

Southern Illinois University School of Medicine Policies on Industry Relations

Table of Contents

Introduction	2
Scope of Policies	2
Definitions	2
Policies	3
A. Site Access by Industry	3
1. Access by Industry Representatives to Provide Product Information – General	3
2. Access by Pharmaceutical Representatives to Provide Product Information	4
3. Invitations to Industry to Train SIU Personnel on Devices and Equipment	4
4. Commercial Exhibits in SIU School of Medicine or SIU HealthCare Buildings	5
B. Gifts and Samples from Industry	5
1. Pharmaceutical (Free) Samples	5
2. Gifts to an Individual from Industry – General	6
3. Gifts to an Individual from Industry – Educational Materials	6
4. Gifts to a Department or SIUSOM from Industry – Equipment, Devices, or Supplies	6
5. Gifts to a Department, Clinical Unit, or Clinical Practice (Not Individual) from Industry	7
6. Gifts of Promotional Items	7
7. Gifts of Funds from Industry to SIUSOM to Support Education and Other Professional Activities	7
C. Continuing Medical Education and Industry	8
D. Industry-Provided Meals, Travel, and Lodging	9
1. Food	9
2. Industry-Sponsored Professional Travel and Lodging	9
a. Industry Research Travel and Lodging	10
b. Sponsored Travel Other Than Research	10
E. Consulting Activities and External Professional Relationships	10
1. Personal External Professional Relationships – Required Approvals and Reporting	11
2. Personal External Professional Relationships – Compensation and Expenses	11
3. Consulting for Industry	12
4. Serving as an Officer or Board of Directors Member for Industry	14
5. Commercial Promotional Speaking	14
F. Honoraria from Industry	15
G. Other	15
1. Public Endorsements	15
2. Ghostwriting	16
3. Purchasing	16
4. Industry-Sponsored Scholarships and Other Educational Funds for Students and Residents/Fellows Not Employed by a Teaching Hospital	16
5. Industry-Sponsored Scholarships and Other Educational Funds for Residents/Fellows Employed by a Teaching Hospital	16
Oversight and Compliance	17
Attachments	18
A. Related Laws and Policies	18
B. Additional Definitions	20
C. Gift Ban Reviews and Approvals (chart)	21
D. Honoraria and Associated Expenses (chart)	24
E. Sponsored Travel Examples – Approval	26
F. Consulting Activities/External Professional Relationships (chart)	28

INTRODUCTION

Appropriate interactions between the SIU School of Medicine (SIUSOM) and industry can help advance the School's mission in education, research, patient care, and community health and service. Collaboration between academia and industry leads to discovery, innovation, and improvement in the health and well-being of patients and communities. However, improper industry influence can reduce the quality of patient care, research, and education, while increasing the cost of health care and eroding public trust in science and medicine. Industry influence needs to be properly managed and monitored.

These industry relations policies are established to assist SIUSOM's faculty, staff, students and other learners in adhering to the highest professional standards regarding interactions with industry.

SCOPE OF POLICIES

As employees and learners in a health care entity and public medical school in Illinois, SIU School of Medicine's faculty, staff, students, and other trainees are subject to federal and state laws such as the Federal Anti-Kickback statute and the Illinois State Officials and Employees Ethics Act, Southern Illinois University policies and procedures, and SIU Board of Trustees policies that govern our interactions with external groups including industry. The industry relations policies outlined below are complementary to and consistent with these federal, state, and university mandates as well as policies and guidelines in place at the SIUSOM by the Springfield Committee for Research Involving Human Subjects (SCRIHS) (policies that address relationships between clinical investigators and industry sponsors of clinical research) and the policies related to Continuing Medical Education (CME). See Attachment A – Related Laws and Policies for more information about these mandates.

SIU School of Medicine's industry relations policies apply to all SIU School of Medicine faculty, staff, students, and other trainees. For those individuals and activities located in teaching hospitals or non-SIU clinical locations, the specific policies of those locations will also apply.

These industry relations policies govern interactions between SIU School of Medicine's employees and learners and industry as defined below. Relationships with other external entities, such as other universities and not-for-profit organizations, are not subject to these industry relations policies; however, they are subject to other State of Illinois and SIU requirements such as the Illinois State Officials and Employees Ethics Act and the SIUSOM Conflict of Interest/Commitment policies.

DEFINITIONS

In these industry relations policies, the following key terms are defined as:

- "Industry" is defined as an organization creating, designing, manufacturing, marketing and/or selling pharmaceutical products, surgical devices, other treatments for patient care, research equipment and supplies, or similar products and services, as well as entities controlled by them such as industry-funded trade associations and foundations. In this context and under these policies, industry does not include other universities, professional associations, public or public service/not-for-profit organizations, and other entities that are not controlled by industry.

- “Other external entities” include non-industry organizations external to SIU School of Medicine such as other academic institutions, professional societies, government agencies, and not-for-profit agencies. As noted, these entities are not considered industry and are not subject to these industry relations policies.
- “Personal external professional relationships” include any professional services, such as consulting, or other relationships with entities other than SIU School of Medicine or SIU HealthCare which are not provided through grants or contracts between the external entity and the medical school and/or practice plan. Medical services provided to affiliated hospitals through contracts between the hospital and SIU as well as research grants/contracts between funding agencies and the medical school are not included in this definition. Personal external professional relationships may be compensated or uncompensated.
- “Job-related activities” are defined as activities that are expressly delineated in the individual's job description; or those clearly implied by the job description, including activities that fall within the general scope of the individual's job description and are consistent with the goals and mission of the university.
- “SIU facilities” are facilities that are operated and/or controlled by SIU School of Medicine or SIU HealthCare. SIU facilities may be owned by the medical school or university or leased from other entities for use by the medical school or practice organization. Sites operated and/or controlled by the medical school's affiliated teaching hospitals or other non-SIU organizations – sites such as hospital operating rooms – are not included in this definition of SIU facilities.

See Attachment B - Additional Definitions.

POLICIES

The SIU School of Medicine recognizes the benefits of and the necessity for faculty, staff and learners to interact with industry in several contexts, including on-site education about new drugs, equipment, devices, and supplies, and on-site training of faculty in new or upgraded industry devices and equipment purchased by SIU HealthCare (SIU HC) or SIU School of Medicine (SIUSOM).

When these interactions are conducted in a principled manner that protects the integrity of research, education, training, and clinical programs, and that protects patients and individual and institutional reputations, they are positive and beneficial in furthering SIU School of Medicine's mission and benefitting the public. These policies provide guidance to faculty, staff, and learners who interact with industry at SIU HC or SIUSOM and in SIU activities elsewhere.

A. SITE ACCESS BY INDUSTRY

The policies detailed below pertain to SIU owned and leased locations. Hospital facilities are covered by their own specific policies.

1. Access by Industry Representatives to Provide Product Information – General

SIU School of Medicine faculty and senior staff members may invite industry representatives to SIU for appointments in non-patient care and non-public areas to provide them with information about company products. Individual faculty members and departments may also host periodic structured, faculty-supervised group conferences at which invited industry representatives provide information

about and demonstrations of their products in a setting that allows critical interaction and evaluation among the participants.

When departments or faculty members host such group conference events, they must invite highly-trained industry representatives, rather than sales and marketing representatives. Highly-trained industry representatives with MD, PhD, or Pharm D degrees would be best suited for transmitting such scientific information in these settings. These conferences will be restricted to SIU faculty, staff, students, and trainees. Industry representatives who participate are not permitted to use such conferences for sales and marketing purposes, nor may they provide any gifts, including, but not limited to, devices, products, food, beverages, and pens.

Industry representatives may be invited to participate in Accreditation Council for Continuing Medical Education (ACCME)-accredited courses managed by SIU's Office of Continuing Professional Development (OCPD) to explain and help operate complex equipment or devices. While physician faculty will be required to teach the indications for use of the equipment and the clinical use and interpretation of data from the equipment, industry representatives may provide the technical information and support to operate the equipment. This type of training is allowable when it is administered by the OCPD in accordance with ACCME guidelines.

2. Access by Pharmaceutical Representatives to Provide Product Information

To protect patients, patient care areas, and work schedules, access by pharmaceutical representatives to individual physicians should be restricted to non-patient care areas and should take place only by appointment or invitation of the clinician. Pharmaceutical representatives are not allowed to be a part of a patient service visit and shall not attend any conferences or meetings at SIU facilities where patient specific information (i.e. the information is not de-identified) or quality assurance activities are being discussed.

3. Invitations to Industry to Train SIU Personnel on Devices and Equipment

Industry representatives who are invited to SIU by SIUSOM faculty and senior staff members to provide essential education and training to medical school faculty, staff, students, and trainees on devices and equipment used in research, administrative processes, and clinical practice are expected to be highly trained and appropriately credentialed in their areas of expertise.

Access by device/equipment manufacturer representatives to SIU patient care areas is permitted only when the representatives are appropriately credentialed and should take place only by appointment or invitation of the clinician. In SIU facilities (as defined in the Definitions section above), representatives are not allowed to be present during any patient care interaction unless there has been prior disclosure to, and with written consent from, the patient, and then only to provide in-service training or assistance with devices or equipment. When the location is one operated by the hospital or other non-SIU clinical entity (such as in a hospital operating room), the rules of those organizations apply regarding the industry representative's visit. Health care product vendors shall not attend any conferences or meetings at SIU facilities where patient specific information (i.e. the information is not de-identified) or quality assurance activities are being discussed.

Student and trainee interactions with representatives should occur only for educational purposes and only with personal faculty supervision.

4. Commercial Exhibits in SIU School of Medicine or SIU HealthCare Buildings

No commercial exhibits, tables, booths, or posted materials may be set up by industry representatives in SIU School of Medicine buildings and other SIU facilities where SIUSOM faculty, staff, students, and trainees work and/or study without prior approval. Authorization is provided by the SIUSOM Director of Facilities and Services for Springfield campus locations, the Executive Director of Administrative Support Services for SIUSOM sites on the SIU Carbondale campus, and the Family and Community Medicine administrator in the particular residency site location. Authorization will not be given for commercial displays in public areas or in patient care areas.

B. GIFTS AND SAMPLES FROM INDUSTRY

This section provides guidelines for decision making regarding the acceptance of gifts and samples from industry. Activities and business interactions conducted on behalf of the SIU School of Medicine or SIU HealthCare must be in compliance with federal and state laws and regulations. (See Attachment A.) Adherence to these restrictions will minimize even the perception of improper relationships with vendors or others who conduct or seek to conduct business with the SIU HC or SIUSOM.

See Attachment C – Gift Ban Reviews and Approvals for a synopsis of review and approval requirements.

1. Pharmaceutical (Free) Samples

The receipt of, dispensing of, or use of pharmaceutical samples, whether prescribed or not, is prohibited unless prior written institutional approval has been obtained.

- The Chair of each department must approve all samples held and dispensed within clinics operated by SIU School of Medicine and/or SIU HealthCare. This approval should be limited to expensive, orphan pharmaceuticals or products that have a strong clinical indication for their dispensing by SIU. Copies of the signed approval form should be forwarded to the Office of Compliance and Ethics, which has administrative responsibility for these policies.
- Pharmaceutical samples should be stored, controlled and dispensed with appropriate, auditable controls that ensure no diversion of the samples can occur and, if necessary, patients who received the samples may be contacted. Dispensed samples must be appropriately recorded according to conditions and procedures specified by SIUHC and University Risk Management.
- Samples may not be used by clinicians or clinical staff, or given to their friends or family members.
- Free samples may never be sold and should be inventoried and stored separately from inventory that is purchased for use by the clinical department.
- The Office of Compliance and Ethics has the authority to at least annually review these controls and report to the department chair and Dean the results of the audit.

2. Gifts to an Individual from Industry - General

The State Officials and Employees Ethics Act (5 ILCS 430/) defines a “gift” as “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 an employee ... “. Gifts of any value or type to SIUSOM faculty and staff, students, and other trainees from industry representatives are prohibited, unless the gift meets one of the exceptions to the gift act (see Attachment C - Gift Ban Reviews and Approvals). This prohibition extends to spouses and immediate family members.

Examples of gifts from industry that are prohibited unless expressly allowed under the gift act include, but are not limited to:

- pens, pads, and other promotional items;
- cash or honoraria;
- food and drink; (See D.1 Food below)
- entertainment such as tickets to events, golf, and other outings;
- medical or research equipment, devices, or other products or services or discounts on same; (See section on B.3 Gifts to an Individual from Industry – Education Material below)
- use of company vehicles or vacation facilities;
- travel expenses; (See D.2 Industry-Sponsored Professional Travel and Lodging below)
- stocks, equity, and other such financial offerings;
- group gifts;
- biological samples; (See B.4 Gifts to a Department or SIUSOM from Industry – Equipment, Devices, or Supplies below)
- software; (See B.4)
- computer hardware and accessories;
- portable electronic devices;
- consulting, financial, and other services; and
- office and research supplies.

3. Gifts to an Individual from Industry – Educational Materials

Gifts of educational materials from industry sources are allowed under the gift act if they advance the SIUSOM mission. Such educational materials may be accepted as gifts to the individual or to the department, if approved in advance by the SIUSOM Ethics Officer in accordance with the State of Illinois Ethics Act. (See Attachment C.)

Occasionally books, brochures, and other materials provided by industry are the best available for educating students, trainees, and patients in a particular area. Examples include, but are not limited to, illustrated drawings of organ systems and treatises on certain diseases. Faculty physicians should avoid displaying such educational materials in patient care areas if the names, marks, and logos of the company are easily visible, as promotional displays for industry are not allowed in public or patient-care areas.

4. Gifts to the Department or SIUSOM from Industry – Equipment, Devices, or Supplies

Gifts of equipment, devices, supplies, biological samples, and the like from industry for use in non-ACCME (Accreditation Council for Continuing Medical Education)-accredited education, research, and clinical care conducted by SIU School of Medicine faculty will be approved by the department

chair/unit administrator. If the value of the gift is \$500 or more, the gift's receipt will be coordinated centrally by the SIU Foundation as "in-kind" donations to the medical school, as appropriate and consistent with institutional policies. The in-kind donations will be documented in agreements. Such gifts will be unrestricted in the sense that the company will have no expectation of, nor will the company receive, a return benefit.

When gifts of equipment, devices, or supplies from industry are used by a faculty member in a training setting, introductory comments should be made that include the following information:

- The use of the equipment, device or supplies is evidence-based.
- The use of the item does not imply its endorsement by SIUSOM or SIU HealthCare.
- Similar equipment, devices or supplies are available from other vendors (if applicable).

Donations or loan of equipment for ACCME-accredited CME activities must be handled by the SIUSOM Office of Continuing Professional Development (OCPD). For each of these "in-kind" donations, there must be a letter of agreement between the OCPD and the corporate entity indicating that the education activity will be planned and implemented without any input from the corporation providing the equipment.

5. Gifts to a Department, Clinical Unit, or Clinical Practice (Not Individual) from Industry

The state's gift ban prohibits even modest, complimentary gifts to individuals and departments. This includes perishable gifts (such as a floral arrangement, box of cookies, candy or similar food items) that are shared by staff members on special occasions, such as holidays. Such gifts should be refused or returned. If it is not feasible to refuse or return the item, the department can remedy the violation to the Gift Ban Act by:

- a. Having one employee or all employees contribute to the next charitable casual day or donation towards the value of the items received to remedy the compliance issue; or
- b. Donating the item to a 501 (c)(3) charity.

Documentation of any donations to remedy non-compliance should be maintained by the department. A further attempt should be made to communicate to the sender of the gift that a donation was made by the department in accordance with State of Illinois ethics guidelines and to communicate the rules regarding the prohibition of gifts from a prohibited source. It should be noted that meals sent from industry representatives to SIUSOM or SIU HC are not permissible and are covered under the Food section of this policy (D.1 below).

6. Gifts of Promotional Items

Gifts of promotional items such as pens, notepads, mugs and similar items from industry are prohibited, unless the items are made available by the industry source under the same conditions to the general public. Examples of this include promotional materials provided to conference attendees in a conference's exhibitor hall.

7. Gifts of Funds from Industry to SIUSOM to Support Education and Other Professional Activities

All gifts of funds from industry to support non-ACCME (Accreditation Council for Continuing Medical Education)-accredited education, other educational initiatives, and other professional activities in the School of Medicine will be managed centrally through the SIU School of Medicine or SIU HealthCare and placed in designated pooled accounts either in the Office of Associate Dean for Research or in the central administrative office of a School of Medicine department, depending on the nature and

purpose of the gift. Receipt, allocation, and use of the funds must be free of real or perceived conflicts of interest.

Funds given by industry for non-ACCME-accredited education, other educational initiatives, and other professional activities may be earmarked for broad areas of interest to the donor, such as education in the broad specialties and large sub-specialties of medicine and science (e.g., neurology, infectious diseases, cardiovascular surgery, microbiology), or broad topical areas (e.g., imaging, vaccines, faculty mentoring), or student support areas (e.g., scholarships for medical and graduate students), but unless otherwise noted in these policies no funds may be given by industry in a way that specifically directs the funds to individuals, small groups of individuals, or specific activities.

The transactions for gifts of funds from industry will be documented with signed agreements through the SIU Foundation or the Office of the Associate Dean for Research that comply with School and institutional policies. Such gifts will be unrestricted in the sense industry will have no expectation of benefit in return, such as:

- identification of the company to the individual recipient of the funds,
- use of the SIU name and marks in industry promotional and marketing activities,
- influence on the curriculum,
- access to SIUSOM employees and students for marketing and sales,
- SIU endorsement for company products,
- a promise to purchase or use industry products,
- use of SIU facilities and resources by industry or uninvited presence of industry in SIU facilities,
- services to industry by SIUSOM faculty, and
- associated research or training agreements for industry.

The ADR and departments will manage the pooled industry funds free of conflict of interest or commitment or industry influence on decision makers or recipients. All reasonable efforts will be taken to ensure that the recipient of industry funds does not know the specific industry source. The ADR or departments, as appropriate, will select the recipients, initiatives, and professional activities to be supported by these funds without input from industry. Examples of allocations of funds from pooled accounts include support for fellowships and scholarships, departmental educational programs and courses, faculty development courses, and faculty and trainee travel expenses to attend meetings. Except as otherwise noted in these policies, in no case will gifts, funds, unrestricted grants, and the like be accepted directly from industry by individual faculty members, department chairs, or staff for deposit into personal or other external accounts.

Acknowledgments of the generosity of industry donors in providing support for education and other professional activities will be memorialized in appropriate departmental and SIU School of Medicine publications and other appropriate venues.

C. CONTINUING MEDICAL EDUCATION AND INDUSTRY

Southern Illinois University School of Medicine will audit continuing medical education (CME) programs to assure compliance with the standards of the Accreditation Council for Continuing Medical Education (ACCME) pertaining to relations with industry, including those with respect to content validation and meals. All activities held on SIUSOM campuses or sites that wish to be CME accredited must go through the SIUSOM Office of Continuing Professional Development for approval.

The Office of Continuing Professional Development of SIUSOM should process all requests for industry support (including in-kind support) and receipt of funds for CME/CPD activity, as well as coordinate and oversee such activities. Industry grants for ACCME-accredited CME activities must be handled by the SIUSOM Office of Continuing Professional Development. Each education grant must be accompanied by a letter of agreement between the School and the corporate entity indicating that the education activity will be planned and implemented without any input from the ACCME-defined commercial interest that is providing the grant. The ACCME defines a commercial interest as any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.

To the extent that educational programs for physicians are supported by any ACCME-defined commercial interest, including pharmaceutical, device, equipment, and service entities, the programs should be offered only by ACCME-accredited providers according to ACCME standards. Activities held on campus must either be solely sponsored through SIUSOM, jointly sponsored with a non-accredited entity, or co-sponsored with another accredited entity.

D. INDUSTRY-PROVIDED MEALS, TRAVEL, AND LODGING

Meals, travel, and lodging provided by industry – when not provided under an approved consulting relationship (see next point, E. Consulting Activities and External Professional Relationships) – are subject to the State of Illinois Ethics Act/Gift Ban. See Attachment C – Gift Ban Reviews and Approvals.

1. Food

Industry representatives may not directly provide meals or other types of food for any educational or professional activity of the SIU School of Medicine. Faculty, staff, students, and other trainees are generally prohibited from accepting meals at any location as this would be considered a gift under the State of Illinois Ethics Act and guidelines. However, de minimus (i.e., small, minor) meals or refreshments served at business meetings or receptions attended (e.g., meals provided at conferences) as part of an employee's official duties are allowed and do not require conflict of interest reporting. Meals and other refreshments paid for by the SIUSOM or the faculty/staff person, such as those included in a conference fee, are allowed and do not require prior approval by the SIUSOM Ethics Officer.

Dinners provided by industry at a restaurant at a site separate from the meeting would not be allowed and would need to be reported to the SIUSOM Ethics Officer for necessary steps to bring the employee into compliance with the State of Illinois Ethics Act. This would also include items reported under the Open Payments Act related to meals, if accepted. See Attachment A.

2. Industry-Sponsored Professional Travel and Lodging

Under the State of Illinois Ethics Act, industry may sponsor a faculty or staff member's travel and lodging for a professional event only if the event meets one of the exceptions to the Act's gift ban as determined by the SIUSOM Ethics Officer. Please review Attachment C – Gift Ban Reviews and Approvals and Attachment E – Sponsored Travel Examples – Approval for details.

Travel and lodging associated with a consultancy or other external professional relationships is also allowed. See E. Consulting Activities and External Professional Relationships below for more information.

a. Industry Research Travel and Lodging

Faculty and staff may accept industry reimbursement for travel, lodging and meals to attend meetings to act as a bona-fide expert or participate in panels regarding development of new research protocols, to discuss research results, or to participate in a conference to understand requirements for future research activities. Examples include investigator or study coordinator meetings.

Regulations regarding payment by industry for travel expenses related to research or clinical trial participation are governed by SCRIHS (Springfield Committee for Research Involving Human Subjects) policies, but also require advance approval by the SIUSOM Ethics Officer in accordance with the State Officials and Employees Ethics Act.

b. Sponsored Travel Other Than Research

In addition to cases pertaining to research or clinical trial-related meetings, payments by industry for travel, meals, and lodging expenses for some other meetings may serve SIUSOM's mission and be acceptable under the Gift Ban's exceptions in the State Ethics Act. Expenses to be paid for by industry must be pre-approved by the SIUSOM Ethics Officer and reported on the faculty/staff member's conflict of interest/commitment disclosure form.

Faculty or staff may accept reasonable honoraria and reimbursement for travel, lodging, meals and conference fees for their attendance at educational conferences or meetings, including those related to research activity, only if the person presents, serves as a panel discussion participant, panel moderator, or otherwise actively participates in the conference or meeting. Acceptance of honoraria must be consistent with State of Illinois law and SIU policies; see F. Honoraria and Industry below. Faculty or staff who are simply attendees at conferences cannot accept either honoraria or reimbursement of travel, lodging, or meal expenses unless participation is approved by the SIUSOM Ethics Officer.

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.

F. HONORARIA AND INDUSTRY

“Honoraria” are payments for service, such as making a presentation at an external event, for which custom or propriety forbids a price to be set. Because honoraria meet the definition of gifts under the Illinois State Officials and Employee Ethics Act and industry is a prohibited source under the Act, the speaking or other engagement performed for industry must be done on the SIUSOM faculty or staff member's own time. Employee benefit vacation time will be taken when the activity relates to the honorarium. This engagement is thus considered secondary employment for the individual and is allowed.

Faculty and staff members wishing to accept an honorarium from industry, regardless of the type of engagement, must obtain approval for the honorarium in advance by the individual's department chair for academic areas or by the individual's unit administrator in the case of non-academic units. The engagement will also be reviewed by the Conflict of Interest Administrator, on behalf of the Conflict of Interest Committee. See Attachment D – Honoraria and Associated Expenses and Attachment E – Sponsored Travel Examples – Approval for additional information.

As noted in E.2 Personal External Relationships – Compensation and Expense above, industry-provided honoraria will be paid directly by the external organization to the faculty or staff member. Agreements between an SIUSOM employee and industry must provide that remuneration paid by the external entity go 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 honoraria should be reasonable and at Fair Market Value (FMV). There is no simple formula or resource for determining FMV. Faculty rank, specialty, SIUSOM and SIUHC compensation amounts, and other considerations will determine what constitutes FMV. Any honoraria must be included on the recipient's conflict of interest/commitment online form within applicable regulatory time frame requirements or at least annually. (See Attachment B – Additional Definitions for a working definition of FMV.)

G. OTHER

1. Public Endorsements

SIU School of Medicine faculty and staff may use their academic and/or position titles and the SIU/SIUSOM logo in their presentation materials for any activities or engagements approved under these industry relations policies. SIUSOM employees engaged in activities or engagements with industry not approved under these policies may not use the University name or their title in connection with those activities or engagements.

SIUSOM faculty and staff may not publicly endorse products or services without the prior written approval of the Dean and Provost of the SIU School of Medicine.

2. Ghostwriting

“Ghostwriting” is defined as the provision of written material that is officially credited to someone other than the writer(s) of the material. Transparent writing collaboration with attribution between academic and industry investigators, medical writers, and/or technical experts is not ghostwriting. The unacknowledged, undisclosed provision of content is not permitted under any circumstances. SIU School of Medicine prohibits physicians, trainees, and students from allowing their professional presentations of any kind, oral or written, to be ghostwritten by any party, industry or otherwise.

3. Purchasing

SIUSOM must follow state purchasing guidelines at all levels.

SIU HealthCare must adhere to guidelines to address conflicts of interest in purchasing similar to the Association of American Medical Colleges’ disclosure recommendations and consistent with guidelines of the SIU School of Medicine.

4. Industry-Sponsored Scholarships and Other Educational Funds for Students and Residents/Fellows Not Employed by a Teaching Hospital

Medical students, other students, and residents and fellows who are not employed in their residencies/fellowships by a teaching hospital may receive industry-sponsored scholarships and other educational funds (including funding for travel to educational events) if the following provisions apply:

- a. The SIUSOM department, program, division or institute selects the student or trainee.
- b. The industry-provided funds are provided to the School, department, program, division or institute and not directly to the student or trainee or to an individual faculty member.
- c. The department, program, division or institute has determined that the funded conference or program has educational merit.
- d. The recipient is not subject to any implicit or explicit expectation of providing something in return for the support, i.e., a "quid pro quo."
- e. The Office of the Associate Dean for Research must process any requests or applications for industry-sponsored funding if that funding will be awarded to the SIU School of Medicine.

Industry-sponsored funding for student/learner support should be free of any actual or perceived conflict of interest and must be specifically for the purpose of education.

5. Industry-Sponsored Scholarships and Other Educational Funds for Residents/Fellows Employed by a Teaching Hospital

Residents and fellows who are employed in their residencies and fellowships by an affiliated teaching hospital must obtain approval for any industry-sponsored scholarships and other educational funding (including funding for travel to educational events) from their teaching hospital employer according to the policies and procedures of the hospital.

These residents and fellows must also obtain prior approval for the funding from their SIU School of Medicine residency/fellowship program director who will consider the educational merit as well as any actual or perceived conflict of interest which might be associated with the funding. Program directors should consult with the SIUSOM Ethics Officer with questions.

OVERSIGHT AND COMPLIANCE

Department/division chairs and unit administrators are responsible for overseeing compliance with the industry relations policies among faculty, staff, and learners assigned to their departments and units. The Dean and Provost (or designate) will monitor compliance at the institutional level. Noncompliance may be addressed through education and professional development; existing disciplinary policies and procedures may be utilized, as warranted.

Approved by the SIU School of Medicine Executive Committee and the Dean and Provost on December 12, 2016.

Attachment A

Related Laws and Policies

Industry relations and conflict of interest policies are governed by state and federal laws and statutes. As such, policies at many institutions can look very similar to those of Southern Illinois University School of Medicine. SIUSOM acknowledges the leadership of the Association of American Medical Colleges (AAMC) regarding industry relations policies. Several of the policies are taken in part from the AAMC policy recommendations outlined in the June 2008 report, *Industry Funding of Medical Education: Report of an AAMC Task Force*. Additionally, policies from several universities were reviewed, including, but not limited to: David Geffen School of Medicine at UCLA, University of Michigan, Emory University, and Texas Tech University Health Sciences Center.

This section references, for information purposes, several U.S. and Illinois laws and university policies that concern potential conflicts between an employee's private outside interests and his/her university responsibilities or that might apply in evaluating the propriety of a particular non-university interest or activity involving industry.

1. University Faculty Research and Consulting Act: An Act of the State of Illinois relating to research or consulting services by members of the faculty of state-supported institutions of higher learning," 110 Ill. Comp. Stat. 100/1 et seq. This statute, enacted in 1969, requires all full-time faculty members to obtain written approval before engaging in outside research or consulting for remuneration, and requires an annual statement of the amount of actual time spent on such activities. SIU policy extends the requirements to staff.
2. SIUC Conflict of Interest: Non-University Activities and Financial Interests: This policy of SIU Carbondale requires the prior approval of outside activities and financial interests exceeding \$1,000 in annual income.
3. SIUC Fund-raising, canvassing, soliciting, vending, and allied advertising University Property Policy: SIUC policy stating that fund-raisers, canvassers, solicitors, vendors and agents are forbidden to pursue their occupations on any property owned or controlled by the university except on official university business unless in accordance with policies to allow certain educational, cultural, or service activities. Prior written approval is required.
4. State Officials and Employees Ethics Act: (5 ILCS 430) Sponsored Travel disclosures and pre-approvals are required for all faculty and staff by the Illinois State Officials and Employees Ethics Act (Ethics Act). The Ethics Act (5 ILCS 430/10-10) also prohibits the solicitation or accepting of a gift from a prohibited source defined below unless it meets an exception under the Act. Certain exceptions require advance approval by the SIUSOM Ethics Officer as delineated in the Gift Ban section of the Illinois Administrative Code (2 IL Admin. Code 1620.700) According to the Ethics Act, **prohibited sources** are people or entities that fit one or more of the following categories:
 - Is seeking official action by the recipient or the recipient's agency;
 - Does business or seeks to do business with the recipient or the recipient's agency;
 - Conducts activities regulated by the recipient or the recipient agency;
 - Has interests that may be substantially affected by the performance or non-performance of the recipient's official duties; or
 - Are registered or required to be registered as lobbyists.

The Ethics Act prohibits a state employee, including employees of the state's public universities, from soliciting or accepting any gift from a prohibited source or in violation of any federal or state statute.

5. Executive Order 15-9: This order of the Governor of Illinois eliminates the \$75 and \$100 thresholds allowed by the State Officials and Employees Ethics Act for Food and Gifts, respectively.
6. Use of University Property: The Policies of the Board of Trustees of Southern Illinois University – University Property and Physical Facilities/Use of University Policy (Policies, Section 6.c) and the SIUC Regulations Governing the Use of University Personal Property govern the use of university property and prohibit the use of university property for private purposes.
7. SIU Intellectual Property Policy: This policy governs ownership and use of inventions, discoveries and certain copyrightable works developed within the scope of an employee's duties to the university or developed through the use of university facilities or resources.
8. Joint Purchasing Rules Governing Procurement and Bidding at State Systems Universities in Illinois: These regulations implement the Illinois Purchasing Act, 30 Ill. Comp. Stat. 505/1 et seq., and govern the purchase of all goods and services for the university.
9. Federal Anti-Kickback statute: [This law](#) makes it a crime to knowingly and willfully solicit, receive, offer or pay, overtly or covertly, directly or indirectly anything of value in cash or in kind in exchange for the referral of patients, items or services payable by a federal health care program (Medicare, Medicaid, etc.). A gift can be improper if it is made to someone in a position to generate referrals (i.e. prescribe drugs or durable medical equipment) or if the payment represents more than fair market value.
10. Open Payments Act: Section 6002 of the U.S. Affordable Care Act requires that applicable manufacturers of covered drugs, devices, biologicals, and medical supplies must report to the U.S. Centers for Medicare and Medicaid payments or other transfers of value that they make to physicians and teaching hospitals. Other requirements include reporting of physician ownership of or investments in drug/device manufacturers.

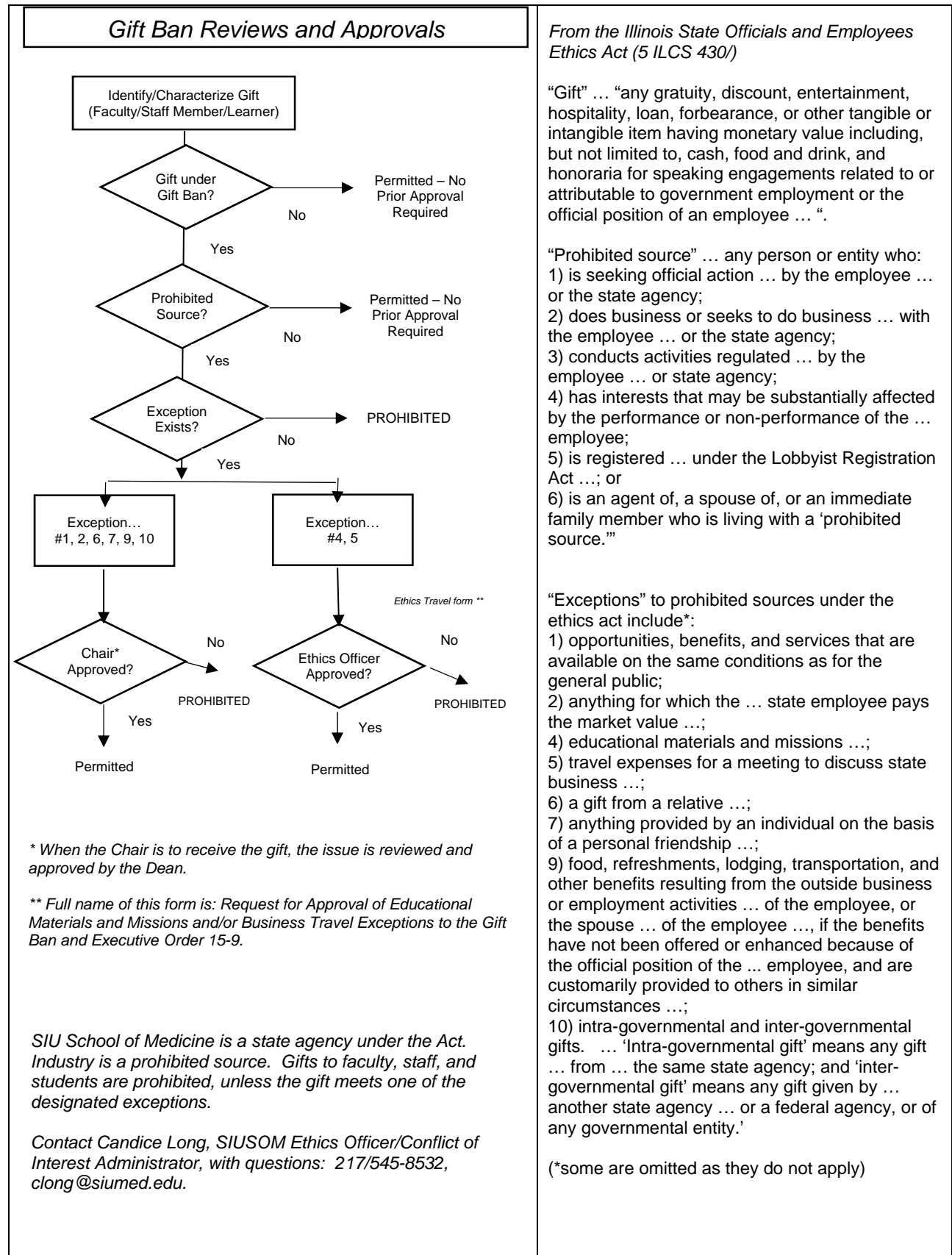
Attachment B

Additional Definitions

- “Continuing Medical Education” (CME) refers to ACCME (Accreditation Council for Continuing Medical Education)-accredited educational activities, conducted in accordance with ACCME and School of Medicine policies.
- “Industry-sponsored education” refers to non-ACCME-accredited activities sponsored by industry at which academic faculty give presentations, usually compensated by the industry sponsor, about their research, the status of research in an area, clinical practice in an area, status of surgical procedures in an area, etc. The activity is not regulated by the U.S. Food and Drug Administration; the industry sponsor does not prepare, review, or impose restrictions on the content of the presentations; and attendees are free to critically discuss and evaluate the presentations. This form of industry-sponsored education often takes place as satellite symposia at professional society meetings or at independent venues. Faculty may not participate as a presenter when the activity is determined by the department chair (unit administrator) or the Dean’s Office to be predominantly promotional.
- “Industry-sponsored training” refers to non-ACCME-accredited activities sponsored by industry at which academic faculty and industry sponsor experts provide training on the sponsor’s equipment and devices, often to physicians invited by the company. Faculty who provide the training are compensated.
- “Speakers bureaus” are distinguished from industry-sponsored education and training in that the content is controlled by industry because of restrictions on discussions related to off-label usage. Speakers’ Bureau presentations are predominantly promotional, and are not regulated by the FDA. Participation as presenters or speakers is prohibited for SIU School of Medicine faculty, staff, students, and trainees.
- “Fair Market Value” means the compensation that would be paid as a result of bona fide bargaining between well-informed parties to a transaction, when neither is otherwise in a position to generate business for the other party. FMV is generally defined as the price, expressed in terms of cash equivalents, at which property would change hands between a hypothetical willing and able buyer and a hypothetical willing and able seller, acting at arm’s length in an open and unrestricted market, when neither is under compulsion to buy or sell and when both have reasonable knowledge of the relevant facts. To determine FMV, valuers typically look to market equivalents for prices, costs to produce the service, or the income lost for time involved in providing the service.*

(*From A. Ferrari, A. Brandt, and S. Safriet “Determining ‘Fair Market Value’ for Physician Consulting Services: The New ‘Big Question’ for Life Sciences Companies”, American Health Lawyers Association – Life Sciences Practice Group. Vol 3, Issue 1. April 2009; available at http://www.healthcareappraisers.com/Publicationpdf/AHLA_LifeSciences_0409.pdf)

Attachment C



Attachment C (continued)

*From the Illinois Administrative Code 2/E/VI
Section 1620.700 Gift Ban*

“Educational Materials and Missions” are those materials and missions that:

- 1) have a close connection to the ... employee’s state employment or the mission of the agency or office;
- 2) predominately benefit the public and not the employee; and
- 3) are approved by the agency’s ethics officer in advance of the mission or receipt of the materials, if practicable ...”

“Travel expenses for a meeting to discuss state business” are those expenses that:

- 1) have a close connection to the ... employee’s state employment;
- 2) predominately benefit the public and not the employee;
- 3) are for travel in a style and manner in character with the conduct of state business; and
- 4) are approved by the agency’s ethics officer in advance of the travel, if practicable ... “

Attachment C (continued)

Gift Ban Reviews and Approvals – Considerations for the Department Chair/Unit Administrator

The department chair/unit administrator reviewing an offered gift from industry to the faculty, staff member, or learner should consider the following questions at a minimum when making the approval decision:

(Note: The employee and the department must complete the Ethics Travel form [*Request for Approval of Educational Materials and Missions and/or Business Travel Exceptions to the Gift Ban and Executive Order 15-9*] for any industry-sponsored travel before the travel occurs.)

1. Does the gift meet one or more of the exceptions under the State of Illinois Ethic Act's gift ban? If the gift does not meet one or more of the exceptions, the department chair/unit administrator should not approve the request. The exceptions are*:

Exception #1 opportunities, benefits, and services that are available on the same conditions as for the general public;

Exception #2 anything for which the ... state employee pays the market value ...;

Exception #4 educational materials and missions ... those that:

- have a close connection to the ... employee's state employment or the mission of the agency or office;
- predominately benefit the public and not the employee; and
- are approved by the agency's ethics officer in advance of the mission or receipt of the materials, if practicable ...”

Exception #5 travel expenses for a meeting to discuss state business ... those expenses that:

- have a close connection to the ... employee's state employment;
- predominately benefit the public and not the employee;
- are for travel in a style and manner in character with the conduct of state business; and
- are approved by the agency's ethics officer in advance of the travel, if practicable ... “

Exception #6 a gift from a relative ...;

Exception #7 anything provided by an individual on the basis of a personal friendship ...;

Exception #9 food, refreshments, lodging, transportation, and other benefits resulting from the outside business or employment activities ... of the employee, or the spouse ... of the employee ..., if the benefits have not been offered or enhanced because of the official position of the ... employee, and are customarily provided to others in similar circumstances ...;

Exception #10 intra-governmental and inter-governmental gifts. ... 'Intra-governmental gift' means any gift ... from ... the same state agency; and 'inter-governmental gift' means any gift given by ... another state agency ... or a federal agency, or of any governmental entity.'

(*some are omitted as they do not apply)

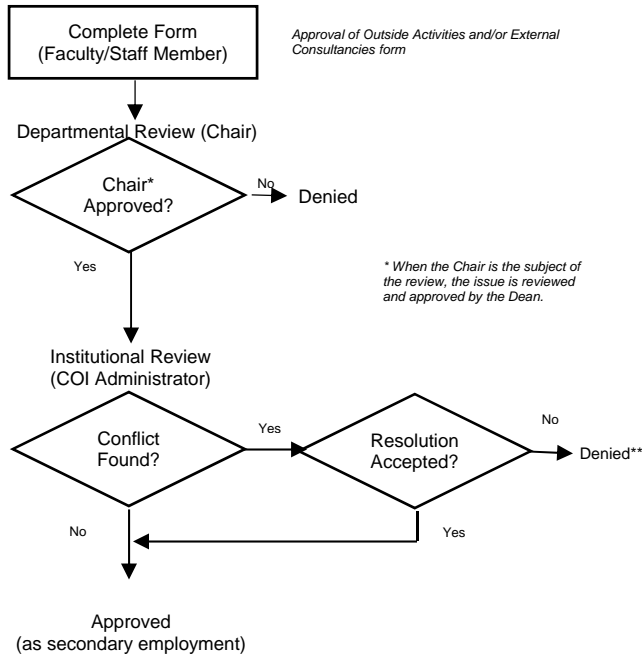
2. Does the gift represent a conflict of interest for the faculty/staff member, department/unit, or medical school? According to the SIUSOM Conflict of Interest/Commitment policy, a conflict of interest occurs when the faculty or staff member is in a position to advance their own economic or reputational interests, or that of the employee's family members, to SIUSOM's detriment. If a real or potential conflict of interest exists, the department chair/unit administrator should not approve the request.
3. Is accepting the gift in the best interests of the SIU School of Medicine and the department/unit? If not, the department chair/unit administrator should not approve the request.
4. Consider any other relevant issues pertinent to the department/unit.

Contact Candice Long, SIUSOM Ethics Officer/Conflict of Interest Administrator, with questions: 217/545-8532. clong@siumed.edu.

Attachment D

Honoraria and Associated Expenses

Prior to Accepting Engagement



*** May be appealed.*

Contact Candice Long, SIUSOM Ethics Officer/Conflict of Interest Administrator, with questions: 217/545-8532, clong@siumed.edu.

Because honoraria meet the definition of gifts under the Illinois State Officials and Employees Ethics Act (5 ILCS 430/) and Industry is a prohibited source under the Act, the speaking or other engagement must be done on the employee's own time. This engagement is considered secondary employment for the individual.

Reviews and approvals by the Departmental Chair/Unit Administrator and the Conflict of Interest Administrator, on behalf of the Conflict of Interest Committee, are required.

Attachment D (continued)

Honoraria and Associated Expenses – Considerations for the Department Chair/Unit Administrator

The department chair/unit administrator reviewing the Approval of Outside Activities and/or External Consultancies Form related to an honorarium/associated expenses engagement from industry and as submitted by the faculty or staff member should consider the following questions at a minimum when making the approval decision:

1. Will the honorarium and associated expenses reimbursement from industry be paid directly to the faculty or staff member? As noted above in E.2 Personal External Professional Relationships – Compensation and Expenses, the faculty/staff member is acting in these engagements in his/her private capacity and not as an agent of SIU School of Medicine or SIU HealthCare. All payments under these agreements must go directly from the external entity to the faculty or staff member. If that is not proposed in this engagement, the department chair/unit administrator should not approve the request.
2. Does the engagement represent a conflict of commitment for the faculty/staff member, department/unit, or medical school? According to the SIUSOM Conflict of Interest/Commitment policy, a conflict of commitment exists when the external activities of the faculty or staff member are so demanding of time or attention that they interfere with the individual's primary responsibilities to SIUSOM. If a real or potential conflict of commitment exists, the department chair/unit administrator should not approve the request.
3. Are the honorarium and associated expenses set at reasonable and fair market value? (See Definitions section in this policy for details.) If not, the department chair/unit administrator should not approve the request.
4. Consider any other relevant issues pertinent to the department/unit.

Contact Candice Long, SIUSOM Ethics Officer/Conflict of Interest Administrator, with questions: 217/545-8532. clong@siumed.edu.

Attachment E

Sponsored Travel Examples – Approval

Below is a chart that summarizes the State of Illinois’ requirements for prior approval of industry-sponsored travel under the Illinois State Officials and Employees Ethics Act. The Ethics Act governs a state employee’s (including university faculty and staff) interactions with industry. The table below gives examples of SIUSOM Ethics Officer prior approval requirements for industry entities.

SIUSOM employees may not claim Gift Ban Exceptions #4 (Educational Materials and Missions) or #5 (Travel Expenses to Discuss State Business) per Executive Order 15-9 unless the trip is approved in advance by the SIUSOM Ethics Officer, as delegated by the Executive Director of the Illinois Executive Ethics Commission.

Industry-Sponsored Travel	
(Educational Materials or Missions and Travel To conduct State Business - excluding Secondary employment)	
Nature of Arrangement	Prior Approval Required SIUSOM Ethics Officer
Travel paid for by industry (directly to the individual, not via SIUSOM)	Yes
Travel to a clinical trial Investigator/Study coordinator meeting related to research conducted at SIU paid for by Industry sponsor of the clinical trial or study	Yes <small>(unless paid to the SIU as part of your University duties or contracted with SIU)</small>
Travel to a research meeting in Chicago paid for with SIUSOM department funds	No
Travel for work related to pharmaceutical company-sponsored contract through SIUSOM (for example, related monitoring or presenting data for a coordinated project)	No
Travel to a private university to give a non-ACCME-accredited educational seminar where the private university reimburses you, but the private university received funding for the seminar from a pharmaceutical company	Yes <small>(private universities require analysis under the Ethics Act)</small>
Travel to a public university to give a non-ACCME-accredited educational seminar where the public university reimburses you, but the public university received funding for the seminar from a pharmaceutical company	No
Travel to an academic meeting to present where the expenses are paid using a SIUSOM account	No
Travel paid for being an expert witness	Yes <small>(unless paid to SIU as part of your University duties or contracted with SIU)</small>
Travel that combines a trip to an advisory board paid for by the company and a family vacation for which I am paying for myself.	Yes for the business portion <small>(It is common to combine a business trip with a personal vacation. It is fine to do so as long as the vacation part of the trip is paid for by personal funds and not by the company that is paying for the</small>

Industry-Sponsored Travel

**(Educational Materials or Missions and Travel
To conduct State Business - excluding Secondary employment)**

Nature of Arrangement	Prior Approval Required
	SIUSOM Ethics Officer
	business trip. (When disclosing the duration you will only need to disclose the duration of the business portion.)

Attachment F (continued)

From the SIU School of Medicine Policy on Conflict of Interest and Conflict of Commitment

“Conflict of Commitment: A conflict of commitment occurs when the external activities of an employee, whether compensated or not, are so demanding of time and attention that they interfere with the individual’s primary responsibilities to SIUSOM.

Conflict of Interest: A conflict of interest occurs when the employee is in a position to advance one’s own economic or reputation interests, or that of one’s family members, to SIUSOM’s detriment.

Management of conflicts will always be the goal, but if remedies mutually satisfactory to the employee and the SIU SOM are not reached, the SIUSOM may prohibit the external activity, subject to appeal.

Requirements for Disclosure: All employees must annually complete and submit an Annual Disclosure Form. Whenever financial interests or external activities change, employees are also required to complete and submit a revised Annual Disclosure Form within a reasonable period after their situation changes.”

Attachment F (continued)

Consulting Activities and External Professional Relationships – Considerations for the Department Chair/Unit Administrator

The department chair/unit administrator reviewing the Approval of Outside Activities and/or External Consultancies Form related to consulting activities/external professional relationships with industry and as submitted by the faculty or staff member should consider the following questions at a minimum when making the approval decision:

1. Does the engagement represent a conflict of interest for the faculty/staff member, department/unit, or medical school? According to the SIUSOM Conflict of Interest/Commitment policy, a conflict of interest occurs when the faculty or staff member is in a position to advance their own economic or reputational interests, or that of the employee's family members, to SIUSOM's detriment. If a real or potential conflict of interest exists, the department chair/unit administrator should not approve the request.
2. Does the engagement represent a conflict of commitment for the faculty/staff member, department/unit, or medical school? According to the SIUSOM Conflict of Interest/Commitment policy, a conflict of commitment exists when the external activities of the faculty or staff member are so demanding of time or attention that they interfere with the individual's primary responsibilities to SIUSOM. If a real or potential conflict of commitment exists, the department chair/unit administrator should not approve the request.
3. Are any compensation and associated expenses set at reasonable and fair market value? (See Definitions section in this policy for details.) If not, the department chair/unit administrator should not approve the request.
4. Will the consulting activities/external professional relationships be in the best interests of the SIU School of Medicine and the department/unit? If not, the department chair/unit administrator should not approve the request.
5. Consider any other relevant issues pertinent to the department/unit.

Contact Candice Long, SIUSOM Ethics Officer/Conflict of Interest Administrator, with questions: 217/545-8532. clong@siumed.edu.

Approved 12/12/2016