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|  | **Policy on Full Disclosure for Continuing Medical Education (CME) Activities** **Policy Number: 3.6.1**  | **Type:** | **TIER 3** |
| **Original Effective Date:** | **October 7, 1991** |
| **Current (Revised) Date:** | **March 1996; March 1998; July 2000; December 2003; March 2005; September 2007; June 2008; March 2012; June 2013; August 2014** |
| **Contact:** | **OFFICE OF CONTINUING MEDICAL EDUCATION** |
| **Approval Signature:** | **Date Approved:** | **09/25/2013** |
| **Typed Name and Title: Edward Abraham, MD, Professor and Dean, Wake Forest School of Medicine** |

1. **General Policy Statement (Entities Affected /Responsible Party for Implementation)**

It is the policy of Wake Forest Baptist Medical Center (WFBMC) to permit Wake Forest University Health Sciences (WFUHS)/Wake Forest School of Medicine (WFSM) to pursue its academic and educational missions with regard to continuing medical education (CME) without undue influence by any individuals or groups associated with these CME activities. It is recognized that faculty and staff – both from WFSM and other institutions – may enter into financial or other materially beneficial relationships with commercial interests. It is important, however, that CME content be based on true, measureable professional practice gaps and resulting learner educational needs – not on the goals or desires of a commercial interest.

A variety of financial relationships between an individual and a commercial interest may raise the issue of a potential conflict in a CME activity. As defined by the Accreditation Council for Continuing Medical Education (ACCME), “financial relationships are those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria for promotional speakers’ bureau, ownership interest, e.g. stocks, stock options or other ownership interest excluding diversified mutual funds or other financial benefit. Financial benefits are usually associated with roles such as employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership and other activities from which remuneration is received, or expected.” Contracted research includes research funding where the institution receives the grant and manages the funds, and the person is the principal or named investigator on the grant. Additionally, relationships of the individual involved in the CME activity: a.) include those of a family member (spouse/partner, parent, sister, brother or child) and b.) do not have a minimum dollar amount for them to be considered significant since inherent in any amount is the incentive to maintain or increase the value of the relationship.

The ACCME considers financial relationships to create actual conflicts of interest in CME when individuals have both a financial relationship with a commercial interest *and* the opportunity to affect the content of CME about the products or services of that commercial interest. This includes content about specific agents/devices, but not necessarily about the class of agents/devices, and not necessarily content about the whole disease class in which those agents/devices are used.

Bias in CME activities may include overstating the performance of a company's product, omitting information about products of competing companies or, more subtly, simply emphasizing a company's product so that learners become most familiar with it.

Although a conflict of interest may create the potential to bias a presentation, it is accepted that most professionals associated with CME do not knowingly bias information. They recognize potential conflicts of interest and put their reputations, their institutions' reputations and their position of trust ahead of personal gain from their relationships with commercial interests. More difficult is the increasing concern that relationships with a commercial interest may change an individual's presentation without the presenter recognizing the bias. Hence, the appearance of bias is an equally important concern, as the mere appearance of a conflict of interest may cast doubt on the objectivity of a presentation and undermine public trust. Full disclosure of conflicting or potentially conflicting interest has been advanced as the primary and usual means to protect the integrity of CME activities.

The perception of a conflict of interest is as important as an actual conflict. Any relationship existing between an individual and a commercial interest that suggests or implies a financial or contractual relationship or one that if brought to public attention would in any way diminish the reputation of the individual, the institution or the commercial interest should be reported to WFUHS/WFSM as the accredited CME provider as well as to the audience participating in the CME activity. In addition, teachers/authors are expected to offer education that is objective, balanced and scientifically rigorous. The OCME will monitor the execution of CME activities to validate the presence or absence of commercial bias and the consistent application of standards of quality education for physicians and other health care providers.

For these reasons and to meet the *Accreditation Requirements of the ACCME*, the following Policy is established and is in effect irrespective of commercial support of a CME activity.

a) Scope: All WFBMC employees, faculty and staff as well as any outside organization/group seeking joint sponsorship for its proposed CME activity are responsible for complying with this policy.

b) Responsible Department/Party/Parties:

1. Policy Owner: Dean, School of Medicine
2. Procedure: Office of CME (OCME) in collaboration with Conflict

 of Interest Office

1. Supervision: Associate Dean, CME
2. Implementation: OCME and CME Committee
3. **Definitions:** For purposes of this Policy, the following terms and definitions apply:
	1. WFBMC: Wake Forest Baptist Medical Center and all affiliated organizations including WFUHS/WFSM, North Carolina Baptist Hospital (NCBH), all on-site subsidiaries as well as those off-site governed by WFBMC policies and procedures.
	2. Policy: As defined in the Policy on Creating and Amending Policy, a statement of principle that is developed for the purpose of guiding decisions and activities related to governance, administration or management of care, treatment, services or other activities of WFBMC. A policy may help to ensure compliance with applicable laws and regulations, promote one or more of the missions of WFBMC, contain guidelines for governance and set parameters within which faculty, staff, students, visitors and others are expected to operate.
	3. CME: The OCME uses the American Medical Association (AMA) House of Delegates’ definition of CME – “educational activities that serve to maintain, develop or increase the knowledge, skills and professional performance and relationships that a physician uses to provide services for patients, the public or the profession. The content of CME is the body of knowledge and skills generally recognized and accepted by the profession as within the basic medical sciences, the discipline of clinical medicine and the provision of health care to the public.”
	4. Financial Relationship: As defined by the ACCME, a relationship in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria for promotional speakers’ bureau, ownership interest, e.g. stocks, stock options or other ownership interest, excluding diversified mutual funds or other financial benefit.
	5. Commercial Interest: Per the ACCME, any entity producing, marketing, re-selling or distributing health care goods or services consumed by, or used on, patients. Providers of clinical services directly to patients, such as WFBMC, are not considered commercial interests.
	6. Conflict of Interest: When an individual has an opportunity to affect CME content about products or services of a commercial interest with which he/she has a financial relationship.
4. **Policy Guidelines**
	1. General Requirements:
		1. It is recognized that WFBMC employees’ participation in CME activities may benefit both the individual and the Institution. However, individuals should carefully monitor their level of support from, and participation in, commercially-supported CME activities. Regular CME with a single commercial supporter may raise concern about the impartiality of the Activity Director, planning committee member, or teacher/author. Similarly, extensive participation in commercially-supported CME activities may reflect adversely on the individual's motives and impartiality and may conflict with commitment of their duties as a WFBMC employee.
		2. All Activity Directors, planning committee members, teachers/authors and others planning or participating in the development and execution of CME activities shall disclose to the OCME any relevant financial relationships between themselves and commercial interests. The ACCME defines “‘relevant’ financial relationships” as financial relationships in any amount occurring within the past twelve (12) months that create a conflict of interest. This disclosure will be primarily accomplished by the completion of a *Full Disclosure Statement* (appended), which will be shared with learners in advance of the CME activity. Presenters are also asked to include disclosure information on the opening slide of the beginning of their presentation(s).
		3. All *Certification Requests for Sponsorship of a CME Activity and AMA PRA Category 1 Credit(s)*TMsubmitted to the CME Committee and OCME for review and approval must include all completed *Full Disclosure Statements* for the Activity Director, Staff Coordinator, and additional planning committee members. *Full Disclosure Statements* for teachers/authors of non-RSS should also be submitted with the *Certification Request* but no later than one month prior to the CME activity start date.
		4. Any individual who refuses to disclose relevant financial relationships will be disqualified from being an Activity Director, planning committee member or teacher/author of CME and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.
		5. When participating in CME activities sponsored by other institutions, faculty and staff shall disclose to the sponsoring institution and CME audience any relevant financial relationships between themselves and a commercial interest.
		6. The content or format of a CME activity and its related materials must promote improvements or quality in health care and not a specific proprietary business interest of a commercial interest. In addition, all CME activities must be compliant with the ACCME statements on Clinical Content Validation:
			* 1. All recommendations involving clinical medicine in a CME activity are based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients.
				2. All scientific research referred to, reported or used in CME in support or justification of a patient care recommendation conforms to the generally accepted standards of experimental design, data collection and analysis.
				3. Education cannot promote recommendations, treatment or manners of practicing medicine that are not within the definition of CME, known to have risks or dangers that outweigh the benefits or known to be ineffective in the treatment of patients.
		7. Educational materials that are part of a CME activity such as slides, abstracts and handouts cannot contain any advertising, trade names or product-group advertising.
		8. Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CME educational material or content includes trade names, trade names from several companies should be used and not just trade names from a single company.

**4) Review/Revision/Implementation**

1. Review Cycle: This Policy shall be reviewed by the CME Committee and the OCME at least every three years from the effective date or as changes in ACCME, AMA, and/or similar accrediting policies/requirements necessitate.
2. Office of Record: After authorization, the OCME shall house this Policy in a policy database and shall be the office of record for this Policy.

**5) Related Policies**

1. *WFBMC Conflict of Commitment and Conflict of Interest Policy*
2. *WFBMC Policy on Identification and Mechanism to Resolve Conflicts of Interest with Commercial Interests for CME Activities*
3. *WFBMC Policy on Commercial Support for CME Activities*

**6) Governing Law or Regulations**

1. *The Accreditation Requirements of the ACCME*
	* 1. *Accreditation Criteria*
			+ 1. Criterion 7
				2. Criterion 8
				3. Criterion 9
				4. Criterion 10
		2. *Standards for Commercial Support: Standards to Ensure Independence in CME Activities*
			+ 1. Standard 1: Independence
				2. Standard 2: Resolution of Personal Conflicts of Interest
				3. Standard 3: Appropriate Use of Commercial Support
				4. Standard 4: Appropriate Management of Associated Commercial Promotion
				5. Standard 5: Content and Format Without Commercial Bias
				6. Standard 6: Disclosures Relevant to Potential Commercial Bias
		3. *ACCME Policies and Definitions*
2. *AMA Physician’s Recognition Award and Credit System: Information for Accredited Providers and Physicians – 2010 Revision*
3. *AMA Code of Medical Ethics*
4. 8.061 Gifts to Physicians from Industry
5. 9.011 Continuing Medical Education

**7) Attachments**

* *Full Disclosure Statement for CME Leadership and Staff, CME Committee Members, Activity Directors, Staff Coordinators, Planning Committee Members and Teachers/Authors*
* *The Accreditation Requirements of the ACCME*
* *AMA Physician’s Recognition Award and Credit System: Information for Accredited Providers and Physicians – 2010 Revision*
* *AMA Code of Medical Ethics*
	+ 8.061 Gifts to Physicians from Industry
	+ 9.011 Continuing Medical Education



**OFFICE OF CONTINUING MEDICAL EDUCATION**

***Full Disclosure Statement for CME Leadership and Staff, CME Committee Members, Activity Directors, Staff Coordinators, Planning Committee Members and Teachers/Authors***

**PART I:**

*It is the policy of Wake Forest School of Medicine (WFSM) to ensure balance, independence, objectivity and scientific rigor in all sponsored or jointly sponsored educational activities. All individuals participating in WFSM-sponsored CME activities are expected to disclose to participants any real or apparent conflict(s) of interest that have a direct bearing on the subject matter of the CME activity. This pertains to relationships with pharmaceutical companies, biomedical device manufacturers or other commercial interests whose products/services are related to the subject matter of the educational topic. This also pertains to relationships with the commercial supporter(s) of the CME activity. The intent of this policy is not to prevent individuals with a potential conflict of interest from participating; it is merely intended that any potential conflict should be openly identified so that CME participants may form their own judgments with full disclosure of the facts. It remains for the audience to determine whether an individual’s outside interests may reflect a possible bias in either the exposition or the conclusions presented.*

**CME Activity Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**CME Activity Date(s):** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **CME Activity Location (*as applicable*):** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Your Name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Your Role in the CME Activity**, ***e.g. Activity Director, Staff Coordinator, Planning Committee Member, Teacher/Author, etc.*:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Content Area(s), *e.g. title of presentation(s), topic(s), etc. (as applicable)*:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**[ ]**  ***Yes, I have something to disclose,*** meaning I (or an immediate family member including spouse/partner, parent, sister, brother or child) have at present and/or have had within the last 12 months or know of an anticipated financial relationship with one or more commercial interests/organizations that could be perceived as a real or apparent conflict of interest in the context of the subject(s) of this CME activity. (*Please note when the case involves a family member.*)

**Financial Relationship(s): Name of Commercial Interest(s)/Organization(s):**

Grant/Research Support \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Consultant \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Speakers’ Bureau \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Stock Shareholder/Ownership \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Other Financial or Material Support \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(*include details/description*)

Company Officer/Board of Directors \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**If you have disclosed financial relationships, please answer the following questions.**

1. For each relationship, what is the specific area of content that you are involved with (e.g. t-PA for stroke, treatment for ischemic heart disease, development of medical devices)? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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2. What products for the company are involved (if any) or related to the above areas? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

3. In what way does this content relate to the planned activity? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**[ ]**  ***No, I have nothing to disclose,*** meaning I (or an immediate family member including spouse/partner, parent, sister, brother or child) have at present and/or have had within the last 12 months or anticipate ***NO*** financial relationship with one or more commercial interests/organizations that could be perceived as a real or apparent conflict of interest in the context of the subject(s) of this CME activity.

**PART II:**

The *Accreditation Requirements of the Accreditation Council for Continuing Medical Education (ACCME)* stipulate:

STANDARD 2: Resolution of Personal Conflicts of Interest

* 1. The provider must be able to show that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any commercial interest to the provider. The ACCME defines “‘relevant’ financial relationships” as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.
	2. An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher or an author of CME and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.
	3. The provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners.

In order to meet these standards and the *WFBMC Policy on Full Disclosure for CME Activities*, you must agree to the following:

*I have read the WFBMC Policy on Full Disclosure for CME Activities and Standard 2 of the Accreditation Requirements of the ACCME and hereby attest that the relationship(s) with commercial interests I have duly disclosed will not influence or bias my presentation and/or planning of the CME activity. I will adhere to the principle that information presented to the learner must be unbiased, scientifically balanced and based on best evidence and best practices in medicine. Additionally, I agree to disclose when products/services are not labeled for the use under discussion or when the product/service is still under investigation. I understand that the information I have listed on this form will be shared in advance with the audience of this CME activity. Further, I will only accept honorarium/payment/reimbursement related to this CME activity from WFSM or the joint sponsor (with the full knowledge and approval of WFSM), agree to obtain all necessary copyright permissions and attest that my material will be compliant with the U.S. Health Insurance Portability and Accountability Act (HIPPA).*

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 **Signature Date**

**Please return both pages of this form to: Office of Continuing Medical Education**

**Wake Forest School of Medicine**

**Medical Center Blvd.**

**Winston-Salem, NC 27157-1028**

**Telephone: 336-713-7700**

**Fax: 336-713-7701**

**Email:** **@wakehealth.edu**

[**www.wakehealth.edu/cme**](http://www.wakehealth.edu/cme)