ownership or management interest in an entity proposing to option, license, or be assigned SIU SOM intellectual property.

Continuing Professional Education (“CPE”):

Conflicts of interest can occur where commercial interests bias, or create the appearance of bias, in the content and material for CPE or continuing medical education. Educational and professional components should be kept separate from marketing and promotional activities at conferences and CPE sessions.

Use of University Facilities and Resources:

SIU SOM does not permit use of SIU SOM facilities and resources for outside research or consulting activities, without prior written approval from the President (or designee). All faculty must request access to facilities and resources for outside activities when completing and submitting the applicable form for outside consulting and research activities.

Involvement of Students and Trainees:

Investigators and employees may not involve students and/or trainees in outside research or outside activities unless they can demonstrate that such participation affords an educational benefit for students/trainees and the Office of Compliance determines an appropriate management plan for potential conflicts of interest.

PROCEDURES:

Disclosures and Attestations:

1. All covered persons must annually complete the conflict of interest disclosure form via iRIS's Conflict of Interest module.
2. iRIS will send out reminders via email to covered persons to complete annual conflict of interest disclosures before the May 1st deadline under the Illinois Governmental Ethics Act.
3. The annual conflict of interest disclosure forms on iRIS will include the statement of economic interests, supplemental disclosure for the EEC, and additional questions related to various types of conflicts of interest and outside activities and relationships.
4. All covered persons must complete all information included in the annual disclosure based on the preceding twelve (12) month period.
5. All covered persons have an ongoing, affirmative duty to submit updates to iRIS, using an intermittent disclosure form within thirty (30) days after a new conflict emerges or their situation changes, and an updated FCOI disclosure form to the ADR Office of Grants and Contracts if they are involved in Federal grant. No covered person may begin any activity related to a potential conflict of interest until he or she has received final approval from the Office of Compliance.
6. Before submitting conflict of interest disclosures, each covered person must electronically sign and affirm through iRIS that he or she:
 - has read and understands the *SIU SOM Conflicts of Interest Policy* and
 - agrees to comply with this *Policy*.
7. Investigators and applicable study team members should submit a disclosure form for study-specific conflicts of interest with any new IRB Application via the appropriately corresponding iRIS module.
8. Investigators (all listed personnel) should submit intermittent FCOI disclosures with new grant submissions and with subsequent continuous years of funding in accordance with the Financial Conflicts of Interest on Federal Grants Policy.
9. As required by the University Faculty Research and Consulting Act, the Office of Compliance and Ethics will be responsible for providing the President's (or designee's) written approval of all disclosed outside consulting or research services. Faculty should note their requirement to provide an annual statement of actual time spent on outside research or consulting services.
10. All covered persons must submit a CPE disclosure form on iRIS before finalizing material and content for CPE presentations and sessions.
11. All covered persons must request written approval for reimbursement of education materials or events, travel, and related expenses from the SIU Ethics Officer and the Executive Director of the EEC, or his/her designee the SIU Ethics Officer, in advance of the trip.

Review and Assessment of Conflicts of Interest:

1. The SIU Ethics Officer will review and file all statements of economic interest with the Illinois Secretary of State, as well as the supplemental disclosures with the EEC by May 1st of each year.
2. Covered persons should submit all intermittent disclosures and online through iRIS and update FCOI forms to ADR

office if federal grants are involved.

3. The ADR Office of Grants and Contracts will review disclosures relative to FCOI and will direct any potential FCOI to the Office of Compliance and Ethics for review and assessment. See also *SIU Medicine Financial Conflicts of Interest on Federal Grants Policy*.

4. IRB administrative staff will review disclosures relative to study-specific COI and will direct any potential COI to the Office of Compliance and Ethics for review and assessment. See also *SIU SOM Springfield Committee For Research Involving Human Subjects ("SCRIHS") Conflict of Interest Policy*.

5. The Office of Compliance will complete the first level of administrative review of the completed/submitted annual and intermittent disclosures. Compliance will request additional information, if needed, and complete the first level administrative review against the *SIU SOM Conflicts of Interest Review Criteria*.

6. The Office of Compliance will endeavor to respond to intermittent disclosures within five (5) business days of receiving all needed documentation. Annual disclosures will be reviewed within one month of the deadline for disclosing.

7. Where the Office of Compliance determines there is a SFI related to an FCOI disclosure, the investigator must present compelling circumstances as to why the research should proceed despite the conflict.

8. In determining whether the research may proceed, the Office of Compliance shall consider:

- the nature of the research;
- the nature of the interest;
- how closely the interest and research are related; and
- the degree to which the research may affect that interest.

If the Office of Compliance determines that there is a potential conflict of interest that may require a management plan, the Office of Compliance will share the disclosure with the Office of General Counsel who will perform a second level review. The Office of Compliance may also enlist the support and input of subject matter experts (e.g., the COI Faculty Liaison, personnel from the Office of Grants and Contracts, personnel from Continuing Professional Education, personnel from the Center for Clinical Research, personnel with knowledge about intellectual property and/or Technology Transfer, and/or others with a specialized understanding of the issues salient to the disclosed conflict).

All individuals involved in the process for review, oversight, and management of conflicts of interest will keep all information confidential to the extent possible.

See additional details regarding FCOI and SFI related to PHS funded research in the Financial Conflict of Interest on Federal Grants Policy.

See additional details regarding IRB study-specific COI in the SCRIHS Conflict of Interest Policy.

Management Plans:

1. The Office of Compliance will discuss the conflict of interest, or potential conflict of interest, and management plan options with the discloser and his or her department chair.
2. The Office of Compliance will also seek input from the Office of General Counsel, a faculty liaison and subject-matter experts, as needed, relative to evaluation of the potential conflict of interest and in developing a management plan.
3. The Office of Compliance will approve and finalize the management plan, if required, with the discloser, department chair, faculty liaison, and Office of General Counsel.
4. The Office of Compliance and appropriate subject matter experts will develop appropriate management plans for SFIs. FCOI management plans must include the following elements:
 - the role and principal duties of the conflicted investigator in the research project;
 - conditions of the management plan;
 - how the management plan is designed to safeguard objectivity in the research project;
 - confirmation of the investigator's agreement to the management plan;
 - how the management plan will be monitored to ensure investigator compliance; and
 - other information as needed.
5. If a COI has been identified through SCRIHS' COI process, SCRIHS staff will report the COI to the Office of Compliance, who will then assess and manage the conflict as necessary and appropriate. When an Investigator or applicable member of the study team has a study-specific conflict of interest that is being managed under this *Policy*, SCRIHS will ultimately decide how to appropriately manage or modify the research study for the appropriate protection of human subjects. However, the Office of Compliance is otherwise responsible for managing the conflict, and SCRIHS may not modify or overturn determinations or management plans from the Office of Compliance.
6. Once the Office of Compliance has approved a conflict of interest and finalized a management plan, as necessary, for full-time faculty, the Office of Compliance will obtain approval in writing from the President (or a designee) before the outside consulting or research services are performed. Additionally and as required by law, faculty must submit the actual time spent on such outside research or consulting services to the President, or such designee.

Appeals:

Individuals who disagree with the final determination or terms of the management plan will have the opportunity to appeal in writing to the Office of Compliance within thirty (30) days after the Office of Compliance issues the final determination and management plan. Appeals will be reviewed by the Executive Compliance Committee.

Accessibility:

This *Policy* will be available online at the SIU SOM conflicts of interest website, along with resources and guidance regarding conflicts of

interest. The Office of Compliance will be responsible for annually reviewing and updating these materials. The Office of Compliance will retain records related to conflicts of interest for at least three (3) years after termination of the conflict.

Training:

All faculty, administrators, and staff must complete training on conflicts of interest through the annual ethics training or annual compliance training.

Individuals involved in evaluating conflicts of interest, including but not limited to the Chief Compliance Officer and/or his/her designee, the Office of General Counsel, and the faculty liaison, should regularly have additional specific education regarding evaluation and management of conflicts of interest

Retrospective Review:

If SIU SOM determines that the institution did not identify or manage a FCOI in a timely manner, the Office of Compliance will complete a retrospective review (within 120 days) of the Investigator's research activities during the time of noncompliance to determine whether there was bias in the design, conduct, or reporting of such research.

Auditing and Monitoring:

The Office of Compliance will include conflicts of interest monitoring in its annual risk assessment and work plan, as appropriate. SIU System Office of Internal Audit will be responsible for auditing relative to the SIU SOM Conflicts of Interest process.

Violations and Enforcement:

Failure to disclose conflicts of interest, comply with management plans, and/or engage in the activity in question prior to receiving final approval from the Office of Compliance and the President or designee (as applicable), in accordance with this policy, may result in the activity being denied, and could result in sanctions, up to and including termination.

REFERENCES:

- Medicare Managed Care Manual, Chapter 21 – Compliance Program Guidelines
- “Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought” 42 CFR Part 50 and “Responsible Prospective Contractor” 45 CFR Part 94.
- The Physician Payment Sunshine Act, § 6002 of the Affordable Care Act of 2010
- Illinois Governmental Ethics Act – 5 ILCS 420
- State Officials and Employees Ethics Act – 5 ILCS 430
- Illinois Procurement Code – 30 ILCS 500
- Illinois Grant Accountability and Transparency Act – 30 ILCS 708
- False Claims Act – 31 USC § 3729
- Anti-Kickback Statute and Stark – 42 USC § 1320a-7b and 42 USC §§ 1395, 1396(b)
- OEIG Year-End-Gift Guide (2016)
- SIU Financial Conflict of Interest on Federal Grants Policy
- Intellectual Property Policy, Southern Illinois University – System
- SIU Procurement Communications Policy
- SRIHS Conflict of Interest Policy
- SIU Industry Relations Policy
- Exec. Order No. 15-09, Executive Order to Ensure Ethical and Responsive Government