

Emory University School of Medicine

Industry and Other External Professional Relationships

Compendium of University and School Policies

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**EMORY UNIVERSITY SCHOOL OF MEDICINE
INDUSTRY AND OTHER EXTERNAL PROFESSIONAL RELATIONSHIPS
Compendium of School and University Policies**

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EMORY UNIVERSITY SCHOOL OF MEDICINE
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Compendium of School and University Policies

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, knowledgeable 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 in carrying out its missions. As part of this commitment, the School supports principled relationships with industry in which its faculty, staff, students, and trainees collaborate with industry on advances in science and medicine that enhance Emory’s missions and are beneficial to the public.

Industry has a long history of principled collaborations with academic faculty that have contributed to our educational, clinical, service, and research missions in ways that 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 primary intent of this policy is to support faculty, staff, students, and trainees in effectively engaging in principled relationships with outside entities. The individual, the School and University can work together to enhance the beneficial outcomes of principled personal external relationships and to prevent situations that might create actual or perceived conflicts of interest and might harm the public, the institution, or the individual.

Definitions. For purposes of this Compendium:

- “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 for and/or sold to 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 VA 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 may include other academic institutions and nonprofit 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.

Applicability

The policies that make up this Compendium apply to School of Medicine faculty, staff, students, and trainees as specified in each component.

I. EXTERNAL PROFESSIONAL RELATIONSHIPS

Overview. The School of Medicine values 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. The School also supports personal external professional relationships with other institutions, medical and scientific professional organizations, and government agencies when they 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 the Department Chair and the Dean's Office. School of Medicine faculty must report personal external professional relationships with industry and other entities, as defined in this policy. Staff, students, and trainees must report personal external professional relationships with industry and other entities that are related to the research projects in which they are involved. All reports must include the financial interests of immediate family members and domestic partners that are related to the reporting party's Emory duties or research. The School of Medicine will assist in managing any associated conflicts of interest or commitment that might arise in permissible personal external professional relationships or in eliminating those that cannot be effectively managed.

A. Reporting External Professional Relationships

1. Procedure for Faculty

Using the on-line process provided at the Emory University Conflict of Interest 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, that are covered under Section B below. Faculty must report each relationship as it arises throughout the year (transactionally) and may not agree to, engage in, or receive remuneration for a relationship until it is reviewed and approved by the Department Chair and the Dean's Office. As part of the on-line reporting process, each faculty member must certify at least annually that all covered personal external professional relationships, if any, have been accurately reported. Faculty investigators must also comply with the Emory University Policy 7.7, Policy for Investigators Holding a Financial Interest in Research, which includes a requirement to report their own significant financial interests in their personal external professional relationships with industry and those of their spouse and dependent children.

Approval by the Department Chair and Dean's Office will be contingent on whether the proposed 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 can be managed. A formal review by the Emory University Conflict of Interest in Research Committee and/or the Office of Technology Transfer may be required before final approval can be given. To the extent feasible, the Dean's Office will assist the faculty member with problematic issues in the agreement, as part of the review. Factors that may be considered in the Chair and Dean's Office reviews include, but are not limited to:

- Whether the commitment of the faculty member's time to this and other external activities is in keeping with School and Department needs, may be beneficial to the academic career of the individual, and is 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, including Emory University Policy 7.6 Intellectual Property Policy, and Emory University Policy 7.7 Policy for Investigators Holding a Financial Interest in Research;

2. Procedure for Staff, Students, and Trainees

Based on the roles of staff, students, or trainees described in research proposals submitted to Emory University, the central offices or Departments may contact the staff, student, or trainee for additional information about the financial interests in industry and other entities for submission to the Office of Sponsored Programs and, when applicable, to the University Conflict of Interest 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 for review and approval to their Department Chairs and Dean, and students must submit to the Dean, proposals for personal external professional relationships with industry and other entities that may create a conflict with their Emory responsibilities and obligations prior to agreeing to or engaging in such activities.

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 (examples provided 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, or 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 to the Dean's Office, unless otherwise directed. Faculty may not receive compensation or reimbursement for expenses associated with an academic activity directly from industry. 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 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 Accreditation Council for Continuing Medical Education (ACCME)-accredited continuing medical education activities sponsored and managed by and hosted at other academic institutions, governmental agencies, and academic professional association and society meetings. Compensated activities that are sponsored and/or managed by for-profit, independent continuing medical education companies or by foundations established by industry must be reported to the Department Chair and Dean's Office for review and approval prior to engaging in or accepting compensation for the activity.

2. Personal External Professional Relationships That Must Be Approved in Advance

School of Medicine faculty must report their proposed personal external professional relationships with industry and other entities, except traditional academic activities (as described above), to the Department Chair and Dean's Office for review and approval prior 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 Investigators Holding a Financial Interest in Research, which includes a requirement to report their own financial interests in their personal external professional relationships with industry and those of immediate family and domestic partners.

Agreements between a faculty member and industry or other entities must provide that remuneration paid by the external entity go 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, and only reasonable travel expenses may be reimbursed by industry or other entity. These 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, Private Consulting, and Other Extraordinary Contributions 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, and if any resulting conflict of interest and commitment can be managed.

a. Consulting for Industry

Faculty members should be aware that even the most principled compensated consulting activities related to research might constitute a perceived conflict of interest in research or clinical service, and might warrant restrictions on a faculty member's ability to engage in related areas of research and/or to involve students and trainees in areas of conflicted research. Faculty members will be required to eliminate conflicts of interest in research or clinical activity that cannot be managed effectively and therefore would compromise or prevent them from carrying out their Emory obligations.

School of Medicine faculty members who propose to serve as consultants to industry should adhere to the highest ethical and professional standards in conducting these external activities, and also the pertinent School of Medicine and Emory University policies that support the following principles.

- Faculty are committed to the School of Medicine for 100% of their professional time as a whole; approval is required for external employment or engagement
- The personal external professional relationship with industry or other entities may not constitute the practice of medicine; this includes individual patient care activities involving health-related internet sites.
- 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 judgment of the Department Chair
- Final approval of the proposed personal external professional relationship may be subject to reviews under and terms of other policies, such as the Emory University Policy 7.7 Policy for Investigators Holding a Financial Interest in Research, the policies of the Institutional Review Board, EHC Compliance Policies, 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 are subject to the Emory University Policy 7.6 Intellectual Property Policy.
- Faculty may not involve students and trainees in conflicted research at Emory or in faculty start-up companies without a management plan approved by the Dean's Office (Emory University Policy 7.9 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. Incidental use of telephone and computer is allowable, and does not require prior authorization.
- School of Medicine faculty and personnel 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 must be made in accordance with the relevant policy-(Emory University Policy 9.2 Use of Emory Name, Logo, or Trademarks/Service Marks).

- Faculty who have personal external financial relationships with industry and other entities that also transact business (such as companies that are vendors to Emory) or compete with Emory cannot participate in Emory or Emory affiliate business decisions concerning those entities (Emory University Policy 2.25 Ethical Guidelines for Procurement Services).
- 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 positions.
- 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 may 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.

b. Serving as an Expert Witness or Providing Legal Consultation

School of Medicine faculty and personnel may be asked to serve as expert witnesses in court or to provide advice to law firms, and may receive compensation and reasonable travel expenses for their services. This proposed activity must be submitted to the Department Chair and Dean's Office for review and approval before agreeing to, engaging in, or receiving compensation for the activity. Details that will be requested for the review include: name and address of the law firm; names of all parties potentially involved in the case; parties on whose behalf the faculty member will be offering testimony; names and/or affiliations of any other expert witnesses, if known; and scope of work and expected compensation.. The Emory University Risk Management Office will review the proposed expert witness/legal consulting activity to ensure that it is compliant with pertinent policies. Failure to obtain Dean's Office approval for an expert witness activity may result in a Reservation of Rights Letter from Clifton Casualty Insurance Company, Ltd.

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, chair of the scientific advisory board, or as a member of a board of directors for industry or other commercial or for-profit entities for review and approval by the Department Chair and Dean, regardless of whether the activity is compensated. If the role is related to the faculty member's Emory responsibilities, these activities with a start-up company or a company that is not publicly traded in which the faculty or staff member or his/her immediate family member or domestic partner has a financial interest may be allowed only for a limited amount of time, generally one year or until the company reaches \$1 million in gross revenue.

d. Accepting a Faculty Appointment at Another Institution

As detailed in the School of Medicine Guidelines for Appointment, Promotion, and Tenure 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 through eCOI to their Department Chairs and Dean for review and approval prior to engaging in the activity or signing any documents.

e. Receiving Licenses, Royalties, and Equity

Using the on-line reporting system, 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 to the Department Chair and Dean's Office for review and approval prior to agreeing to, engaging in, or accepting remuneration for the licensing or other activities.

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

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. 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 Policy 7.6 Intellectual Property Policy. Faculty must report these relationships to the Department Chair and Dean's Office for review and approval prior to engaging in or accepting remuneration for the activities. The review of start-up companies will include analysis of the following policy issues, where applicable and relevant.

- Being a founder of and/or having a financial interest in a start-up company that licenses Emory-owned intellectual property may require restrictions on research that may be related to a start-up company. Faculty will be expected to work closely with the Research Conflict of Interest Office to develop a management plan before grant funds may be accepted, or human subject research may be performed.
- Written documentation, such as a Business Plan or Consulting Agreement, that describes the faculty member's roles and responsibilities with the start-up company should be submitted in support of the Dean's Office review.
- University policy does not allow employees to negotiate with the University on behalf of their own external financial interests and companies.
- Faculty may be permitted to serve as an officer in a start-up company (CEO, COO, CFO, President, Vice-President, Secretary, Treasurer, Chair of the Scientific Advisory Board) on a time-limited basis (usually one year) until a permanent CEO is appointed, or until the company reaches \$1,000,000 in funding.
- Students and trainees (e.g., post-doctoral students) may not be employed by a faculty start-up company while they are in training or employment status at the University.
- Faculty external commitments, including start-up activities, may not exceed 20% of total professional activity.
- Any proposed supervisory relationship between the faculty member and other Emory faculty involved in the start-up company should be reported to the Dean's Office for review and approval.
- Faculty may not use any Emory facilities, resources, or staff in support of a start-up company unless this use is covered under an institutional agreement such as sponsored research or other fee-for-service agreement between Emory and the 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

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, the actual

content of the faculty member's or other's presentation is promotional, the industry requires oversight of the content and provides materials for the presentation, or the event is hosted directly by the industry or by a for-profit, independent entity on behalf of the company. If faculty, staff, students, and trainees choose to attend such events, they may not receive compensation, gifts, food or beverages, travel expenses, or other forms of remuneration for attending. Emory's name, marks, and resources may not 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, and independent industry events for industry customers and clients.

b. Advising Investment Firms

Faculty, staff, students, and trainees are prohibited from 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 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.

c. Advising, Creating Materials or Training for Industry on Marketing and Promoting Products

School of Medicine faculty, staff, students, and trainees are prohibited from providing advice to industry or training sales and marketing representatives on selling, marketing, or promoting a company's products. Faculty are also prohibited from participating in 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 proposed consulting agreements between industry and faculty members, the Dean's Office will assist faculty in removing these activities from the applicable agreement.

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 by industry representatives, or for attending industry-sponsored activities except as part of an approved personal external professional relationship as a consultant.

II. GIFTS FROM INDUSTRY

Overview. Industry has a long history of generosity in its gifts and donations to medical schools. The funds support medical education, biomedical research, and faculty development; help 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. Some gifts and their acceptance, particularly when they establish individual relationships between an individual and a company, may be perceived as unduly influencing mission-related decisions and therefore, inappropriate in an environment of unbiased education, research, and clinical care.

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 Office; and Emory Healthcare Compliance Office.

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

The acceptance of gifts from industry, including faculty start-up companies, by individual School of Medicine faculty, staff, trainees, and students, regardless of the purpose or value, is prohibited. 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 outings; medical or research equipment, devices, or other products or services or discounts on same; use of company vehicles or vacation facilities; travel expenses; stocks, equity, and other such financial offerings; group gifts; textbooks; biological samples; software; computer hardware and accessories; portable electronic devices; 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. For example, School of Medicine personnel may not accept gifts, travel funds, reimbursement, or meals to attend activities hosted by industry unless they are providing services at the activity that have been approved by the Chair and Dean's Office in advance.

Prior to purchasing a product, faculty investigators may accept samples from industry to determine whether the product will meet the needs of their specific research, if the following requirements are met.

- The vendor offering the sample must be an approved Emory vendor.
- The sample would not be ordinarily covered under a Materials Transfer Agreement (MTA).
- The intent of the use of the sample is that the investigator will purchase more if it meets the research needs.

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. 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, and drug company representatives should be directed to EHC Pharmacy. 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 Chief Compliance Officer 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. 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.

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 will be managed centrally through the School of Medicine, Woodruff Health Sciences Center, or University Development Offices and placed in designated pooled accounts either in the Dean's Office or in the central administrative office of a School of Medicine Department, depending on the nature and purpose of the gift. Receipt, allocation, and use of the funds must be free of real or perceived conflicts of interest.

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

The transactions for gifts of funds from industry will be documented with signed agreements through the School of Medicine Development Office that comply with School and institutional policies. Such gifts will be unrestricted in the sense industry will have no expectation of benefit in return, such as identification of the company to the individual recipient of the funds, 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.

The Dean's Office and Departments will manage the pooled industry funds free of conflict of interest or commitment or industry influence on decision makers or recipients. All reasonable efforts will be taken to ensure that the recipient of industry funds does not know the specific industry source. The 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, 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.

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

Industry grants for ACCME-accredited CME activities must be handled by the School of Medicine Office of Continuing Medical Education. For each education grant, there must be a letter of agreement between the School and the corporate entity indicating that the education activity will be planned and implemented without any input from the corporation providing the grant.

D. Donation of Equipment and Devices from Industry

Gifts of equipment, devices, supplies and the like from industry for use in non-ACCME-accredited education, research, and clinical care conducted by School of Medicine faculty will be coordinated centrally by 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 agreements. Such gifts will be unrestricted in the sense that the company will have no expectation of, nor will the company receive, a return benefit.

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

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

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

E. Gifts to the School of Medicine by Faculty

The School of Medicine is grateful for 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 derive direct personal benefit. 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 gift agreement will fully describe the nature of this transaction and will be reviewed for adherence to policies.

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.

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 pay the fair market value for the materials. Faculty physicians should avoid displaying such educational materials in patient care areas if the names, marks, and logos of the company are easily visible, as promotional displays for industry are not allowed in public or patient-care areas.

III. SITE ACCESS BY INDUSTRY

Overview. The School of Medicine recognizes the necessity for faculty and staff to interact with industry in several contexts, including on-site education about new 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 research, education, training, and clinical programs, and that protects patients and individual and institutional reputations, they are positive and beneficial in furthering School of Medicine missions and benefitting the public. This policy provides guidance to faculty and staff who interact with industry at Emory and in Emory activities elsewhere.

A. Access to Emory and Affiliate Buildings

Industry may not use public areas in School of Medicine buildings and other public spaces for marketing, sales, and promotion. Industry representatives are not permitted in Emory and Emory affiliate buildings unless they are invited by a faculty member or authorized senior staff member. Faculty and senior staff members may invite industry representatives only for legitimate sales, servicing (e.g., installation, repair, or removal), demonstration, and training purposes. Industry representatives are permitted in patient care areas only when 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. They may not engage in sales, marketing, and promotional activities at any time before, during or after the training. Industry representatives are not permitted to 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 promotional 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 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

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, and are expected to be highly trained 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 and other 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 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 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 must invite highly 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 are not be permitted to use such conferences for sales and marketing purposes, nor may they provide any gifts, including, but not limited to, food, beverages, and pens.

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

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, to teach, and to serve as 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 on such occasions.

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

Pursuant to Emory University Policy 4.67, Solicitation, industry representatives are not permitted to solicit or distribute literature to guests, visitors, or patients on Emory University or Emory Healthcare property.

D. School of Medicine and EHC Building Access for Industry Representatives

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 Emory Healthcare facilities must be credentialed by and registered through the Status Blue system to confirm the appointment and to receive a badge. More details about the procedure may be obtained from the Emory Healthcare Purchasing Office.

Industry representatives are required to schedule an appointment to meet with a faculty or staff member in a School of Medicine facility.

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 by 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 of the company's representatives.

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 commercial displays in public areas or in patient care areas.

IV. ACADEMIC ACTIVITIES RELATED TO INDUSTRY

Overview. Relationships between faculty and industry may create conflicts of interest and commitment as faculty engage in their educational and scholarly activities. ACCME-accredited continuing medical education (CME), non-accredited educational programs, and publication must be scientifically based and developed independent of industry influence.

ACCME-accredited and non-accredited educational programs are valuable to faculty investigators, educators, and clinicians. The Emory Office of Continuing Medical Education (OCME) is accredited by ACCME to provide continuing medical education to physicians. Educational activities accredited by the OCME are planned and implemented under ACCME policies and the Standards for Commercial Support that eliminate the influence of industry on the content of the activity. When School of Medicine faculty propose to direct a CME activity, they are required to engage Emory's Office of CME to manage the activity; any exceptions to this must be approved by the Dean's Office. 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, 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. This form of industry-sponsored education often takes place as satellite symposia at professional society meetings or at independent venues. Faculty may not participate as a presenter when the activity is determined by the Dean’s Office to be predominantly promotional.
- “Industry-sponsored training” refers to non-ACCME-accredited activities sponsored by industry at which academic faculty and industry sponsor experts provide training on the sponsor’s equipment and devices, often to physicians invited by the company. Faculty who provide the training are compensated.
- “Speakers Bureaus” are distinguished from industry-sponsored education and training in that the content is controlled by industry because of restrictions on discussions related to off-label usage. Speakers’ Bureau presentations are predominantly promotional, and are not required by the FDA. Participation as presenters or speakers is prohibited for School of Medicine faculty, staff, students, and trainees.

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. 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.

B. Participation in Industry-Sponsored Education and Training

1. Attending Industry-Sponsored Education and Training Activities

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 content of the programs before they attend. Faculty, staff, students, and trainees who attend these events may not accept gifts, meals, compensation, or travel expenses or other forms of remuneration for attending or for listening if the activity is on-line.

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

A School of Medicine faculty member who wishes to speak, organize or provide training at a non-ACCME-accredited industry-sponsored education or training activity 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. Individuals who propose to organize such courses should make all reasonable efforts to organize and present the course in compliance with ACCME accreditation policies, and to have the course managed by Emory’s Office of Continuing Medical Education. The proposed activity for faculty who wish to be compensated speakers or trainers at industry-sponsored education and training events will be carefully reviewed. 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 public areas of the 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 between industry and the speaker/trainer 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 outside speakers/trainers in the course, if applicable.
- Preferably the event will have more than one sponsor, and possibly an institutional co-host.
- 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 a full disclaimer to attendees about the equipment is made. The faculty trainer must state that the use of this device does not imply an endorsement of the device by him or her, or by Emory; and should list other devices indicated for this diagnosis or procedure
- 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 content of the presentation is not FDA-regulated relative to off-label use.
- The industry sponsor will fully disclose to attendees its financial support of the activity.
- School of Medicine speakers may accept reasonable travel expenses, including modestly-valued meals, as part of their compensation for approved speaking activities, 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 the fair market value.
- 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.
- Except in faculty titles, Emory's name, marks, resources, and buildings will not be used in connection with the activity.
- To the extent possible, the activity and participation will concur with the ACCME guidelines.

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 at Emory 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 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 to use new equipment or devices to enhance 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 contingent on meeting the following requirements:

- 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 highest priority. The patient will be fully informed and will consent to participate in the training session. The trainees will be required to sign HIPAA-compliance documents 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.

- When Emory facilities will be used and/or an Emory patient will be involved in the training, activity, it will be governed by a written agreement between Emory and the company, the terms of which are consistent with all pertinent institutional and School of Medicine policies.
- 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 involved, Emory Healthcare administration will also approve the activity before submission to the Dean's Office.
- 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. They will depart from Emory and the Emory-affiliated facility as soon as the training event ends and their expertise is no longer required.
- 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: (a) 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); (b) 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; (c) the training session is a fee-for-service activity; and (d) if a patient is involved, the patient gave informed consent.
- All aspects of the training activities will be consistent with pertinent institutional policies and government regulations.
- Emory faculty may not receive compensation from outside industry to train Emory students, fellows, or faculty.
- The company will be responsible 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.
- 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.
- Funds received from the company for the training course will be directed to a central departmental fund for support of medical education, faculty research, fellowship salaries, and the like.
- The company and the School of Medicine faculty participants are not authorized to use the Emory name and marks to advertise 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 advertise 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 will disclose their personal, professional financial relationships with industry in each presentation.

V. 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. These individuals will comply with the Emory University Bylaws, Ethical Principles, Emory University Policy 4.87 Conflict of Interest, Emory University Policy 7.7 Policy for Investigator Holding a Financial Interest in Research, and other Emory policies related to conflict of interest

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 has with industry and other external entities. The determination of whether Emory personnel have real or perceived conflicts of interest or commitment is 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 exert influence regarding any transaction or organization in which they or their immediate family members or domestic partner has a personal financial interest.

A. 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 Investigators Holding a Financial Interest in Research. Other related information may be found at the web site for the Emory University Conflict of Interest Office. Briefly, the Emory Conflict of Interest in Research policies and the procedures within and associated with them 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' reputations for academic integrity.

Each faculty member will complete an Annual Certification to ensure that all external activities and financial relationships related to their Emory roles and responsibilities have been disclosed. Faculty who serve as a Research Investigator must report his/her domestic partner's and immediate family member's external personal financial relationships with industry that are related to the faculty member's roles and responsibilities at Emory. 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, review and action by the Emory University Conflict of Interest in Research Committee may be required.

B. 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 Policy 4.87 Conflict of Interest. This policy provides, in part, that Emory employees 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 be perceived as influencing, 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.

The term "financial interests" as used in this policy does 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.

C. 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.

D. Conflict of Interest in ACCME Accredited Education

School of Medicine faculty serving as instructors in education activities accredited by the OCME must disclose all personal external relationships and any conflicts of interest must be resolved or managed prior to the activity. Presentations at accredited-CME activities must be evidence based and free from commercial bias.

E. Use of Textbooks and Other Educational Materials in Which 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 an ad hoc, unbiased committee to determine whether the book or other educational material is the most appropriate for the educational activity, compared to similar resources. If so, the individual may use the book or other materials with full disclosure of his/her ownership interests.

VI. POLICY ON COMMITMENT

Overview

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 professional volunteer work and service so that appropriate and legitimate external activities do not interfere with primary commitments to the University.

A. 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. Faculty and staff members who have full-time employment at Emory may not hold appointments or employment of any type in any other organization, except faculty who hold joint appointments in the Atlanta Veterans Affairs Medical. Exceptions require written approval by the Department Chair or Unit Director and the Dean. Requests for approval for exceptions to this policy will be submitted to the Department Chair and Dean via the on-line reporting system.

B. Professional Practice by School of Medicine Faculty

Compensation earned by School of Medicine faculty for activities that constitute any clinical profession practiced for Emory, including all clinical (patient-care) activities and other activities in which the faculty member performs as a physician or licensed healthcare professional, 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.

External activities that are part of a health-related internet site which constitute the practice of a clinical profession are not allowed. Examples of activities that constitute medical practice on the internet – and thus are not allowable – include 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. 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. The underlying principle is that such activity is an extension of the public education that healthcare professionals have always provided. The faculty member should clearly explain the details of the external activity when the external activity report is submitted to the Department Chair and Dean for review.

C. 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.

D. 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 to engage in 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. If there is a question about whether to report an external activity, faculty are advised to err on the side of reporting.

E. 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. Joint appointments, which include compensation from the secondary department, require prior approval of the Dean.

F. 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:

- Directing continuing medical education courses
- Evening at Emory courses
- Instruction at Morehouse (when paid through Emory)

G. Adjunct (Volunteer) Appointments of School of Medicine Faculty at Other Institutions

Faculty in the School of Medicine may be allowed to hold voluntary, non-compensated (adjunct, 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 by the other institution. Voluntary activities may not exceed 20% of the faculty member's total professional work, in combination with other personal external professional relationships. 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.

H. 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 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 via the on-line reporting system for review and approval prior to agreeing

to, engaging in, or accepting compensation for the activity. In such cases, contractual agreements between Emory and the other institution may be required. Clinical activities at other institutions may not include medical services billed at the other institution. Such activities external to Emory must be compliant with other University, School of Medicine, and Emory Healthcare policies.

I. 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, except for incidental use, without the written permission of the Department Chair or Unit Head and Dean, in which case the individual may be required to compensate Emory.

J. 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 must be made in accordance with the relevant Emory University Policy 9.2 Use of Emory Name, Logo, or Trademarks/Service Marks.

K. Submission of Research Proposals

Faculty, staff, students, and trainees must submit all 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.ora.emory.edu/>.

L. 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 he/she would have a direct supervisory relationship with a relative. 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 the Dean. (Emory University Policy 4.11, Employment of Relatives)

VII. ADMINISTRATIVE ACTIONS BY SCHOOL OF MEDICINE OFFICIALS, FACULTY, AND STAFF RELATED TO THEIR EXTERNAL PROFESSIONAL RELATIONSHIPS WITH INDUSTRY

Overview. The School of Medicine expects that its officials to adhere to the highest standards of ethics, professionalism, and integrity in its administrative decisions and in its oversight and engagement in its academic programs.

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 a 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 that are allowable for others, when actual or perceived conflicts of commitment or interest would result. Additionally, officials should be aware that their decisions may create institutional conflicts of interest in the missions.

B. Business and Administrative Transactions

School of Medicine officials, faculty, staff, trainees, and students are referred to Emory University Policy 4.87 Conflict of Interest, 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 Emory employee or any member of the employee's family.

Officials must refrain from participating in or influencing any institutional decisions or transactions and must 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 family members 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.

For examples of situations in which disclosure and recusal would be required, see section V.B. of this compendium. 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 for assistance in resolving issues.

C. Supervisory Relationships When Supervisors Have External Professional Relationships which Create a Conflict of Interest

School of Medicine faculty investigators may not involve students and trainees in their research projects in which the Emory University Conflict of Interest Office has determined that the faculty member has a conflict of interest unless it is determined by the Dean's Office to be in the best interest of the student or trainee. If approval is given by the Dean's Office to involve a student or trainee in conflicted research, a management plan will be put into place to minimize or eliminate the supervisory conflict. 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 employment at the start-up company or at the company in which the faculty member has a financial interest.

VIII. SANCTIONS FOR BREACH OF POLICIES

The School of Medicine will impose sanctions for violations of any component of this Compendium. 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/or major.

Depending on the nature of the violation and whether the individual is faculty, staff, student, or trainee, 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 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 7.8, 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 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 or restriction 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;
- 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 that 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.

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

APPENDIX A

Industry Training at Emory Locations

1. Industry representatives must be invited by Emory School of Medicine faculty and/or senior staff members to provide essential education and training. Provide department contact name.
2. The vendor must be an approved Emory University or Emory HealthCare vendor.
3. The activity must be approved in advance by the School of Medicine Dean's Office and/or Emory Healthcare's Office of Compliance, as appropriate. Provide a description of the activity.
4. If a patient is involved in the training, the patient will be fully informed and will consent to participate in the training.
5. The industry representatives must be highly trained and educated in their areas of expertise and appropriately credentialed. Sales representatives may not be present.
6. Attendance at the activity must be restricted to Emory faculty, staff, students and trainees (i.e., no external guests). Community physicians credentialed to practice at Emory hospitals may attend and should pay fair market value for the training.
7. Emory introductory comments should include the following information:
 - a. The selection of the device or equipment is an evidence-based decision;
 - b. The training activity does not imply an endorsement of the device by Emory University or Emory Healthcare, or by the faculty member;
 - c. Faculty participants have no personal financial interest in the activity.
8. Industry will pay reasonable compensation for the use of Emory facilities, personnel, and resources.
9. The setting should allow critical interaction and evaluation among the participants.
10. Industry representatives cannot engage in sales, marketing, and promotional activities during, before, or after the training, nor can the course literature contain promotional information.
11. Industry should be instructed not to provide gifts of any value (meals, pens, magnets, raffle ticket, etc.) as they cannot be accepted. Emory School of Medicine faculty, staff, students & trainees are prohibited from accepting gifts of any kind or value, on-campus and off-campus, for attending the training.
12. School of Medicine personnel may not provide mailing lists, email address lists, or other group contact information to industry for use in inviting Emory personnel to the training activity or for distribution of promotional material to School of Medicine personnel. The sponsoring Department is responsible for communications pertaining to the training program.
13. Training and promotional materials provided by the industry trainers cannot contain sales or marketing information, and should be restricted to the appropriate and necessary training documentation.

These guidelines do not replace the School of Medicine's Industry Relations Policy Compendium.

APPENDIX B

Industry Equipment Provided to Emory for Training

When School of Medicine faculty are offered a loan of equipment or devices from industry to be used in training of faculty, staff, residents or students, the following guidelines apply.

1. The activity must be approved in advance by the Department Chair, the Dean's Office, and Emory Healthcare's Office of Compliance, as appropriate.
2. The faculty trainer will present a balanced assessment of the research and/or therapeutic options, and the attendees will be allowed to engage in a critical assessment and evaluation of the topic with the speaker, including discussion of other approaches to achieve desired clinical outcomes.
3. Information about other devices or equipment that may be available to perform the same procedure should be presented to the trainees. Other vendors' equipment should be made available during the training, if possible.
4. The industry sponsor will not have control of the content and will not provide material (except the equipment or device) to be included in the content.
5. 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.
6. Industry representatives cannot engage in sales, marketing, and promotional activities during, before, or after the training.
7. The audience must be made up of other physicians and/or scientists. No sales or marketing personnel can be present.
8. The faculty member cannot have a financial relationship with the sponsor other than the agreement to participate in the training activity.
9. Emory introductory comments should include the following information:
 - a. The selection of the device or equipment is an evidence-based decision;
 - b. The training activity does not imply an endorsement of the device by Emory University or Emory Healthcare, or by the faculty member;
 - c. Faculty participants have no personal financial interest in the sponsor;
10. Training materials provided by the industry trainers cannot contain sales or marketing information, and should be restricted to the appropriate and necessary training documentation.

These guidelines do not replace the School of Medicine's Industry Relations Policy Compendium.

APPENDIX C

Gifts from Industry

The School of Medicine Policy on gifts from the drug or medical device industry states that gifts may be solicited and accepted by the School for broad areas of interest (such as residency education, faculty development, or research) in broad specialties or large sub-specialties of medicine and science, or in broad topical areas or centers (such as imaging, vaccines, or stroke). These gifts will be placed in pooled accounts with other gifts received for the same purpose from other companies, individuals or charitable organizations. The use of the funds in the pooled accounts will be determined by authorized fund administrators in accordance with University policies and oversight.

The gift policy has two broad goals: to minimize or eliminate feelings of reciprocity by unlinking the donor from the beneficiary of the funds; and to minimize or eliminate the perception or possibility that industry is unduly influencing decisions in research, teaching or clinical care.

The following guidelines are provided for amplification of the policy.

1. Faculty, staff, students and trainees in the School of Medicine may not accept any personal gifts from industry, regardless of value.
2. Medications or pharmaceutical samples cannot be accepted. Company representatives should be directed to the Emory Healthcare Pharmacy.
3. Gifts cannot be solicited or accepted for a specific or distinct activity, such as travel to a particular meeting or funding for a specific speaker or topic.
4. Gifts cannot be accepted to fund a specific fellow or sub-specialty fellowship program.
5. Gifts cannot be accepted for a specific researcher or research lab.
6. There can be no commitment by Emory, or by Emory faculty, staff, students or trainees, of anything in return for a gift, such as patient data, survey or research results, endorsement of a product, or the purchase of products or services.
7. The departmental senior administrators will select the specific activities to be supported by gift funds while keeping within the broad designation of the donor.
8. All gift funds will be expended in accordance with Emory University expense policies, which will allow the use of funds only in support of the missions of the University. All expenditures are subject to the review of the Department and School, as well as internal and external audit by Emory University's Division of Finance and Administration.
9. The use of donated funds for a purpose other than that stipulated by the donor is prohibited.
10. Gifts cannot be accepted for a "named activity" such as the ABC Drug Company Scholars.
11. Departments in the School of Medicine may provide a broad outline to industry of how funds in a pooled account are projected to be used, if requested. Additionally, at the end of a fiscal year, the Department may provide a recap of the broad use of the funds in the pooled account into which a gift was placed. This recap will not identify specific recipients or activities, but will instead describe what broad categories of activity were supported by the pooled fund.

These guidelines do not replace the School of Medicine's Industry Relations Policy Compendium.

APPENDIX D

Clinical Training Sponsored by Industry at Emory Locations

When School of Medicine faculty are asked by the drug or device industry to provide training to other physicians on new procedures, equipment, or devices, the following guidelines apply.

1. The activity must be governed by a formal agreement between Emory and the Company which is approved in advance by the Department Chair, the Dean's Office, and Emory Healthcare, as appropriate. This activity cannot be conducted under a personal agreement between the Faculty Trainer and Industry.
2. If the Faculty Trainer has a financial interest in the industry sponsor, or has research that is related in any way to the sponsor, this must be disclosed to the Dean's Office for review prior to engaging in the training activity.
3. Industry representatives cannot engage in sales, marketing, or promotional activities during, before, or after the training.
4. No sales or marketing personnel may be present in the training.
5. The company must invite the trainees to attend, although the Emory Faculty Trainer and his/her Department Chair reserve the right to review the list of attendees and select those for whom the training at Emory is suitable.
6. Any patient involved must be fully informed and must consent to participate in the training session. (Please refer to Emory HealthCare Policy.)
7. The Faculty Trainer will elect to use the company device or equipment for a particular patient only if the decision is demonstrably evidence-based and is in the best interest of the patient.
8. The Faculty Trainer's introductory comments must include the following information:
 - a. The selection of the device or equipment is an evidence-based decision;
 - b. The training activity does not imply an endorsement of the device by Emory University or Emory Healthcare, or by the Faculty Trainer; and,
 - c. A description of the Faculty Trainer's financial interest in the sponsor, if any.
9. The Faculty Trainer will present a balanced assessment of the clinical information and therapeutic options, and the trainees will be allowed to engage in a critical assessment and evaluation of the topic with the Faculty Trainer.
10. Emory's name and marks will not be used in connection with the training event, other than citing the faculty member's title.
11. Training materials cannot contain sales or marketing information, and should be restricted to the appropriate and necessary training documentation.

These guidelines do not replace the School of Medicine's Industry Relations Policy Compendium.