

**EMORY UNIVERSITY SCHOOL OF MEDICINE  
POLICY ON INDUSTRY AND OTHER EXTERNAL PROFESSIONAL RELATIONSHIPS**

**Table of Contents**

**EMORY UNIVERSITY SCHOOL OF MEDICINE  
POLICY ON INDUSTRY AND OTHER EXTERNAL PROFESSIONAL RELATIONSHIPS**

**Overview  
Definitions  
Applicability**

**I. SCHOOL OF MEDICINE POLICY ON EXTERNAL RELATIONSHIPS AND REPORTING**

**Overview**

**Applicability**

**A. Reporting External Professional Relationships**

- 1. Procedure for Faculty**
- 2. Procedure for Staff, Students, and Trainees**

**B. Consulting and Other External Professional Relationships**

- 1. Traditional Academic Activities That Usually Are Not Reported**
- 2. Personal External Professional Relationships That Must Be Reported and Approved in Advance**
  - a. Consulting for Industry**
  - b. Serving as an Expert Witness or Providing Legal Consultation**
  - c. Serving as an Officer or Board of Directors Member**
  - d. Accepting a Faculty Appointment at Another Institution**
  - e. Receiving Licenses, Royalties, and Equity**
  - f. Forming or Engaging in a Faculty Start-up Company**
- 3. Personal, Professional External Activities with Industry and Other Entities That Are Prohibited**
  - a. Participating in Speakers Bureaus; Sales and Marketing for Industry**
  - b. Advising Investment Firms, Matchmakers, Hedge Funds, Investment Bankers, Venture Capital Firms, Brokerage Houses**
  - c. Advising or Creating Materials for Industry on Marketing and Promoting Their Products; Training Sales and Marketing Representatives on Selling, Marketing, and Promoting Industry Products**
  - d. Accepting Remuneration for Listening to Sales Talks or Attending Industry-Sponsored Education and Training**

**II. SCHOOL OF MEDICINE POLICY ON GIFTS FROM INDUSTRY**

**Overview**

**Applicability**

**General Policy**

- A. Gifts from Industry to Individuals in the School of Medicine**
- B. Gifts of Medications and Pharmaceutical Samples to Individuals**
- C. Gifts of Funds from Industry to School of Medicine to Support Education and Other Professional Activities**
- D. Donation of Equipment and Devices from Industry**

- E. Gifts to the School of Medicine from Faculty Related to Their Personal, Professional Relationships with Industry
- F. Gifts of Food from Industry
- G. Gifts of Educational Materials to Individuals or Departments in the School of Medicine

### III. SCHOOL OF MEDICINE POLICY ON SITE ACCESS BY INDUSTRY

#### Overview

#### Applicability

- A. Access to Emory and Affiliate Buildings and Emory Personnel
  - 1. Invitations to Industry to Train Emory Personnel on Devices and Equipment; Facilitation of Clinical Procedures by Industry Representatives
  - 2. Invitations to Industry Representatives to Provide Sales information and Product Information
- B. Interaction of Industry With School of Medicine Students and Trainees
- C. Solicitation of Emory Patients, Visitors, and Guests by Industry Representatives
- D. Procedure for Industry Representatives to Register
- E. Commercial Exhibits in School of Medicine Buildings

### IV. SCHOOL OF MEDICINE POLICY ON ACADEMIC ACTIVITIES RELATED TO INDUSTRY

#### Overview

#### Definitions

#### Applicability

- A. Ghostwriting
- B. Participation in Industry-Sponsored Education and Training
  - 1. Attending Industry-Sponsored Education and Training Activities
  - 2. Speaking and Training at Industry-Sponsored Events; Organizing Industry-Sponsored Events
- C. Training at Emory in the Use of Devices and Equipment for Industry Purposes
- D. Disclosure to Medical Students
- E. Use of Textbooks and Other Educational Materials When the Educator Has a Financial Interest

### V. EMORY UNIVERSITY SCHOOL OF MEDICINE POLICY AND PROCEDURES ON START-UP COMPANIES, FOUNDER'S EQUITY, AND SIMILAR ACTIVITIES

### VI. SCHOOL OF MEDICINE GENERAL CONFLICT OF INTEREST POLICY

- A. School of Medicine Policy on Conflict of Interest in Research
- B. School of Medicine Policy on Vendors, Confidentiality, and Competition with Emory
- C. School of Medicine Policy on Conflict of Interest in Clinical Practice Related to Industry

### VII. SCHOOL OF MEDICINE POLICY ON COMMITMENT

#### Background

#### Applicability

- A. School of Medicine Policy Regarding External Employment
- B. School of Medicine Policy on Medical Practice by School of Medicine Faculty
- C. School of Medicine Policy on Authority of Department Chairs in Assignment of Duties
- D. School of Medicine Policy on Commitment of Time in External Personal Professional Relationships
- E. School of Medicine Policy on Services to Other University Units
- F. School of Medicine Policy on Extra Duty at Emory
- G. School of Medicine Policy on Clinical and Adjunct (Volunteer) Appointments of School of Medicine Faculty at Other Institutions
- H. School of Medicine Policy on Joint and Secondary Appointments of School of Medicine Faculty at Other Institutions

- I. School of Medicine Policy on Use of Emory Resources**
- J. School of Medicine Policy on Use of Emory's Name, Logo, or Marks**
- K. School of Medicine Policy on Submission of Research Proposals**
- L. School of Medicine Policy on Employment of Relatives (Nepotism)**

**VIII. SCHOOL OF MEDICINE POLICY ON ADMINISTRATIVE ACTIONS BY SCHOOL OF MEDICINE OFFICIALS, FACULTY, AND STAFF RELATED TO THEIR EXTERNAL RELATIONSHIPS WITH INDUSTRY**

**Overview**

**Applicability**

- A. Administrative Actions by Officials in the School of Medicine**
- B. Business and Administrative Transactions**
- C. Supervisory Relationships When Supervisors Have Personal External Relationships with Industry**

**IX. SANCTIONS FOR BREACH OF POLICIES**

**EMORY UNIVERSITY SCHOOL OF MEDICINE  
POLICY ON INDUSTRY AND OTHER EXTERNAL PROFESSIONAL RELATIONSHIPS**

**Overview**

The primary missions of the School of Medicine are to provide outstanding educational programs for medical and graduate students and trainees; to provide the highest standard of clinical care for patients; to develop outstanding, compassionate physicians and scientists who serve the community and the world; and to conduct innovative and collaborative research and integrate this knowledge into the practice of medicine. The School of Medicine is committed to ensuring that its faculty, staff, students, and trainees strive for the highest degree of ethical and professional standards and integrity in carrying out its missions.

Industry, which includes pharmaceutical, device, equipment, biotechnology, service, software, supplies, biomedical investment, and for-profit educational companies and foundations sponsored by companies such as drug and device companies, has a long history of collaborations with academic faculty physicians and researchers that have contributed to our educational, clinical, community service, and research missions in ways that continue to benefit individual and public health through the development of new drugs, devices, equipment, computer technology, therapies, and services. For example, industry provides grants to Emory University to fund clinical trials and other research conducted by faculty, and faculty consult with industry to advise on research directions and health needs. The related personal financial ties with industry in some of these relationships, however, have the potential to influence the judgment of faculty, staff, students, and trainees, despite their best intentions, as they engage in the missions of the School of Medicine, thus creating conflicts of interest or the appearances of conflicts. The School of Medicine supports principled relationships with industry in which its faculty, staff, students, and trainees collaborate with industry scientists and engineers on advances in science and medicine that enhance the missions and are beneficial to the public and that do not involve promotion and marketing. The School of Medicine *Policy on Industry and Other External Professional Relationships* promotes the highest standards of professionalism and ethics in industry collaborations to protect the integrity of research, the objectivity of education, the safety of human subjects in research, the quality of patient care, the reputations of School of Medicine faculty, staff, students, and trainees, and their professional commitment to the School – all of which enhance the public’s trust in the institution and in the profession of medicine. Any conflicts of interest that might arise in principled collaborations with industry will be reduced, managed or eliminated, pursuant to School of Medicine, Emory Healthcare, and Emory University policies.

Faculty, staff, students, and trainees of the School of Medicine sometimes wish to have personal external professional relationships that are related to their professional duties at Emory (including clinical duties, course of studies, field of research, or scholarly expertise) with external entities that are not part of industry. Many of these are beneficial and sometimes necessary for individuals to carry out their Emory duties, for example relationships with other academic institutions and government agencies. This policy also provides assistance to faculty for establishing these relationships while remaining in compliance with School of Medicine and Emory University policies in view of potential conflicts of interest and commitment.

The primary intent of this policy is to help faculty, staff, students, and trainees effectively report and address potential conflicts of interest and commitment in their professional activities. Once reported,

the individual and the School and University can work together to enhance the beneficial outcomes of principled personal external professional relationships to the institution and the public and prevent even the appearance of undue influence that might harm the public, the institution, or the individual.

**Definitions.** For purposes of the over-arching School of Medicine *Policy on Industry and Other External Professional Relationships* and its components, including this policy:

- “Industry” includes, but is not limited to, pharmaceutical, device, equipment, biotechnology, service, software, supplies, biomedical investment, and for-profit educational companies, and foundations sponsored by companies such as drug and device companies.

- “Personal external professional relationships” include any professional services performed or products created and/or sold for any person or entity (including but not limited to industry and other entities) other than Emory University and Emory-approved practice plans, including but not limited to The Emory Clinic, the Emory Medical Care Foundation, the Emory Children’s Center, and the Veterans Affairs Medical Center. Personal external professional relationships may or may not be remunerated. As used in this policy, the phrase “personal external professional relationship” encompasses but is not limited to consulting.

- “Other entities,” as in relationships with “other entities” that must be reported, includes but is not limited to other academic institutions and not-for-profit foundations.

- “Faculty” includes the full-time and part-time faculty of the School of Medicine. It also includes senior officials of the School of Medicine – deans, directors of School of Medicine administrative units, department chairs, and department division directors -- regardless of whether they hold faculty appointments. For the purposes of this policy, each senior official is treated as a faculty member and must adhere to the obligations of faculty members, regardless of whether he/she holds a faculty appointment.

### **Applicability**

The applicability of the policies that make up the School of Medicine *Policy on Industry and Other External Professional Relationships* to School of Medicine faculty, staff, students, and trainees is specified in each component.

## **I. SCHOOL OF MEDICINE POLICY ON EXTERNAL PROFESSIONAL RELATIONSHIPS AND REPORTING**

**Overview.** The School of Medicine promotes the highest degree of ethical and professional standards and integrity in carrying out its missions and the administrative functions that support them. The School is committed to ensuring that its faculty, staff, students, and trainees strive to protect the integrity of research, the objectivity of education, the safety of human subjects in research, the quality of patient care, and their professional commitment to the School – all of which maintain and enhance the public’s trust in the School and in the profession of medicine and protect the reputations of the School and the individuals who work and study here.

The School supports principled personal external professional relationships in which its faculty, staff, students, and trainees collaborate with industry scientists and engineers on advances in science and medicine that enhance the School’s missions, are beneficial to the public, and do not involve promotion and marketing. At the same time, the School recognizes that the financial ties associated with some of these relationships have actual or perceived conflicts of interest and commitment and is committed to the management or elimination of such conflicts as appropriate. The School also supports other personal external professional relationships with other institutions, medical and scientific professional

organizations, and government agencies when they benefit the missions of the School and comply with School and University policies. This policy advises faculty, staff, students, and trainees about personal external professional relationships that require the prior review and approval of Department Chair only, personal external professional relationships that require the prior review and approval of the Department Chair and the Dean's Office, and personal external professional relationships that are prohibited. It provides assistance to faculty for establishing appropriate, beneficial, principled personal external professional relationships while remaining in compliance with School of Medicine and Emory University policies in view of potential conflicts of interest and commitment. As part of their mutual obligations, School of Medicine faculty must report their personal external professional relationships with industry and other entities, as defined in this policy. Staff, students, and trainees must report their personal external professional relationships with industry and other entities that are related to their jobs at Emory and may be asked to report their personal external professional relationships related to the research projects in which they are involved. In both groups, individuals must report the financial interests of their immediate families and domestic partners that are related to their Emory duties or research. The School of Medicine will assist faculty in managing any associated conflicts of interest or commitment that might arise in permissible personal external professional relationships or eliminating those that cannot be effectively managed.

**Applicability.** The School of Medicine Policy on External Professional Relationships and Reporting applies to faculty, staff, students, and trainees. Each section defines more precisely the group(s) to which it applies.

## **A. Reporting External Professional Relationships**

### **1. Procedure for Faculty**

Using the on-line process provided at the Emory University Conflict of Interest in Research Office website <http://www.coi.emory.edu/>, each School of Medicine faculty member (including deans, directors of School of Medicine administrative units, departmental chairs, departmental division directors) is required to report to the Department Chair and Dean's Office all of his/her proposed personal external professional relationships with industry and other entities, written or unwritten in any form, that are covered under this policy (School of Medicine Policy on External Professional Relationships and Reporting: Consulting and Other External Professional Relationships, section B below). Faculty must report the proposed personal external professional relationships as they arise throughout the year (transactionally) and may not agree to, engage in, or receive remuneration for these personal external professional relationships until the Chair and Dean's Office reviews and approves them. As part of the on-line reporting process, each faculty member must complete a certification at least annually that all covered personal external professional relationships, if any, other than traditional academic activities, have been accurately reported. Faculty investigators must also comply with the Emory University Policy 7.7, Policy for Researchers Holding Financial Interest in Sponsored Program, which includes a requirement to report their own significant financial interests in their personal external professional relationships with industry and those of their spouses and dependent children using the Investigator Financial Interest Form (form and details of policy available at <http://www.coi.emory.edu/>).

Approval by the Department Chair and Dean's Office will be contingent ultimately on whether the proposed personal external professional relationship poses a conflict of interest or commitment in the individual's primary duties to the School of Medicine, Emory Healthcare, and other components of Emory University and whether the conflict, if any, can be managed. A formal review by the Emory University Conflict of Interest in Research Committee and/or the Office of Technology Transfer might be

required before final approval can be given. If possible, the Dean's Office will assist the faculty member with problematic issues in the agreement, as part of the prior review. Factors that may be considered in the Chair and Dean's Office reviews include but are not limited to:

- Whether the proposed personal external professional relationship is consistent with the academic and clinical needs of the Department, School, Emory Healthcare, and Emory University;
- Whether the commitment of the faculty member's time to this and other external activities is in keeping with School and Department needs and compliant with all sections of the School of Medicine Policy on Commitment;
- Whether the proposed relationship is compliant with other School of Medicine and Emory University policies, especially the School of Medicine Policy on Consulting and Other External Professional Relationships, the Emory University Intellectual Property Policy, the School of Medicine Policy on Conflict of Interest, and the Emory University Policy for Researchers Holding Financial Interest in Sponsored Program;
- Whether the conflicts of interest and commitment created by the proposed relationship, if any, are manageable;
- Whether the proposed relationship satisfies standards of professionalism and ethics; and
- Whether the proposed relationship is beneficial to the academic career of the individual and Emory.

## **2. Procedure for Staff, Students, and Trainees**

Based on their roles described in research proposals submitted to Emory University, the central offices of Departments may contact and seek additional information about their financial interests in industry and other entities from Emory staff, students, and trainees for submission to the Office of Sponsored Programs and possibly to the University Conflict of Interest in Research Office. Emory School of Medicine staff, students, and trainees must cooperate with these Offices in complying with School and University policies on conflict of interest in research.

School of Medicine staff and trainees must submit in writing to their Department Chairs and Dean, and students must submit to the Dean, their proposals for personal external professional relationships with industry and other entities that are related to their professional expertise and Emory responsibilities and obligations for review and approval prior to agreeing to, engaging in, or receiving compensation for such activities. Consideration will be based on whether the proposed activity creates a real or perceived conflict of interest or commitment under School of Medicine and Emory University policies with the individual's Emory duties and obligations.

[Approved by the School of Medicine Council of Chairs 1996; revised and approved by the Council of Chairs 2001; revised and approved by the Council of Chairs May 2009.]

## **B. Consulting and Other External Professional Relationships**

### **1. Traditional Academic Activities That Usually Are Not Reported**

School of Medicine faculty are encouraged to engage in traditional academic activities (defined below) external to Emory that advance the missions of the School of Medicine, promote the academic programs and goals of the Department and the individual, and benefit the public. The Department Chair may require a faculty member to report his/her traditional academic activities to the Chair for assessment in view of the needs of the Department, Emory Healthcare, and the School of Medicine. Faculty are not required to report these activities in the on-line reporting system for personal external professional relationships or to the Dean's Office, unless otherwise directed. Compensation for

such activities should not exceed \$2,500 per event plus reimbursement for reasonable travel expenses, and in no case may faculty receive the compensation or reimbursement for expenses directly from industry. Faculty are encouraged to be aware of the indirect funding source when possible and should consider whether accepting compensation for presentations named for a particular company or clearly funded indirectly by a single company is appropriate. Faculty who have questions about whether an activity should be reported may contact the Dean's Office.

Examples of traditional academic activities include invited lectures by and at other academic institutions, invited presentations by academic professional associations and societies at their formal meetings and conferences, serving on government advisory panels and grant review bodies, and speaking at ACCME-accredited continuing medical education activities sponsored and managed by and hosted at other academic institutions and academic professional association and society meetings. Compensated speaking and other activities that are sponsored, managed, and/or compensated by for-profit, independent continuing medical education companies or by foundations established by industry might be approved but must be reported to the Department Chair and Dean's Office for review and approval using the on-line reporting system prior to agreeing to, engaging in, or accepting compensation for the activity.

[Approved by the School of Medicine Council of Chairs 1996; revised and approved by the Council of Chairs 2001; revised and approved by the Council of Chairs May 2009.]

## **2. Personal External Professional Relationships That Must Be Reported and Approved in Advance**

The School of Medicine supports principled personal external professional relationships with industry and other entities. The Dean's Office will facilitate these relationships when possible. Pursuant to the School of Medicine Policy on External Professional Relationships and Reporting: Reporting External Professional Relationships and using the on-line reporting system available at <http://www.coi.emory.edu>, School of Medicine faculty must report their proposed personal external professional relationships with industry and other entities, except their traditional academic activities, in advance to the Department Chair and Dean's Office for review and approval prior to agreeing to, engaging in, or accepting remuneration for the activities. Faculty investigators must also comply with the financial reporting requirements specified in Emory University Policy 7.7, Policy for Researchers Holding Financial Interest in Sponsored Program, which includes a requirement to report their own significant financial interests in their personal external professional relationships with industry and those of their immediate family and domestic partners using the Investigator Financial Interest Form (another part of the on-line reporting process), if appropriate for the situation (form and details of policy available at <http://www.coi.emory.edu/>).

To be approved, the proposed personal external professional relationship must advance the missions of the School and Emory University; contribute to the needs of the Department, Emory Healthcare, and other components of Emory University; be clearly related to and within the scope of the expertise of the faculty member; not have unmanageable real or perceived conflicts of interest and commitment; and benefit the public. More details on the criteria for approval are provided in Reporting External Professional Relationships: Procedure for Faculty, section I.A.1.

Agreements between a faculty member and industry or other entities must use the home address of the faculty member, and remuneration must be paid by the external entity directly to the faculty

member, who is acting in his/her private capacity and not as an agent of Emory University. The faculty member is personally responsible if any claims or damages arise from his/her personal external professional relationship. Remuneration in any form must be at fair market value for the services provided by the faculty member, and only reasonable travel expenses may be reimbursed by industry or other entity. These personal external professional relationships with industry and other entities cannot create unmanageable real or perceived conflicts of interest or commitment for Emory.

As detailed in the School of Medicine Policy on Commitment, a faculty member may be permitted up to twenty percent (20%) of his/her professional time for personal external professional relationships with industry and other entities (including travel time) if the agreement (written or unwritten in any form) is approved in advance by the Departmental Chair and the Dean's Office, pursuant to the procedures and policies provided in the School of Medicine Policy on External Professional Relationships and Reporting, and if any resulting conflict of interest and commitment can be managed.

It is not possible to foresee and describe every personal external professional relationship that will arise and provide a policy that addresses it. Faculty should ask the Dean's Office if they have questions about what should be reported and should err on the side of over-reporting. The following sections describe School of Medicine policy on specific examples of personal external professional relationships that might be allowed and must be reported.

**a. Consulting for Industry**

Faculty members should be especially thoughtful about engaging in external consulting activity for industry that is related in any way to their research. Even the most principled compensated consulting activities related to research might constitute a conflict of interest in research, as decided by the University, and might impose restrictions on a faculty member's ability to engage in related areas of research and/or involve students and trainees in areas of conflicted research. Faculty members will be required to eliminate any conflicts of interest in research that cannot be managed effectively and therefore would compromise or prevent them from carrying out their Emory obligations.

School of Medicine faculty members who propose to serve as consultants to industry should keep in mind not only the highest ethical and professional standards in conducting these external activities but also the pertinent School of Medicine and Emory University policies that support the following principles. More details are provided within each policy.

- Faculty are committed to the School of Medicine for 100% of their professional time as a whole and require approval for external employment or engagement (School of Medicine Policy on Commitment: Regarding External Employment).

- The personal external professional (consulting) relationship with industry or other entities may not constitute the practice of medicine; this includes activities involving health-related internet sites (School of Medicine Policy on Commitment: Medical Practice by School of Medicine Faculty).

- The total amount of time a faculty member might be permitted to commit to personal external professional relationships for industry and other entities is 20% of his/her professional time, subject to the authority of the Department Chair (School of Medicine Policy on Commitment: Commitment of Time in External Personal Professional Relationships).

- Final approval and/or conduct of the personal external professional relationship might be subject to reviews and terms that might be imposed by other policies, such as the Emory University Policy for Researchers Holding Financial Interest in Sponsored Program (conflict of interest in research), the policies of the Institutional Review Board on research involving human subjects, and others.

- Emory University has ownership rights in intellectual property generated by its employees, including School of Medicine faculty members, and Emory's rights cannot be assigned to other entities without the approval of the Dean's Office and the Emory University Office of Technology Transfer and subject to the Emory University Intellectual Property Policy.

- Faculty may not involve students and trainees in conflicted research at Emory or in faculty start-up companies (School of Medicine Policy on Supervisory Relationships, Emory University Policy for Researchers Holding Financial Interest in Sponsored Program; Emory University Guidelines for Responsible Conduct of Scholarship and Research).

- Faculty may not use School of Medicine or Emory University resources in their personal external professional relationships, including but not limited to facilities, personnel, letterhead, equipment, funds, supplies, services, and communication networks, without the written authorization of the Department Chair, Unit Head, or Dean (School of Medicine Policy on Use of Emory Resources and several related Emory University policies).

- Faculty may not use Emory's name, logo, or marks in their approved personal external professional relationships for industry and other entities (School of Medicine Policy on Use of Emory's Name, Logo, or Marks).

- Faculty who have personal external financial relationships with industry and other entities that also transact business or compete with Emory (such as companies that are vendors to Emory) cannot participate in Emory or Emory affiliate business decisions concerning those entities (School of Medicine Policy on Vendors, Confidentiality, and Competition with Emory containing numerous examples).

- Officials of the School of Medicine (deans, department chairs, directors of School of Medicine administrative units, department division directors) are held to a higher standard than others and sometimes will not be allowed to participate in personal external professional relationships with industry because of their fiduciary duty to Emory and their status as a role model (School of Medicine Policy on Administrative Actions by Officials of the School of Medicine).

- Many of the principles listed here also apply if the faculty member's immediate family member or domestic partner has a financial interest in industry or other entities that is related to the Emory responsibilities of the faculty member.

Examples of private, external consulting with industry that might be approved include but are not limited to serving on scientific advisory boards to review research on novel products; serving on panels to review and objectively evaluate the data from clinical trials sponsored by industry; developing educational materials for websites that are directed towards the public for health promotion, explanation of diseases, and evidence-based diagnostic and therapeutic measures; advising industry about the structure of clinical trials; and advising industry about the design, appropriate clinical use, or internal research on its products or the direction of its research and development.

#### **b. Serving as an Expert Witness or Providing Legal Consultation**

School of Medicine faculty, staff, students, and trainees usually may serve as expert witnesses in court or provide advice to law firms and may receive compensation and reasonable travel expenses for their services. School of Medicine faculty must report this proposed personal external professional activity in the on-line reporting process, pursuant to the School of Medicine Policy on External Professional Relationships and Reporting: Reporting External Professional Relationships, Procedure for Faculty, to the Department Chair and Dean's Office for review and approval in advance before agreeing to, engaging in, and receiving compensation for the activity. Staff, students, and trainees must inform the School of Medicine Industry Relationships Office in writing of this proposed activity in advance. The scope of work and expected compensation for the proposed activity must be described in

writing by the law firm. When the scope of work is related to their professional expertise and/or their Emory responsibilities, the Industry Relationships Office will consult with the Emory University Risk Management Office and the Office of General Counsel before its final decision about the activity to ensure that the activity is not likely to adversely affect Emory's interests and is compliant with pertinent School of Medicine, Emory Healthcare, and Emory University policies. The activity must be free of any real or perceived conflict of interest or commitment with the responsibilities of the Emory personnel.

**c. Serving as an Officer or Board of Directors Member**

School of Medicine faculty must report in advance proposals to serve as a corporate officer or member of a board of directors for industry or other entities, using the on-line reporting system, pursuant to the School of Medicine Policy on External Professional Relationships and Reporting: Reporting External Professional Relationships, Procedure for Faculty, for review and approval by the Department Chair and Dean, regardless of whether the activity is compensated. Usually if the activity is unrelated to the Emory responsibilities of the individual, and if it does not create a real or perceived conflict of interest or commitment, it will be allowed. Serving as an officer or member of the board of directors or as chair of the scientific advisory board of a start-up company or a company that is not publicly traded in which the School of Medicine faculty or staff member or his/her immediate family member or domestic partner has a financial interest and that is related to the individual's Emory responsibilities usually will not be allowed, although time-limited exceptions might be granted on a case-by-case basis, pursuant to the School of Medicine Policy on Start-Up Companies.

**d. Accepting a Faculty Appointment at Another Institution**

As detailed in the School of Medicine Policy on Clinical and Adjunct (Volunteer) Appointments of School of Medicine Faculty at Other Institutions and the School of Medicine Policy on Joint and Secondary Appointments of School of Medicine Faculty at Other Institutions, requests from School of Medicine faculty to accept voluntary, joint, or secondary appointments at other academic institutions might be approved. Faculty are required to submit proposals for such voluntary faculty appointments to their Department Chairs and Dean for review and approval before engaging in the activity or signing any documents.

[Excerpted from the School of Medicine Guidelines on Appointment, Promotion, and Tenure, last revised 2006.]

**e. Receiving Licenses, Royalties, and Equity**

Pursuant to the School of Medicine Policy on External Professional Relationships and Reporting: Reporting External Professional Relationships, Procedure for Faculty and using the on-line reporting system available at <http://www.coi.emory.edu>, School of Medicine faculty must report their proposed personal external professional relationships with industry and other entities in which they expect to receive royalties or equity or under which they or Emory University is expected to license its Emory-owned technology, as defined in the Emory University Intellectual Property Policy. Faculty must report these relationships in advance to the Department Chair and Dean's Office for review and approval prior to agreeing to, engaging in, or accepting remuneration for the activities.

**f. Forming or Engaging in a Faculty Start-up Company**

As detailed in the School of Medicine Policy on External Professional Relationships and Reporting: Reporting External Professional Relationships, Procedure for Faculty and the School of Medicine Policy and Procedures on Start-up Companies, Founder's Equity, and Similar Activities and using the on-line reporting system available at <http://www.coi.emory.edu>, School of Medicine faculty

must report their proposed personal external professional relationships with their own and other Emory faculty start-up companies in which they have or expect to have a financial interest or under which they or Emory University is expected to license its Emory-owned technology, as defined in the Emory University Intellectual Property Policy. Faculty must report these relationships in advance to the Department Chair and Dean's Office for review and approval prior to agreeing to, engaging in, or accepting remuneration for the activities.

[Approved by the Council of Chairs May 2009.]

### **3. Personal, Professional External Activities with Industry and Other Entities That Are Prohibited**

#### **a. Participating in Speakers Bureaus; Sales and Marketing for Industry**

School of Medicine faculty, staff, students, and trainees may not speak, be panelists, or give presentations in any other form at industry events when the primary purpose of the event is marketing and sales to industry customers, regardless of whether compensation is provided, whether the actual content of the faculty member's or other's presentation is promotional, whether the industry requires oversight of the content and provides materials for the presentation, or whether the event is hosted directly by the industry or by a for-profit, independent entity on behalf of the company. Faculty, staff, students, and trainees are encouraged not to attend such events, but if they choose to do so, they may not receive compensation, gifts, travel expenses, or other forms of remuneration for attending. Such promotional events are not for the primary purpose of presenting evidence-based medical information and do not meet the standards of professionalism expected from School of Medicine personnel. In no such instance will Emory's name, marks, and resources be used in sales and marketing for industry, even in faculty titles. Examples include but are not limited to dinners hosted by industry in restaurants, industry-sponsored events and dinners associated with professional society meetings, and independent industry events for industry customers and clients. When such events are unavoidably centered around a meal, School of Medicine personnel who decide to attend will reimburse the industry for the meal.

[Approved by the Council of Chairs May 2009.]

#### **b. Advising Investment Firms, Matchmakers, Hedge Funds, Investment Bankers, Venture Capital Firms, Brokerage Houses**

Faculty, staff, students, and trainees are prohibited from accepting any remuneration in return for advising representatives of investment companies (including but not limited to investment firms, matchmakers, hedge funds, investment bankers, venture capital firms, and brokerage houses) on the status of areas of research and development, usually within the realm of the individual's professional expertise, whether by telephone or email, in meetings, or otherwise. Directly or indirectly disclosing material, confidential information from a clinical trial prior to publication to individuals or companies that trade stock or advise such companies based on the information is prohibited. Such personal, professional activities are not part of the mission of the School of Medicine. Faculty are encouraged not to participate at all, but if they do, they must report it to the Department Chair and Dean's Office in advance for review and approval, prior to agreeing to or engaging in the activity, using the on-line reporting system available at <http://www.coi.emory.edu>.

[Approved by the Council of Chairs May 2009.]

#### **c. Advising or Creating Materials for Industry on Marketing and Promoting Their**

## **Products; Training Sales and Marketing Representatives on Selling, Marketing, and Promoting Industry Products**

School of Medicine faculty, staff, students, and trainees are prohibited from providing advice to industry or training to the sales and marketing representatives on selling, marketing, or promoting the company's products. Faculty are also prohibited from participating in compensated marketing activities on-line and from producing marketing and promotional materials for industry or for independent, for-profit third parties that produce such materials for industry. When these activities are included in the scope of work in otherwise principled and permissible consulting agreements between industry and faculty members, the Dean's Office will assist faculty in removing these activities from the applicable agreement.

[Approved by the Council of Chairs May 2009.]

### **d. Accepting Remuneration for Listening to Sales Talks or Attending Industry-Sponsored Education and Training**

School of Medicine faculty, staff, students, and trainees are not permitted to accept remuneration, reimbursement, or compensation in any form for listening to sales presentations in person, on-line, or on the telephone from industry representatives, or for attending industry-sponsored activities except as part of an approved personal external professional relationship as a speaker.

[Approved by the Council of Chairs May 2009.]

## **II. SCHOOL OF MEDICINE POLICY ON GIFTS FROM INDUSTRY**

**Overview.** Industry has a long history of generosity in its gifts and donations to medical schools. The funds are important for the support of medical education, biomedical research, and faculty development, helping medical schools achieve new discoveries for the prevention and treatment of disease and support new and ongoing programs in the education of faculty, students, and trainees – all beneficial to improved public health. A large and growing body of evidence, however, shows that gifts from industry elicit feelings of reciprocity that unwittingly influence decision making by institutional and individual recipients. Some gifts and their acceptance, particularly when they establish individual relationships between an individual and a company, are inappropriate in an environment of unbiased education, research, and clinical care.

**Applicability.** The applicability of the policies that make up the School of Medicine *Policy on Gifts from Industry* to School of Medicine faculty, staff, students, and trainees is specified in each component.

**General Policy.** The School of Medicine will accept and use appropriate gifts and donations from industry through a transparent, documented, principled process that protects objectivity in its decision making; helps to prevent the establishment of individual reciprocal relationships with industry; and minimizes the perception and the actuality that gifts are directed to or for the benefit of specific individuals. Information about gifts from industry to the School of Medicine will be coordinated through communications among the School of Medicine Office of Development; School of Medicine Office for Industry Relationships; Emory University, Emory Healthcare, and School of Medicine Purchasing Offices; Emory University Conflict of Interest in Research Office; and Emory Healthcare Compliance Office. This policy on gifts supports the integrity, ethics, and professionalism that School of Medicine faculty, staff, students, and trainees demonstrate to each other and to the public, and thereby promotes the

public trust in the School and its employees and students and in industry.

**A. Gifts from Industry to Individuals in the School of Medicine**

The acceptance of gifts, regardless of the nature, purpose, or value, from industry and from Emory or faculty start-up companies by individual School of Medicine faculty, staff, trainees, and students is prohibited, on and off the Emory campus. Examples include but are not limited to pens, pads, and other promotional items; cash; food and drink; entertainment such as tickets to events, golf, and other sports outings; medical or research equipment, devices, or other products or services or discounts on same; use of company vehicles or vacation facilities; hotels, transportation, and other travel expenses; stocks, equity, and other such financial offerings; group gifts; text books; biological samples; software; computer hardware and accessories; electronic devices such as cell phones, pagers, music and video players, PDAs; consulting, financial, and other services; and office and research supplies.

The acceptance of compensation for travel expenses directly from industry by School of Medicine faculty, staff, students, and trainees is not allowed except under the terms of a personal external compensated professional agreement that has been reviewed and approved by the Department Chair and Dean's Office pursuant to the School of Medicine Policy on External Professional Relationships and Reporting. For example, School of Medicine personnel may not accept gifts, travel funds, reimbursement, or meals to attend activities hosted by industry unless they are speaking at the activity and the agreement has been approved by the Chair and Dean's Office in advance.

[Approved by the School of Medicine Council of Chairs May 2009.]

**B. Gifts of Medications and Pharmaceutical Samples to Individuals**

Individual School of Medicine faculty, staff, students, and trainees may not accept medications and pharmaceutical samples from industry, even when purportedly for use by the individual and colleagues for patient care or education. Further, individual faculty, staff, trainees, and students in the School of Medicine may not accept medications and pharmaceutical samples from industry representatives on behalf of Emory. Pharmaceutical samples may be donated to the Emory Healthcare pharmacy or to the pharmacies of Emory affiliate health care facilities in which School of Medicine personnel provide patient care. If the donation to the health care facility is not possible and patients will be disadvantaged because they do not have access to the medication or drug, the faculty physician should contact the Emory Healthcare/Emory Medical Care Foundation Chief Compliance Officer (<http://www.eushc.org/departments/compliance/index.html> or <http://www.eushc.org/departments/compliance/General/Team.html>) for assistance in arranging patient access to the medication or drug.

Gifts of medications and pharmaceutical samples for clinical use will be centrally managed by Emory Healthcare to ensure that needy patients have timely access to optimal therapeutic care. The policies and procedures that govern the donation and access to donated samples and medications for Emory Healthcare are available at [http://www.med.emory.edu/dean/facultyaffairs\\_policies.cfm#coi](http://www.med.emory.edu/dean/facultyaffairs_policies.cfm#coi). Gifts of medications and pharmaceutical samples for use in research will be centrally managed by the Emory Investigational Drug Service, consistent with Emory University Policy 7.14, Investigational Drug Management for Clinical Studies, found at <http://policies.emory.edu/7.14>.

[ Harmonized with the Emory Healthcare Policy on Pharmaceutical Company Representative Activity (2003) and approved by the School of Medicine Council of Chairs May 2009.]

### **C. Gifts of Funds from Industry to School of Medicine to Support Education and Other Professional Activities**

All gifts of funds from industry to support non-ACCME-accredited education, other educational initiatives, and other professional activities in the School of Medicine must be given centrally through the School of Medicine, Woodruff Health Sciences Center, or University Development Offices and placed in designated pooled accounts used only for receipt of such funds either in the Dean's Office or in the central administrative office of a School of Medicine Department, as appropriate, depending on the nature and purpose of the gift. These funds will be used only for support of non-ACCME-accredited education, other educational initiatives, and other professional activities for School of Medicine students, trainees, and faculty. Receipt, allocation, and use of the funds will be free of real or perceived conflicts of interest or commitment.

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

The transactions for gifts of funds from industry will be documented with signed formal agreements through the School of Medicine Development Office that comply with School and institutional policies. Such gifts will be unrestricted in the sense that the company will have no *quid pro quo*; i.e., in return for the gifts of funds industry will have no expectation of reciprocal returns, such as identification of the company to the individual recipient of the funds, establishment of the fund or gift in the name of the company, use of the Emory name and marks in industry promotional and marketing activities, influence on the curriculum, access to School of Medicine employees and students for marketing and sales, Emory endorsement for company products, a promise to purchase or use industry products, use of Emory facilities and resources by industry or uninvited presence of industry in Emory facilities, services to industry by School of Medicine faculty, associated research or training agreements for industry, and the like.

The Dean's Office and Departments will establish mechanisms for allocation and management of the pooled industry funds free from any form of conflict of interest or commitment or industry influence on decision makers or recipients. Decision makers will not have personal financial relationships with industry donors to the pooled accounts. All reasonable efforts will be taken to ensure that the recipient of industry funds does not know the specific industry source. The Dean's Office or Departments, as appropriate, will select the recipients, initiatives, and professional activities to be supported by these funds without input from industry. Examples of allocations of funds from pooled accounts include support for fellowships and scholarships, sabbaticals for faculty, departmental educational programs and courses, faculty development courses, and faculty and trainee travel expenses to attend meetings. In no case will gifts, funds, unrestricted grants, and the like be accepted directly from industry by individual faculty members, department chairs, or staff for deposit into personal or other external accounts or into departmental, discretionary, School of Medicine, Emory Clinic, Emory Healthcare, or other Emory accounts.

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

[Approved by the Council of Chairs May 2009.]

**D. Donation of Equipment and Devices from Industry**

Gifts of equipment, devices, supplies and the like from industry for use in education, research, and clinical care conducted by School of Medicine faculty must be made centrally to the School of Medicine through the School of Medicine, Woodruff Health Sciences Center, or Emory University Development Offices, as appropriate and consistent with institutional policies. The gift transactions will be documented in formal agreements and managed centrally. Such gifts will be unrestricted in the sense that the company will have no expectation of return benefit, no “*quid pro quo*.” For example, no promise to purchase from the gifting company; to provide any services to or conduct any research for or with the company; to provide any form of reciprocal advertizing or promotion; or to assign Emory intellectual property to the company will be associated with the gift. When the equipment is for teaching a specific non-ACCME-accredited course or use in a particular kind of research or other professional activity, the donor may designate it for that purpose but not for receipt by individuals.

[Approved by the Council of Chairs May 2009.]

**E. Gifts to the School of Medicine from Faculty Related to Their Personal, Professional Relationships with Industry**

The School of Medicine needs and depends upon the generosity of its faculty who contribute funds to support its missions and encourages them to donate to support research and educational initiatives and to support more generally the operation of the medical school and its departments. Faculty may not, however, donate funds or other gifts for the discretionary accounts over which they exercise spending authority and from which they derive direct personal benefit for use in their own research, teaching, and medical services. Faculty who engage in compensated personal external professional relationships with industry may not direct industry to transfer the remuneration from their compensated personal external professional relationships to Emory for their discretionary accounts or for other accounts that directly benefit the faculty member. If faculty arrange for such compensation to be donated by industry to the School of Medicine for other purposes, a formal gift agreement will fully describe the nature of this transaction and will be reviewed for potential conflict of interest.

[Approved by the Council of Chairs May 2009.]

**F. Gifts of Food from Industry**

School of Medicine faculty, staff, trainees, students, departments, and administrative units may not solicit or accept food and drink from industry representatives for School of Medicine activities at Emory or away from Emory.

[Approved by the Council of Chairs May 2009.]

**G. Gifts of Educational Materials to Individuals or Departments in the School of Medicine**

Occasionally books, brochures, and other materials provided by industry are the best available for educating student, trainees, and patients in a particular area. Examples include but are not limited to

illustrated drawings of organ systems and treatises on certain diseases. School of Medicine faculty, staff, students, and trainees, departments, or units that wish to use such materials in their educational activities for Emory must reimburse industry the fair market value for the materials. Emory personnel should disclose the purchase to patients if the materials are used or displayed in a patient care area and to students and trainees if the materials are used in the curricula of the medical school and residency training programs. Faculty physicians should use thoughtful discretion in displaying such educational materials in patient care areas if the names, marks, and logos of the company are easily visible.

[Approved by the Council of Chairs May 2009.]

### **III. SCHOOL OF MEDICINE POLICY ON SITE ACCESS BY INDUSTRY**

**Overview.** The School of Medicine recognizes and appreciates the necessity for faculty and staff to interact with industry in several contexts, including on-site sales and marketing of drugs, equipment, devices, and supplies; on-site training of faculty in new industry devices and equipment purchased by Emory; and on-site education about industry products. When these interactions are conducted in a principled manner that protects the integrity of our research, educational, training, and clinical programs and that protects patients and individual and institutional Emory reputations, they are positive and beneficial in furthering School of Medicine missions of the School of Medicine and benefitting the public. This policy provides guidance to faculty and staff who interact with industry at Emory and in Emory activities elsewhere.

**Applicability.** The applicability of the *School of Medicine Policy on Site Access by Industry* to School of Medicine faculty, staff, students, and trainees is specified in each section of the policy.

#### **A. Access to Emory and Affiliate Buildings and Emory Personnel**

The School of Medicine will not allow industry to use its buildings and other spaces where School of Medicine faculty, staff, students, and trainees work and study for marketing, sales, and promotion. Industry representatives are not permitted in Emory and Emory affiliate buildings or space in which School of Medicine faculty, staff, students, and trainees work and study unless they are invited by a faculty member or authorized senior staff member. Faculty and senior staff members will invite industry representatives only for legitimate sales, servicing (e.g., installation, repair, or removal), demonstration, and training purposes. When the purpose for the invited visit is completed, industry representatives are not permitted to remain in the area and interact with others. Sales, marketing, and other industry representatives are not permitted in patient care and public areas unless they are invited by a faculty member or senior staff member to provide necessary training on devices and equipment or, under limited circumstances and when their expertise is essential, to facilitate a clinical procedure involving a pertinent device, and then they may not engage in sales, marketing, and promotional activities. Industry representatives are not permitted to solicit faculty, staff, students, and trainees for sales, marketing, and promotional purposes or announce promotional events through Emory communication systems or using Emory personnel. School of Medicine Departments, personnel, and administrative offices may not provide mailing lists, email address lists, or other group contact information to industry for use in inviting Emory personnel to promotion activities or for distributing promotional material to School of Medicine personnel. All of the interactions with industry must be free of conflicts of interest and commitment that could compromise the integrity of our research, educational, training, and clinical programs or compromise patient safety and individual and institutional Emory reputations.

#### **1. Invitations to Industry to Train Emory Personnel on Devices and Equipment;**

## **Facilitation of Clinical Procedures by Industry Representatives**

Industry representatives who are invited to Emory by School of Medicine faculty and senior staff members to provide essential education and training of School of Medicine faculty, staff, students, and trainees on devices and equipment used in research, administrative processes, and clinical practice or to provide essential facilitation of clinical procedures will be highly trained and educated in their areas of expertise and appropriately credentialed. Their presence, participation, and credentials must be approved in advance by the School of Medicine or Emory Healthcare, as appropriate. Prior disclosure to the patient and the patient's consent must occur in advance if device and equipment representatives are present during patient care, and representatives will comply with Emory's patient privacy policies, all pursuant to Emory Healthcare policies. Education, training, and clinical care activities described here will be restricted to Emory faculty, staff, students, and trainees.

### **2. Invitations to Industry Representatives to Provide Sales Information and Product Information**

School of Medicine faculty and senior staff members may invite industry representatives to Emory for appointments in non-patient care and non-public areas to provide them with sales and marketing information and information about company products. Individual faculty members and departments may also host periodic structured, faculty-supervised group conferences at which invited industry representatives provide information about and demonstrations of their products in a setting that allows critical interaction and evaluation among the participants. When departments or faculty members host such events, they are encouraged to invite highly educated and trained industry representatives, rather than sales and marketing representatives. These conferences will be restricted to Emory faculty, staff, students, and trainees. Industry representatives who participate would not be permitted to use such conferences directly for sales and marketing purposes.

[Approved by the Council of Chairs May 2009.]

### **B. Interaction of Industry With School of Medicine Students and Trainees**

Learning to have principled interactions with industry is an important component of the education of all School of Medicine students and trainees, and the School places considerable responsibility on the faculty to supervise and to teach and be role models for the ethical and professional standards that govern these interactions. When faculty and senior staff invite representatives to Emory and Emory affiliate buildings and spaces, students and trainees will be included in the invited interactions only for Emory's educational and training purposes and under the supervision of a faculty member. Industry representatives will not be permitted to engage in sales, marketing, and promotional activities with faculty, staff, students, and trainees when they are invited to educational and training events held in Emory and Emory affiliate buildings and spaces.

[Approved by the Council of Chairs May 2009.]

### **C. Solicitation of Emory Patients, Visitors, and Guests by Industry Representatives**

Pursuant to Emory University Policy 4.67, No Solicitation at <http://policies.emory.edu/4.67>, industry representatives are not permitted to solicit or distribute literature to guests, visitors, or patients on Emory University or Emory Healthcare property.

[Excerpted from Emory University Policy 4.67, No Solicitation, last revised June 2007.]

#### **D. Procedure for Industry Representatives to Register**

Pursuant to the Emory Healthcare Vendor Representative Access Policy, industry representatives who are invited by a faculty or senior staff member to an appointment in EHC facilities must be credentialed by and register through the Status Blue system to confirm the appointment and to receive a badge. More details about the procedure are provided in the policy.

Faculty and senior staff members who issue the invitations to industry representatives for access to other buildings in which Emory School of Medicine personnel work or study will instruct them to register either at the departmental central administrative office or at the School of Medicine reception desk in the School of Medicine Building (4<sup>th</sup> floor) to receive a lapel label that permits the visit on the date and for the time and purpose specified on the label.

Industry representatives who do not comply with the Emory Healthcare and School of Medicine policies on access to buildings and space and on permissible interactions with faculty, staff, students, and trainees will be subject to sanctions including warnings to the individual and company; suspension of access and notice to the company; and permanent revocation of access to the representative with notice to the company. In cases of continued abuse by company representatives, the School of Medicine will consider revocation of access to all the company's representatives.

[Harmonized with the Emory Healthcare Policy on Vendor Representative Access, approved by the Council of Chairs May 2009.]

#### **E. Commercial Exhibits in School of Medicine Buildings**

No commercial exhibits, tables, or booths may be set up by industry representatives in School of Medicine Buildings and other Emory and affiliate buildings where School of Medicine faculty, staff, students, and trainees work and study without authorization from the Dean's Office. Authorization will not be given for sales and marketing.

[Approved by the Council of Chairs May 2009.]

### **IV. SCHOOL OF MEDICINE POLICY ON ACADEMIC ACTIVITIES RELATED TO INDUSTRY**

**Overview.** The personal, professional relationships between some faculty and industry have the potential to create conflicts of interest and commitment as these individuals engage in their educational and scholarly activities, including research. ACCME-accredited continuing medical education (CME), non-accredited educational programs, and publication are some of these activities because of the intense interest of industry in each as a means to educate about, promote, and sell industry products.

CME and non-accredited educational programs are valuable to faculty investigators, educators, and clinicians. Both are also subject to potential conflicts of interest because of the opportunity for excessive influence on the integrity of the educational, research, and clinical content of the activities from industry sponsors. Revisions in national and School of Medicine guidelines and policies on continuing medical education are underway. Therefore, this policy currently contains only limited revisions at this time. The current ACCME-compliant School of Medicine policies on CME are available at <http://www.med.emory.edu/CME/index.htm>.

**Definitions.** For purposes of this *School of Medicine Policy on Academic Activities Related to*

*Industry:*

- “Continuing medical education” or “CME” refers to ACCME-accredited educational activities, conducted in accordance with ACCME and School of Medicine policies.
- “Industry-sponsored education” refers to non-ACCME-accredited activities sponsored by industry at which academic faculty give presentations, usually compensated by the industry sponsor, about their research, the status of research in an area, clinical practice in an area, treatment of disease in an area, status of surgical procedures in an area, etc. The activity is not FDA-regulated; the industry sponsor does not prepare, review, or impose restrictions on the content of the presentations; and attendees are free to critically discuss and evaluate the presentations. Nevertheless, the industry sponsor usually engages in sales, marketing, and promotion of its products; often subsidizes, defrays, or reimburses attendees’ expenses; and sometimes compensates them for attending. This form of industry-sponsored education often takes place as satellite symposia at professional society meetings or at independent venues (hotels and resorts).
- “Industry-sponsored training” refers to non-ACCME-accredited activities sponsored by industry, at its headquarters or an independent venue, at which academic faculty and industry sponsor experts provide training on the sponsor’s equipment and devices, often to physicians invited by the company. Faculty who provide the training are compensated. Attendees may be compensated for attending and/or their expenses for attending are defrayed. These activities may be FDA-regulated and the industry sponsor prefers to control the content of the presentations. Sales, marketing, and promotion of the host company’s equipment or device occurs but is also inherent in the activity.
- “Speakers bureaus” are distinguished from industry-sponsored education and training. Speakers bureau presentations are predominantly promotional, regardless of the speakers’ content. Participation as presenters is prohibited for School of Medicine faculty, staff, students, and trainees.

**Applicability.** The applicability of the components of this *School of Medicine Policy on Academic Activities Related to Industry* to School of Medicine faculty, staff, students, and trainees is specified in each.

**A. Ghostwriting**

School of Medicine faculty, staff, students, and trainees must not allow their professional presentations and publications of any kind, written or oral, to be prepared by a ghostwriter, whether from industry or otherwise. Industry investigators, medical writers, and technical experts who contribute to presentations and publications on which School of Medicine faculty, staff, students, or trainees appear as authors must also be listed as contributors or authors, and their industry affiliations must be disclosed in the published document.

[Approved by the Council of Chairs May 2009.]

**B. Participation in Industry-Sponsored Education and Training**

**1. Attending Industry-Sponsored Education and Training Activities**

Potential conflict of interest is problematic in the content of industry-sponsored education and training activities, and also sometimes for the attendee who receives remuneration from the industry sponsor. School of Medicine faculty, staff, students, and trainees who choose to attend industry-sponsored education and training activities and events away from Emory should critically evaluate the programs before attending and the content if they attend. The following apply to School of Medicine faculty, staff, students, and trainees who attend the events:

- They may not accept gifts, compensation, or other forms of remuneration from industry for

attending or for listening if the activity is on-line.

- They may not accept funds or any other form of reimbursing or defraying their expenses for travel to attend the activity.

- They will pay their own tuition for the activity or reimburse the industry sponsor at fair market value for the activity, if possible.

- They will reimburse the industry sponsor if refreshments and meals are an inevitable part of the activity. Faculty should impress upon industry sponsors the necessity for providing fair market tuition bills and tickets for meals and refreshments for such events to assist faculty in avoiding conflicts of interest.

- The industry sponsor will disclose its financial support at the event.

## **2. Speaking and Training at Industry-Sponsored Events; Organizing Industry-Sponsored Events**

A School of Medicine faculty member who wishes to speak or provide training at a non-ACCME-accredited industry-sponsored education or training activity away from Emory must report this external personal, professional relationship in advance to the Department Chair and Dean's Office for review and approval prior to agreeing to, engaging in, or accepting remuneration for the activity. The report must be done as specified in the [School of Medicine Policy on External Professional Relationships and Reporting](#) and using the on-line reporting system available at <http://www.coi.emory.edu>. Faculty who wish organize and present a non-ACCME-accredited industry-sponsored course away from Emory also must report this activity in advance for review and approval using the on-line reporting system. However, individuals who propose to organize such courses should make all reasonable efforts to organize and present the course in compliance with ACCME accreditation policies.

The proposed activity for faculty who wish to be compensated speakers or trainers at industry-sponsored education and training events will be carefully reviewed because of the high potential for conflict of interest in content and participation. The ultimate decision might be contingent on whether any conflict of interest that might be created can be effectively managed.

To receive approval for speaking or training at or organizing a non-ACCME-accredited educational or training event, the following conditions apply:

- Industry-sponsored education and training events will not occur in School of Medicine or other Emory buildings or in Emory affiliates where School of Medicine faculty, staff, students, and trainees work and study.

- The agreement will document that the speaker/trainer will present a balanced assessment of the research and/or therapeutic options and that the attendees and speaker will be able to engage in a critical assessment and evaluation of the topic. Course organizers will ensure the same objectivity for speakers/trainers in the course.

- Preferably the event will have more than one industry sponsor, and possibly an institutional co-host.

- For those who propose to speak or train at such industry-sponsored educational events, the industry sponsor will have no review or control of content and will not provide material (except possibly the equipment or device) to be included in the content. The content for educational activities will not be focused on a single company and its product(s) and will provide evidence-based data and information. For those who propose to organize a course to train other physicians/scientists, the sponsor will not review or control the content, but might provide equipment centrally to the School that is designated for use in the training course, as long as full disclosure to attendees about the donation is made.

- The event must be primarily educational and designed to provide evidence-based medical or scientific information and to promote evidence-based clinical care and/or to advance scientific research.
- The event and content of the speaker's presentation(s) is not FDA-regulated.
- The industry sponsor will fully disclose to attendees its financial support of the activity, and the faculty will not have financial relationships with the sponsor(s) other than the agreement to participate in the educational or training activity.
- School of Medicine speakers may accept reasonable travel expenses, including modestly-valued meals, as part of their compensation for speaking, but may not accept the gift of travel expenses for spouses, dependents, and domestic partners. They may accept an honorarium for speaking or training, not to exceed \$2,500 per event.
- The faculty member will disclose that he/she is receiving compensation for the presentation and will disclose all his/her other related financial interests, current, past, and expected.
- The industry sponsor will not reimburse the travel expenses of other attendees, provide meals and refreshments, or compensate them for attendance.
- Except in faculty titles, Emory's name, marks, resources, and buildings will not be used in connection with the event and Emory will not be an institutional host.
- To the extent possible, the activity and participation will concur with ACCME guidelines.

[Adapted, revised, and approved by the School of Medicine Council of Chairs May 2009.]

### **C. Training at Emory in the Use of Devices and Equipment for Industry Purposes**

The Dean's Office will consider requests from School of Medicine faculty to conduct training courses from time to time for industry's employees and its customers in the use of devices and equipment sold by the company, using Emory facilities and resources. Such activities cannot encroach on the faculty member's academic and clinical duties at Emory and must be approved by the Department Chair and, if appropriate, Emory Healthcare. These training sessions are beneficial to the sales and marketing of company products but are also beneficial to the public in training the non-Emory scientists or physicians who attend to use new equipment or devices to provide more competent patient care or advance research. The School of Medicine is aware of both the need for such training and also the inherent risks that the content might be influenced and that Emory's name and resources might be used to endorse the device or equipment. Therefore, approval to conduct these training courses will be given only with the following requirements:

1. In any training event that includes the implantation of the company's device in a patient or the use of the company's equipment in providing clinical care to a patient, the patient's safety and optimal care will always be the first and highest priority. The patient will be fully informed and will consent to participate in the training session. All reasonable measures will be taken to protect the confidentiality of the patient's identification in connection with the medical record and treatment, consistent with institutional policies and federal regulations. The physician will elect to use the company device or equipment for the particular patient only if the decision is demonstrably evidence-based. Participation in the training session will not expose the patient to greater risk than the performance of the therapeutic measure during usual clinical care. In no case will the training session be based on the off-label use of the company device or equipment or of a device or equipment in which the physician has a financial interest.
2. The training event will be governed by a formal agreement, the terms of which are consistent with all pertinent institutional and School of Medicine policies.
3. The Department Chair will review the activity and approve it before the request is submitted to the Dean's Office. When Emory Healthcare facilities, personnel, and resources are implicated, Emory Healthcare administration will also approve the training activity before submission to

the Dean's Office.

4. Only technical experts from the company will attend and participate in the training session, and they will not engage in sales and marketing activities with other participants on site. They will depart from Emory and Emory-affiliated hospitals as soon as the training event ends and their expertise is no longer required.

5. The School of Medicine faculty members who participate in the training will not have personal external compensated arrangements with the company.

6. On any published material describing the training event and in their introductory comments during the training session, School of Medicine faculty participants will state that (1) the selection of the device or equipment for the particular use or for the particular patient is an evidence-based decision appropriate for the use or for the patient and that the faculty member uses competing devices and equipment for other uses or for other patients when appropriate (if competing devices and equipment are available); (2) the training session and the use of the device or equipment do not imply an endorsement of the sponsoring company, device, or equipment by the faculty member or by Emory University, Emory School of Medicine, or Emory Healthcare; (3) the training session is a fee-for-service activity in which the faculty participants have no personal financial interest; (4) the fees are centrally managed and are not used directly for the benefit of the faculty members; (5) any proceeds, after actual costs are paid, will be managed by a central office and used to support the academic activities of faculty and trainees; and (6) if a patient is involved, the patient gave informed consent.

7. All aspects of the training activities will be consistent with pertinent institutional policies and government regulations.

8. Emory students, fellows, and faculty will not be trained in the use of the device or equipment as part of these particular training activities.

9. The company will have the responsibility for inviting non-Emory individuals to attend, though the Emory faculty participant and the Department Chair reserve the right to review the list of attendees and select those for whom the training at Emory is suitable in advance. The company will manage the terms for attendance of its invitees.

10. The training event will be conducted at Emory for the company as a taxable, fee-for-service activity.

11. The funds received from the company will be reasonable in relation to the services rendered and will include reasonable compensation for the use of Emory facilities, personnel, and resources and reasonable compensation for faculty effort and expertise.

12. Funds received from the company for the training course will be directed to a central fund in the Dean's office for use in support of medical education, faculty research, fellowship salaries, and the like. Independent of the presentation of the training course, faculty may apply to the Dean's office for fund from the central fund to support these and other departmental or divisional academic activities.

13. The company and the School of Medicine faculty participants are not authorized to use the Emory name and marks to advertize the course or in the brochures and internet publications about the course, except that faculty may use their Emory title in the listing of course faculty and the Emory address may be provided for course attendance. Care should be taken to prevent any implied endorsement by Emory or Emory employees of the company or its devices or equipment. In no case will the company use Emory's name to advertize and market its products or the company's name.

#### **D. Disclosure to Medical Students**

School of Medicine faculty who present formal lectures in the School of Medicine undergraduate medical curriculum or residency training programs must disclose all their personal, professional financial relationships with industry in each presentation.

#### **E. Use of Textbooks and Other Educational Materials When the Educator Has a Financial Interest**

When a School of Medicine faculty member has a personal financial interest in a book or other educational materials that he/she wishes to use in the conduct of his/her educational activities at Emory, the Department Chair will form a small, unbiased committee to determine whether the book or other educational material is the most appropriate for the educational activity, compared to similar others. If so, the individual may use the book or other materials with full disclosure of his/her ownership interests.

#### **V. EMORY UNIVERSITY SCHOOL OF MEDICINE POLICY AND PROCEDURES ON START-UP COMPANIES, FOUNDER'S EQUITY, AND SIMILAR ACTIVITIES**

The School of Medicine supports innovative and entrepreneurial activities by the faculty that will benefit the School, Department, and Emory University, as well as the individuals. Such activities must be conducted in compliance with University, School, and government regulations. Any faculty member who is considering participation in founding a start-up company in which there is the intent or expectation that Emory University will license Emory-owned technology to the start-up company ("Emory start-up company") will first submit a written description of the proposed activity to the Department Chair and Dean and receive a preliminary approval to proceed before any further steps are taken. This preliminary approval will allow the faculty member to proceed to more detailed considerations by the Offices of Research Administration and Technology Transfer and, if appropriate, the University Conflict of Interest in Research Committee. The faculty member will then work with the Office of Technology Transfer when structuring the start-up arrangement to avoid foreseeable problems and to allow Emory's participation. When the details are sufficiently clarified, the faculty member must report his/her personal, professional relationship with the proposed start-up company and its business plan, using the on-line process provided at the Emory University Conflict of Interest in Research Office website <http://www.coi.emory.edu/>, to the Department Chair and Dean's Office for review and approval, pursuant to the School of Medicine Policy on External Professional Relationships and Reporting: Consulting and Other External Professional Relationships.

When one or more faculty members in the School of Medicine wish to participate as founders in an Emory start-up company, Emory will have the right to equity in the company. The split of equity between Emory and the founders of the Emory start-up company will be determined prior to the organization of the Emory start-up company on a case-by-case basis by Emory's Office of Technology Transfer. Founders equity issued to School of Medicine faculty who are founders of an Emory start-up company will be issued directly to the Emory founders by the company. Equity received by Emory will be allocated in accordance with Emory's Intellectual Property Policy. No portion of equity received by Emory will be distributed to School of Medicine faculty who have received founder's equity.

Faculty investigator start-up companies involving University intellectual property have inherent conflicts of interest in research because of their equity ownership and potential or actual royalty stream from the licensed invention and potential conflicts of commitment in supervisory relationships, administrative roles, use of Emory resources and name, and time away from Emory responsibilities. These will be reviewed and could result in restrictions on the ability of the faculty member to carry out his/her Emory responsibilities, especially in research. When such conflicts cannot be managed by Emory, the related activities will not be permitted. Therefore, the Dean's Office approval may be subject to the conclusions and directives concerning conflict of interest and commitment.

School of Medicine faculty who are inventors in Emory-owned technology that is licensed to companies or who own equity or have other financial interests in the company are not permitted to be officials or board of director members in the Emory start-up company. As long as the company is privately held, they may not chair the scientific advisory board. Exceptions will be considered on a case-by-case basis during the initial start-up and formation period by the Dean's Office, in consultation with the Emory University Office of Research Administration. Agreements to serve as consultants to the company, including service as a member of the scientific advisory board, must be reported, using the on-line process provided at the Emory University Conflict of Interest in Research Office website <http://www.coi.emory.edu/>, to the Department Chair and Dean's Office for review and approval, pursuant to the School of Medicine Policy on External Professional Relationships and Reporting: Consulting and Other External Professional Relationships.

[Approved by the Council of Chair July 1996; revised and approved by the Council of Chairs January 3, 2000; revised and approved by the Council of Chairs May 2009.]

## **VI. SCHOOL OF MEDICINE GENERAL CONFLICT OF INTEREST POLICY**

School of Medicine faculty, staff, students, and trainees enjoy the trust and confidence of the School and will act in good faith in the best interests of the School in their professional activities as they engage in its missions. These individuals will comply with the Emory University Bylaws, Ethical Principles, Conflict of Interest Policy, Policy for Researchers Holding Financial Interest in Sponsored Program, School of Medicine Policy on Industry and Other External Professional Relationships, and other Emory policies related to conflict of interest. School of Medicine faculty must report all of their personal external professional relationships with industry and other entities and the financial interests of their immediate families and domestic partners related to their Emory responsibilities to the School and University as described in the School of Medicine Policy on External Professional Relationships and Reporting. Staff, students, and trainees also must report their financial interests in industry when requested to do so by the Emory University Conflict of Interest in Research Office.

A conflict of interest, commitment, or both exists when the judgment and/or commitment of an individual faculty or staff member, student, or trainee in carrying out the mission of the School of Medicine might be influenced by the personal external professional relationships that he or she, his/her immediate family members, or his/her domestic partner have with industry and other external entities. The determination of whether Emory personnel have real or perceived conflicts of interest or commitment are made by institutional officials based on the information reported to the School and University by the individuals. School of Medicine faculty, staff, students, and trainees will cooperate with the School and University in managing or eliminating conflicts of interest and commitment that might arise and will not engage in personal external professional relationships and activities that would preclude their ability to carry out their School of Medicine duties because of a conflict of interest or commitment that cannot be managed effectively. School of Medicine faculty and staff will not make decisions on behalf of the School of Medicine or Emory University and will not exert influence regarding any transaction or organization in which they or their immediate family members or domestic partners have a personal financial interest.

[Approved by the School of Medicine Council of Chairs May 2009; in accord with Emory University Bylaws, Ethical Principles, and policies on Conflict of Interest, Policy for Researchers Holding Financial Interest in Sponsored Program, and others.]

#### **A. School of Medicine Policy on Conflict of Interest in Research**

The School of Medicine promotes the highest standards of professionalism and ethics in industry collaborations to protect the integrity of research and the safety of human subjects in research – all of which enhance the public's trust in the institution and in the profession of medicine. Any conflicts of interest in research that might arise in principled collaborations between School of Medicine faculty, staff, students, or trainees and industry will be managed or eliminated, pursuant to School of Medicine and Emory University policies. Therefore, School of Medicine faculty, staff, students, and trainees must comply with Emory University Policy 7.7, Policy for Researchers Holding Financial Interest in Sponsored Program (Emory COI-Research Policy), available at <http://www.policies.emory.edu/7.7> or at the web site for the Emory University Conflict of Interest in Research Office <http://www.coi.emory.edu/>. The details for compliance with this policy are provided at the office link and in the policy. Briefly, the Emory COI-Research Policy and the procedures within and associated with it foster research and technology transfer by providing guidelines and mechanisms for faculty, staff, students, and trainees to work with the School and University to reduce, manage, or eliminate any perceived or actual conflicts of interest in research they might have, based on their financial relationships with industry; and by safeguarding Emory's and Emory investigators' reputation for academic integrity.

Each School of Medicine faculty member must report his/her proposed personal external professional relationships with industry and other entities, as defined in the School of Medicine Policy on External Professional Relationships and Reporting, in advance as they occur throughout the year (transactionally) to the Department Chair and Dean's Office for review and approval, and must not agree to, engage in, or receive remuneration for the relationship until approval is granted. The faculty member must use the on-line reporting process provided at the Emory University Conflict of Interest in Research Office website <http://www.coi.emory.edu>. As part of the on-line reporting process, each faculty member must also complete a certification at least annually that all covered personal external professional relationships, if any, have been reported and all requisite information about each has been accurately provided. Also, using the Investigator Financial Interest Form (another part of the on-line reporting process), the faculty member must report his/her domestic partner's and immediate family's external personal financial relationships with industry that are related to the faculty member's research. When the responses to certain questions in the on-line reporting process indicate to University officials that there is a potential conflict of interest in research, the approval from the Chair and Dean will be contingent on review and action by the Emory University Conflict of Interest in Research Committee.

[Approved by the School of Medicine Council of Chairs in 2006; revised and stated as a separate policy approved by the Council of Chairs in May 2009; in accord with the Emory University Policy 7.7, Policy for Researchers Holding Financial Interest in Sponsored Program.]

#### **B. School of Medicine Policy on Vendors, Confidentiality, and Competition with Emory**

As part of its General Conflict of Interest Policy, the School of Medicine specifically refers faculty, staff, students, and trainees to the Emory University Conflict of Interest Policy, 4.87, available in more detail at <http://policies.emory.edu/4.87>. This policy provides, in part, that Emory employees must report in advance their and their immediate family members' personal professional business and financial relationships that are related to their Emory responsibilities (including clinical duties, course of studies, field of research, or scholarly expertise), pursuant to the *School of Medicine Policy on External Professional Relationships and Reporting*, and must avoid any business or financial relationship, transaction, or event that may be viewed, internally or externally, as a conflict of interest between an employee and contractors, consultants, vendors, suppliers and other third parties. Interactions must be

maintained without any direct or indirect personal or financial benefit accruing to any employee of Emory or any member of the employee's family. Specific circumstances that might constitute a conflict of interest include, but are not limited to, the following:

- Holding, either directly or indirectly, a position or financial interest in an outside concern that provides services competitive with services rendered by Emory, or an outside concern from which Emory secures goods or services if the employee is involved in or may influence the ordering of such goods or services.
- Competing, either directly or indirectly, with Emory in the purchase or sale of property or property rights, interests or services.
- Disclosing or using non-public information obtained through Emory employment for personal profit or gain or for the profit or gain of an immediate family member.
- Accepting gratuities, gifts, or special favors, such as money, meals, travel expenses, hotel accommodations, entertainment, sporting event tickets, etc., from any outside concern that does or is seeking to do business with Emory.
- Extending gratuities or special favors to employees of Emory, under circumstances that might reasonably be interpreted as an attempt to influence the employees in the performance of their duties.
- Retaining, directly or indirectly, consultants who have a financial interest or employment that conflicts with services (including sponsored research) provided by Emory.
- Accepting, soliciting, or offering bribes, kickbacks, payoffs, or other improper incentives or payments from a third party or another employee in the course of Emory employment.

“Financial interests” as used in this policy do not include ownership of interests in diversified investments (e.g., mutual funds, retirement plans) where the employee or consultant does not control investment decisions, nor does it include non-controlling ownership of securities in large, publicly-held corporations unless the activities of the employee or consultant could have an other than inconsequential effect on the value of such securities.

[Approved by the School of Medicine Council of Chairs in 2009; excerpted and expanded from the Emory University Conflict of Interest Policy at <http://policies.emory.edu/4.87> and based in part on Emory University Bylaws, Article IX at <http://www.emory.edu/secretary/governance/bylaws.html>.]

### **C. School of Medicine Policy on Conflict of Interest in Clinical Practice Related to Industry**

School of Medicine faculty physicians and allied health professionals may not receive any form of gift or compensation from industry for prescribing or changing a patient's prescription or for recommending or using a specific diagnostic or therapeutic device.

School of Medicine faculty physicians, allied health faculty, medical students, and trainees must consciously and actively avoid any influence on their clinical care decisions, including their diagnostic and therapeutic decisions, from real or perceived personal or professional benefits they have received or expect to receive from industry.

School of Medicine faculty physicians must not make clinical referrals to non-Emory entities in which they or their immediate family members or domestic partners have a financial interest.

## **VII. SCHOOL OF MEDICINE POLICY ON COMMITMENT**

### **Background**

The primary professional allegiance of School of Medicine faculty and staff is to the School of Medicine and Emory University and its components. Therefore, their professional intellectual endeavors and time are committed to the School's missions in education, scholarship, and service and to the administrative activities that support them. A conflict of commitment occurs when the time, the nature of the activity, or the use of Emory resources in external activities interferes with, compromises, or diminishes the individual's capacity to meet School, Emory Healthcare, and other University responsibilities. The intent of this policy is for the School of Medicine to work with its faculty and staff members to manage any external employment, industry relationships, and even professional volunteer work and service so that appropriate and legitimate external activities do not interfere with primary commitment to the University. Department chairs and the Dean's Office will review the proposed personal external professional relationships reported by the faculty and staff pursuant to the School of Medicine Policy on External Professional Relationships and Reporting prior to the individual's engagement in the activity and will base approvals on the appropriateness of the activity within the context of professionalism and ethics; compliance with School and University policies; the benefit to the individual, the School, and the University; and the amount of time proposed for the activity. The review is coordinated with other Emory Healthcare and University offices, such as Emory University and Emory Healthcare Purchasing, Emory University Conflict of Interest in Research Office, School of Medicine, Woodruff Health Science Center, and Emory University Development Offices, and the Emory University Research Administration Office or its components.

### **Applicability**

The applicability of the sections of the *School of Medicine Policy on Commitment* is specified in each section.

#### **A. School of Medicine Policy Regarding External Employment**

A School of Medicine faculty or staff member is compensated by Emory University and Emory-owned or Emory-approved medical practice plans for 100% of professional time and activity as a whole, through the regular compensation mechanisms. Faculty and staff members who have full-time employment at Emory may not hold full-time appointments or employment of any type in any other organization, except faculty who hold joint appointments in the Atlanta Veterans Affairs Medical Center or a few faculty who receive compensation from Children's Healthcare of Atlanta through specific contractual arrangements between Emory and Children's. Well justified exceptions will be considered in rare and unusual circumstances and will require written approval by the Department Chair or Unit Director and the Dean or designee. Requests for approval for exceptions to this policy will be submitted to the Department Chair and Dean in writing.

Part-time faculty and staff may not hold full- or part-time employment or appointments in external entities if the scope of the external employment or appointment is related to the individual's course of studies, field of research, or scholarly expertise at Emory without prior written approval from the Department Chair and Dean.

[Revised and approved by the School of Medicine Council of Chairs April 1999; revised and approved by the School of Medicine Council of Chairs May 2000; revised and approved by the School of Medicine Council of Chairs May 2009 as a revision and adaptation from the Emory University School of Medicine Policies on Commitment, Private Consulting, and Other Extraordinary Contributions.]

#### **B. School of Medicine Policy on Medical Practice by School of Medicine Faculty**

Compensation earned by School of Medicine faculty for activities that constitute the practice of medicine, including all clinical (patient-care) activities and other activities in which the faculty member performs as a physician, must be through established Emory owned or approved faculty practice plans, such as The Emory Clinic, the Emory Medical Care Foundation, the Children's Heart Center, the Atlanta Veterans Affairs Medical Center, and the Emory Children's Center, and in accordance with the practice plans' individual policies and practices; or through established and approved agreements with Emory owned or affiliated hospitals. Any exceptions must be approved in advance by the Department Chair and the Dean, with the concurrence of the administration of the practice plans and the Emory hospitals.

When a report is made by a faculty member, pursuant to the *School of Medicine Policy on External Professional Relationships and Reporting*, for approval of a private compensated arrangement in which the activity is owning, consulting with, reviewing for, or generating a product for a health-related internet site, the Department Chair and Dean will apply the policy that a faculty member may not engage in the practice of medicine in any capacity outside the Emory-approved practice plans. Examples of the many activities that constitute medical practice on the internet include, but are not limited to, providing information or advice about an individual patient, prescribing treatments for individual patients, and recommending particular physicians in the users' geographical area, generally based on medical specialty. On the other hand, using the internet as an effective means of informing the general public about health promotion, diseases, and diagnostic and therapeutic measures does not constitute the practice of medicine. Such compensated activities must be reported in advance and might be approved. The underlying principle is that such activity is an extension of the public education that physicians have always provided. The faculty member should clearly explain the details of the external activity when the external relationship is submitted to the Department Chair and Dean for review.

[Emory School of Medicine policy last revised May 2000.]

#### **C. School of Medicine Policy on Authority of Department Chairs in Assignment of Duties**

School of Medicine Department Chairs are responsible for the assignment of duties to faculty members with due consideration to the resources of the Department, including sources of compensation.

[Emory School of Medicine policy last revised May 2000.]

#### **D. School of Medicine Policy on Commitment of Time in External Personal Professional Relationships**

Principled and appropriate external personal, professional relationships with industry benefit the public and the missions of the School of Medicine. A faculty member may be permitted up to twenty percent (20%) of his/her time for engaging in such personal external professional relationships that are related to his/her Emory responsibilities (including clinical duties, course of studies, field of research, or scholarly expertise) and that are reported by the faculty member and approved in advance by the Departmental Chair and the Dean, pursuant to the *School of Medicine Policy on Reporting External Professional Relationships*. Compensation at fair market value for such approved private relationships will ordinarily be paid by the external entity directly to the faculty member, who is acting in his/her private capacity and not as an agent of the University. This policy on private personal external professional relationships applies to external entities and does not apply to a faculty member's professional academic and service commitments to the various departments of the School of Medicine or components of the Health Sciences Center or to certain traditional academic activities, for example, services provided to external government agencies and academic professional organizations such as grant

review panels, study sections, invited academic lectureships at other academic institutions, etc. These professional academic and service commitments will be reported to the Department Chair, but reporting to and approval by the Dean's Office will usually not be required. If there is a question about whether to report, faculty are advised to err on the side of reporting.

[School of Medicine policy last revised May 2000.]

#### **E. School of Medicine Policy on Services to Other University Units**

Faculty ordinarily should not expect compensation for limited services rendered to other departments or units of the University. When such compensation is contemplated, approval must be obtained in advance from the Department Chair and the Dean. Seminars, teaching assignments, interdepartmental consultation, etc. usually will, over time, equalize among departments. Joint appointments, which include compensation from the secondary department, require prior approval of the Dean.

[School of Medicine policy last revised May 2000.]

#### **F. School of Medicine Policy on Extra Duty at Emory**

Compensation over and above the faculty member's regular salary may be paid for services that are clearly over and above the faculty member's usual and customary duties and where regular duties are not reduced in recognition of the extraordinary service, with the approval of the Department Chair and Dean. Examples of such instances are:

- Instructing in continuing medical education courses. Note that certain personal expenses paid by the University in conjunction with these programs may be considered a taxable ordinary income to the individual faculty member.
- Providing night coverage for certain clinics.
- Evening at Emory courses.
- Instruction at Morehouse (when paid through Emory).

[School of Medicine policy last revised May 2000.]

#### **G. School of Medicine Policy on Clinical and Adjunct (Volunteer) Appointments of School of Medicine Faculty at Other Institutions**

Faculty in the School of Medicine might be allowed to hold voluntary, non-compensated (adjunct, clinical, honorary) faculty appointments at other academic institutions with the prior written approval of their Department Chairs and the Dean of the School of Medicine, which will be granted only as long as the faculty member's external activities do not interfere with his or her obligations to or breach the policies of Emory University or the School of Medicine and are beneficial to the School. Such approvals might allow School of Medicine faculty to teach, participate in clinical or other professional service activities, or participate in research at other institutions, depending upon the circumstances. School of Medicine faculty who hold volunteer faculty appointments at other academic institutions may not submit research proposals or be listed as compensated investigators on research grants at other institutions or entities. Clinical activities at other institutions may not include medical services billed at the other institution. Voluntary activities, if approved, may not exceed 20% of the faculty member's total professional work, in combination with other personal external professional relationships external to Emory, such as external consulting, without the prior written approval of the Department Chair and Dean. Faculty are required to submit proposals for such voluntary faculty appointments to their Department

Chairs and Dean for review and approval before engaging in the activity or signing any documents.

[Excerpted from the School of Medicine Guidelines on Appointment, Promotion, and Tenure, last revised 2006.]

#### **H. School of Medicine Policy on Joint and Secondary Appointments of School of Medicine Faculty at Other Institutions**

Faculty in the School of Medicine will not hold primary faculty appointments at other institutions. Faculty usually will not hold compensated joint or secondary faculty appointments at other institutions, except in the joint Emory School of Medicine - Georgia Institute of Technology Department of Biomedical Engineering. Exceptions might be made on a case-by-case basis to allow faculty to teach, participate in clinical or other professional service activities, or participate in research at other institutions. Faculty must submit proposals for such exceptions in writing to their Department Chairs and Dean for review and approval prior to agreeing to, engaging in, or accepting compensation for the activity. Approval will be granted only if the arrangement is beneficial to the School of Medicine and if the faculty member's activities do not interfere with his or her obligations to or breach the policies of Emory University or School of Medicine. In such cases, contractual agreements between Emory and the other institution will be required. Faculty may not submit research proposals or be listed as compensated investigators on research grants at other institutions or external entities; contractual arrangements between Emory and the other institution might be feasible to accommodate special research needs and would be required. Clinical activities at other institutions may not include medical services billed at the other institution. In any case, such activities external to Emory must be compliant with other University, School of Medicine, and Emory Healthcare policies.

[Excerpted from the School of Medicine Guidelines on Appointment, Promotion, and Tenure, last revised 2006.]

#### **I. School of Medicine Policy on Use of Emory Resources**

School of Medicine faculty, staff, students, and trainees will use School of Medicine and Emory University resources only for School of Medicine and Emory University activities and functions that are related to their School and Emory responsibilities. Emory resources include, for example, facilities, personnel, letterhead, equipment, funds, supplies, services, and communication networks. Faculty, staff, students, and trainees will not use Emory resources in performing their personal external professional relationships without the written permission of the Department Chair or Unit Head and Dean, in which case the individual will compensate Emory except for *de minimis* use. Examples of personal external professional relationships include but are not limited to activities with industry, law firms as expert witnesses, foundations and other organizations for solicitation of funds for non-University purposes, and personal communications unrelated to the individual's professional Emory responsibilities.

[Approved by the School of Medicine Council of Chairs in 2009 as a restatement of University policy.]

#### **J. School of Medicine Policy on Use of Emory's Name, Logo, or Marks**

School of Medicine faculty, staff, students, and trainees who wish to use Emory's name, logo, or marks in any commercial setting or personal external relationship with industry or other entities must obtain prior approval from Emory. Requests for such approval are submitted to the Vice President for Public Affairs, and a decision will be made in conjunction with the Office of the General Counsel.

[Approved by the School of Medicine Council of Chairs in 2009 as a restatement of University policy.]

#### **K. School of Medicine Policy on Submission of Research Proposals**

Faculty, staff, students, and trainees must submit all their research proposals through administrative channels at Emory if the research is related to the individual's normal professional duties at Emory (including clinical duties, course of studies, field of research or scholarly expertise), except the Veterans Affairs Merit Award and other awards that derive from the VA. Additional information on how to submit grant proposals is available from the Emory University Office of Research Administration <http://www.or.emory.edu/>.

#### **L. School of Medicine Policy on Employment of Relatives (Nepotism)**

No person shall be employed by, transferred to, or promoted into a department or unit of the School of Medicine where a direct supervisory relationship would exist between two relatives. A supervisory relationship exists when either relative could have a direct effect on the other's performance evaluation, salary, schedule, or other working conditions. Hiring officials will adhere to the spirit, as well as the letter, of this policy, to ensure that the basic criteria for employee selection or promotion are the appropriate qualifications of the candidate in terms of education, experience, training, and performance, consistent with Emory's needs. Thus, relationships by family, marriage, or domestic partnership will constitute neither an advantage nor a disadvantage to selection, promotion, salary level, or other conditions of employment. If the special talents, background, or training of the relative would be in the overall interest of the School of Medicine or Emory, the Department Chair or Unit Head may request an exception to this policy by writing the Executive Associate Dean for Administration in the School of Medicine, who will confer with the Dean, appropriate vice president, or the vice president for Human Resources or designee, if appropriate, prior to making any employment decision about the individual.

[Approved by the School of Medicine Council of Chairs in 2009 as a restatement of Emory University Policy on Employment of Relatives at <http://policies.emory.edu/4.11.>]

### **VIII. SCHOOL OF MEDICINE POLICY ON ADMINISTRATIVE ACTIONS BY SCHOOL OF MEDICINE OFFICIALS, FACULTY, AND STAFF RELATED TO THEIR EXTERNAL PROFESSIONAL RELATIONSHIPS WITH INDUSTRY**

**Overview.** The School of Medicine strives for the highest standards of ethics, professionalism, and integrity in its administrative decisions and in its oversight and engagement in its academic programs. Emory University, the Woodruff Health Sciences Center including Emory Healthcare, and the School provide extensive guidance and policy to officials, faculty, and staff to assist them as they carry out their multi-faceted responsibilities in their decision-making and academic engagement. The purpose of this policy is to provide guidance and policy to officials, faculty, and staff who have personal, professional relationships with industry and other entities for their administrative decisions, supervisory roles in the workplace, and educational interactions with students and trainees.

**Applicability.** This policy applies to School of Medicine officials (deans, department chairs, directors of School of Medicine administrative units, and department division directors), faculty, and staff.

#### **A. Administrative Actions by Officials in the School of Medicine**

Officials in the School of Medicine include deans, department chairs, department division directors, and directors of School of Medicine administrative units. Because of their leadership roles, their authority to make important decisions, their fiduciary duty to act in the best interests of the School and University, and their positions as role models for other faculty, staff, trainees, and students, officials are held to an even higher standard of ethics, integrity, professionalism, and objectivity in their decisions and conduct. Officials might not be permitted to engage in some personal, professional relationships with industry that are allowable for others, when actual or perceived conflicts of commitment or interest would result. Officials should always be aware that their decisions may create institutional conflicts of interest in all the missions.

#### **B. Business and Administrative Transactions**

School of Medicine officials, faculty, staff, trainees, and students are referred to the Emory University Policy 4.87 Conflict of Interest at <http://policies.emory.edu/4.87>, which requires all Emory employees to avoid any business or financial relationship, transaction or event that may be viewed, internally or externally, as a conflict of interest between an employee and an outside party. The Emory University By-laws further state that relations between Emory and contractors, consultants, vendors, suppliers, and other third parties are to be maintained without any direct or indirect personal or financial benefit accruing to any employee of Emory or any member of the employee's family.

School of Medicine faculty and staff must report their existing or proposed personal, professional relationships with industry and those of their immediate families and domestic partners according to the instructions provided in the School of Medicine Policy on External Professional Relationships and Reporting: Reporting External Professional Relationships. Faculty and staff must refrain from participating in or influencing any institutional decisions or transactions and disclose their personal external professional relationships to any Emory committee, group, or official that has decision-making authority in the matter if they, their immediate families or domestic partners, or the external entity with which they have the relationship might substantially benefit from the decision. They must also disclose any research or educational interest that they or their department have that might substantially benefit from the decision; the decision-making authority or body will decide whether this interest necessitates recusal by the individual from making or participating in the decision. This policy does not apply to financial interests in investment funds when the individual does not have separate control over the investment in the company.

Examples of situations in which disclosure and recusal would be required include but are not limited to:

1. Having a personal, professional relationship in an outside concern that provides services competitive with services rendered by Emory, or an outside concern from which Emory secures goods or services if the employee is involved in or may influence the ordering of such goods or services.
2. Competing, either directly or indirectly, with Emory in the purchase or sale of property or property rights, interests or services.
3. Disclosing or using non-public information obtained through Emory employment for personal profit or gain or for the profit or gain of an immediate family member.
4. Accepting gifts on behalf of Emory from any outside concern that does or is seeking to do business with Emory. School of Medicine policy prohibits acceptance of personal gifts from industry and other external entities by individuals.
5. Retaining, directly or indirectly, consultants who have a financial interest or employment that conflicts with services (including sponsored research) provided by Emory.

School of Medicine officials, faculty, or staff who have questions about particular personal external professional relationships in relation to their involvement in decision-making at Emory may contact the Dean's Office, the School of Medicine Development Office, the ECH Compliance Office, and the School of Medicine Development for assistance in resolving issues.

### **C. Supervisory Relationships When Supervisors Have External Professional Relationships with Industry**

School of Medicine faculty investigators will not involve students and trainees in their research projects in which the Emory University Conflict of Interest in Research Office has determined that they have a conflicts of interest in research. Faculty will not engage students and trainees in research projects if they are required to keep the results confidential or if there are restraints on their ability to publish and communicate freely.

School of Medicine faculty who have financial interests in industry, including start-up companies, will not involve students and trainees in company projects or employment external to Emory and will not involve students and trainees in Emory research sponsored by the companies.

## **IX. SANCTIONS FOR BREACH OF POLICIES**

The School of Medicine will impose sanctions for violations of the *School of Medicine Policy on Industry and Other External Professional Relationships* or any of its parts. The sanction will in each case depend on the extent of the violation. Less severe sanctions will be imposed when the violations are found to be unintentional, minor, and/or inadvertent and are not part of a pattern of disregard for the policy. Severe sanctions will be imposed when the violation is found to be deliberate and major.

Depending on the nature of the violation and whether the individual is faculty, staff, student, or trianee, the Dean's Office may involve the School of Medicine Faculty Relations Committee, an *ad hoc* advisory committee, or committees specified in the handbooks for students and trainees; the Emory University Research Administration Office, Conflict of Interest in Research Office, Institutional Review Board, Research Compliance Office, or General Counsel's Office; and/or the Emory Healthcare Compliance Office in the inquiry or investigation. A violation might also require application of the Emory University Policy on Research Misconduct or policies from the student and trainee handbooks. An individual who is suspected of a violation will be informed about the process that will be used for the particular inquiry or investigation.

Examples of sanctions that the School of Medicine might impose, singly or in combination, depending on factors such as the nature of the violation, whether the violation is a first or single offense or has occurred before, whether the individual was forthright in reporting the violation, and the impact of the violation on the School of Medicine and Emory University, include but are not limited to:

- Education of the individual about the policy and its principles;
- Written reprimand, placed in the individual's personnel or record;
- Correction of information published by the individual;
- Elimination or restriction of some or all of the individual's personal external professional relationships for a period of time or permanently;
- Payback of remuneration received by the individual to industry or other external entity;
- Further training in aspects of conflict of interest and commitment;
- Prohibition of further supervision of other faculty, staff, students, and/or trainees;

- Restrictions on or prohibition of conducting research;
- Revocation of clinical privileges;
- Removal from administrative positions;
- Fines and or salary reductions or denial of merit pay;
- Suspension, non-renewal of the faculty appointment, or termination; and/or
- Any of the sanctions specified in the student and trainee handbooks .

Appeal of decisions that deny or restrict their participation in a personal, professional relationship with industry or other entities or impose sanctions may be available to School of Medicine faculty, staff, students, or trainees, depending on the procedures and policies that are available to them. Depending on the nature of the sanction, faculty may ask the Dean for reconsideration or may appeal to the Executive Vice President for Health Affairs. They should refer to the School of Medicine Faculty Grievance Procedure and the Emory University Statement on Principles on Faculty Relationships. Staff may ask the Dean for reconsideration and should refer to the Emory University Policies on Employee Relations. Students and trainees may ask the Dean for reconsideration and should refer to their respective Handbooks.

[Approved by the Council of Chairs May 2009.]