SUNY Upstate Medical University

Policy on the
Identification and Management of
Conflicts of Interest and Commitment
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Introduction

Purpose of Policy
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, medical device and other companies and organizations, such as federal, state and local governments, foundations and individuals.

As part of SUNY Upstate Medical University’s research missions, Upstate faculty, staff, and students are encouraged to engage in appropriate outside relationships with private industry and other organizations and individuals who sponsor research. Without these relationships our academic research could not be translated into products that benefit society. A principled partnership between the academic community and these research sponsors is essential if we are to realize the promise of biomedical research. Such collaborations must be free of conflicts of interest to assure that research is objectively designed, conducted, and reported.

This policy establishes expectations for behavior in relations with the pharmaceutical, medical device, biotechnology, and other companies (hereafter referred to as Industry), and other organizations in accordance with the expressed values of SUNY Upstate Medical University. It is intended to guide interactions with Industry and other organizations so that institutional and professional integrity is maintained while we care for patients, teach clinicians, scientists, and students, and carry out biomedical research.

In addition, this policy promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of sponsored research will be free from bias resulting from investigator conflicts of interest, including financial conflicts of interest.

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. With regard to research, this policy applies to project directors/principal investigators and all other persons, regardless of title or position, who are responsible for the design, conduct or reporting of sponsored research, including their consultants and contractors, and related parties, defined as their immediate family members, including spouses, domestic partners, and dependent children.

This policy incorporates and, at times augments existing laws, including the New York State Public Officers Law; state, SUNY, and campus policies; PHS Financial Conflict of Interest regulations (42 CFR Part 50 Subpart F and 45 CFR Part 94); 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.

**Oversight and Implementation**
The President of SUNY Upstate Medical University is responsible for overseeing the implementation of this policy. The President has delegated implementation of this policy to the Conflict of Interest and Commitment Officer and Research Conflict of Interest Committee.

An Upstate Conflict of Interest and Commitment (COIC) 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 COIC 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 Section 3C. The Research Conflict of Interest (COI) Committee); and (6) ensure that this policy is accessible to all Upstate personnel and the public through the Upstate Medical University website.

An Upstate Research Conflict of Interest (COI) Officer will be appointed by the VP for Research.

The RCOI Officer will (1) oversee the implementation, evaluation, and revision of this policy as it relates to sponsored research; (2) receive, review and evaluate disclosures by investigators regarding relations with industry and other conflict of interest as described in Section 2, including financial conflict of interest in sponsored research; (3) report all disclosures in need of management to the Research Conflict of Interest Committee and oversee development of plans to manage and/or eliminate conflicts; (4) monitor compliance with this policy as it relates to sponsored research; (5) chair the Research Conflict of Interest Committee; (see below, D. 3. 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 and is fully compliant with all research sponsor requirements.

The Vice President for Research will establish a Research Conflict of Interest Committee (RCOI).

This committee will include representation from the IRB; the Counsel’s office; the Sponsored Programs Office; the clinical and basic science faculty; Upstate administration representing faculty development, research integrity, technology transfer, and relations with industry; and non-Upstate individuals. Committee members are appointed for two year terms and may be reappointed. 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 industry sponsorship of clinical research, the Chair of the RCOI Committee, the RCOI Officer, will be a faculty person with personal experience in conducting Industry sponsored research. The RCOI
Committee will establish standing monthly meetings to review and manage identified conflicts of interest, but will only meet when it has business to conduct.

RCOI Committee members and all meeting guests will sign Confidentiality Agreements assuring that no information regarding investigator disclosed financial interests, deliberations regarding these conflicts used to develop management plans, or other confidential information is discussed or disclosed outside of RCOI Committee meetings.

Section 1. Relations with Industry\(^1\) 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 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.

\(^1\) Unless otherwise noted in this report, “Industry” is meant to refer collectively to the pharmaceutical, medical device and equipment, and biotechnology industries.
C. Specific Topics Requiring Scrutiny

1. Detailing by Industry representatives

   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 inservice 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.

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

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2 Adapted from the AAMC’s report, Industry Funding of Medical Education (2008).
3 Adapted from University of Massachusetts policy
a. All individuals are prohibited from accepting gifts of any kind from representatives of Industry. 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.

4. Free drug samples

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

4 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.
5 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.
Department will conduct routine on-site inspections and annual review of written procedures.

5. **Industry-sponsored speakers’ bureaus**

   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**

   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, 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.

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6 Adapted from AMSNYS Common Policy
7 Adapted from *Accreditation Council for Continuing Medical Education Standards for Commercial Support of Educational Programs* (2007) and University of Pittsburgh policy
f. Industry support for CE in the form of donated funds shall be recognized in a manner that does not promote a particular product.

D. Implementation

1. Responsibility for Implementation

The operational responsibility for the implementation of this policy is delegated to the Conflict of Interest (COI) Officer.

2. Declaration, Disclosure, and Referral

a. 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.

b. 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.

Section 2. Conflict of Interest in Sponsored Research

A. Introduction and Purpose

As part of SUNY Upstate Medical University’s research missions, Upstate faculty, staff, and students engage in relationships with state and federal government, private industry and other organizations and individuals who sponsor research. These partnerships enable academic research to be translated into products that benefit society. A principled partnership between the academic community and these research sponsors, essential if we are to realize the promise of biomedical research, must be free of conflicts of interest to assure that research is objectively designed, conducted, and reported.

This section describes Upstate’s policy to identify, review, manage, or eliminate potential conflicts of interest, including financial conflict of interest, and is fully compliant with 42 CFR Part 50 Subpart F and 45 CFR Part 94, Promoting Objectivity in Research, as adopted by the Public Health Services on August 24, 2011 and The Research Foundation of SUNY Conflict of Interest Policy, adopted 8/17/12. By Upstate research and educational employees being aware of and following this policy, 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
participate in research projects, and the public, by diminishing bias in the experimental design, conduct of the research, or interpretation of data.

This policy establishes standards that provide a reasonable expectation that the design, conduct and reporting of sponsored research will be free from bias resulting from investigator financial conflicts of interest. Standards are established to identify financial interests held by investigators and related parties; determine if those financial interests could result in financial conflicts of interest that could bias the design, conduct or reporting of the research; and manage or eliminate the conflicts.

B. Scope of Policy

This section applies to all covered individuals, as defined in the Introduction, as well as voluntary faculty, contractors and consultants who are involved in the design, conduct, or reporting of research and their related parties: spouses, domestic partners, and dependent children.

All covered individuals must disclose all significant financial interest related to their institutional responsibilities held by them or their related parties (spouse, domestic partner, or dependent children), which will be reviewed by the Research COI Officer to determine if these significant financial interests could bias their involvement in a specific research project and, if so, to develop plans to eliminate or manage these conflicts, in consultation with the RCOI Committee.

C. Definitions

The following definitions apply to Section 2 of this policy:
1. Disclosure of significant interests means an investigator’s disclosure of significant financial interests to an institution.
2. Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct or reporting of sponsored research.
4. FCOI report means an institution’s report of a financial conflict of interest to a sponsored research entity.
5. Financial interest means anything of monetary value, whether or not the value is readily ascertainable.
6. Institution means any organization that applies for or receives sponsored research funding, such as Upstate Medical University.
7. Institutional responsibilities means an investigator’s professional responsibilities on behalf of the Institution, and as defined by the Institution, which may include research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as IRBs and Data and Safety Monitoring Boards.
8. Investigator means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of
sponsored research, or proposed for such funding, which may include, as an example, collaborators or consultants.

9. *Manage* means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

10. *PD/PI* means a project director or principal investigator of a sponsored research project; the PD/PI is included in the definitions of senior/key personnel and investigator in this policy.


12. *Research* means a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences research. This term encompasses basic and applied research and product development, and includes any such activity for which research funding is available through a grant, cooperative agreement or contract.

13. *Research Conflict of Interest Committee* means the committee appointed by the Upstate Vice President for Research to review decisions by the Research Conflict of Interest Officer that significant financial interest of an investigator may constitute financial conflict of interest and to develop plans for managing or eliminating the financial conflicts of interest at Upstate.

14. *Research Conflict of Interest Officer* means that individual appointed by the Upstate Vice President for Research who has the authority to review significant financial interests disclosed by investigators to determine if a financial conflict of interest may be present.

15. *Senior/key personnel* means the PD/PI and any other persons identified as senior/key personnel by the institution in the grant application, progress report, or any other report submitted to the research sponsor.

16. *Significant financial interest (SFI)* means

   a. a financial interest consisting of one or more of the following interests of the investigator and related parties that reasonably appears to be related to the investigator's institutional responsibilities and includes:

   1) with regard to any publicly traded entity, the value of remuneration received from that entity during the 12 months preceding and the value of any equity interest as of the date of disclosure that when aggregated exceeds $5,000 (including salary and any payment for services not otherwise identified as salary, such as consulting fees, honoraria, paid authorship);

   2) with regard to any non-publicly traded entity, the value of remuneration received from that entity during the 12 months preceding the date of disclosure that when aggregated exceeds $5,000 or when the investigator or related parties hold any equity interest; or

   3) intellectual property rights and interests (e.g. patents, copyrights) upon receipt of income related to such rights and interests.

   b. the occurrence of any reimbursed or sponsored travel related to institutional responsibilities paid by an entity, including a nonprofit, but excluding travel sponsored by a government agency, institution of higher education, an academic teaching hospital or medical center, or a research institute affiliated with an institution of higher education. Travel disclosures must include the purpose of the trip, name of sponsor/organizer, destination, and duration.

   c. *significant financial interest* does not include salary, royalties or other remuneration paid by the institution where the investigator is currently employed or appointed, including intellectual property rights assigned to the institution and agreements to share in royalties
related to such rights; any ownership interest in the institution if it is a commercial or for-
profit organization; income from investment vehicles, such as mutual funds and retirement
accounts, provided the investigator does not directly control investment decisions; income
from seminars, lectures, or teaching engagements sponsored by government agencies,
institutions of higher education, academic teaching hospitals, medical centers, or research
institutes affiliated with institutions of higher education; or income from service on
advisory committees or review panels for a government agency, institution of higher
education, academic teaching hospital, medical center, or research institute affiliated with
an institution of higher education.

17. Small Business Innovation Research (SBIR) Program means the extramural research
program for small businesses that was established by awarding entities of the federal
government in 1982 under Pub. L. 97-219 and also includes the Small Business Technology
Transfer Program, established in 1992 by by Pub.L. 102-564 and reauthorized under Pub L.
112-81 as the SBIR/STTR Reauthorization Act of 2011 under the National Defense
Reauthorization Act.

18. Sponsored Programs Office Director means that individual at Upstate who is responsible for
the submission of sponsored research applications and acceptance sponsored research funds
on behalf of the Research Foundation of SUNY, and who is responsible for obtaining
significant financial interest disclosures from all investigators prior to submission of
sponsored research applications.

19. Vice President for Research means that individual at Upstate who appoints the Research
Conflict of Interest Officer and members of the Research Conflict of Interest Committee,
approves management plans when it has been determined that significant financial interests
constitute financial conflicts of interest, imposes administrative sanctions when there is
noncompliance with this policy or with an approved management plan, and assures
compliance with 42 CFR Parts 50 Subpart F and 94 of the PHS Conflict of Interest
regulations in terms of reporting and public disclosure.

D. Policy

Upstate Medical University shall take the following steps to identify and manage financial
conflict of interests to assure that research conducted at Upstate by faculty and subrecipients is,
to the extent possible, free from bias that could result from such financial conflicts of interest:

1. Upstate establishes and maintains this up-to-date, written, enforced policy, including Section
2 related to financial conflicts of interest that complies with the PHS Financial Conflict of
Interest regulations of 42 CFR Part 50 Subpart F and 45 CFR Part 94. This policy is posted
on the Upstate Medical University publically accessible section of Upstate’s web site at
http://www.upstate.edu/researchadmin/policies.php and will also be made available to any
requestor within five business days of a request.

2. Upstate informs all of its investigators of this policy, including this financial conflict of
interest section of the policy and of investigators’ responsibilities regarding disclosure of
significant financial interests under this policy, and requires each investigator to complete
FCOI training prior to engaging in sponsored research and at least every four years thereafter,
and immediately when this Upstate policy is revised or procedures changed in any manner
that affects the requirements of investigators, when an investigator is new to Upstate, or Upstate finds that an investigator is not in compliance with this policy or management plan.

3. Upstate ensures that subrecipient investigators comply with this policy by incorporating language into subrecipient written agreements that state whether the Upstate Policy on the Identification and Management of Conflicts of Interest and Commitment or the policy of the subrecipient institution will apply to subrecipient investigators and, if complying with subrecipients' policies, require the subrecipient to certify that their policy is in compliance with 42 CFR Part 50 Subpart F and 45 CFR Part 94. If the subrecipient institution cannot provide such certification, Upstate will require that subrecipient investigators comply with the Upstate policy. In its subrecipient agreements, Upstate will require subrecipients to report FCOI to Upstate within 45 days and report subrecipient financial conflicts of interest to PHS prior to expenditure of funds or within 60 days of identification of subrecipient FCOI, or according to the timeframes required by other research sponsors.

4. Upstate designates the Sponsored Programs Office Director as the individual responsible for receipt of investigator disclosures of SFI and the Research Conflict of Interest Officer as the Upstate official responsible for review of such disclosures of SFI.

5. Upstate requires that each investigator planning to participate in the design, conduct or reporting of sponsored research must disclose SFI at the time of application for funds for that project, disclose updated SFI annually during the funded period, and submit an updated disclosure of SFI within 30 days of discovering or acquiring new SFI.

6. Upstate has established the following guidelines to be used by the RCOI Officer to determine if the SFI is likely to be an FCOI:
   a. that the SFI is related to the sponsored research and could be affected by the sponsored research or is in an entity whose financial interest could be affected by the research or
   b. that the SFI could directly and significantly affect the design, conduct or reporting of the sponsored research.

7. Upstate requires that FCOI must be managed or eliminated, including conflicts of a subrecipient investigators, before the expenditure of sponsored research funds and delegates development of management plans to the Research Conflict of Interest Committee and approval by the VP for Research, as well as the conduct of retrospective reviews and mitigation reports, as might be necessary per 42 CFR 50.605(a) of the PHS regulations.

8. Upstate will provide FCOI reports to the Research Foundation of SUNY and all research sponsors, according to their reporting requirements.

9. Upstate will maintain records related to all investigator disclosures of SFI, review of and response to such disclosures, and all actions under this policy or retrospective reviews, for three years from the date the final expenditures report is submitted to the research sponsor, or where applicable, other dates as specified in 45 CFR 74.53(b) and 92.42(b) for different situations.

10. Upstate delegates enforcement mechanisms that provide for employee sanctions or other administrative actions to assure investigator compliance to the Offices of VP for Research and President, respectively.

11. In each sponsor application, Upstate, through the Sponsored Programs Office, will certify that it has an up-to-date, written policy and enforced administrative procedures to identify and manage FCOI with respect to all sponsored research projects, promotes and enforces investigator compliance with the policy and procedures, manages FCOI, and fulfills all sponsor reporting requirements.
12. Upstate’s policy complies with all provisions of 42 CFR Parts 50 Subpart F and 94 and applies these provisions to all sponsored research.

13. Upstate has established procedures to publicly post this policy and all disclosed significant financial interest that meets the following three criteria on the public portion of its website to assure that the public has access to this information:
   a. the SFI was disclosed and is still held by the senior/key personnel,
   b. it has been determined by Upstate that the SFI is related to the sponsored research, and
   c. the SFI is an FCOI

14. Upstate will post the following information on the public portion of its website, to be updated annually or within 60 days of receipt and/or identification of previously undisclosed SFI or upon the disclosure of SFI of senior/key personnel new to the research project, for all SFI that meets the above three criteria:
   a. Investigator name
   b. Investigator title and role with respect to the research project
   c. The research sponsor and title of the research project
   d. Name of the entity in which the SFI is held
   e. Nature of the SFI
   f. Approximate dollar value of the SFI in ranges or a statement that the SFI is one whose value cannot be readily determined

15. Upstate will retain this publicly disclosed information on its public website for three years from the date that the information was most recently updated.

E. Implementation

Implementation of the FCOI portion of this policy at Upstate Medical University will commence on or before August 24, 2012 and continue until amended. Implementation will include the following components: Education and Training, Disclosure of SFI, Review of SFI Disclosure and Determination if SFI May Be FCOI, Development and Oversight of Management Plans, Actions to Address Noncompliance with this Policy or Management Plans, Reporting to Research Sponsors, and Public Access to Upstate FCOI Policy and Identified FCOI.

1. Education and Training
   a. All Upstate faculty, staff, students and fellows who engage in the design, conduct or reporting of sponsored research will be provided with a copy of the Upstate Policy on the Identification and Management of Conflicts of Interest and Commitment on/before 8/24/12 (or upon hire after that date) and be familiar with the policy as it applies to their patient care, research, and educational responsibilities at Upstate.
   b. All Upstate faculty, staff, students and fellows who engage in the design, conduct or reporting of sponsored research must successfully complete training. At the time of the incorporation of the PHS regulations into this policy, this training will consist of successful completion (score of 80 or higher) the CITI Conflict of Interest Modules, “Financial Conflicts of Interest: Overview, Investigator Responsibilities, and COI Rules” and “Institutional Responsibilities as They Affect Investigators” by 9/15/12 or prior to submission of a sponsored research application or acceptance of sponsored research funds between 8/24/12 and 9/14/12 and repeat this training every four years thereafter. Successful completion of this CITI training will be required in order to participate in a sponsored
research project application as an investigator in the design, conduct, or reporting of the research, and additional CITI modules or training activities may be required at a later date.

c. Subrecipients investigators must document that they have completed CITI or an equivalent FCOI training program according to the timeframes in E.a.ii. above.

2. Disclosure of Significant Financial Interests (SFI) by Investigators

   a. All investigators who participate in the design, conduct, or reporting of a research project will be required to submit an Upstate Medical University Disclosure Form (attached) prior to the submission of an application for sponsored research support, within 30 days of discovering or acquiring new SFI, and annually during the period of the sponsored research to the Upstate Sponsored Programs Office. PIs on sponsored research applications will be expected to identify everyone on the research team who is responsible for the design, conduct or reporting of research and, therefore, must submit a Disclosure Form to the Sponsored Programs Office.

   b. Disclosure Forms must be submitted to the Sponsored Programs Office prior to the submission of a sponsored research application in a manner determined by that office.

   c. Investigators must disclose all SFI, including related parties' SFI, on the disclosure form.

   d. The Sponsored Programs Office will transmit completed disclosure forms to the Research Conflict of Interest (RCOI) Officer for review.

   e. The Sponsored Programs Office will determine if subrecipients on Upstate applications for sponsored research will follow the Upstate policy or the policy of their institution.

      1) If subrecipients follow the Upstate policy, all subrecipient investigators must submit an Upstate Disclosure Form to the Upstate Sponsored Programs Office prior to the submission of the sponsored research application.

      2) If subrecipients follow their institution's policy, they must provide a copy of that policy or a certification that their institution's policy is compliant with 42 CFR Parts 50 Subpart F and 94 prior to submission of the sponsored research application.

3. Review of SFI Disclosure and Determination if SFI May Be FCOI

   a. All disclosure forms transmitted from the Sponsored Programs Office to the RCOI Officer will be reviewed by the RCOI Officer to determine if disclosed SFI could be FCOI using the following guidelines:

      1) that the SFI is related to the sponsored research and could be affected by the sponsored research or is in an entity whose financial interest could be affected by the research, or

      2) that the SFI could directly and significantly affect the design, conduct or reporting of the sponsored research.

   b. When the RCOI Officer determines that SFI could be FCOI, the RCOI Officer will notify the investigator and the RCOI Committee.

4. Development and Oversight of Management Plans

   a. When it has been determined by the RCOI Officer that SFI may be FCOI, the RCOI Committee will meet with the investigator (including a subrecipient investigator if the Upstate FCOI policy applies to the subrecipient) to review the RCOI's findings to confirm that there is a financial conflict and to create a plan to manage or eliminate the financial conflict. Key elements of the management plan include:

      1) the role and principal duties of the conflicted investigator in the research project
      2) conditions of the management plan
      3) how the management plan is designed to safeguard objectivity in the research project
      4) confirmation of the investigator's agreement to the management plan
5) other information as needed to determine the FCOI is being managed or eliminated

b. This management plan may include one or more of the following:
   1) public disclosure of FCOI
   2) for human subjects research projects, disclosure of FCOI directly to participants
   3) appointment of an independent monitor to take measures to protect the design, conduct or
      reporting of research
   4) modification of the research plan
   5) change of personnel or personnel responsibilities, or disqualification of personnel from
      participation in all or a portion of the research
   6) reduction or elimination of the financial interest
   7) severance of relationships that create financial conflicts

c. The RCOI Committee will meet monthly and its schedule will be posted on the Research
   Administration website along with the names of the RCOI members and the RCOI Officer.

d. Once the investigator and RCOI Committee have agreed to a plan to manage/eliminate
   FCOI, the plan will be submitted to the VP for Research for final approval.

e. The investigator will be required to comply with the terms of the Management Plan during
   the funded period of the sponsored research.

f. The RCOI Committee will determine if oversight of the Management Plan is required, and
   if so, include the names and duties of the oversight committee in the plan.

g. All Management Plans must be developed and approved prior to the acceptance of funds
   from a research sponsor by the Sponsored Programs Office on behalf of the Research
   Foundation of SUNY.

5. Actions to Address Noncompliance with the Disclosure Requirements

   a. When Upstate identifies SFI that was not disclosed in a timely manner by an investigator or
      not previously reviewed by Upstate during a sponsored research funded period, within 60
      days of the discovery, the RCOI Officer shall request and review the SFI and determine if
      the SFI is related to the sponsored research and whether an FCOI is likely to exist.

   b. The RCOI Officer will notify the investigator of the results of this review and the actions to
      be taken to manage the FCOI going forward, including the development and approval of a
      management plan.

   c. Within 120 days of the discovery of the failure to disclose or review a disclosure, Upstate
      shall complete a retrospective review of the investigator’s activities and the sponsored
      research project to determine whether any sponsored research, or portion thereof, conducted
      during the time period of the noncompliance, was biased in the design, conduct, or reporting
      of such research.

   d. The following will at a minimum be documented in a retrospective review: project number,
      project title, PI/PD contact, name of investigator with FCOI, name of entity with which the
      investigator has an FCOI, reason(s) for the retrospective review, detailed methodology used
      for the retrospective review, findings of the review, and conclusions of the review.

   e. If the results of the review warrant, Upstate will update a previously submitted FCOI report
      specifying the actions to be taken to manage the FCOI.

   f. If bias is found, Upstate will notify the research sponsor and submit a mitigation report that
      includes the key elements documented in the retrospective review and a description of the
      impact of the bias on the research project, and Upstate’s plans to eliminate or mitigate the
      effect of the bias and any additional measures that are determined to be necessary with
      regard to the investigator’s participation in the sponsored research project.
6. Actions to Address Noncompliance with an Approved Management Plan
   a. Whenever it is determined that an investigator is noncompliant with an approved
      Management Plan, the VP for Research will be notified of the noncompliance. The VP for
      Research may impose administrative actions or sanctions or take other action.
   b. In addition, within 120 days of the identification of noncompliance, Upstate shall complete
      a retrospective review of the investigator’s activities and the sponsored research project to
      determine whether any sponsored research, or portion thereof, conducted during the time
      period of the noncompliance, was biased in the design, conduct, or reporting of such
      research.
   c. The description of the retrospective review and actions taken to update previously submitted
      FCOI reports and mitigate any bias that is found are described above in E.e.iv-vi.

7. Reporting to Research Sponsors and the Research Foundation of SUNY
   a. Upstate will comply with all research sponsor reporting requirements regarding disclosure
      of SFI, determination that SFI is FCOI, development and implementation of management
      plans, retrospective reviews and results, and public disclosure of FCOI.
   b. With regard to PHS-sponsored research, Upstate will submit the following to the PHS
      awarding component (CDC, NIH, HRSA, SAMSHA):
      1) an FCOI report regarding any SFI determined to be FCOI and an assurance that a
         management plan to mitigate/eliminate the FCOI has been implemented prior to the
         expenditure of any PHS funds and annually during the funded period specifying any
         changes to the management plan and if the FCOI is still being managed or why the FCOI
         no longer exists.
      2) for any SFI that has been identified as FCOI subsequent to the submission of the initial
         FCOI report, including the FCOI of an investigator new to the research project, an FCOI
         report and assurance of implementation of a Management Plan will be submitted within
         60 days.
      3) When it is determined that SFI was not disclosed by an investigator or not previously
         reviewed or managed by Upstate, Upstate will complete and submit a retrospective
         review within 120 days.
      4) If bias is found, Upstate will immediately submit a mitigation report.
      5) All FCOI reports will include the following at a minimum: project number, PI/PD, name
         of investigator with FCOI, name of entity with which the investigator has FCOI, nature of
         the FCOI, value of financial interest specifically or in dollar ranges, a description of how
         the financial interest related to the PHS-funded research and the basis for the
         determination that SFI is FCOI, and a description of key elements of the management
         plan. Key elements may include role and principal duties of the conflicted investigator in
         the research project, conditions of the management plan, how the management plan is
         designed to safeguard objectivity in the research project, confirmation of the
         investigator’s agreement to the management plan, how the management plan will be
         monitored to ensure investigator compliance, and other information as needed and
         appropriate.
   c. Upstate will comply with all Research Foundation of SUNY reporting requirements.

8. Public Disclosure of Upstate’s FCOI Policy and Identified FCOI
   a. Upstate’s FCOI policy, incorporated into the Policy on the Identification and Management
      of Conflicts of Interest and Commitment, is located on Upstate’s publicly accessible website
at http://www.upstate.edu/researchadmin/policies.php. Updated/modified versions of this 
policy will be posted within 30 days of update at this URL.
b. The following information will be publicly disclosed and updated annually or within 60 
days of receipt and/or identification of previously undisclosed SFI or upon the disclosure of 
SFI of senior/key personnel new to the research project, for all SFI that meets these three 
criteria: the SFI was disclosed and is still held by the senior/key personnel, it has been 
determined by Upstate that the SFI is related to the sponsored research, and the SFI is an 
FCOI
   1) Investigator name
   2) Investigator title and role with respect to the research project
   3) Title of research project and the research sponsor
   4) Name of the entity in which the SFI is held
   5) Nature of the SFI
   6) Approximate Dollar value of the SFI in ranges or a statement that the SFI is one whose 
value cannot be readily determined
c. the above publicly disclosed information will remain on the publicly accessible section of 
the Upstate website for three years from the date that the information is most recently 
updated.

F. Other Specific Topics Requiring Scrutiny

1. Relations with Industry and Other Organizations in Sponsored Research

SUNY Upstate Medical University is committed to promoting objectivity in research and 
complying with all applicable federal and state regulations regarding conflict of interest. A 
conflict of interest has the potential to compromise or bias the professional judgment or 
objectivity of the holder of the interest or has the appearance of having the potential to 
compromise or bias the holder of the interest.

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.

2. 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 an investigator's institutional responsibilities is appropriate but must be disclosed by that investigator (for example, travel to an investigator's meeting, when the investigator is conducting the clinical trial at Upstate).

3. 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.

4. Purchasing, contracting, and other business transactions on behalf of the University

Upstate employees must not make personal investments in organizations that they have reason to believe may be directly involved in or related to decisions made by the employee on behalf of Upstate or will otherwise create substantial conflict between duties on behalf of Upstate and private interests.

Upstate employees may not represent Upstate in any transactions with a business entity or organization if they or their family have a financial or other interest in that entity.

Procurement of goods or services on behalf of Upstate must be consistent with Upstate, SUNY,
and Research Foundation procurement policies.

Upstate employees may not accept employment or engage in any business or professional activities that will impair the independence of their judgment in the exercise of duties for Upstate.

Upstate employees may use confidential information gained in the course of their duties only in furtherance of their official Upstate duties and may not use Upstate, Research Foundation or SUNY confidential information to further their personal interests or that of family members. Upstate employees cannot accept employment or engage in any outside business or professional activity that will require them to disclose Upstate, SUNY or Research Foundation confidential information.

Upstate employees cannot misappropriate the property, services or other resources of Upstate, SUNY, the RF or others – whether for themselves or for someone else.

Upstate employees may not, by their conduct, give reasonable basis for the impression that any person can improperly influence them or unduly enjoy their favor in the performance of their Upstate duties, or that they are affected by the kinship, rank, position, or influence of any party or person.

Upstate employees may not use, or attempt to use, their positions to secure unwarranted privileges or exemptions for themselves or others. Bribery, extortion, and other attempts to exert undue influence are strictly prohibited.

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 “Financial Conflict of Interest in Sponsored Research.”

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.

5. 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), through the Upstate Office of Technology Transfer, attempts to license those inventions, approved by the Upstate Institutional Patent Committee and Vice President for Research, to appropriate Industry partners. In this way, new technologies created by Upstate faculty, staff, and students may reach the market for the public good. Licensing of these patentable technologies is for the benefit of Upstate and its employees, including the inventors, SUNY RF, and the public. Any time an Upstate inventor or a member of their immediate family (including a spouse, domestic partner, or dependent child), has the potential for financial benefit from an invention or patent owned by or licensed to a pharmaceutical or device company except for patent income paid directly from Upstate under the Patent Policy, the Upstate inventor must report this potential financial interest to the Research COI Committee using the UME Financial Disclosure Form. 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. Prior approval by the Research COI Committee is required before any Upstate inventor can undertake a founding role in any company. 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. Financial disclosure is required upon receipt of income related to intellectual property rights and interests (e.g., patents, copyrights), other than income received under the Patent Policy.

6. 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 dependent 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.

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 -sponsored research 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 “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 platform and poster presentations.

G. Implementation

The operational responsibility for the implementation of this policy is delegated to the Research of Interest (COI) Officer, described above.

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.8

D. Implementation

1. Scope
This section will address implementation of the policy regarding Personal Financial Interests of University Leadership in Industry.

2. Responsibility for Implementation

The operational responsibility for the implementation of this policy is delegated to the Conflict of Interest (COI) Officer.

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8 This list is adapted from the AAMC report, Protecting Patients, Preserving Integrity, Advancing Health (2008)
Section 4. Conflict of Commitment

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\(^9\) 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
- Research proposals submitted under the name of another organization, when Upstate could also have sponsored such research
- Membership on boards or directorships

\(^9\) 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.

\(^10\) SUNY Policy 6001
• 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

1. 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.

2. 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.

      1) 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.

      2) 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).

3. 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.

4. Limits on time spent on external activities. This guideline refers to total external effort.
a. **For full-time** faculty and Management Confidential employees, a limit of 3 work days per month or 36 work days per year on external commitments 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.

5. **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.

1) **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.

2) **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. Review and Evaluation of the Policy on the Identification and Management of Conflicts of Interest and Commitment

This policy shall be reviewed and evaluated periodically by the University to determine if it is working as intended and whether any modifications are needed. This review and evaluation as well as any changes in the Policy will be made available to the University community.

This policy incorporates all requirements of the August 24, 2012 PHS Financial Conflict of Interest regulations (42 CFR Parts 50 Subpart F and 94) and apply to all sponsored research applications submitted by Upstate or conducted at Upstate on/after 8/24/12.

Appendices:
1. PHS Policy on Financial Conflict of Interest 42 CFR Parts 50 Subpart F and 94
2. Upstate Medical University Disclosure Form
Upstate Medical University
Financial Disclosure Form

Name:

Title of Position:

Department: Phone/Email:

Proposal Title:

Sponsor Name:

Application Due Date: Disclosure Submission Date:

WHO MUST DISCLOSE

Investigator: the project director or principal investigator or any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of sponsored research

Investigator's Related Parties: spouse, domestic partner, and dependent children

WHAT MUST BE DISCLOSED

Significant Financial Interest: consists of one or more of the following

- With regard to a publicly traded entity, the value of remuneration received from that entity during the prior 12 months, including salary and any payment for services, such as consulting fees, honoraria, paid authorship; and equity interest, including stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.
- With regard to a non-publicly-traded entity, the value of remuneration received from the entity in the prior twelve months.
- With regard to any non-publicly traded entity, any equity interest held, such as stock, stock option, or other ownership interest.
- Intellectual property rights and interests (patents, copyrights) upon receipt of income related to such rights and interests.
- Reimbursed or sponsored travel that is paid on behalf of the investigator/related parties not reimbursed, related to institutional responsibilities but excluding sponsored travel by a federal, state or local government; an institution of higher education; an academic teaching hospital; a medical center; or a research institute affiliated with an institution of higher education.
WHAT NEED NOT BE DISCLOSED

- income from the investigator's employer, including salary, royalties, or other remuneration paid by the investigator's employer; intellectual property rights assigned to the institution and agreements to share in royalties related to such rights; or equity interest in that employer institution.
- income from investment vehicles that the investigator does not directly control, such as mutual funds and retirement accounts.
- income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government; an institution of higher education; an academic teaching hospital; a medical center; or a research institute that is affiliated with an institution of higher education.
- income from service on advisory committees or review panels for a federal, state, or local government agency, an institution of higher education; an academic teaching hospital; a medical center; or a research institute affiliated with an institution of higher education.

WHEN MUST SIGNIFICANT FINANCIAL INTEREST BE DISCLOSED BY INVESTIGATORS

- prior to submitting an application for sponsored research
- annually during the sponsored research funding period
- if any significant financial interest not previously disclosed is discovered or acquired
- when an investigator is new to a research project following application and/or an award

1. List the names of all publicly traded entities from which you or a Related Party receive remuneration or in which you or a Related Party hold an equity interest. Report only those entities that reasonably appear to be related to your institutional responsibilities and from which the aggregate of (i) remunerations received in the preceding 12 months, and (ii) the current value of equity interests exceeds $5,000.

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2. List the names of all non-publicly traded entities other than the Research Foundation or the State of New York from which you or a Related Party receive a remuneration. Report only those entities that reasonably appear to be related to your institutional responsibilities and from which remunerations received over the preceding 12 months exceed $5,000.

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3. List the names of all non-publicly traded companies in which you or a Related Party hold an equity interest. Report only those entities that reasonably appear to be related to your institutional responsibilities.

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<tr>
<th>Name</th>
<th>Relationship</th>
<th>Entity</th>
<th>Nature</th>
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</table>
4. List and describe intellectual property rights or interests (e.g., patents, copyrights) held by you or a Related Party, royalties from such rights, and/or agreements to share in royalties related to such rights that reasonably appear to be related to your institutional responsibilities. Do not include intellectual property rights assigned to SUNY or the Research Foundation, or agreements to share in royalties related to such rights.

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<tr>
<th>Name</th>
<th>Relationship</th>
<th>Nature</th>
<th>Income Received (Y/N)</th>
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5. List and describe any reimbursed or sponsored travel related to your institutional responsibilities. You do not need to disclose travel that was reimbursed or sponsored by a federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

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<tr>
<th>Purpose of Trip</th>
<th>Sponsor/Organizer</th>
<th>Destination</th>
<th>Duration</th>
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☐ I have read and understand the Upstate Medical University Policy on the Identification and Management of Conflicts of Interest and Commitment.

http://www.upstate.edu/researchadmin/policies.php

Declaration:
I declare that the above information is true and correct.

_________________________________  ____________
Signature                          Date

8/17/2012
FEDERAL REGISTER

Vol. 76  Thursday,
No. 165  August 25, 2011

Part IV

Department of Health and Human Services

42 CFR Part 50
45 CFR Part 94
Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought and Responsible Prospective Contractors; Final Rule