

**Title:** Conflict of Interest Regarding Interactions with Industry

## **Standard Operating Procedure**

**PRR General Subject Matter:**

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**Authority:** Brody School of Medicine

**History:** Approved December 3, 2014; Effective January 1, 2015

**Related Policies:** Regulation on Promoting Objectivity in Research funded under Public Health Service Grants or Cooperative Agreements or Contracts (REG10.45.2) <http://www.ecu.edu/PRR/10/45/02>

### **Additional References:**

Pew Charitable Trusts Conflict-of-Interest Policies for Academic Medical Centers report published December 2013 <http://www.pewhealth.org/reports-analysis/reports/conflicts-of-interest-policies-for-academic-medical-centers-85899514090>

AAMC, “In the Interest of Patients: Recommendations for Physician Financial Relationships and Clinical Decision Making” (June 2010), available at [https://services.aamc.org/publications/showfile.cfm?file=version163.pdf&prd\\_id=303&prv\\_id=375&pdf\\_id=163](https://services.aamc.org/publications/showfile.cfm?file=version163.pdf&prd_id=303&prv_id=375&pdf_id=163)

AAMC, “Implementing the Recommendations of the AAMC Task Force on Industry Funding of Medical Education: A Selected Policy Language Compendium,” (June 2010), available at <https://www.aamc.org/download/49708/data/compendium2008.pdf>

**East Carolina University “CONFLICTS OF INTEREST AND COMMITMENT AND EXTERNAL ACTIVITIES OF FACULTY AND OTHER PROFESSIONAL STAFF”**

<http://www.ecu.edu/csacad/fsonline/customcf/currentfacultymanual/part8.pdf>

N.C.G.S. §133-32. Gifts and Favors Regulated

N.C.G.S. §14-234 Public officers or employees benefitting from public contracts

“Transparency Reports and Reporting of Physician Ownership or Investment Interests”. 42 USC §1800, sec. 6002 (2010).

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## 1. Introduction

- 1.1. With the tripartite emphasis on education, scientific investigation, and clinical service at the Brody School of Medicine (BSOM), interaction with representatives of vendors and manufacturers is a frequent occurrence. These interactions provide an opportunity to learn about new products, keep up to date with developments in the professional discipline, and understand how other leading experts have applied new products to their professional work. As a result, faculty, staff, and learners can develop their knowledge and skills, contribute to the growth and development of the group's area of expertise, enhance the department's academic and clinical activities, and improve patient care. These activities must be conducted with the highest ethical standards in a fashion that does not create favoritism, or the appearance of favoritism, or other non-professional and non-objective interactions.
- 1.2. This standard operating procedure (SOP) complements existing University policies related to conflicts of interest and conflict of commitment by providing specifications for BSOM personnel that are relevant to the complexities of the healthcare setting, medical education, and biomedical research.
- 1.3. This SOP applies to all faculty, staff, and learners of the Brody School of Medicine. It is the responsibility of every member of the medical school's community to conduct him or herself in compliance with this SOP and all other relevant institutional policies and regulations.
- 1.4. This SOP is intended to supersede any existing BSOM departmental policies or guidelines on conflict of interest or interactions with industry representatives, as well as any applicable policies or guidelines enacted by other facilities where our employees work or our learners receive education.
- 1.5. If an activity is not specifically mentioned in this SOP, the activity is governed by university policy and applicable state and federal laws and regulations.

## 2. Definitions

- 2.1. Conflict of Interest (COI) exists when financial or other personal considerations, circumstances, or relationships may compromise, may involve the potential for compromising, or may have the appearance of compromising a Covered Individual's objectivity in fulfilling their University duties or responsibilities. The University utilizes the definition of Conflict of Interest specified in the University of North Carolina's Policy on Conflict of Interest and Commitment, *The UNC Policy Manual* 300.
- 2.2. Covered Individual refers to several categories of BSOM-related individuals. First, Covered Individuals include all BSOM EPA employees (Faculty and non-Faculty), SPA employees, and CSS employees. Second it includes any individual, regardless of employment status or type, involved in externally funded University activities including the design, conduct or reporting of research. Third, Covered Individuals include all learners registered in formal educational programs at BSOM, including students, resident physicians, and fellows. Every Covered Individual is required by this SOP to not engage in activities or decisions that create, or could potentially create, or may have the appearance of creating a Conflict of Interest.
- 2.3. Gift refers to any item, product, or service, regardless of the nature, purpose or value thereof. This includes, but is not limited to the following: writing implements, note pads, coffee mugs, calendars, and other promotional items; medication or product samples; vouchers or coupons; food and drink, except within the limited circumstances described in sections 3.1 and 4.1; entertainment such as tickets to events, golf, and other sporting outings; hotels, transportation,

and other travel expenses, except within the limited circumstances described in section 5.1; stock, equity, and other ownership interests; and discounts on any products or services.

- 2.4. Independent Medical Education programs are educational activities on clinical subjects where no Industry influence or interest guides the development of the material presented or the manner in which it is presented.
- 2.5. Industry (or Vendor) refers to any person or company that produces health care goods or services, including pharmaceutical, medical device, medical publishing, or medical equipment company. It also includes any person or company seeking to do or doing business with the Brody School of Medicine or ECU Physicians. A public healthcare entity sponsored by a governmental agency is not considered to be Industry or Vendor.
- 2.6. Speakers' Bureau refers to a situation in which a Covered Individual provides services as a speaker for industry under any of the following circumstances:
  - 2.6.1. The company has the right to dictate or control the content of the material presented;
  - 2.6.2. The company creates the slides or presentation material; or
  - 2.6.3. The Covered Individual acts as a representative of the company to disseminate information from the company.

### **3. Gifts**

- 3.1. Persons covered under this SOP may not accept any gifts from industry representatives (defined as any item, product, or service, regardless of the nature, purpose or value) except in the following specific and limited circumstances:
  - 3.1.1. When provided as part of attendance at independent medical education programs compliant with the requirements of the Accreditation Council for Continuing Medical Education or other nationally recognized accrediting bodies; or
  - 3.1.2. When provided as part of attendance at scientific or professional society meetings where the gift is provided to all attendees of the meeting.
- 3.2. Persons covered under this SOP may not accept compensation in any form for attending marketing programs and cannot attend hospitality events sponsored by industry.

### **4. Food and Drink**

- 4.1. Industry-supplied food or drink are defined under this SOP as personal gifts. This applies to settings both on- and off-campus except as outlined in this SOP.
- 4.2. Participation at industry-sponsored dinner programs, symposia, and meals in clinical settings or associated conference settings, product theaters and similar events that are held independent of professionally organized activities is not permitted.

### **5. Travel Expenses**

- 5.1. Covered Individuals may not accept reimbursement for any travel expense from industry representatives or allow industry representatives to directly pay for any travel expense. This includes, by example only, direct payment or reimbursement for airfare, hotel accommodations, meals, cabfare, entertainment, baggage fees, or other travel expenses, whether routine or unusual in nature.
  - 5.1.1. An exception occurs when a formal contract with the university for a product or item of equipment specifically provides for training or to present information about the product to occur at another site and the expense of travel to that site for directly relevant university employees or learners is covered as part of the contract.

## **6. Educational Scholarships or Events, Training, Visiting Professorships, and Graduate Medical Education**

**6.1.** Industry support for this work can only be provided in the form of unrestricted educational gifts to the ECU Medical & Health Sciences Foundation or one of its accounts. The use of such funds cannot be limited by the gift or beyond general terms, e.g., to support graduate medical education in a specific department, to support development of faculty expertise, and the like.

**6.1.1.** The sponsor of the gift must relinquish in writing any role in decision-making relative to the disbursement of the gift.

**6.2.** In no case can the sponsor of the gift stipulate by name(s) which Covered Individual(s) will receive benefit from the funds, whether directly or indirectly.

## **7. Medical or Educational Equipment or Resources**

**7.1.** Any equipment or resources supplied by an industry representative to support medical or educational activities must be accompanied by a formal letter of agreement that clearly outlines the intent of providing the equipment or supplies. The letter must state that no *quid pro quo* is expected or intended by either party. The letter of agreement must be approved by the academic department chair and signed by an official of the university duly authorized to sign agreements.

**7.2.** Textbooks, journals, software and educational devices may be accepted by an academic department without a letter of agreement if there is nothing in the material that indicates the industry sponsor who provided the material. Hard copy materials and log-in sites must be free of promotional pages, logos, smart tags, and all other references to any industry sponsor.

**7.3.** Patient education materials may be accepted if they are directly relevant to clinical services provided by ECU Physicians and approved for distribution to patients by the Department Chair or designate.

**7.4.** Marketing materials cannot be accepted for distribution to patients.

## **8. Medication Samples**

**8.1.** The acceptance, use, distribution, control, and oversight of medication samples at ECU Physicians sites is not permitted except as outlined in the ECU Physicians Prescription Samples policy in its most recent approved edition.

## **9. Training Assistance**

**9.1** Training for new or existing equipment, supplies or procedures may not be provided by the vendor at the vendor's expense unless the specific aspects of training are included in formal contractual agreement and cost, regardless of whether the training is provided on-site or at another location.

**9.2** Training activities must be clearly differentiated from sales activities.

**9.3** Medical device representatives' presence in ECU Physicians patient care areas is permitted solely to provide training and technical assistance on devices and other equipment already purchased, only with appointment, and only after disclosure to and consent from any patients directly involved.

## **10. Speaking and Training for Vendors**

**10.1** Participation in a Speakers' Bureau (as defined above) is not permitted.

**10.2** Content of training or other educational material must be controlled by the educator.

**10.3** Participation as a trainer in settings where the main purpose of the presentation is to promote a vendor's product or services is not permitted.

**10.4** Participation as a trainer must be conducted in compliance with applicable ECU and UNC requirements, e.g., ECU REG10.45.02 Regulation on Promoting Objectivity in Research funded

under Public Health Service Grants or Cooperative Agreements or Contracts and UNC Policy Manual 300.2.2-Conflicts of Interest and Commitment (and its subparts).

## **11.0 Pharmacy & Therapeutics Review and Purchasing Activities**

**11.1** Participation in Pharmacy & Therapeutics Committee meetings or other settings at ECU Physicians is not permitted if the Covered Individual or any immediate family member have had a personal financial relationship or funded research with a pharmaceutical or device company within the past five years and a related pharmaceutical or medical device is being considered at that setting.

**11.1.1** All members of the ECU Physicians Pharmacy & Therapeutics Committee must submit an annual disclosure of financial relationships with pharmaceutical and medical device companies to the Chair of the Committee, for review by the Medical Director and the Executive Director of ECU Physicians.

**11.2** Industry representatives may only interact with Covered Individuals at ECU Physicians sites or at BSOM facilities when invited for specific educational and scientific discussions that do not involve marketing of any specific product(s). In such instances, at least one BSOM clinical faculty member must be present to supervise the interaction and assist any learners present in judging the veracity and applicability of the information presented, including the use of alternative therapies.

## **12.0 Continuing Medical Education**

**12.1** All continuing medical education (CME) activities sponsored in whole or in part by BSOM must be compliant with applicable requirements of the Accreditation Council for Continuing Medical Education (ACCME).

## **13.0 Ghost Authorship**

**13.1** Covered Individuals may not participate in ghost authorship, i.e., cause or allow to publish any material under their name(s) when the material is principally authored by another individual(s) without including that individual(s)'s name and, as applicable, relationship to any vendor relevant to the material published.

## **14.0 Monitoring**

**14.1** Covered Individuals encountering any situation not specifically permitted by this SOP, or any situation which the Covered Individual is not certain is permitted by this SOP, must provide the Dean of the Brody School of Medicine with a brief description of the situation so the Dean may determine if the situation is permitted, or if it requires a management plan, or if it is not permitted. Whenever possible, this information must be provided to the Dean with sufficient notice to allow reasonable time for the Dean to reach a determination prior to the situation occurring. The description of the situation should provide specifics on the name(s) of the Covered Individual(s) involved, the name of the Industry or Vendor, the nature of the interaction, the type and value of any Gift received, and any other details which will assist the Dean in making a determination. The Dean may consult with relevant other parties to reach a determination.

## **15.0 Disciplinary Action**

**15.1** Any instance of noncompliance with these requirements will be referred to the appropriate University Official for consideration for disciplinary action in accordance with applicable University policies.