Wake Forest™
School of Medicine

Office of Continuing Medical Education

POLICY ON IDENTIFICATION AND MECHANISM TO RESOLVE CONFLICT OF INTEREST WITH COMMERCIAL SUPPORT

BACKGROUND:

This policy is designed to ensure quality, objective, balanced, and scientifically rigorous Wake Forest School of Medicine (WFSM) sponsored or jointly sponsored continuing medical education (CME) activities by identifying and managing all potential conflicts of interest. The undesirable outcome of conflicts of interest is the introduction/demonstration of bias in favor of a commercial product/service in return for personal gain. While it is recognized that commercial support is important to the ongoing development of learner-centered, need-based CME activities, all CME activities affiliated with WFSM will strictly adhere to the *2004 Updated Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support: Standards to Ensure the Independence of CME Activities*. In accordance with these standards, the following decisions will be made free of the control of a commercial interest: identification of CME needs, determination of educational objectives, selection and presentation of content, selection of all persons and organizations that will be in a position to control the content, selection of educational methods, and evaluation of the activity.

GOAL:

The purpose of this policy is to describe appropriate processes and procedures to identify all potential conflicts of interest and describe the mechanism to resolve them prior to the CME activity, resulting in a successful conclusion consistent with the public good. All individuals involved in WFSM CME activities and in a position to control the content of an activity - WFSM CME Committee members, Office of Continuing Medical Education (OCME) staff, Activity Directors, activity planning committee members, and teachers/authors – will strictly adhere to the *ACCME Standards for Commercial Support*, including disclosing all relevant financial relationships with any commercial interest. The ACCME defines relevant financial relationships as those in any amount occurring within the past 12 months.

POLICY:

1.) The OCME will provide a mechanism for the identification of any financial relationships prior to awarding AMA PRA category 1 credit for CME activities. All persons in a position to influence or control CME content will complete a *Full Disclosure Statement*. This includes WFSM CME Committee members, OCME staff, Activity Directors, activity planning committee members, and teachers/authors.

2.) All *Certification Requests for Sponsorship of a CME Activity and AMA PRA Category 1 Credit* submitted to the OCME and the WFSM CME Committee for review must include a *Full Disclosure Statement* from each member of the activity planning committee (including Activity Directors and staff) and teachers/authors.

3.) The primary responsibility to identify, address, and attempt to resolve any potential conflicts of interest belongs to the Activity Director. The OCME staff will be available to assist the activity planning committee members and the Activity Director to this end.

4.) The WFSM CME Committee members will be responsible for the approval of all *Certification Requests*, the implementation of this policy, and that all potential conflicts have been adequately resolved.

5.) Any identified financial relationship between a WFSM CME Committee member and a submitted activity will require that CME Committee member to recuse him/herself from the discussion and vote.

6.) All WFSM faculty and key administrative staff will be encouraged to complete the WFSM institutional conflict of interest process, managed by the Office of Research.

7.) All appropriate disclosure information gathered by the OCME will be openly shared with the Office of Research.

8.) All *Full Disclosure Statements* will be reviewed by the Activity Director and submitted with the *Certification Request* to the OCME staff and WFSM CME Committee. The WFSM CME Committee will determine whether conflict of interest resolution actions are needed prior to the approval of the activity. The CME Committee will withhold CME activity approval until the Activity Director has used appropriate mechanisms for resolving any identified conflicts of interest. In the case of regularly scheduled conferences (RSC), *Certification Requests* will be approved contingent that all disclosure information is submitted to the OCME at least 1 week prior to the RSC activity and all potential conflicts of interest have been resolved.

9.) The activity planning committee and Activity Director will document in a formal letter how the identified, perceived conflicts of interest will be resolved. This documentation will be submitted with the *Certification Request* to the OCME and WFSM CME Committee prior to the approval of the activity. Additional information about the CME activity may be collected, as needed, for review by the OCME staff and WFSM CME Committee.

10.) The following mechanisms for resolving conflicts of interest may be used to bring a successful conclusion:

A. *Altering financial relationships*: An individual may change his/her relationships with commercial interests, e.g. discontinue contracted services, and in doing so, no duty, loyalty, or incentive remains to introduce bias into the CME content. However, when an individual divests themselves of a relationship, it is immediately not relevant to conflicts of interest but it must be disclosed to the learners for 12 months.

B. *Altering control over content*: An individual's control of CME content can be altered in several ways to remove the opportunity to affect content related to the products/services of a commercial interest. These include:

- *Choosing someone else to control that part of the content* - If a proposed teacher/author has a conflict of interest related to the content, choose someone else who does not have a relationship to the commercial interests related to the content.

- *Change the focus of the CME activity* - The CME provider can change the focus of the activity so that the content is not relevant to the products/services of the commercial interest that is the basis of the conflict.

- *Change the content of the person's assignment* - The role of a person with a conflict of interest can be changed within the CME activity so that he/she is no longer teaching about issues relevant to the products/services of the commercial interest. For example, an individual with a conflict of interest regarding products for treatment of a disease state could address the pathophysiology or diagnosis of the disease rather than the therapeutics.

- *Limit the content to a report without recommendations* - If an individual has been funded by a commercial company to perform research, the individual's presentation may be limited to the data and results of the research. Someone else can be assigned to address broader implications and recommendations.

- *Limit the sources for recommendations* - Rather than having a person with a conflict of interest present personal recommendations or personally select the evidence to be presented, limit the role of the person to reporting recommendations based on formal structured reviews of the literature with the inclusion and exclusion criteria stated (evidence-based). For example, the individual could present summaries from the systematic reviews of a peer reviewed source, e.g. the Cochrane Collaboration (www.cochrane.org).

C. *Attestation:* Persons who indicate the existence of such relationships (potential or actual conflicts of interest) will be asked to agree in writing that said conflicts or relationships will not bias or otherwise influence their involvement in the CME activity. Furthermore, teachers/authors will be required to limit practice recommendations to those based on the best available evidence (or absence of evidence) and that such recommendations be consistent with generally accepted medical practice.

D. *Evaluation:* Attendees will be queried regarding their impressions concerning bias (or the absence of bias) within the activity. (See attached sample.) Activity Directors and teachers/authors will receive copies of the evaluation summaries and comments.

E. *Peer Evaluation:* An informed learner or peer (not involved in the planning and/or teaching of the activity) will be present, to the fullest extent possible, at CME activities. This evaluator will be asked to complete a formal, detailed evaluation to measure any bias in the activity.

F. *Independent content validation*: Scientific abstracts or free-standing papers or articles in enduring materials are often peer-reviewed or judged against predetermined criteria to ensure the data supports the conclusions before they are accepted for presentation or publication. Similarly, individuals working together to do reviews of activity content can resolve conflicts of interest by ensuring the content is valid, aligned with the interests of the public, and:

- All the recommendations involving clinical medicine are based on best available evidence - evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients.

- All scientific research referred to, reported, or used in a CME activity in support or as justification of patient care recommendations conforms to the generally accepted standards of experimental design, data collection, and analysis.

G. *Elimination:* Activity Directors, activity planning committee members, and/or teachers/authors who are perceived as either manifesting conflicts of interest or being biased may be eliminated from consideration as resources (committee members, teachers, authors, etc.) in subsequent certified CME activities.

11.) All identified potential conflicts of interest and the Activity Director's/activity planning committee's steps in resolution will be disclosed to CME activity participants.