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**Upstate Medical University**

**CAMPUS  
ADMINISTRATIVE  
MANUAL**

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**Policy on Relations with the  
Pharmaceutical, Medical Device  
and Biotechnology Industries**

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## **Preamble**

The mission of SUNY Upstate Medical University is to improve the health of the communities we serve through education, biomedical research, and health care. Clinicians have a primary responsibility to work for patients' welfare. Researchers are dedicated to furthering scientific biomedical understanding in ways that can be translated into products and techniques that benefit society. To achieve these ends, SUNY Upstate's faculty, staff, and students interact and, at times, partner with the pharmaceutical and medical device industries.

This policy establishes expectations for behavior in relations with the pharmaceutical, medical device, and biotechnology industries (hereafter referred to as Industry) in accordance with the expressed values of SUNY Upstate Medical University. It is intended to guide interactions with Industry so that institutional and professional integrity is maintained while we care for patients, teach clinicians, scientists, and students, and carry out biomedical research. We also interact with other industries that are not named specifically in this policy. With regard to those interactions, we should maintain a standard of reasonable conduct that is consistent with the intent of this policy.

**Covered Individuals:** This policy applies throughout SUNY Upstate to all employees (including faculty, staff, residents, fellows, others in training), students, employees of the Research Foundation of the State University of New York, employees of MedBest, and members of the SUNY Upstate Council, who shall be known as covered individuals, unless otherwise noted.

This policy augments existing laws, including the New York State Public Officers Law; state, SUNY, and campus policies; and negotiated agreements. Nothing in this policy shall take precedence over existing laws, policies, and negotiated agreements with any union of employees. Individual departments and units shall review their policies and revise them if necessary to ensure that they are consistent with this policy.

## **Section 1. Relations with Industry<sup>1</sup> in Patient Care and Education**

### **A. Introduction and Purpose**

Academic health centers and their clinicians have fundamental responsibilities to save lives, ameliorate disease, and relieve suffering. The pharmaceutical, medical device, and biotechnology industries have developed and brought to market drugs, devices, and other products that help achieve these ends. Clinicians have the ethical duty to recommend and prescribe specific drugs

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<sup>1</sup> Unless otherwise noted in this report, "Industry" is meant to refer collectively to the pharmaceutical, medical device and equipment, and biotechnology industries.

and devices based on the patient's best interests, and not out of personal gain. The following guidelines are intended to:

1. help ensure that clinicians select products based primarily on the patient's welfare, and
2. minimize the influence of Industry on clinical decision-making through gifts, personal or institutional financial interests in Industry, or uncritiqued marketing presentations or materials.

## **B. Scope of Policy**

This section focuses on the clinical realm and education of health care professionals and applies to all covered individuals, as defined in the Preamble, at all times, both on and off-duty, and to all interactions at SUNY Upstate, including its hospital, clinics, MSG practices, and any other locations that may be added to Upstate's space inventory. An exemption for part-time, paid faculty may be granted by the department chair with the concurrence of the dean, provided that the part-time faculty's clinical, teaching, and research commitments and obligations to Upstate are not compromised and remain fulfilled. A department chair may choose to extend this policy to the department's voluntary faculty and must inform the voluntary faculty in writing if he or she does so.

In addition to complying with this policy, covered individuals must comply, where applicable, with the legal requirements as expressed in the New York Public Officers Law, other relevant State and Federal laws and regulations, and the Research Foundation of the State University of New York policies and procedures.

## **C. Specific Topics Requiring Scrutiny**

### **1. Detailing by Industry representatives<sup>2</sup>**

**a.** Access to premises of Upstate by Industry representatives may occur only by appointment or invitation of the physician. Pharmaceutical representatives are allowed only in non-patient care areas and nonpublic areas, except when it is necessary for them to traverse a public area (e.g., lobby or hallway) to reach an approved destination. Device manufacturer representatives are permitted in patient care areas only when they are appropriately credentialed by the relevant Upstate department. They may be present during patient care only to provide in-service training or assistance on devices and equipment, and then only with prior disclosure to and consent by the patient. Departments that allow the presence of medical device representatives must develop written guidelines for clarifying the credentialing of such representatives.

**b.** Contact with residents, fellows, students, and others in training by Industry representatives should occur only for educational purposes under the supervision of a faculty member, with faculty-supervised critical analysis of the information provided. The department or unit of the primary person who invited the representative must have written methods and resources that are used for critical analysis.

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<sup>2</sup> Adapted from the AAMC's report, *Industry Funding of Medical Education* (2008).

## **2. Institutional decisions regarding purchasing and the role of covered individuals with financial interests**

**a.** Individuals with any financial interest in Industry, excluding mutual funds and similar investments, or whose immediate family member (spouse, domestic partner, child) has such an interest, must disclose such interest to their supervisor, if applicable, and to the COI Officer of Upstate (see Section 5. B. Conflict of Interest Officer) and withdraw from involvement in purchasing decisions relevant to the conflicting interests.

**b.** If an individual's expertise is necessary in evaluating a product, and that person also has financial ties to any manufacturer of that or any related product, the ties must be disclosed in writing to those charged with the responsibility for making the decision, and only written testimony will be accepted for consideration in deciding whether to adopt the drug, device, or product. (See Section 2. C. 6. for discussion of sponsored research agreements with Industry, including clinical trials.)

**c.** Those who request that a drug, device, or product be adopted by the institution must disclose any financial interests they have in the product to those making the purchasing decision at the time of the request.

## **3. Gifts and meals from Industry<sup>3</sup>**

**a.** All individuals are prohibited from accepting gifts of any kind from representatives of Industry.<sup>4</sup> Gifts are defined as anything of monetary value, regardless of amount, and include, but are not limited to pens, pads, stethoscopes, textbooks, money, services, favors, discounts, food, conference fees, lodging, travel to conferences, entertainment, or other hospitality provided at any time or location (including individual or group meals and meals at local restaurants sponsored by Industry).

**b.** Educational materials for patients, students, and others that are developed by Industry may be accepted if they are the best source of such materials available and are for the purpose of education. They may not be accepted if it is evident that they are primarily for the purpose of selling a product. Also, written materials are permitted for products for which manufacturers' information and instructions are required.

**c.** Travel funded by Industry to be trained on equipment already purchased by or approved for use at Upstate, is not considered a gift and is permitted. Provision for such travel should be included in the contract or memorialized in some other manner. Travel funded by Industry to evaluate equipment not yet purchased by Upstate is allowed if the equipment to be purchased is included in the open bid process. For sole-source vendors, the purchasing entity (e.g., University Hospital, medical service group) should pay for the travel.

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<sup>3</sup> Adapted from University of Massachusetts policy

<sup>4</sup> State employees also are bound by the New York Public Officer's Law. Please refer to that law for restrictions regarding receipt of gifts from sources other than the pharmaceutical and medical device industries.

#### **4. Free drug samples<sup>5</sup>**

**a.** Drug samples may be dispensed only to patients being cared for at the practice site. They may not be used by employees, students, volunteers, family members, or anyone else who is not a patient at the practice site.

Samples may be dispensed only to patients meeting one of the following conditions:

- medically indigent
- no prescription coverage and extraordinarily expensive agents are required
- access to pharmacy services is temporarily unavailable (e.g., the pharmacy is closed)
- a short trial (1 week or less) of the medication is necessary to determine whether it has the desired effect or the medication needs to be changed before taking the prescription to the pharmacy, thus avoiding unnecessary costs.

**b.** Drug samples must be managed centrally within the practice site. Samples must be dispensed consistent with standards of pharmaceutical practice, which include, but are not limited to, correct labeling (including patient name, date, medication name and dosage, instructions for use, prescribing clinician), a log tracking the medication and documenting that the patient has received appropriate medical counseling, and secure storage. The Pharmacy Department will conduct routine on-site inspections and annual review of written procedures.

#### **5. Industry-sponsored speakers' bureaus<sup>6</sup>**

**a.** Industry-sponsored speakers' bureaus are defined as follows. Industry hires faculty speakers to deliver promotional talks, using Industry-prepared and approved presentations. These talks are confined to FDA-approved product safety and efficacy discussions and approved disease-state education. By the nature of their content and origin of their authorship, such talks do not qualify for CME certification.

**b.** Participation in Industry-sponsored speakers' bureaus by covered individuals is prohibited. (Covered individuals may provide certified CME talks.) Covered individuals or Upstate departments may not sponsor or promote Industry-sponsored speakers' bureau talks, and Industry-sponsored speakers' bureau talks are prohibited on University premises.

#### **6. Continuing education<sup>7</sup>**

**a.** The following applies to all continuing education (CE), whether it is continuing medical education (CME) or CE in other disciplines. SUNY Upstate units (e.g., departments,

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<sup>5</sup> Adapted from the Associated Medical Schools of New York State's *Common Policy for Interacting with Pharmaceutical Company Representatives* (2008) [hereafter referred to as "AMSNYS Common Policy"], AAMC's *Industry Funding of Medical Education*, and University Hospital policy CM D-06 and University Hospital policy M-12.

<sup>6</sup> Adapted from AMSNYS Common Policy

<sup>7</sup> Adapted from *Accreditation Council for Continuing Medical Education Standards for Commercial Support of Educational Programs* (2007) and University of Pittsburgh policy/

colleges, University Hospital) may accept funds from Industry for CE, but Industry may not specify the content or the speakers. Industry may request the overall topic, such as a condition or disease state (e.g., epilepsy, hypertension, lung cancer). All agreements for Industry support must be negotiated through and executed by the Office of CME (CME Office).

**b.** In order to ensure that potential for bias is minimized and that CE programs are not a guise for marketing, all CE events hosted or sponsored by SUNY Upstate must comply with Accreditation Council for Continuing Medical Education standards (or other similarly rigorous, applicable standards required by other health professions), whether or not CE credit is awarded for the event. CE programs must be open on equal terms to all interested practitioners and may not be limited to attendees selected by Industry.

**c.** Industry funding for such programming should be used to improve the quality of the education, not to support meals or social activities. Industry funding may be used to support the costs of internal department meetings, if the subject and content of these meetings is determined solely by the department, in consultation with the CME Office. The CME Office will audit CE programs to ensure that departments comply with these policies.

**d.** Training programs designed solely for sales or marketing, presented by personnel supported by Industry, are prohibited.

**e.** Upstate facilities may not be rented by or used for Industry-funded or directed programs, unless there is a CE agreement for Industry support that complies with these policies.

**f.** Industry support for CE in the form of donated funds shall be recognized in a manner that does not promote a particular product.

## **Section 2. Relations with Industry in Research and the Training of Scientists<sup>8</sup>**

### **A. Introduction and Purpose**

As part of SUNY Upstate Medical University's research, teaching, and public service missions, Upstate faculty, staff, and students are encouraged to engage in appropriate outside relationships with private industry and the non-profit sector. Without these relationships our academic research could not be translated into products that benefit society. A principled partnership between the academic community and Industry is essential if we are to realize the promise of biomedical research. Such collaborations also can create serious conflicts of interest.

This section describes Upstate's approach to identify, review, manage, or eliminate potential conflicts of interest. By Upstate research and educational employees being aware of and following these policies we can protect the institution and its employees and students involved in research from real or perceived challenges to the integrity of our missions. We also avoid jeopardizing public trust in support of these missions. Finally, we protect human subjects who

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<sup>8</sup> portions of these recommendations are adapted from policies from University of North Carolina (Chapel Hill) and the AAMC's report, *Protecting Patients, Preserving Integrity, Advancing Health* (2008)

participate in research projects, and the public, by diminishing bias in the experimental design, conduct of the research, or interpretation of data.

## **B. Scope of Policy**

This section applies to all covered individuals, as defined in the Preamble, as well as voluntary faculty, who are involved in the design, conduct, or reporting of research and their immediate family members.<sup>9</sup> Immediate family members include spouse, domestic partner, and children.

All covered individuals must report to the Research Conflict of Interest Committee (see Section 5. C. 2. b. The Research Conflict of Interest (COI) Committee) any potential conflict of interest caused by them or a member of their immediate family having a personal financial interest or an external position that could affect their involvement in research. The Research COI Committee can then determine whether a conflict of interest exists that requires oversight and management.

## **C. Specific Topics Requiring Scrutiny**

### **1. Gifts from research sponsors**

**a.** Gifts to members of the research team from research sponsors are prohibited because such gifts are intended or may appear to influence the individual in the performance of his or her research activities. Even gifts of nominal value, such as logo pens, pads, mugs, and other items, should be declined. Gifts offered to study subjects, may be allowed, if approved in advance by the Institutional Review Board (IRB).

**b.** Reimbursement for travel and associated expenses, such as lodging and meals, related to conducting research is appropriate (for example, travel to an investigator's meeting, when the investigator is conducting the clinical trial at Upstate).

### **2. Use of University resources including privileged information**

**a.** Covered individuals must not use confidential or privileged information acquired by the University for personal gain. As an example, covered individuals should avoid consulting arrangements with Industry through which they may risk sharing confidential proprietary information acquired through sponsored University projects.

**b.** University resources, including but not limited to laboratory facilities, work products, results, or information developed with University funding or other Upstate support should not be used for personal gain. This includes using the SUNY Upstate Medical University name in a manner that implies that the University is associated with, sponsors, or endorses this external activity. It is appropriate to use the University name on abstracts for meetings or publications where no monetary personal gain is involved. One can utilize the University name on a research or teaching textbook or chapter, where personal gain is involved, as long as it is clear that Upstate is not sponsoring or endorsing the contents of the textbook or book chapter.

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<sup>9</sup> Definition recommended by the Association of American Medical Colleges

### **3. Purchasing, contracting, and other business transactions on behalf of the University**

A covered individual may not participate in awarding, negotiating, reviewing, or approving a financial transaction (including but not limited to purchases, contracts, and subcontracts) involving the university and an entity in which the individual has a personal financial interest without prior review and approval as described below. Where an individual is involved in the design, conduct, or reporting of University research related to that individual's personal financial interest, that potential conflict of interest is governed by the sections below titled "Intellectual Property" and "Research and Sponsored Projects."

A covered individual may assist in the negotiation of license agreements for University intellectual property. However, only an individual duly authorized by the Research Foundation of SUNY may execute a license agreement.

Covered individuals routinely involved in the negotiation, approval or administration of University contracts with external entities must file a Conflicts of Interest *Declaration Form* annually with the Research Conflict of Interest Committee.

If an individual has not filed a Conflict of Interest *Declaration Form* and is prospectively involved in awarding, negotiating, reviewing, or approving a financial transaction involving the University and a private interest of that individual, the conflict of interest must be reported to the individual's supervisor to the Research Conflict of Interest Committee and the supervisor shall reassign that transaction to another employee under such supervision management as is deemed appropriate by the Research Conflict of Interest Committee.

Covered individuals must involve the appropriate institutional contract professionals in finalizing all contracts. For instance, for clinical trials, the Sponsored Programs Office and the Research Foundation of SUNY will finalize and execute all contracts, respectively.

### **4. Intellectual property**

The SUNY Upstate Medical University "Strategic Plan for Strengthening Research (2008)" calls for Upstate fostering the invention and development of new patentable technologies by entrepreneurial faculty, staff, and students. The SUNY Research Foundation (RF) then attempts to license those inventions, approved by the Institutional Patent Committee and Vice President for Research, to appropriate Industry partners. In this way, work performed by Upstate faculty, staff, and students may reach the market for the public good. Upstate and SUNY RF must be protected from either real or perceived "pipelining" of University inventions to companies in which the Upstate inventor(s) have personal financial interests. For this reason, all Upstate inventors must report their financial interests, and those of their immediate family (including a spouse, domestic partner, or child), at the start of the licensing process by completing a Project Specific Conflict of interest *Declaration and/or Disclosure Form* and submitting it to the Research COI Committee. These forms must be evaluated and approved by the Research COI Committee before licensing can be executed. In addition, any external consulting relationship between the Upstate inventor and the Industry holder of the license must be requested and approved, in advance, by the Research COI Committee. Any covered individual inventor (or an

immediate family member) who holds equity in, is an officer or director of, or provides consultative services without prior Research COI Committee approval to an entity that has licensed or acquired rights to a SUNY Upstate Medical University invention will be deemed to have a conflict of interest under this policy.

## **5. Individuals on University review panels**

Important conflict of interest responsibilities also exist for individuals participating on panels providing scientific and/or administrative review and evaluation on behalf of the University – such as the Institutional Review Board (IRB) for the Protection of Human Subjects, the Institutional Animal Care and Use Committee (IACUC), the Research Conflict of Interest Committee, purchase evaluation committees, etc.

All panel members will submit a *COI Declaration Form* and a *COI Disclosure Form* (if necessary) at the time of their initial appointment with updating annually and more often when circumstances change. If any member of a University review panel has a financial interest, or has a member of the immediate family (including a spouse, domestic partner, or child) with a financial interest, in a matter subject to the panel's review, that individual must report the conflict of interest to the panel's chair. If the panel chair deems the conflict to be material to the matter under review, the panel member shall recuse him/herself from the deliberations and voting on the matter. The recusal shall be documented in the panels' minutes.

## **6. Research and sponsored projects**

As part of the commitment of SUNY Upstate Medical University to promoting objectivity in research and in compliance with federal regulations on conflict of interest, this policy includes rules regarding sponsored research projects.

All individuals involved in the conduct or reporting of an Industry-sponsored study or project must report any possible personal conflict of interest related to the sponsored research project to their supervisor and the Research COI Committee. This applies particularly in instances where participation in the project allows for the temptation or possibility, or even the perceived possibility, of influencing the results of the study. Those individuals with direct access to the research data, i.e., control over its collection or analysis, have substantial involvement in the project and have the opportunity to influence the results.

Any personal monies that covered individuals receive from pharmaceutical and/or medical device companies must be reported to their supervisor and the Research COI Committee, regardless of the amount or type of compensation.

Recruitment incentives are offered by some study sponsors to investigators or other persons on the research team for enrolling or accelerating the enrollment of subjects. These referral fees are paid to doctors or other practitioners for referring their patients to another investigator's study. The practice of accepting or offering financial incentives (bonuses) for subject enrollment and referrals, sometimes referred to as "finder's fees," may compromise the integrity of the study and

may generate an unethical conflict of interest. Therefore, Upstate does not allow covered individuals to accept or to offer recruitment incentives, including finder's fees.

Also, any payments to the University or other professional or research accounts received from such companies that are not directly related to the conduct of a sponsored project and any consultancy or board membership for an external agency involved in the research or sponsored project in any way must be reported by the covered individual to the Research COI Committee. The report should include the sponsor's name, any subcontractor or sub-recipient, or owner or licensee of any product, process or technology studied in the project.

University investigators must disclose in any publication or presentation of their research the existence and nature of all possibly related personal financial interests and related external executive positions.

## **7. Ghostwriting**

Articles written by Industry-paid writers who are not credited as an author ("ghostwriters") hide conflicts of interest in that the real writers' ties to Industry go unreported. Typically, such ghost authors are professional medical writers who are employees or consultants for a pharmaceutical or medical device company. The practice raises further concerns when physicians sign their names to articles containing data which the physicians have not carefully reviewed and may not have access to the original data. The International Committee of Medical Journal Editors (ICMJE) has adopted a set of authorship principles that are considered to be the "gold standard." The University will ensure that employees and students are aware of these principles, and that they understand that they are responsible for upholding these standards.

Therefore, all covered individuals involved in the reporting of an Industry-sponsored study or project should follow the guidelines of the ICMJE, which state that authorship means "substantive intellectual contributions," including conception or analysis of the subject and drafting or critical revision of the document. It is dishonest to claim authorship on a paper to which one has not substantially contributed.

Similarly, every person who has made actual contributions to an article that satisfies the qualifications for authorship outlined by the ICMJE needs to be included in the list of authors, with a full disclosure of their conflicts of interest.

A covered individual should not be listed as co-author of any manuscript that has been drafted by one or more Industry-sponsored "ghost authors." In addition, covered individuals should always be responsible for the content of any papers or talks that they give, including the content of slides.

## **Section 3. Personal Financial Interests of University Leadership in Industry**

### **A. Introduction and Purpose**

University officials with leadership or supervisory positions have unique authority over the allocation of University resources, procurement, or adoption of specific technologies or materials, and the shaping of how the institution carries out its educational, research, and clinical missions. For this reason, financial interests of leadership pose not only potential individual conflicts of interests, but concerns of institutional conflicts of interest. As is often the case with alleged conflicts of interest, a co-existing financial interest does not inevitably affect decision-making. However, the very appearance of a potential conflict for a leader, between doing what is in the institution's best interest and what is in one's own personal financial interest, can undermine trust and the ethical climate within an institution.

### **B. Scope of Policy**

This policy applies to:

1. President, SUNY Upstate
2. Vice Presidents of the University
3. Chief Executive Officer, University Hospital
4. Deans of the Colleges of Graduate Studies, Health Professions, Medicine, and Nursing
5. Chair of the Pharmacy and Therapeutics Committee, University Hospital
6. Chair of the Institutional Review Board, the IRB Administrator, and Chief Compliance Officer for Research
7. Chair, Values Analysis Committee, University Hospital and the Values Analysis Coordinator

### **C. Policy**

Those individuals indicated above under "Scope of Policy" are required to divest themselves of all personal investments and other financial relationships with Industry. These include:

1. Equity interests in Industry, but does not include mutual funds or similar investment vehicles over which the owner does not have direct control of purchasing or selling;
2. Acceptance of consulting fees, advisory board fees, honoraria, "in kind" compensation, gifts, or other remunerations from an Industry source;
3. Service as an officer, director, or board member of an Industry entity;
4. Service on the scientific advisory board of a commercial sponsor of research conducted at Upstate.<sup>10</sup>

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<sup>10</sup> This list is adapted from the AAMC report, *Protecting Patients, Preserving Integrity, Advancing Health* (2008)

Vice presidents, the CEO of University Hospital, and the deans of the colleges (categories 2-4 under B above) shall submit to the President a yearly accounting of their relations with Industry.

## **Section 4. Conflict of Commitment<sup>11</sup>**

### **A. Introduction and Purpose**

It is in the interest of Upstate Medical University and its faculty and staff to encourage and embrace collaboration and interaction with external partners in the development of ideas, research, policy, or the application of university work to real world concerns. At the same time, fulfilling their responsibilities to Upstate requires the primary and full commitment of faculty and staff. A conflict of commitment may arise when a covered individual's efforts on outside activities interfere, or may appear to interfere, with the amount or quality of their efforts fulfilling primary obligations to Upstate in the areas of education, research, patient care, service, and/or administration. This policy provides a definition and context for conflict of commitment and provides guidelines for managing external efforts when conflicts arise.

Conflicts of commitment arise when either the amount of time an individual spends on external efforts interferes with his or her ability to meet responsibilities to Upstate or the external efforts adversely affect the quality of their efforts in fulfilling obligations to Upstate. Conflicts of commitment also may arise in use of the Upstate name/brand or use of Upstate facilities or resources in the support of external activities.

The Conflict of Interest policy of the State University of New York<sup>12</sup> states that "University faculty and staff may not engage in other employment which interferes with the performance of their professional obligation" and "In instances where potential or actual conflicts exist, faculty and staff are expected to consult with appropriate university officers.... It is the responsibility of campus officials...to identify potential or actual conflicts...and take appropriate steps to manage, reduce, or eliminate them." Nothing in this policy shall take precedence over existing laws, policies, and negotiated agreements with any union of employees.

### **B. Scope of Policy**

This section applies to all SUNY Upstate employees (including faculty, staff, residents, fellows, others in training), and employees of the Research Foundation, the Medical Service Groups (MSGs), and MedBest.

Examples of potential conflicts of commitment include, but are not limited to:

- External consulting, employment, or contract work, including contracts for clinical service or teaching in other institutions, whether in person or online

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<sup>11</sup> This sections is informed by the AAMC report, *Protecting Patients, Preserving Integrity, Advancing Health*, SUNY Conflict of Interest Policy, SUNY Faculty Disclosure Policy, and institutional policies from Cornell University, Indiana University, Purdue University, Johns Hopkins University, Stanford University, the University of North Carolina at Chapel Hill, University of Oregon, and Vanderbilt University.

<sup>12</sup> SUNY Policy 6001

- Research proposals submitted under the name of another organization, when Upstate could also have sponsored such research
- Membership on boards or directorships
- Significant involvement with professional organizations
- Serving as expert witness in legal cases
- Development of spin-off or start-up businesses, especially when the individual has management or administrative responsibilities (n.b., using the Upstate brand or logo in association with a business is prohibited without University approval.)
- Spending time on external efforts on behalf of another Upstate employee (e.g., preparing briefs, preparing presentations, managing billing for services)

### **C. Policy**

**Guidelines regarding conflict of commitment.** These guidelines address the identification of potential conflict of commitment, provide limits on time spent on external efforts, and outline the process for disclosing, reviewing, and resolving conflicts of commitment. The guidelines apply to any potential conflict of commitment related to the definition or examples above.

**1. Identification of potential conflict of commitment.** Ideally, conflicts of commitment will be prevented by discussion prior to making external commitments, but conflicts may also be identified after they have occurred.

**a. Role of the statement of professional expectations (or the performance program).**

A clear statement of professional expectations or obligations is essential in the assessment of whether or not a faculty or staff member is meeting 100% of their commitments to Upstate. This statement is the responsibility of the department chair or supervisor and should be updated annually.

**b. Clarifying potential conflict before external commitments are made.** Each faculty or staff member is responsible for obtaining approval from his or her department chair or supervisor for any external efforts prior to committing to that effort.

**c. Identifying potential conflict of commitment after commitments are made.**

- **Incidental awareness.** Covered individuals who identify any concerns about potential conflict of commitment for themselves or for others should bring this to the attention of the department chair or supervisor.

- **Periodic surveillance.** Department chairs and supervisors are responsible for obtaining and reviewing annual disclosure information from covered individuals regarding their external efforts (see below for annual disclosure).

**2. Limits on type of external activities allowed.** Only activities that demonstrably enhance the covered individual's professional career and fulfill or enhance, in some way, the University's mission are permissible.

**3. Limits on time spent on external activities.** This guideline refers to total external effort.

**a. For full-time** covered individuals, a limit of 3 work days per month or 36 work days per year on external commitment is acceptable, *provided they continue to fulfill 100% of their commitments and professional obligations to the University* as determined by their department chair or supervisor. These 36 days exclude vacation time, sick leave, pass days, and holidays. Nothing in this policy shall take precedence over existing negotiated agreements with any union of employees. Covered individuals may engage in other employment or other activities when they are not “on duty” at Upstate, provided relevant conflicts are declared.

**b. For part-time** covered individuals, a proportionate limit of time on external efforts should be determined. In some circumstances, especially for part-time work less than 0.5 effort, it may be appropriate to limit further or exclude allowable external effort, based on the responsibilities outlined in their statement of expectations.

**c. Instances of exceeding the time limit guidelines** should be exceptional and may be granted only if approved by the department chair in consultation with the dean of the relevant college or the unit head in University Hospital in consultation with the CEO of University Hospital. Deans, vice presidents, and the CEO of University Hospital should seek approval for exceptions from the person to whom they report. The president should seek approval from the chair of the Upstate Medical University Council.

#### **4. Disclosure, review and resolution**

**a. Annual disclosure.** All covered individuals are required to disclose potential conflicts of commitment on an annual basis to their department chairs or supervisors.

**b. Review and resolution of conflicts.** Department chairs and supervisors will review annual disclosure statements and meet with covered individuals when potential conflicts are identified. Initial meetings will be informal at which time the department chair or supervisor and faculty or staff will try to identify a resolution. Concerns that cannot be addressed in this manner will be referred to the appropriate dean or administrator for resolution. If the conflicts remain unresolved, they will require institutional review.

- **Institutional review.** Unresolved conflicts will be brought to the institutional Conflict of Interest Officer. The COI officer, with input from the Research COI Committee if appropriate, will make recommendations to the Associate Senior Vice President for Operations or the Vice President for Research, as appropriate, who will determine a resolution within 30 calendar days of receipt. Extensions may be granted for extenuating circumstances.

- **Appeal.** If the covered individual does not agree with the resolution recommended above, he/she may submit a written appeal to the President within ten working days from receipt of the recommended resolution. The President will review the case, seeking advice of appropriate experts, and notify the covered individual of his/her decision and reasons for it within 30 calendar days of receipt. Extensions may be granted for extenuating circumstances.

Determining the appropriate balance between fulfilling obligations to the University and external obligations is challenging and requires reflection, communication, and judgment informed by thoughtful and collaborative members of the Upstate community. Department chairs and heads of units within University Hospital may wish to develop more circumscribed guidelines for external activity within their own departments or units, with the approval of their dean or supervisor.

## **Section 5. Policy Implementation**

### **A. Responsibility for Implementation**

The President of SUNY Upstate Medical University is responsible for overseeing the implementation of this policy. The operational responsibility for the implementation of this policy is delegated to the Conflict of Interest (COI) Officer.

### **B. Conflict of Interest Officer**

A Conflict of Interest (COI) Officer will be appointed by the President and will report to the Associate Senior Vice President of Operations or other designee of the President.

The COI Officer will (1) oversee the implementation, evaluation, and revision of this policy; (2) respond to questions about this policy and provide authoritative guidance as to how the policy applies to particular situations; (3) receive and evaluate declarations of conflicts of interest and make recommendations regarding them to covered individuals and, where appropriate, to the President and senior leadership; (4) monitor compliance with this policy; (5) serve ex officio, with vote, on the Research Conflict of Interest Committee (see below, C. 2. b. The Research Conflict of Interest (COI) Committee and its process); and (6) ensure that this policy is accessible to all Upstate personnel and the public through the Upstate Medical University website.

### **C. Declaration, Disclosure, and Referral**

#### **1. Disclosure of financial interests in Industry**

All covered individuals must disclose to the COI Officer any financial arrangements with Industry that exceed \$1,000 from any single company annually.

#### **2. Disclosure of relationships with Industry to students**

Covered individuals in a teaching capacity should inform their students and other learners of their relationships with Industry. This may be done at the beginning of a course or session or other appropriate time. In situations that are transient or inconvenient (e.g., patient rounds), the teacher should use his/her discretion in informing students, being guided by the relevance of the relationship with Industry to the situation at hand.

### **3. Issues related to relations with Industry in research**

#### **a. Disclosure of relationships with Industry for research**

Individuals responsible for the design, conduct, or reporting of the research will submit a Conflict of Interest Declaration Form each time an agreement is submitted to the office of sponsored programs. The Declaration Form requests information about significant financial interests and management interests (e.g., officer, trustee, director, employee or consultant of an entity that would reasonably appear to be directly and significantly affected by the work proposed) in outside related entities held by the covered individual (including immediate family members – spouse, domestic partner, and children). If any of the answers to the questions on the Declaration Form (Part 1) are affirmative, the individual should also complete and submit a Conflict of Interest Disclosure Form (Part 2). In addition, all faculty must submit an annual COI Declaration Form (Part 1) on or before October 1.

The Office for Sponsored Programs will not submit any application for grant or contract funding until all required annual Declaration and/or Disclosure Forms have been submitted. Compliance with this requirement is also a prerequisite to the acceptance by the Research Foundation of any research grant or contract.

If a covered individual discloses a Conflict of Interest in Sponsored Research, the sponsored programs office will forward the proposed project and the Disclosure Form to the Research Conflict of Interest Committee for review and management.

For research involving human subjects, potential conflicts of interest disclosed by a covered individual or other member of the local study team, as listed on the IRB application form, whether or not the research is sponsored, will be referred to the Research Conflict of Interest Committee for review. In addition, any potential conflicts of interest identified by the IRB, will be referred to the Research Conflict of Interest Committee for review. Investigators and/or study team members may be asked to complete a Conflict of Interest Disclosure Form.

If the interests of a covered individual change during the funding period so as to introduce a new, previously undisclosed significant financial interest or management interest in a sponsored research project, the individual is expected to submit a new or revised Disclosure Form.

Submission of the Declaration and Disclosure (when applicable) Forms satisfies the requirements of the Department of Health and Human Services (PHS) and the National Science foundation (NSF). These agencies require that, by the time an application is submitted, each investigator planning to participate in PHS or NSF-funded research has disclosed his/her significant financial interests (and those of his/her immediate family members).

#### **b. The Research Conflict of Interest (COI) Committee and its process**

The Vice President for Research will establish a Research Conflict of Interest Committee. The committee has five to seven members including representation from the IRB, the Counsel's

office, the clinical faculty, the basic science faculty, and non-Upstate individuals. Committee members are named by the Vice President for Research for a two year term. The COI Officer will serve ex officio, with vote, on the Research Conflict of Interest Committee. Because the major sources of conflict of interest are related to pharmaceutical sponsorship of clinical research, the Chair of the Research COI committee will be a faculty person with personal experience in conducting Industry sponsored research.

#### • **The Review Process**

At the outset of every case considered by the Research COI Committee, it will advise the Investigator of the matter under consideration and invite the Investigator to comment on the case. In any such case where human subjects research is involved, it will additionally advise the IRB Chair of the matter under consideration and consult with him/her as needed.

The Research COI Committee will determine if the conflict of interest can be managed, and if so, what conditions or restrictions, if any, should be imposed by the institution to manage, reduce or eliminate such conflicts.

Any or all of the following conditions or restrictions might be imposed to resolve actual or potential conflicts of interest:

- Public disclosure of significant financial interests;
- Monitoring of research by independent reviewers;
- Modification of the research plan;
- Disqualification from participation in the portion of the externally funded research that would be affected by the significant financial interests;
- Divestiture of significant financial interests;
- Severance of relationships that create actual or potential conflicts
- Removal of investigator as Principal Investigator/Project Director.
- Additional remedies specific to the conduct of research involving human subjects, including but not limited to the removal of ability to recruit and/or obtain consent from research subjects.

If the University is unable to resolve a real or potential conflict of interest or the appearance of same, it will decline to perform the activity in question.

The Research COI Committee may meet with the Investigator to draft a management plan at either party's request. This process will be completed within 30 calendar days. Extensions may be granted for extenuating circumstances. Recommendations of the Research COI Committee (e.g., management plans, etc.) will be conveyed in writing by the Research COI Committee to the Vice President for Research and to the IRB, where human subjects research is involved.

Pending approval by the Vice President for Research, the Research COI Committee will convey the recommendations, etc. in writing to the Investigator, with copy to the Department Chair or Dean, and the Director of Sponsored Programs. The Investigator's written concurrence and

certification for compliance with the management plan will be required in order for the award in question to be established.

The committee will re-review projects under conflict of interest management at least annually in order to assess compliance with the management plan.

The review of COI Disclosure Forms requires the exercise of the utmost discretion by all participants. To the maximum extent permitted by federal and state law, and by University policy, all elements of this process are to be treated as strictly confidential. The purpose of confidentiality is to assure that the integrity of the research and the Investigator, as well as the interests of the University are protected at all times.

#### **• Reporting Conflicts of Interest to Outside Agencies**

The Vice President for Research shall report to the appropriate external funding agency/agencies: (1) Any instances in which the institution finds it is unable to manage satisfactorily an actual or potential conflict of interest and (2) Any instances where an Investigator participating in externally or selected internally funded research has not complied with this policy and the specific corrective measures taken by the University.

#### **• The Appeal Process**

If an Investigator fails to concur with the management plan recommended by the Research COI committee and approved by the VP for Research, he/she may transmit a written appeal to the President within ten working days from receipt of the committee's recommendation.

In such a case, the President will review the case (which may include seeking the advice of appropriate impartial experts and holding discussions with the investigator and/or the Research COI Committee, and the VP for Research) and notify the investigator, Research COI Committee and VP for research of his/her decision and the reasons for it. The President will respond to any appeal within 30 calendar days of receipt. Extensions may be granted for extenuating circumstances.

If the President identifies a financial Conflict of Interest, the decision will be made by the Associate Senior Vice President for Operations.

Awards for external and selected internal support of a program, project, activity or service may not be activated by the University unless a management plan is in place.

#### **• Record Retention**

The University will maintain all declaration and disclosure forms and records of all actions taken to resolve actual or potential conflicts of interest until at least three (3) years after the termination or completion of the award to which they relate, or the resolution of any audit or proceeding (e.g., allegation of scientific misconduct) involving those records. These materials will be the maintained in the Office of the Vice President for Research.

The Office of the Vice President for Research will be the repository for all original investigator declaration and disclosure forms, and Research COI Committee correspondence.

**c. Policy breaches**

Failure to comply with the procedures outlined in Section 2; furnishing false, misleading, or incomplete information; refusal to respond to requests for additional information; failure to remedy conflicts or to comply with the prescribed management agreement or monitoring plan can lead to possible sanctions ranging from administrative intervention to termination of the research. The VP for Research will review all alleged violations of this Policy and make recommendations to the President for possible disciplinary action or necessary sanctions.

**D. Review and Evaluation of the Policy on Relations with Industry**

This policy shall be reviewed periodically by the University to determine if it is working as intended and whether any modifications are needed. Initial review is to be done no later than two years after the policy's effective date. This review and evaluation as well as any changes in the Policy will be made available to the University community.

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Approved by the President's Leadership Council, January 26, 2010