Emory Healthcare Policy on Relationships with Vendors, Industry and Other External Professional Relationships

- 1. Scope
- 2. Overview
- 3. Applicability
- 4. General Policy
- 5. Gifts/Donations of Food, Lunches, Dinners, Snacks
- 6. Gifts from Industry/Vendors to Individuals at EHC
- 7. Gifts of Funds from Industry to EHC to Support Education and Other Professional Activities
- 8. Donation of Equipment and Devices from Industry
- 9. Gifts of Education Materials to Individuals or Departments
- 10. Attending Industry-Sponsored Education and Training Activities
- 11. Personal External Professional Relationships that Must be Reported and Approved in Advance
- 12. Consulting for Industry
- 13. Sanctions for Breach of Policies

Emory Healthcare Policy on Relationship with Vendors and Industry and Other External Professional Relationships

- 1. Scope. Emory Healthcare and its related entities include, but are not limited to: Emory University Hospital, Emory University Hospital Midtown, The Emory Clinic, Inc., (and CHC) Emory-Children's Center, Inc., Emory Healthcare Corporate Office, Emory Specialty Associates, The Wesley Woods Center for Emory University, Inc., Dialysis Access Centers of Atlanta, and Emory Dialysis and LLC. All are collectively referred to as Emory Healthcare.
- **2. Overview.** Industry, vendors and others we do business with have a long history of generosity of gifts and donations to Emory Hospitals, The Emory Clinic, Wesley Woods and Emory-Children's Center and other Emory Healthcare related entities (EHC). These funds are important for the support of medical education, research, and patient care. They help us achieve new discoveries for the prevention and treatment of disease and support new and ongoing programs in the education of staff, physicians, and students all beneficial to improve the health of the community that we serve.

A large and growing body of evidence supports that gifts from industry and those that we do business with can elicit feelings of reciprocity that unwittingly influence decision making by organizational and individual recipients. Some gifts and their acceptance, particularly when they establish individual relationships between an individual and a company, are inappropriate in an environment of unbiased education, research, and clinical care. Selection of vendors, suppliers, contractors and others that EHC does business with will be made on the basis of objective criteria.

As health care providers that conduct business with government agencies, EHC also must comply with laws governing payment to or from referral sources or sources that produce products that are reimbursed by a federal healthcare benefit program. Items of value received from vendors may be viewed as a reason to conduct business with a particular vendor. Violations of these laws may result in criminal or civil actions against EHC.

The terms Industry, Vendor, Business Associate/Partner may be used interchangeably and includes, but is not limited to, pharmaceutical, device, equipment, biotechnology, service companies, construction companies, consulting companies, financial companies, software companies, suppliers, biomedical investment, and for-profit educational companies and foundations sponsored by companies such as drug and device companies.

3. General Policy. EHC may 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 EHC, including those made from fundraising efforts for EHC facilities, will be coordinated through communications among the Woodruff Health Sciences Office of Development, Emory University, Emory Healthcare, Emory University Conflict of Interest in Research Office, and Emory Healthcare Compliance Office.

This policy on gifts supports the integrity, ethics, and professionalism that EHC staff, nurses, physicians, students, and trainees demonstrate to each other and to the public, and thereby promotes the public trust in EHC and its employees and in industry.

Note: If you are employed by various Emory University entities the most stringent policy will apply to your activities.

4. Gifts/Donations of Food, Lunches, Dinners, Snacks. EHC may not solicit or accept food, lunches, dinners, snacks or the like and/or drink from industry representatives, vendors, or business associates at Emory Healthcare facilities or away from Emory Healthcare facilities. It may be acceptable in some cases to provide reciprocity of meals during extensive meetings or conference.

During holidays individuals or departments might receive unsolicited cookies, candy or gift baskets from vendors. These small tokens may be accepted as long as they are shared within the department. It is recommended that you contact your vendors and those that you may do business with and provide with them our policy and discourage holiday gifts.

- 5. Gifts from Industry to Individuals at EHC. The acceptance of gifts by individuals, regardless of the nature, purpose, or value, from industry is prohibited on and off the Emory campus. Examples include, but are not limited to: pens, pads, and other promotional items, cash, food and drink, entertainment such as tickets to events, golf, and other sports outings, medical or research equipment, devices, or other products or services or discounts, use of company vehicles or vacation facilities, hotels, transportation, and other travel expenses, stocks, equity, and other such financial offerings, group gifts, text books, biological samples, software, computer hardware and accessories, electronic devices such as cell phones, pagers, music and video players, PDAs, consulting, financial, and other services, and office and research supplies. Gifts must be returned to the sender along with a small note Thanks and explanation of our policy and an invitation to contact the Development Office.
- **6. Gifts of Funds from Industry to EHC to Support Education and Other Professional Activities.** All gifts of funds from industry to support education, other educational initiatives, and other professional activities at EHC must be given centrally through the Development Office and placed in designated pooled accounts used only for receipt of such funds as appropriate, depending on the nature and purpose of the gift. Receipt, allocation, and use of the funds will be free of real or perceived conflicts of interest or commitment.

Funds given by industry for 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), 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 and where appropriate may have signed formal agreements through the Development Office. Such

gifts will be unrestricted in the sense that the company will have no *quid pro quo*; i.e., in return for the gifts of funds industry will have no expectation of reciprocal returns, such as identification of the company to the individual recipient of the funds, establishment of the fund or gift in the name of the company, use of the Emory name and marks in industry promotional and marketing activities, influence on the curriculum, access to EHC employees for marketing and sales, EHC 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, nor services to industry by EHC. In some instances it may be appropriate for EHC to have a collaborative relationship with Industry for educational materials and those instances will be reviewed on a case by case basis.

There will be allocation and management of the pooled industry funds free from any form of conflict of interest or commitment or industry influence on decision makers or recipients. Decision makers will not have personal financial relationships with industry donors to the pooled accounts. All reasonable efforts will be taken to ensure that the recipient of industry funds does not know the specific industry source. Management and Development, 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 scholarships, departmental educational programs and courses, staff 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 physicians, employees or staff for deposit into personal or other external accounts or into departmental, discretionary, School of Medicine, The Emory Clinic, Emory Healthcare, or other Emory accounts.

- 7. **Donation of Equipment and Devices from Industry**. Gifts of equipment, devices, supplies and the like from industry for use in education, research, and clinical care conducted at EHC must be made centrally to the WHSC Development Offices, as appropriate and consistent with institutional policies. The gift transactions will be documented in formal agreements, if needed, and managed centrally. Such gifts will be unrestricted in the sense that the company will have no expectation of return benefit, no "quid pro quo." For example, no promise to purchase from the gifting company, to provide any services to or conduct any research for or with the company, to provide any form of reciprocal advertising or promotion, or to assign Emory intellectual property to the company will be associated with the gift.
- 8. Gifts of Educational Materials to Individuals or Departments. Occasionally, books, brochures, and other materials provided by industry are the best available for educating staff, students, trainees, and patients in a particular area. Examples include but are not limited to illustrated drawings of organ systems and treatises on certain diseases. EHC departments, staff, students, and trainees, or units that wish to use such materials in their educational or clinical activities for EHC must reimburse industry the fair market value for the materials. Emory personnel should disclose the purchase to patients if the materials are used. Industry educational material that promotes or markets the drugs, devices or products shall not be provided to patients nor displayed in patient care areas. Educational material that is non-promotional may be used. If there is a question regarding use of industry educational material it should be reviewed by the EHC Conflicts of Interest Committee.

- 9. Attending Industry-Sponsored Education and Training Activities. Potential conflict of interest is problematic in the context of industry-sponsored education and training activities, and sometimes for the attendee who receives remuneration from the industry sponsor. Emory Healthcare employees, physicians, staff, and trainees who choose to attend industry-sponsored education and training activities and events away from Emory should critically evaluate the programs and content before attending. The following apply to EHC employees, physicians, staff, and trainees who attend the events:
 - They may not accept gifts, compensation, or other forms of remuneration from industry for attending or for listening if the activity is on-line.
 - They may not accept funds or any other form of reimbursement or defraying their expenses for travel to attend the activity.
 - They will pay their own tuition for the activity or reimburse the industry sponsor at fair market value for the activity.
 - They will reimburse the industry sponsor if refreshments and meals are an inevitable part of the activity. Employees should impress upon industry sponsors the necessity for providing fair market tuition bills and tickets for meals and refreshments for such events to avoid conflicts of interest.

The acceptance of compensation for travel expenses from industry is not allowed. For example, EHC personnel may not accept gifts, travel funds, reimbursement, or meals to attend activities hosted by industry unless they are speaking at the activity and the agreement has been approved by their manager. A limitation to this section is when a negotiated contract provides for education and includes reasonable cost of travel and meals during the education session.

Employees that attend professional conferences on their own time and at their own expense are strongly discouraged from attending any Industry Sponsored programs that are not provided through conference sponsorship. If the employee in anyway recommends, has the ability to influence or purchases the type of products sold by the vendor the employee may not attend the Industry Sponsored Program.

10. Personal External Professional Relationships That Must Be Reported and Approved in Advance. EHC supports principled personal external professional relationships with industry and other entities. EHC employees must report and gain approval of their proposed personal external professional relationships with industry and other entities in advance from their Department Director or Administrator prior to agreeing to, engaging in, or accepting remuneration for the activities. Any external professional relationships must be reported on the EHC Annual Conflict of Interest Disclosure Statement.

Additionally, any EHC employee involved in clinical trials as an investigator or coinvestigator must also comply with the financial reporting requirements specified in Emory University Policy 7.7, Policy for Researchers Holding Financial Interest in Sponsored Program, which includes a requirement to report their own significant financial interests in their personal external professional relationships with industry and those of their immediate family and domestic partners using the Investigator Financial Interest Form (another part of the on-line reporting process), if appropriate for the situation. The form and policy are available at http://www.coi.emory.edu/). To be approved, the proposed personal external professional relationship must advance the missions of EHC, be clearly related to and within the scope of the expertise of the employee, not have unmanageable real or perceived conflicts of interest and commitment, and must benefit the public.

Agreements between an EHC employee and industry or other entities must use the home address of the employee, and remuneration must be paid by the external entity directly to the employee, who is acting in his/her private capacity and not as an agent of Emory Healthcare. The employee is personally responsible if any claims or damages arise from his/her personal external professional relationship. Remuneration in any form must be at fair market value for the services provided by the employee, and only reasonable travel expenses may be reimbursed by industry or other entity. These personal external professional relationships with industry and other entities cannot create unmanageable real or perceived conflicts of interest or commitment for EHC. Any external activity referred to in this policy shall be conducted on the employee's own time and not attributable to the employee's work effort. Employees may use paid time off.

Employees should ask their manager if they have questions about what should be reported and should err on the side of over-reporting.

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

Employees who propose to serve as consultants to industry should keep in mind not only the highest ethical and professional standards in conducting these external activities, but also the pertinent EHC and Emory University policies that support the following principles.

- Final approval and/or conduct of the personal external professional relationship might be subject to reviews and terms that might be imposed by other policies.
- Emory University has ownership rights in intellectual property generated by its employees, and Emory's rights cannot be assigned to other entities without approval of the Emory University Office of Technology Transfer and subject to the Emory University Intellectual Property Policy.
- Employees may not use EHC 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.
- Employees may not use EHC or Emory's name, logo, or marks in their approved personal external professional relationships for industry and other entities.
- Employees who have personal external financial relationships with industry and other entities that also transact business or compete with Emory (such as companies that are vendors to Emory) cannot participate in Emory or Emory

- affiliated business decisions concerning those entities (<u>School of Medicine Policy on Vendors, Confidentiality, and Competition with Emory</u> containing numerous examples).
- Executive Leadership of EHC are held to a higher standard than others and sometimes will not be allowed to participate in personal external professional relationships with industry because of their fiduciary duty to Emory and their status as a role model (see also School of Medicine Policy on Administrative Actions by Officials of the School of Medicine).
- Many of the principles listed here also apply if the employee's immediate family member or domestic partner has a financial interest in industry or other entities that are related to the Emory responsibilities of the employee.

Examples of private, external consulting with industry that might be approved include, but are not limited to: serving on scientific advisory boards to review research on novel products, developing educational materials advising industry about the structure of clinical trials, and advising industry about the design, appropriate clinical use, or internal research on its products or the direction of its research and development.

13. Sanctions for Breach of Policy. EHC will impose sanctions for violations of this policy or any of its parts. The sanction will in each case depend on the extent of the violation. Less severe sanctions will be imposed when the violations are found to be unintentional, minor, and/or inadvertent and are not part of a pattern of disregard for the policy. Severe sanctions will be imposed when the violation is found to be deliberate and/or major.

Depending on the nature of the violation and whether the individual is faculty, staff, student, or trainee, various departments may be involved in the inquiry or investigation. These might include, but are not limited to, Emory Healthcare Compliance Office, Human Resources, department administrators, an *ad hoc* advisory committee, the Emory University Research Administration Office, Conflict of Interest in Research Office, Institutional Review Board, Research Compliance Office, or General Counsel's Office.

Examples of sanctions:

- Education of the individual about the policy and its principles;
- Written reprimand, placed in the individual's personnel file or record;
- Payback of remuneration received by the individual to industry or other external entity;
- Further training in aspects of conflict of interest and commitment;
- Revocation of clinical privileges;
- Removal from administrative positions;
- Fines and/or salary reductions or denial of merit pay;
- Suspension, non-renewal of the faculty appointment, or termination