

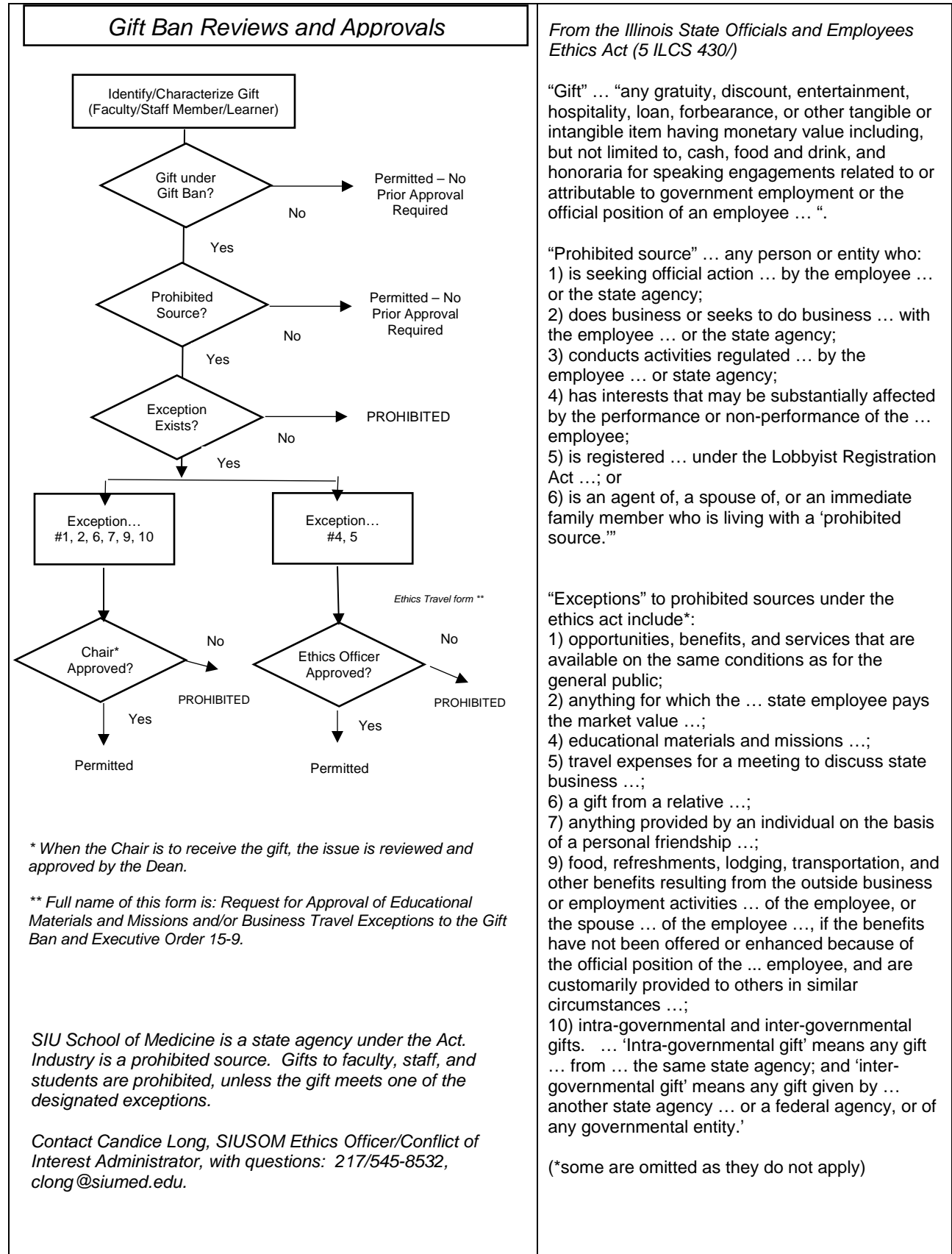
Attachment B

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)

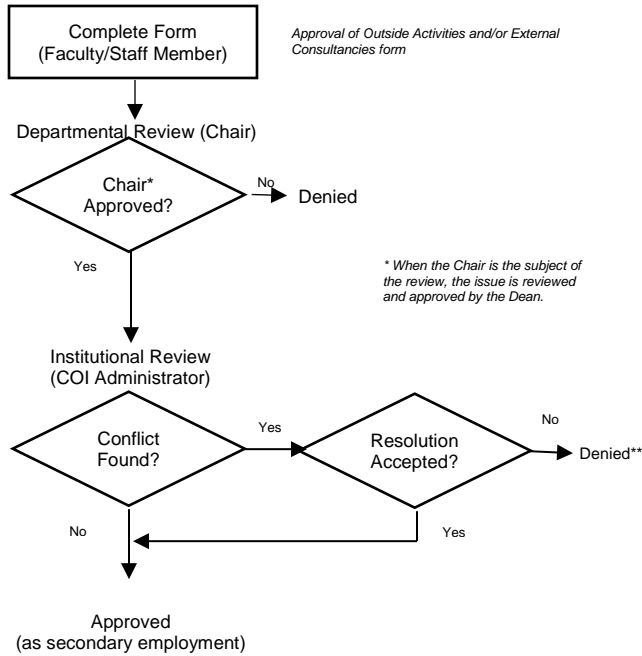
2. Does the gift represent a conflict of interest for the faculty/staff member, department/unit, or medical school? According to the SIUSOM Conflict of Interest/Commitment policy, a conflict of interest occurs when the faculty or staff member is in a position to advance their own economic or reputational 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@siumedu.

Attachment D

Honoraria and Associated Expenses

Prior to Accepting Engagement



*** May be appealed.*

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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.

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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.

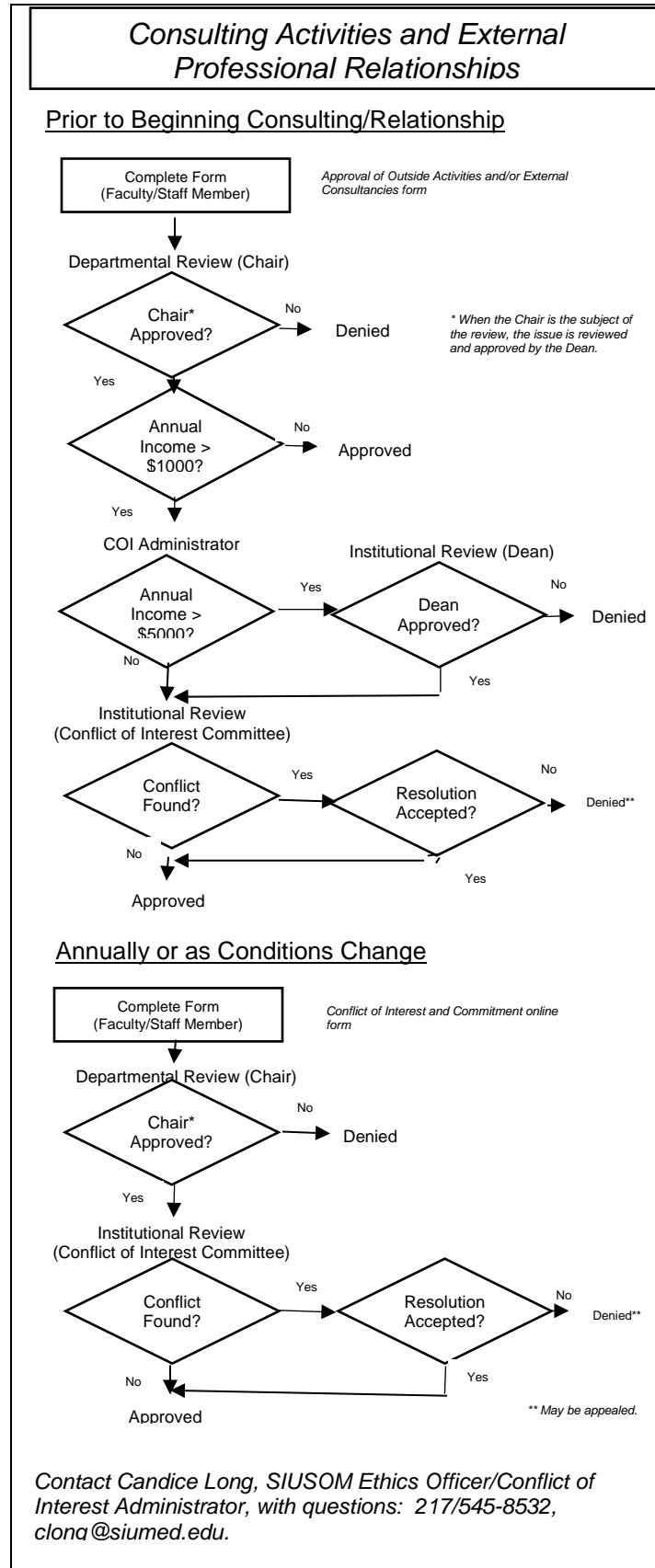
Industry-Sponsored Travel	
(Educational Materials or Missions and Travel To conduct State Business - excluding Secondary employment)	
Nature of Arrangement	Prior Approval Required SIUSOM Ethics Officer
Travel paid for by industry (directly to the individual, not via SIUSOM)	Yes
Travel to a clinical trial 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

Attachment F



From the Illinois University Faculty Research and Consulting Act (110 ILCS 100/)

Sec. 1 ... "No full time member of the faculty of any State-supported institution of higher learning may undertake, contract for or accept anything of value in return for research or consulting services for any person other than that institution on whose faculty he serves unless:

- a) he has the prior written approval of the President of that institution, or a designee of such President, to perform the outside research or consulting services ...; and
- b) he submits to the President of the institution or such designee, annually, a statement of the amount of actual time he has spent on such outside research and consulting services."

Department chairs (unit administrators) serve as the SIU President's designee for these reviews.

From SIU Conflict of Interest: Non-University Activities and Financial Interests

"The following procedures implement an Illinois law requiring university faculty and, by extension, all employees to obtain written approval before engaging in remunerated research or consulting services for outside persons or organizations.

A full-time employee planning to engage in any non-university employment, business, professional activity, or any job-related activity that will produce non-university income may be required to complete and submit (a request) through appropriate administrative channels ...

The chair or director of the unit to which the individual employee is assigned, and the dean, as appropriate, shall review and evaluate all proposed non-university activities before recommending approval or disapproval.

All disclosure reports requesting approval for any non-university activity generating total gross annual income exceeding \$5,000 shall be forwarded to the ... (dean and) provost (School of Medicine) for final approval or disapproval."

Annual income is cumulative for the 12 months, beginning with the date of the request for pre-approval.

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.

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Approved 12/12/2016