

E. CONSULTING ACTIVITIES AND EXTERNAL PROFESSIONAL RELATIONSHIPS

SIU School of Medicine faculty are encouraged to engage in consulting activities and other professional relationships with industry (where employee title and position at SIU are utilized) external to SIU School of Medicine or SIU HealthCare that advance the mission of the SIUSOM, promote the academic programs and goals of the department and the individual, and benefit the public. Such interactions allow the expertise, skills, and creativity of personnel of both the medical school and industry to cooperate on important health issues as well as in the development and application of new, effective technologies and therapies.

These policies address personal external professional relationships as defined in the Definitions section of this document. They do not pertain to grants or contracts between SIU School of Medicine and/or SIU HealthCare and any affiliated hospital, funding agency, or other entity.

1. Personal External Professional Relationships - Required Approvals and Reporting

The Illinois University Faculty Research and Consulting Act and the conflict of interest and commitment policies of Southern Illinois University and SIU School of Medicine require prior approval and regular reporting pertaining to personal external professional relationships. While the approval and reporting requirements are more extensive for relationships with industry, approval and reporting requirements also exist for other external entities (i.e., non-industry) such as other academic institutions and not-for-profit agencies. (See the school's and university's conflict of interest policies.)

See the chart in Attachment F – Consulting Activities/External Professional Relationships for a graphic depiction of this policy.

a. Prior Approval Before Beginning a Consulting Activity or Other Personal External Professional Relationship with Industry

SIU School of Medicine faculty and staff are required to seek prior approval from their department chair (or unit administrator) for consulting activity or other personal external professional relationships with industry, as specified in the Illinois University Faculty Research and Consulting Act and related university regulations. In cases where the annual income from the engagement is expected to be \$1,000 or more, the department chair (unit administrator) will forward the request to the Conflict of Interest Administrator in the Office of Compliance and Ethics; if the annual income is expected to exceed \$5,000, the COI Administrator will seek the prior review and approval of the request by the Dean and Provost.

To initiate the review/approval process, the faculty or staff member should complete the Approval of Outside Activities and/or External Consultancies form and route it to the department chair (or unit administrator). After reviewing the form, the department chair will forward the form to the Office of Compliance and Ethics. As necessary, the Conflict of Interest Administrator in the Compliance office will route the form to the Dean and Provost for the final review/approval step.

Approval must be obtained before the engagement is begun.

b. Conflict of Interest/Commitment Disclosure and Reporting

Consistent with SIUSOM's Policies on Conflict of Interest and Commitment, applicable employees of the medical school must complete conflict of interest/compliance reports using the School's online COI/C system annually and again as changes to the individual's external

relationships are encountered. These reports are reviewed by the pertinent department chair (or unit administrator) as well as by the medical school's Conflict of Interest Committee. If real or possible conflicts of interest or commitment are identified, the COI Committee will work with the faculty/staff member and the department to resolve the problem.

See the School's Conflict of Interest/Commitment policy for details.

2. Personal External Professional Relationships — Compensation and Expenses

Using the Approval of Outside Activities and/or External Consultancies form, SIU School of Medicine faculty and staff members must report their proposed personal external professional relationships with industry to the department chair (or unit administrator) for review and approval. In cases where the cumulative income of the engagement is expected to exceed \$1,000 annually, the department chair (unit administrator) will forward the request to the Conflict of Interest Administrator; when the cumulative income is expected to exceed \$5,000 annually, the Dean will review and approve the engagement prior to the individual engaging in or accepting remuneration for the activities. Faculty and staff members must also comply with the financial reporting requirements specified in SIUSOM Conflict of Interest and Commitment Policy, which includes a requirement to report their own financial interests in their personal external professional relationships with industry and those of immediate family and domestic partners.

Agreements between an SIUSOM employee and industry must provide that remuneration paid by the external entity goes directly to the faculty/staff member, who is acting in his/her private capacity and not as an agent of SIUSOM or SIU HC. The SIUSOM employee is personally responsible if any claims or damages arise from his/her personal external professional relationship.

Remuneration in any form must be at fair market value for the services provided. (See Attachment B – Additional Definitions for a definition of FMV.) These relationships with industry cannot create unmanageable real or perceived conflicts of interest or commitment for SIUSOM.

Compensated activities that are sponsored and/or managed by for-profit, independent continuing medical education companies or by foundations established by industry must be reported to the department chair and Dean's Office for review and approval prior to engaging in or accepting compensation for the activity.

3. Consulting for Industry

Faculty members should be aware that even the most principled compensated consulting activities with industry might constitute a perceived conflict of interest in research or clinical service, and this might warrant restrictions on a faculty/staff member's ability to engage in related areas of research and/or to involve students and trainees in areas of conflicted research. Faculty members will be required to eliminate conflicts of interest in research or clinical activity that cannot be managed effectively and therefore would compromise or prevent them from carrying out their SIU School of Medicine obligations.

SIUSOM employees who propose to serve as consultants to industry should adhere to the highest ethical and professional standards in conducting these external activities, and also the pertinent SIU School of Medicine and Southern Illinois University policies that support the following principles:

- Full-time faculty and staff are committed to SIU School of Medicine/SIU HealthCare for 100% of their professional time as a whole; approval is required for external employment or engagement in accordance with the policy of the SIU Board of Trustees.
- The total amount of time a faculty/staff member might be permitted to commit to personal external professional relationships for industry and other entities is subject to the approval and judgment of the department chair.
- Final approval of the proposed personal external professional relationship may be subject to reviews under and terms of other policies, such as the SIU Carbondale Non-Universities Activities and Financial Interests Policy, SIU Carbondale's Financial Conflict of Interest on Federal Grants Policy, the policies of the Institutional Review Board, SIU HC Compliance Policies, and others.
- SIU has ownership rights in intellectual property generated by its employees, including SIUSOM faculty and staff members. SIU School of Medicine's rights cannot be assigned to other entities without the approval of the Dean's Office and the SIU Office of Technology Transfer, and are subject to the Southern Illinois University Intellectual Property Policy.
- Faculty may not involve students and trainees in industry-sponsored research at SIU School of Medicine or in faculty start-up companies without a management plan approved by the department chair and the Conflict of Interest Committee.
- Faculty may not use SIUSOM or SIU University resources in their personal external professional relationships, including, but not limited to, facilities, personnel, letterhead, equipment, funds, supplies, services, and communication networks, without the written authorization of the department chair (or unit administrator), or Dean. Incidental use of telephone and computer is allowable, and does not require prior authorization.
- SIUSOM faculty and staff members who wish to use SIU School of Medicine's name, logo, or marks in any commercial setting or personal external relationship with industry or other entities must obtain prior approval from SIU School of Medicine. Requests should be made through the department chair (or unit administrator) for approval and forwarded to the Office of Public Affairs.
- Faculty and staff members who have personal external financial relationships with industry that also transact business (such as companies that are vendors to SIU School of Medicine) or compete with SIU School of Medicine cannot participate in SIU School of Medicine or SIU School of Medicine-affiliate business decisions concerning those entities (SIU Conflict of Interest Policy - Procurement).
- Officials of the SIU School of Medicine (deans, department chairs, directors of SIUSOM administrative units, department/division directors) are held to a higher standard than others and sometimes will not be allowed to participate in personal external professional relationships with industry because of their fiduciary duty to SIUSOM and their positions.
- Many of the principles listed here also apply if the faculty/staff member's immediate family members or domestic partner have a financial interest in industry that is related to the SIUSOM employee's responsibilities.

Examples of private, external consulting with industry that may be approved include, but are not limited to:

- serving on industry's scientific advisory boards to review research on novel products;
- serving on industry panels to review and objectively evaluate the data from clinical trials sponsored by industry;
- developing educational materials for industry websites that are directed towards the public for health promotion, explanation of diseases, and evidence-based diagnostic and therapeutic measures;
- advising industry about the structure of clinical trials; and
- advising industry about the design, appropriate clinical use, or internal research on its products.

4. Serving as an Officer or Board of Directors Member for Industry

SIU School of Medicine acknowledges the value of permitting SIUSOM employees to interact appropriately with industry. Examples of appropriate interactions include employee participation on industry boards of directors and scientific advisory boards as well as services provided through professional services agreements and consulting contracts, provided such activities are conducted in full compliance with the policies of SIUSOM, and that compensation, if any, reflects the fair market value of the services provided.

As discussed in section E.1 and Attachment F, all proposed engagements with industry must be approved in advance by the employee's department chair for academic departments, or unit administrators in all other units of the SIUSOM, using the Approval of Outside Activities and/or External Consultancies form. The recipient's conflict of interest/commitment disclosure form must indicate the position, time commitment, and compensation.

Service with a start-up company brings additional requirements. If the company officer/director role is related to the faculty/staff member's SIU School of Medicine responsibilities, these activities with a start-up company (or a company that is not publicly traded) in which the faculty or staff member or his/her immediate family member(s) or domestic partner has a financial interest may be allowed only for a limited amount of time, generally one year or until the company reaches \$1 million in gross revenue.

5. Commercial Promotional Speaking

A Commercial Promotional Speaking event is defined as an arrangement with industry, or with an entity having significant industry support and/or influence, that contracts or makes arrangements with physicians or other health care providers to deliver talks at informational programs or sessions, public service engagements or other events billed as educational, but that actually serve to advertise or promote products sold by the sponsor(s). These events typically do not grant CME credit, either because they are geared towards the lay public or because they have not successfully and demonstrably managed conflicts in a manner that would allow them to grant CME credit to physician attendees.

SIU School of Medicine and/or SIU HealthCare employees are prohibited from participating in industry-sponsored non-CME programs as a promotional speaker for drug, device or treatment industries, e.g., a commercial speaker's bureau. This prohibition applies to programs or events that promote specific products, services or treatment protocols on industry's behalf, regardless of whether or not industry provides the presentation materials.

An exception to this policy involves settings in which academic investigators are presenting results of industry-sponsored studies in which they participated to their peers and there is opportunity for critical exchange of ideas. Investigators may accept compensation for their legitimate travel, meals, and lodging expenses, as well as fair market value compensation for their time and effort. Pre-

authorization by the SIUSOM Ethics Officer is required. The values of all categories of support must be reported on the conflict of interest/commitment disclosure forms within the time period required by the SIUSOM conflict of interest policy and at least annually. (See section D. Industry-Provided Meals, Travel, and Lodging.)

Presentations given to employees of industry institutions for educational or health benefit where no potential prescribers or customers of that industry are present and no product is endorsed would generally be permitted. Participants may accept compensation for their legitimate travel, meals, and lodging expenses, as well as fair market value compensation for their time and effort. Pre-authorization by the SIUSOM Ethics Officer is required and the values of all categories of support must be reported on the recipient's conflict of interest/commitment form within applicable regulatory time frame requirements or at least annually.