



# Continuous Professional Development

UNIVERSITY OF CENTRAL FLORIDA

**University of Central Florida College of Medicine**



## **COURSE DIRECTOR MANUAL**

**2017 - 2018**

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# Continuous Professional Development

UNIVERSITY OF CENTRAL FLORIDA

## MISSION

The University of Central Florida College of Medicine's Continuous Professional Development (CPD) Mission is to change our learners' competence, performance or patient outcomes. In order for the CPD Program to achieve its mission, 70% of the activity respondents will have indicated changes in competence, performance or patient outcomes on the evaluations and outcome surveys as a result of their participation in CPD educational activities. CPD will accomplish the expected results by developing and implementing a broad range of educational activities designed to convey up-to-date clinical practices and faculty development.

Integral to our mission, is the ongoing Program evaluation and analysis to assess the efficacy of the Program's activities in attaining the intended changes in our learners, the extent to which our mission is being met, and the identification of needed or desired changes in the overall Program to improve our ability to meet the mission. Lastly, we will support the mission of the University of Central Florida College of Medicine *by inspiring individuals to be exemplary physicians and scientists, leaders in medicine, scholars in discovery, and adopters of innovative technology to improve the health and well-being of all.*



# Continuous Professional Development

UNIVERSITY OF CENTRAL FLORIDA

## FACULTY INFORMATION FORM

**Please use this form to collect your faculty information for the CPD application**

THIS FORM MUST BE RETURNED BY (DATE) \_\_\_\_\_

TO: \_\_\_\_\_  
(CONTACT NAME AND EMAIL ADDRESS)

Title of the Conference \_\_\_\_\_

Date of the conference \_\_\_\_\_

Name of the conference site \_\_\_\_\_

Address of the conference site \_\_\_\_\_

- 1) Last Name/Credentials/First Name (*Smith, MD, John*):
- 2) Address/City/State/Zip Code:
- 3) Area Code/Telephone:
- 4) Email Address:
- 5) BIOSKETCH (PLEASE FOLLOW THE EXAMPLE BELOW EXACTLY AS IT APPEARS – DO NOT COPY AND PASTE YOUR RESUME – IT WILL NOT BE ACCEPTED)

**EXAMPLE: (NAME AND CREDENTIALS)** Smith, MD, PhD, John is a **(TITLE AND CURENT POSITION)** Professor of Psychiatry in the College of Medicine at the University of Central Florida, Orlando, Florida. He is a member of **(ORGANIZATIONAL MEMBERSHIPS)** the National Board of Trustees and Chair of Southern Association of Colleges. Dr. Smith received his **(DEGREES AND WHERE THEY WERE EARNED)** B.S. Degree from University of Central Florida and his MD, PhD from Yale University. Dr. Smith has **(WHY ARE YOU QUALIFIED TO TEACH ON THIS TOPIC)** published

several books and articles on the subject of mood disorders, he has taught mood disorders at XYZ University for 20 years. In addition, he has written three books and a number of articles on the topic of mood disorders.

### **SESSION REQUIREMENTS**

**Session Title:**

**Abstract: (PLEASE INCLUDE A DESCRIPTION OF YOUR PRESENTATION)**

**Educational Objectives: (List ONE OR MORE Objectives for this Presentation)**

**START EACH OBJECTIVE WITH AN ACTION VERB.**

**EXAMPLE:** Describe, Discuss, Identify, List, Cite, Name, Evaluate, Design, Prepare, Determine, Diagnose, Calculate, Classify, Examine, Appraise, Define, Label, Debate.

- 
- 
- 

**Cite one OR MORE recent Articles on the subject of this Presentation (**REQUIRED**):**

- 
- 
- 

### **SESSION REQUIREMENTS**

**Session Title:**

**Abstract: (PLEASE INCLUDE A SHORT DESCRIPTION OF YOUR PRESENTATION)**

**Educational Objectives: (List ONE OR MORE Objectives for this Presentation)**

**START EACH OBJECTIVE WITH AN ACTION VERB.**

**EXAMPLE:** Describe, Discuss, Identify, List, Cite, Name, Evaluate, Design, Prepare, Determine, Diagnose, Calculate, Classify, Examine, Appraise, Define, Label, Debate.

- 
- 
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**Cite one OR MORE recent Articles on the subject of this Presentation:**

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- 
- 
- 

**Cite one OR MORE recent Articles on the subject of this Presentation:**

- 
- 
- 

**PLEASE COPY/PASTE ADDITIONAL PAGES IF YOU ARE PRESENTING MORE  
THAN THREE TOPICS**



UNIVERSITY OF CENTRAL FLORIDA

# Continuous Professional Development

## EXHIBITOR FORM

NAME OF ORGANIZATION \_\_\_\_\_

☐ COMMERCIAL INTEREST or ☐ NON-COMMERCIAL INTEREST

NAME OF ORGANIZATION'S CONTACT PERSON \_\_\_\_\_

EMAIL ADDRESS OF THE ORGANIZATION'S CONTACT PERSON \_\_\_\_\_

TOTAL NUMBER OF EXHIBIT SPACES REQUESTED \_\_\_\_\_

AMOUNT OF PAYMENT FOR EXHIBIT SPACE \_\_\_\_\_

### GUIDELINES

-Arrangements for commercial exhibits or advertisements will not influence planning or interfere with the presentation, nor be a condition of the provision of commercial support for CPD activities (CPD does not accept commercial support).

-Product promotion material or product specific advertisement of any type is prohibited in or during CPD activities.

-Commercial Exhibitors must adhere to ACCME Standards for Commercial Support, UCF Industry Relations Policy and Guidelines (<http://med.ucf.edu/media/2011/08/UCF-COM-Industry-Relations-Policy-and-Guidelines3-4-14.pdf>) and the CPD policies.

-Exhibit space will include a table and two chairs

-Only two exhibitors per organization per exhibit space.

**Please contact Continuous Professional Development Coordinator, Alaina West at 407-266-1128 for more information.**

**Commercial Interest** is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. The ACCME does not consider providers of clinical service directly to patients to be commercial interests.

**Non-commercial Interest** are Providers of clinical services directly to patients, such as hospitals, health systems, medical group practices, blood banks, and diagnostic laboratories, are an integral component of accredited CME and because they represent the provision of CME by the profession for the profession.



## **Policy 1.0**

**Policy Name:** Advisory Committee Membership

### **Policy**

With consideration to the recommendation for the Committee, the chair and Committee members' appointment will be made by the Dean of the College of Medicine.

### **Procedures**

- 1) The term of appointment is two years with the option of renewal without limit.
- 2) Committee members will complete a disclosure annually. No one will be permitted to serve on the Committee if they refuse to disclose.
- 3) If a member has a conflict of interest concerning a CPD educational activity, the member will recuse them self from reviewing the activity application.
- 4) If a Committee member elects to discontinue service on the Committee, another committee member will be appointed.
- 5) If a Committee member does not attend or review CPD applications for one fiscal year, the member is contacted to see if they want to remain a member. If not, they will be released from the Committee and another appointed.

### **Duties**

- 1) Ensure that the Criteria and Standards for Commercial Support of the Accreditation Council for Continuing Medical Education (ACCME), UCF Industry Relations Policy and Guidelines and the UCF/CPD missions are maintained when reviewing CPD activity applications for credit.
- 2) Committee members will have final decision on approval/denial of CPD educational activity applications.
- 3) Review faculty presentations for possible conflicts of interest.
- 4) If no member opposes approval of an educational activity application (regardless of the number of responses) the activity is approved.





## **Policy 2.0**

**Policy Name:** Expenditures and Income for Educational Activities

### **Policy**

CPD will maintain oversight of the income and expenses for provider, co-provider and joint providership educational activities.

### **Procedures**

- 1) In a co-provider or joint providership arrangement, CPD will designate which party manages the income and expenses with oversight by CPD. The co-provider or joint provider will forward a financial wrap-up of income and expenditures to the CPD office one month from the activity date.
- 2) If CPD develops and submits a grant application and handles all income and expenses for an educational activity, after expenses are paid, any remaining proceeds will remain with CPD for future educational development (this would not be a commercial support grant).
- 3) CPD will not be responsible for any debt incurred for an educational activity.



## Policy 3.0

**Policy Name:** Planning an Educational Activity

### Policy

CPD will serve as a provider, co-provider or joint provider of educational activities that **do not** accept commercial support.

### Procedures

- 1) Prior to planning a CPD educational activity, planners complete the CPD disclosure form and forward to the CPD coordinator for identification and resolution of conflicts of interest.
- 2) The planners will work with the CPD staff to complete the Application/Planning Form to ensure that the educational activity has been planned in compliance with ACCME Criterion, Standards for Commercial Support, UCF Industry Relations Policy and Guidelines (<http://med.ucf.edu/media/2011/08/UCF-COM-Industry-Relations-Policy-and-Guidelines3-4-14.pdf>) and CPD policies.
- 3) The application is then submitted to the CPD coordinator who reviews before emailing to the Accreditation Administrator for review. If changes are needed to the application, the course director is advised.
- 4) Once the Application/Planning Form is completed, it is submitted to the CPD Committee for review and decision.
- 5) If the educational activity is approved, the following will apply:
  - A) Prior to the start date of the educational activity, the course director forwards all remaining disclosure forms of anyone in control of content to the CPD coordinator for identification and resolution of conflicts of interest using the ACCME conflict of interest/resolution flowchart.
  - B) CPD must approve advertising materials prior to printing.
  - C) CPD prepares the activity evaluation, outcomes survey and welcome letter for participants. The welcome letter contains the disclosures of everyone in control of content.
  - D) CPD maintains participant records of attendees for six years and beyond.
  - E) CPD provides verbiage and usage of the accreditation statement(s) and logo(s).
  - F) CPD will provide participant credit certificates.
  - G) A month or two after the date of the educational activity, co-provider or joint provider submits all documents to CPD, i.e., sign-in sheets, summary of participant evaluation (RSS) and any documents deemed necessary.
  - H) Social events or meals at the activity will not compete with or take precedence over the educational activity.

A **providership activity** is planned, implemented and evaluated by the accredited provider.

A **co-providership activity** (offered by two accredited providers) is planned by both with one accredited provider awarding the credit.

A **joint providership activity** is planned, implemented and evaluated by the accredited provider and a non-accredited entity.



## Policy 4.0

**Policy Name:** Honorarium, Out-of-Pocket Expenses and Travel

### Policy

CPD will follow ACCME Standards for Commercial support and CPD policies concerning honorarium, out-of-pocket expenses and travel for educational activities.

### Procedures

- 1) Honorarium, out-of-pocket expenses and travel may be paid to planners, faculty and/or authors by the provider, co-provider or joint provider however, if CPD designates an educational partner to pay, documentation of payment must be submitted to CPD.
- 2) If a planner, teacher or author is listed on the agenda as facilitating or conducting a presentation, they may receive honorarium and reimbursement of expenses for that portion of their participation. If they choose to be a learner for the remainder of an activity; they cannot receive any payment for learner participation.
- 3) No other payment is given to the director of the activity, planners, faculty and/or authors, learners, co-provider, joint provider or any others involved with the supported activity.
- 4) If CPD accepted commercial support, it would use commercial support to pay for travel, lodging, honoraria, or personal expenses for bona fide employees and volunteers of the provider, co-provider or joint provider.
- 5) If CPD accepted commercial support, it would not pay for travel, lodging, honoraria, or personal expenses for non-teacher or non-author participants of a CPD activity.
- 6) All decisions regarding honorarium and travel will be done in accordance with ACCME Standards for Commercial Support, UCF Industry Relations Policy and Guidelines (<http://med.ucf.edu/media/2011/08/UCF-COM-Industry-Relations-Policy-and-Guidelines3-4-14.pdf>) and the CPD policies.



## Policy 5.0

**Policy Name:** Commercial Exhibitors

### **Policy**

CPD will be a provider, co-provider or joint provider for educational activities that accept commercial exhibitors.

### **Procedures**

- 1) CPD makes all decisions regarding the disposition and disbursement of funds collected from commercial exhibitors.
- 2) Arrangements for commercial exhibits or advertisements will not influence the planning or interfere with the presentation, nor be a condition for the provision of commercial support for CPD activities. **CPD does not accept commercial support.**
- 3) Commercial exhibitors must complete the CPD Exhibitor form.
- 4) Exhibit space includes one table and two chairs for two representatives. Additional exhibit space(s) may be purchased. **See the Table of Contents for the page number of the exhibit form.**
- 5) Commercial Exhibitors must adhere to ACCME Standards for Commercial Support, UCF Industry Relations Policy and Guidelines (<http://med.ucf.edu/media/2011/08/UCF-COM-Industry-Relations-Policy-and-Guidelines3-4-14.pdf>) and the CPD policies.



## Policy 6.0

**Policy Name:** Independence from the Control of a Commercial Interest

### Policy

CPD will ensure that its educational activities are free of the control of a commercial interest.

### Procedures

- 1) CPD makes the following decisions free of the control of a commercial interest:
  - A) Identification of needs
  - B) Identification of professional practice gaps
  - C) Determination of educational objectives
  - D) Selection and presentation of content
  - E) Selection of all persons and organizations that will be in a position to control the content of an educational activity
  - F) Selection of education methods
  - G) Evaluation of the educational activity
- 2) CPD will not be a provider, co-provider or joint provider for organizations accepting commercial support.
- 3) CPD will insure a faculty and/or planner employed by an ACCME-defined commercial interest does not participant in a CME activity. (Faculty and/or planners employed by an ACCME-defined commercial interest are prohibited by University of Central Florida Continuous Professional Development program from participating in an accredited CME activity).
- 4) CPD will ensure no non-accredited partner (in a joint provider relationship) of an ACCME-defined commercial interest participates in an accredited CME activity.  
*“Standard 1.2 - A commercial interest cannot take the role of non-accredited partner in a joint provider relationship.”*
- 5) All person in control of the content will attest on the activity application/planning and disclosure/attestation forms that they are not an employee of an ACCME-defined commercial interest.
- 6) All person in control of the content will attest on the activity application/planning and disclosure/attestation forms that they are not in a joint provider relationship with an ACCME-defined commercial interest.



## Policy 7.0

### Policy Name: Management of Associated Commercial Promotion

#### Policy

CPD will follow the ACCME policies for Managing Commercial Promotion, which are outlined in the ACCME Standards for Commercial Support and recapped below.

#### Procedures

- CPD will not arrange commercial exhibits and advertisements that influence planning, interfere with presentations or are a condition for the provision of commercial support of CME activities.
- CPD prohibits product-promotion material or product-specific advertisement of any type in or during CME activities. The juxtaposition of editorial and advertising material on the same products or subjects will be avoided.
- **Live** (staffed exhibits, presentations) or enduring (printed or electronic advertisements) promotional activities will be kept separate from CME.
- **Print**, advertisements and promotional materials will not be interleaved within the pages of the CME content.
- Advertisements and promotional materials will face the first or last pages of printed CME content as long as these materials are not related to the CME content they face; and are not paid for by the commercial supporters of the CME activity.
- **Computer based**, advertisements and promotional materials will not be visible on the screen at the same time as the CME content and will not interleaved between computer 'windows' or screens of the CME content.
- CPD will not place its CME activities on a Web site owned or controlled by a commercial interest.
- CPD will have clear notification when a learner is leaving the educational Web site, links from the Web site of an ACCME accredited provider to pharmaceutical and device manufacturers' product.
- If CPD has an educational website, it may have pharmaceutical and device manufacturers' products before or after the educational content of a CME activity, but will not embed within the educational content of a CME activity.
- CPD will not have advertisement of any type within the educational content of CME activities on the Internet including, but not limited to, banner ads, subliminal ads, and pop-up window ads.
- **Computer based CME** activities provided by CPD will not advertise and offer promotional materials on the screen at the same time as the CME content and will not be interleaved between computer windows or screens of the CME content.
- **Audio and video recording**, advertisements and promotional materials will not be included within the CME.
- There will be no commercial breaks for live, face-to-face CME.
- Advertisements and promotional materials will not be displayed or distributed in the educational space immediately before, during, or after a CME activity.

- CPD will not allow representatives of Commercial Interests to engage in sales or promotional activities while in the space or place of the CME activity.
- **Journal-based CME** will not contain any of the elements of journal-based CME such as advertising or product group messages of commercial interests. The learner will not encounter advertising within the pages of the article or within the pages of the related questions or evaluation materials.
- Educational materials that are part of a CME activity, such as slides, abstracts and handouts, will not contain any advertising, corporate logo, trade name or a product-group message of an ACCME-defined commercial interest.
- CPD may someday include product-promotion material or product-specific advertisement in the print or electronic information distributed about the non-CME elements of a CME activity that are not directly related to the transfer of education to the learner, such as schedules and content descriptions.
- CPD will not use a commercial interest as the agent providing a CME activity to learners, e.g., distribution of self-study CME activities or arranging for electronic access to CME activities.



## **Policy 8.0 (This policy is only if CPD changed its current policy regarding commercial support)**

**Policy Name:** Appropriate Handling of Commercial Support

### **Policy**

CPD will adhere to the ACCME Standards for Commercial Support concerning appropriate handling of commercial support.

### **Procedures**

- 1) CPD would make all decisions regarding the disposition and disbursement of commercial support.
- 2) CPD would not be required by a commercial interest to accept advice or services concerning teachers, authors, or participants or other education matters, including content, from a commercial interest as conditions of contributing funds or services.
- 3) All commercial support associated with a CPD educational activity is given with the full knowledge and approval of CPD.
- 4) CPD would make sure the terms, conditions, and purposes of the commercial support are documented in a written agreement between the commercial supporter that includes CPD and its educational partner(s). The agreement includes CPD, even if the support is given directly to the provider's educational partner or a joint provider.
- 5) The written agreement would specify the commercial interest that is the source of commercial support.
- 6) Both the commercial supporter and CPD would sign the written agreement, which is between the commercial supporter and CPD.

**Commercial Support** for a CME activity is financial, and/or in-kind, contributions given by a commercial interest, which is used to pay all or part of the costs of a CPD activity.

**A Commercial Interest** is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. The ACCME does not consider providers of clinical service directly to patients to be commercial interests.





## Policy 9.0

**Policy Name:** Disclosure of Relevant Financial Relationships

### Policy

All persons involved in the development of a CPD educational activity must disclose all relevant financial relationships.

### Procedures

- 1) CPD shows that everyone who is in a position to control the content of an educational activity has disclosed all relevant financial relationships with any commercial interest. The ACCME defines "relevant financial relationships" as financial relationships in any amount occurring within the past 12 months that create a conflict of interest. This includes a spouse, partner or immediate family member.
- 2) An individual who refuses to disclose relevant financial relationships will be disqualified from the planning committee, presenter, teacher, or an author of a CPD educational activity, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the educational activity.
- 3) CPD discloses to the learner prior to the educational activity any relevant financial relationship(s) and includes the name of the individual, the name of the commercial interest and the nature of the relationship the person has with each commercial interest. This includes a spouse, partner or immediate family member.
- 4) For an individual with no relevant financial relationship(s), CPD discloses to the learner that the individual has no relevant financial relationship(s).
- 5) The source of all support from commercial interests is disclosed to learners. When commercial support is "in-kind" the nature of the support is disclosed to learners.
- 6) Disclosure will not include the use of a corporate logo, trade name or a product-group message of an ACCME-defined commercial interest.
- 7) CPD discloses the above information to learners prior to the beginning of the educational activity.
- 8) CPD has implemented the ACCME flowchart to identify and resolve all conflicts of interest prior to the educational activity being delivered to learners.

The ACCME defines **relevant financial relationships** as financial relationships in any amount, which occurred in the twelve-month period preceding the time that the individual was asked to assume a role controlling content of the CME activity, and which relate to the content of the educational activity, causing a conflict of interest.

The ACCME considers **financial relationships** to create 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. The potential for maintaining or increasing the value of the financial relationship with the commercial interest creates an incentive to influence the content of the CME—an incentive to insert commercial bias.

The ACCME defines **financial relationships** as those relationships individuals benefit by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, 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 independent contractor (including contracted research), consulting, promotional speaking and teaching, membership on advisory committees or review panels, board membership, and other activities for which remuneration is received or expected. ACCME considers relationships of the person involved in the CME activity to also include financial relationships of a spouse or partner.



## Policy 10.0

**Policy Name:** Resolution for Conflicts of Interest

### Policy

CPD will identify and resolve all conflicts of interest.

### Procedures

- 1) CPD coordinator reviews disclosures of everyone in a position to control the content of an educational activity and identifies conflicts of interest prior to the educational activity.
- 2) CPD uses the ACCME Flowchart for the Identification and Resolution of Personal Conflicts of Interest. **See Below**

Conflict of interests occur when an individual has a relevant financial relationship with a **commercial interest** and has the opportunity to affect the content of a CPD educational activity regarding the products or services of that **commercial interest**.

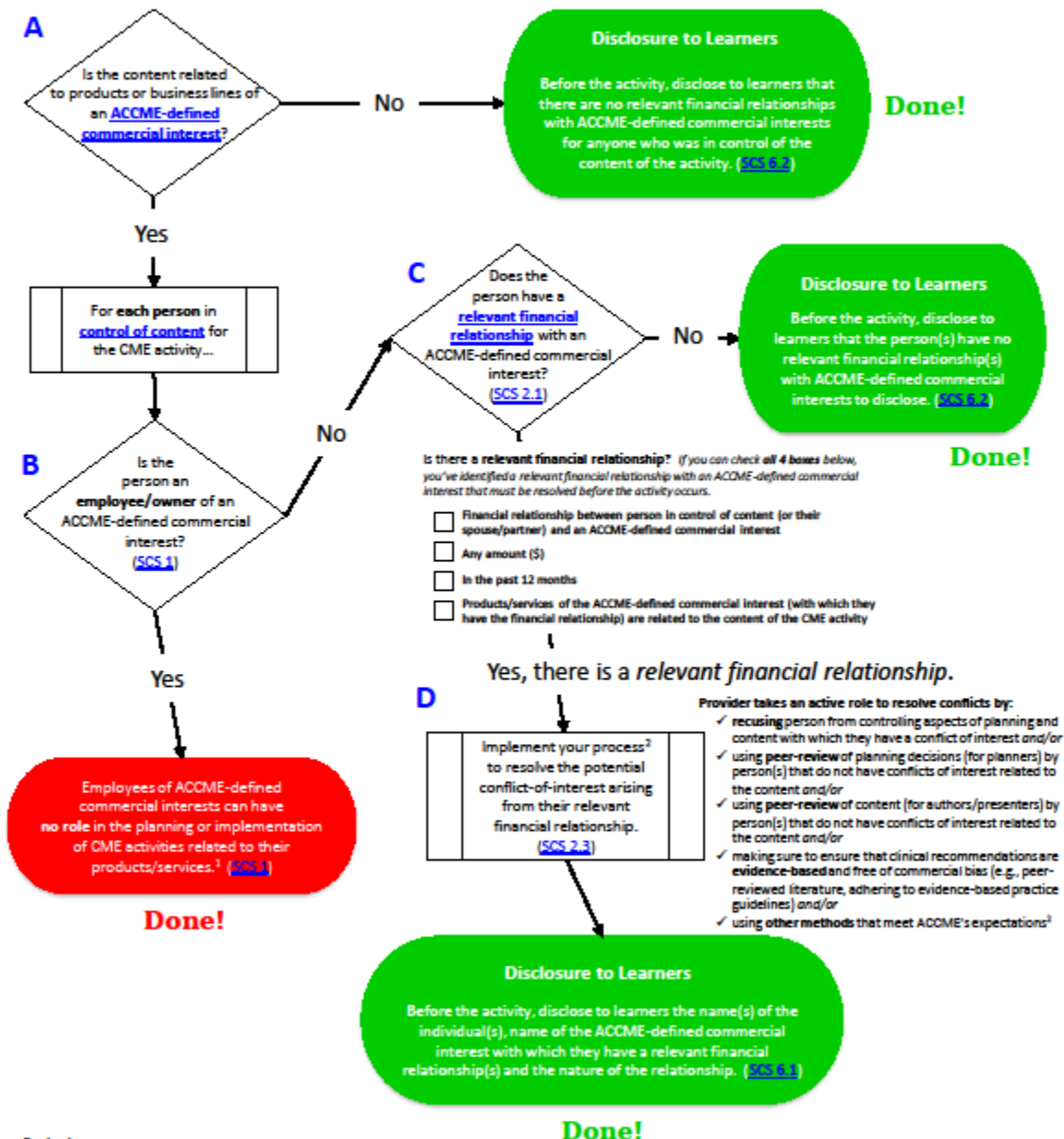
A **commercial interest** is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.



## Flowchart for the Identification and Resolution of Personal Conflicts of Interest Meeting the Expectations of ACCME's Criterion 7

(Last updated : February 1, 2017)

Use this flowchart at the beginning of your planning process for CME activities to ensure independence from ACCME-defined commercial interests. **Start at A below.** For step-by-step instructions for using this flowchart, visit [www.accme.org/coiflowchart](http://www.accme.org/coiflowchart).



### Footnotes

1. The use of employees of ACCME-defined commercial interests as faculty and planners or in other roles where they are in a position to control the content of accredited CME is prohibited, except in specific situations. For more information, visit [this Ask ACCME frequently-asked-question](#) regarding commercial employees.
2. There are a range of approaches providers can use to resolve potential conflicts of interests. For more information, visit ACCME's [Provider Examples of Compliance and Noncompliance](#) for Criterion 7 on [www.accme.org](http://www.accme.org).



## Policy 11.0

**Policy Name:** Commercial Bias in Content and Format

### Policy

The content, format and related materials of a CPD educational activity will encourage improvements in healthcare and will not promote the business interest of a commercial entity.

### Procedures

- 1) Presentations provide a balanced view of therapeutic options.
- 2) Presenters use generic names to show impartiality.
- 3) CPD educational content and materials use trade names (where available) from several companies and not just trade names from a single company.
- 4) CPD activities promote improvements or quality in healthcare and not promote any specific proprietary business interest of a commercial entity.
- 5) Presentations give a balanced view of therapeutic options in the planning and/or delivery of this CME activity.
- 6) No direct payment from an ACCME-defined commercial interest is given to the director of this educational activity, any planning committee member, teacher or author, joint provider, or any others involved in this CPD educational activity.
- 7) All who are in control of the educational content attest on the disclosure form they are not employed by an ACCME-defined commercial interest.
- 8) All who are in control of the educational content attest on the disclosure they are not a non-accredited partner (in a joint provider relationship) of an ACCME-defined commercial interest. *“Standard 1.2 - A commercial interest cannot take the role of non-accredited partner in a joint provider relationship.”*



## **Policy 12.0**

**Policy Name:** Content Validation and Verification

### **Policy**

CPD will document content validation and verification on its Application/Planning and Disclosure/Attestation Forms.

1. All the recommendations involving clinical medicine in a CME activity must be 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 must conform to the generally accepted standards of experimental design, data collection and analysis.
3. Providers are not eligible for ACCME accreditation or reaccreditation if they present activities that promote recommendations, treatment, or manners of practicing medicine that are not within the definition of CME, or known to have risks or dangers that outweigh the benefits or known to be ineffective in the treatment of patients. An organization whose program of CME is devoted to advocacy of unscientific modalities of diagnosis or therapy is not eligible to apply for ACCME accreditation.
4. All person in control of the content will attest on the activity application/planning and disclosure/attestation forms that they will adhere to the content validation and verification statements.

## Standards for Commercial Support: Standards to Ensure Independence in CME Activities

### Standard 1: Independence

**STANDARD 1.1** A CME provider must ensure that the following decisions were made free of the control of a commercial interest. (See [www.accme.org](http://www.accme.org) for a definition of a "commercial interest" and some exemptions.) (a) Identification of CME needs; (b) Determination of educational objectives; (c) Selection and presentation of content; (d) Selection of all persons and organizations that will be in a position to control the content of the CME; (e) Selection of educational methods; (f) Evaluation of the activity.

**STANDARD 1.2** A commercial interest cannot take the role of non-accredited partner in a joint provider relationship.

### Standard 2: Resolution of Personal Conflicts of Interest

**STANDARD 2.1** 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.

**STANDARD 2.2** 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.

**STANDARD 2.3** The provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners.

### Standard 3: Appropriate Use of Commercial Support

**STANDARD 3.1** The provider must make all decisions regarding the disposition and disbursement of commercial support.

**STANDARD 3.2** A provider cannot be required by a commercial interest to accept advice or services concerning teachers, authors, or participants or other education matters, including content, from a commercial interest as conditions of contributing funds or services.

**STANDARD 3.3** All commercial support associated with a CME activity must be given with the full knowledge and approval of the provider.

**STANDARD 3.4** The terms, conditions, and purposes of the commercial support must be documented in a written agreement between the commercial supporter that includes the provider and its educational partner(s). The agreement must include the provider, even if the support is given directly to the provider's educational partner or a joint provider.

**STANDARD 3.5** The written agreement must specify the commercial interest that is the source of commercial support.

**STANDARD 3.6** Both the commercial supporter and the provider must sign the written agreement between the commercial supporter and the provider.

**STANDARD 3.7** The provider must have written policies and procedures governing honoraria and reimbursement of out-of-pocket expenses for planners, teachers and authors.

**STANDARD 3.8** The provider, the joint provider, or designated educational partner must pay directly any teacher or author honoraria or reimbursement of out-of-pocket expenses in compliance with the provider's written policies and procedures.

**STANDARD 3.9** No other payment shall be given to the director of the activity, planning committee members, teachers or authors, joint provider, or any others involved with the supported activity.

**STANDARD 3.10** If teachers or authors are listed on the agenda as facilitating or conducting a presentation or session, but participate in the remainder of an educational event as a learner, their expenses can be reimbursed and honoraria can be paid for their teacher or author role only.

**STANDARD 3.11** Social events or meals at CME activities cannot compete with or take precedence over the educational events.

**STANDARD 3.12** The provider may not use commercial support to pay for travel, lodging, honoraria, or personal expenses for non-teacher or non-author participants of a CME activity. The provider may use commercial support to pay for travel, lodging, honoraria, or personal expenses for bona fide employees and volunteers of the provider, joint provider or educational partner.

**STANDARD 3.13** The provider must be able to produce accurate documentation detailing the receipt and expenditure of the commercial support.

#### **Standard 4: Appropriate Management of Associated Commercial Promotion**

**STANDARD 4.1** Arrangements for commercial exhibits or advertisements cannot influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CME activities.

**STANDARD 4.2** Product-promotion material or product-specific advertisement of any type is prohibited in or during CME activities. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Live (staffed exhibits, presentations) or enduring (printed or electronic advertisements) promotional activities must be kept separate from CME. For print, advertisements and promotional materials will not be interleaved within the pages of the CME content. Advertisements and promotional materials may face the first or last pages of printed CME content as long as these materials are not related to the CME content they face and are not paid for by the commercial supporters of the CME activity. For computer based, advertisements and promotional materials will not be visible on the screen at the same time as the CME content and not interleaved between computer 'windows' or screens of the CME content. (Supplemented February 2014; the information that follows previously appeared in ACCME policies. No changes have been made to the language.) Also, ACCME-accredited providers may not place their CME activities on a Web site owned or controlled by a commercial interest. With clear notification that the learner is leaving the educational Web site, links from the Web site of an ACCME accredited provider to pharmaceutical and device manufacturers' product Web sites are permitted before or after the educational content of a CME activity, but shall not be embedded in the educational content of a CME activity. Advertising of any type is prohibited within the educational content of CME activities on the Internet including, but not limited to, banner ads, subliminal ads, and pop-up window ads. For computer based CME activities, advertisements and promotional materials may not be visible on the screen at the same time as the CME content and not interleaved between computer windows or screens of the CME content. For audio and video recording, advertisements and promotional materials will not be included within the CME. There will be no 'commercial breaks.' For live, face-to-face CME, advertisements and promotional materials cannot be displayed or distributed in the educational space immediately before, during, or after a CME activity. Providers cannot allow representatives of Commercial Interests to engage in sales or promotional activities while in the space or place of the CME



activity. (Supplemented, February 2014; the information that follows previously appeared in ACCME policies. No changes have been made to the language.) For Journal-based CME, None of the elements of journal-based CME can contain any advertising or product group messages of commercial interests. The learner must not encounter advertising within the pages of the article or within the pages of the related questions or evaluation materials.

**STANDARD 4.3** Educational materials that are part of a CME activity, such as slides, abstracts and handouts, cannot contain any advertising, corporate logo, trade name or a product-group message of an ACCME-defined commercial interest.

**STANDARD 4.4** Print or electronic information distributed about the non-CME elements of a CME activity that are not directly related to the transfer of education to the learner, such as schedules and content descriptions, may include product-promotion material or product-specific advertisement.

**STANDARD 4.5** A provider cannot use a commercial interest as the agent providing a CME activity to learners, e.g., distribution of self-study CME activities or arranging for electronic access to CME activities.

#### **Standard 5: Content and Format without Commercial Bias**

**STANDARD 5.1** The content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest.

**STANDARD 5.2** 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, where available trade names from several companies should be used, not just trade names from a single company.

#### **Standard 6: Disclosures Relevant to Potential Commercial Bias**

**STANDARD 6.1** An individual must disclose to learners any relevant financial relationship(s), to include the following information: The name of the individual; The name of the commercial interest(s); The nature of the relationship the person has with each commercial interest.

**STANDARD 6.2** For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.

**STANDARD 6.3** The source of all support from commercial interests must be disclosed to learners. When commercial support is "in-kind" the nature of the support must be disclosed to learners.

**STANDARD 6.4** 'Disclosure' must never include the use of a corporate logo, trade name or a product-group message of an ACCME-defined commercial interest.

**STANDARD 6.5** A provider must disclose the above information to learners prior to the beginning of the educational activity.



# Continuous Professional Development

UNIVERSITY OF CENTRAL FLORIDA

## Industry Relations Policy and Guidelines

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#### **1. Introduction and Scope of Policy**

The UCF College of Medicine (COM) strives to be a leader in assuring the highest levels of ethics and professionalism in all dealings with the health care industry, which includes, but is not limited to, the pharmaceutical, biotechnology, medical device, and medical equipment supply industry (“Industry”), and in establishing a culture of ethical behavior and accountability for its administrators, faculty, staff, students, residents, and fellows (“COM Personnel”). The COM greatly values its Industry partners and works openly in collaboration with these partners and vendors to promote positive, productive, and ethical relationships. As leaders in science and medicine, COM experts participate in appropriate Industry advisory roles, Industry-funded scientific studies, and development of new health care discoveries and resources. As a leader in health care transformation, the COM develops collaborative partnerships and business arrangements with Industry partners. As a non-profit educational institution, the COM seeks and accepts charitable donations from Industry that support the COM mission. This policy will guide all COM Personnel in structuring and participating in Industry relationships to assure integrity of professional judgment, the highest ethical behaviors, and the objectivity of medical education.

This policy applies to all individual and institutional financial relationships, business arrangements, and interactions with Industry vendors and developers of products and services that are marketed and sold to medical schools, academic health science centers, researchers, educators, and clinicians. This policy applies to all COM Personnel and covers relationships and activities that occur during both work and non-work hours.

Indirect minority investment interests, such as ownership of stock of, or investments in a mutual fund that owns shares in companies constituting Industry are not considered conflicting interests for purposes of this policy.

#### **2. Statement of Policy**

It is the intent of the COM to work collaboratively with Industry partners that share a heightened commitment to maintaining the highest ethical standards. All COM relationships and interactions with Industry will be structured, managed, and monitored to assure adherence to such ethical standards. Individual and institutional decisions, actions, and relationships must be free from even the appearance of bias relating to vendor/Industry relationships. Clinical judgments, business agreements, education, and research activities must not be impacted by undue influence resulting from financial relationships with, or gifts provided by, Industry. All collaborations and financial relationships with Industry must be based on the goals of advancing science, education, and clinical care consistent with the COM mission and values. For questions or further guidance, COM Personnel should consult with COM Legal Affairs, COM Compliance, a member of the COM Industry Relations Committee (the “Committee”) or with the Dean. It is the responsibility of each individual to seek necessary guidance and approvals in advance of participating in an Industry relationship. Philanthropic gifts provided by Industry are subject to Section 8 of this policy and may be subject to additional policies of the COM or affiliated entities or foundations fundraising on its behalf. In addition to review for ethical issues, all financial and business relationships with Industry must be carefully reviewed for compliance with all applicable legal, regulatory, reimbursement, and accreditation requirements. Associated contracts must be reviewed, approved and signed in accordance with the COM and university policies and procedures.

### **3. Gifts and Individual Financial Relationships with Industry**

#### **3.1 Gifts and Meals**

COM Personnel shall not accept or use personal gifts (including food) from representatives of Industry, regardless of the nature or dollar value of the gift.

Gifts from Industry that incorporate a product or company logo on the gift (e.g., pens, notepads, or office items such as clocks) introduce a commercial, marketing presence that is not appropriate to a non-profit educational and healthcare system<sup>1</sup>. COM Personnel may not accept complimentary tickets to sporting or other events or other such benefits from Industry.

1 Exception: This provision does not prohibit acceptance of items bearing Industry logos provided as part of an off-campus educational program (such as a meeting of a professional society), including name tag lanyards and totes where the items are provided and used incidental to attendance, the items are of nominal value, and the items are not brought into or used in any COM facilities.

2 A Significant Financial Interest is defined as \$10,000 or more based on Association of American Medical Colleges (AAMC) recommendations.

Meals or other food and hospitality funded directly by Industry may not be offered to, or accepted, by COM Personnel in any COM facility. COM Personnel may not accept free meals or other food or hospitality funded by Industry, whether on-campus or off-campus. However, meals or other food provided in connection with an educational program accredited by the Accreditation Council for Continuing Medical Education (ACCME) or a professional society-sponsored meeting with paid registration may be accepted by COM Personnel.

**3.2 Outside Relationships with Industry** (e.g., any consulting arrangement, advisory board, speaking, publishing, attending meetings or Significant Financial Interest arrangements<sup>2</sup>)

Outside Arrangement means a written or verbal arrangement with Industry for COM Personnel to perform consulting services, to serve on an advisory board, to speak at or attend an Industry sponsored event, to publish in Industry funded publications, or to have a Significant Financial Interest.

COM Personnel may engage in Outside Arrangements with Industry in accordance with this policy provided such activities further the COM's mission and do not conflict with the individual's duties, responsibilities and obligations to the COM. All Outside Arrangements with Industry must be reviewed in accordance with this policy and approved in advance by the individual's Supervisor and one of the following: the individual's Chair, Director, Associate Dean or Associate Vice President, or the Dean or the Dean's designee. It is the individual's responsibility to obtain approval and to furnish a copy of such approval to COM Compliance prior to the start of the arrangement.

All written agreements for Outside Arrangements with Industry when the COM is a party must be reviewed, approved and signed in accordance with the COM and university policies and procedures. For Outside Arrangements with Industry entered into in a personal capacity, it is the responsibility of the COM Personnel to ensure that any such Outside Arrangement meets the requirements of this policy, is consistent with university regulations and policies, complies with the state and federal laws and has appropriate liability coverage. A copy of the agreement or summary of key terms shall be provided to the individual's supervisor and to COM Compliance. COM Personnel may not use the COM or the university's resources, including its names or logos for Industry, without the express written approval of the university.

For Outside Arrangements with Industry that exceed \$10,000 per company per year in fees received by the individual, in addition to securing the approvals described above, the individual must submit annual reports describing activities, payments, time spent, and the name of the company to COM Compliance for the duration of the relationship.

**3.2.1 Consulting.** Consulting arrangements with Industry must be fully transparent and documented, including the services to be performed, fair market value payment terms, estimated time involved in performance of the service, and the name of the company. COM Compliance will periodically audit Industry consulting arrangements for compliance with this provision. A list of Industry consulting

arrangements entered into by COM employees in their personal capacity shall be made available annually by COM Compliance to the COM Industry Relations Committee. These procedures apply whether the consulting fees are received by COM or the individual or donated to another organization. A similar process is required for any part-time employment arrangement with Industry.

**3.2.2 Advisory board.** Membership on Industry advisory boards by COM Personnel is permitted so long as the board regularly meets and provides scientific advice or other guidance that advances academic values and promotes ethical relationships between academic health sciences and Industry. Honoraria for serving on advisory boards, whether received by the individual or by the COM, must be modest and consistent with fair market value. In addition, the individual may receive reasonable travel expenses (such as airfare, mileage, lodging, meals and other transportation costs).

**3.2.3 Industry Funded Speaking Relationships, Meetings, and Publications.** COM Personnel must assure that participation in Industry-funded speaking relationships, meetings, and publications serves to advance scientific knowledge or patient care and are not primarily Industry marketing activities. Honoraria for speaking engagements, whether received by the individual or by the COM, must be modest and consistent with fair market value for the time spent in preparing and presenting the talk. In addition, the individual may receive reasonable travel expenses (such as airfare, mileage, lodging, meals and other transportation costs).

COM Personnel are responsible for the scientific integrity of material presented in any talk or publication. COM Personnel shall not participate in educational presentations or scientific publications (a) if the content is controlled by or requires prior approval by Industry, (b) if the content is not based on the best available scientific evidence, or (c) if significant portions are written by someone who is not an author or otherwise properly acknowledged. Participation by COM Personnel in “Speakers’ Bureau Activity” is prohibited. “Speakers’ Bureau Activity” means any speaking engagement in which COM Personnel would be speaking on behalf of Industry. The COM shall not sponsor and/or host any Speakers’ Bureau Activities. COM Personnel may participate in Industry-sponsored meetings where there is opportunity for critical exchange. If an individual is speaking at such an Industry-sponsored meeting, acceptance of meeting registration fee, a modest honorarium consistent with fair market value and reasonable travel expenses is permitted as described above. Otherwise, COM Personnel may not accept payment, gifts, or financial support from Industry to attend lectures or participate in Industry-sponsored meetings other than through an approved consulting or business arrangement.

### **3.2.4 Disclosure of Outside Arrangements involving Industry**

#### **A) University Conflict of Interest Review**

In addition to the COM approval process provided in this policy, COM Personnel shall report their Outside Arrangements with Industry through the regular university conflicts of interest disclosure process, using the Request for an Exemption/Disclosure Under Section 112.313(12)(h), Florida Statutes, available online at <http://www.coi.ucf.edu/forms.html>, at least annually and more often as needed to disclose new relationships. All such reports are open to the public.

#### **B) Disclosure to students, residents, colleagues and patients**

COM Personnel shall disclose Industry, business or consulting relationships and Significant Financial Interests that are relevant to the topic discussed in scholarly publications, lectures, and presentations to students, residents or colleagues (e.g., showing a slide during each lecture/presentation). Disclosure of such relevant relationships and financial interests should also be made to patients when appropriate to enable patients to make informed decisions respecting their medical care. All such disclosures must specify when the COM Personnel is participating in an individual capacity and not on behalf of the COM or university.

#### **C) Disclosure to purchasing unit or procurement committee**

COM Personnel having a direct role in making institutional decisions on equipment, or drug or medical device procurement must disclose to the purchasing unit or procurement committee, prior to making any such decision, any Significant Financial Interest they or their immediate family have in companies that might substantially benefit from the decision. Such individuals may participate in discussions with full disclosure but shall not vote or otherwise participate in purchasing decisions where there is a conflict or potential conflict.

### **3.2.5 Publicly Accessible Website**

The COM shall post, on a publicly accessible website, at least annually, a list of Industry consulting arrangements of COM Personnel, regardless of whether the consulting fees are received by the COM or the individual or donated to another organization.

### **3.3 Travel Fund**

The COM shall allow Industry and others to contribute, through the University of Central Florida Foundation, to (i) a central COM fund to be used at the Dean's discretion to provide travel assistance to COM Personnel, including students, for professional development; or (ii) other approved Department account for use at the particular Department Chair's discretion to provide travel assistance to Department personnel, including students, for professional development. Contributions to such fund shall be disclosed and acknowledged.

### **3.4 Educational Symposia Fund**

The COM shall allow Industry and others to contribute, through the University of Central Florida Foundation, to (i) the central COM Educational Symposia Fund to be used in the Dean's discretion to provide COM-sponsored educational programs and symposia; or (ii) other approved Department account for use at the particular Department Chair's discretion for Department-sponsored educational programs and symposia. Contributions to such fund shall be disclosed and acknowledged.

## **4. Pharmaceutical, Medical Device and Medical Supply Samples**

The COM prohibits acceptance of samples of pharmaceuticals, medical devices or medical supplies ("Samples") by COM practitioners or faculty members except in limited circumstances as provided in this policy and with prior approval. Samples may be accepted (i) for use in research, provided such use is in a manner that assures full clinical evaluation of its use and adheres to applicable protocols and is approved by the Associate Dean for Research, and (ii) by a Nurse Manager for patient care under circumstances involving a vulnerable patient population, when a COM physician believes lack of provision of samples to their patient would jeopardize their patient's health, provided that the COM physician has requested, and received, a waiver from both the Medical Director and the Director of Quality and Safety of Pegasus Health. The request must outline a clear and convincing benefit to the patient and provide safeguards for the appropriate distribution and control of samples. The request and approval must be documented in writing. No sample may be used personally by COM Personnel. The Pegasus Health Director of Quality and Safety may inspect sample storage areas at any time and may revoke permission if non-compliance is identified.

## **5. Purchasing and Formularies**

COM Personnel are not eligible to participate in product evaluation decisions if they or members of their immediate family have, or have had within the prior 5 years, a Significant Financial Interest or funded research with a related pharmaceutical or medical device company that is being considered or discussed. Every COM employee must avoid both actual conflicts of interest and the appearance of conflicts of interest and be in compliance with the university's Conflicts of Interest policy and procedures. COM Personnel who have such conflicting interests may share information regarding the drug or device, provided that the conflict is fully disclosed in advance, and the individual may participate in discussions

but shall not vote or otherwise participate in selection decisions where there is conflict or potential conflict.

## **6. Site Access to Industry Representatives**

COM does not allow use of its facilities or other resources for Industry marketing activities. Visits to COM facilities by representatives of Industry may be appropriate for exchange of scientifically valid information and other data, improving patient care, providing essential training and instruction in use of medical and research equipment and devices or community relationship building.

### **6.1 Vendor Trade Displays**

Industry is not permitted to participate in trade shows conducted in COM facilities except in accordance with this policy and with the prior written approval of the Dean or the Dean's designee. Permitted vendor trade displays may consist of vendor displays where several brands of medical or research devices, permitted equipment or materials are displayed simultaneously for users and key decision makers to compare them in order to recommend or make purchasing or standardization decisions.

### **6.2 Sales or Marketing Representatives**

Sales or marketing representatives of Industry may access COM facilities only if they have registered with the COM and they have been specifically invited to meet with a COM representative for a particular purpose. Individual physicians or other COM Personnel may request a presentation by or other information from a particular company. While in the COM facilities, all Industry representatives must sign in and out and must wear visible identification that includes their name and current company affiliation. All Industry representatives with access to COM facilities and personnel must comply with the COM Industry Relations Policy (a copy of which must be given in advance and an acknowledgement of receipt and review obtained by the time of site visit) and procedures. Failure of the Industry representative to register or to comply with the COM Industry Relations Policy shall result in adverse actions up to and including denial of access. Meetings with sales and marketing Industry representatives shall not be held in direct patient care areas or education areas. Involvement of students or trainees in meetings with Industry representatives should occur only for educational or training purposes and only under the supervision of a faculty member. All Industry representatives seeking sales or vendor relationships must work directly with their designated COM representative and shall not solicit other COM Personnel.

### **6.3 Patient Care Areas**

Access by medical device or equipment representatives to patient care areas is permitted when (a) a COM representative requests essential instruction in use of the equipment or device, (b) the representative is appropriately credentialed by Pegasus Health, and (c) all necessary patient consents have been obtained and documented. Educational materials or product information that includes Industry marketing information may not be placed in patient care areas or waiting rooms.

## **7. Education**

### **7.1 Support by Industry of Continuing Medical Education and On-site Educational Activities**

All continuing medical education (CME) events hosted or sponsored by the COM must comply with the Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support of Educational Programs (or other similarly rigorous, applicable standards required by other health professions), whether or not CME credit is awarded for attendance at the event. The COM hosts and sponsors CME events through ACCME accredited affiliates until it is ACCME accredited.

Industry interested in sponsoring a CME program hosted by the COM, may contribute to a fund in accordance with Section 3.4. Programs hosted or sponsored by the COM through such funds may include modest food and beverage. All CME programs hosted by the COM must be academically oriented.

Industry may not restrict program content or specify who is selected as presenters or attendees. Industry funding sources will be directly acknowledged in all announcements and literature about particular CME

offerings. Industry funding may not be accepted for social events that do not have an educational component or to sponsor COM meetings or retreats (either on or off-campus). Such meetings and events may be supported through a general Dean's discretionary fund, and Industry may contribute to the Dean's Discretionary Fund. COM facilities (clinical and non-clinical) may not be rented by or used for Industry funded and/or directed programs, except for programs structured in accordance with this policy.

### **7.2 Industry Support for Scholarships, Fellowships, and Other Support for Trainees**

The COM solicits and welcomes Industry contributions for scholarships, fellowships, and other support for trainees, so long as the funds are given centrally to the administration of the COM, either directly or through an affiliated entity or foundation; there is no expectation of benefit to the donor; the evaluation and selection of recipients is in the sole discretion of the COM; and the allocation and distribution of funds is managed by the COM.

### **7.3 Training of COM Personnel**

The COM medical school curriculum includes instruction for medical students in understanding and addressing individual and institutional conflicts of interest in interactions with Industry and how the potential for conflicts of interest impacts/influences education, research and patient care/clinical judgment. Medical students at the COM receive specific instruction regarding this policy through attending a live session, and a copy of the policy and the training materials are posted online for easy reference by the students. Other COM Personnel are provided online access to this policy and training materials.

## **8. Philanthropy**

The COM welcomes and solicits donations from Industry that support the COM missions so long as the donations are given centrally to the administration of the COM, either directly or through an affiliated entity or foundation and the allocation and distribution of donation is managed by the COM. Gifts and loans to the COM of equipment, devices, supplies and similar items from Industry for use in education, research or clinical care cannot suggest the expectation of return benefit to the donor, or "quid pro quo." The gift transaction will be documented as a gift in-kind donation.

The UCF Foundation and other tax exempt entities will assist COM in soliciting, receiving, and managing charitable donations. All charitable donations must be free of any implication or expectation of a benefit to the donor, are not tied to any purchase or business arrangement, and are openly acknowledged.

Donations from Industry are reviewed in accordance with this policy and any additional standards that may be developed by the COM Industry Relations Committee and approved by the Dean. The COM Industry Relations Committee may recommend to the Dean steps needed in structuring and acknowledging donations to avoid or minimize conflicts of interest or the appearance of conflicts. Offers of donations over \$10,000 shall be submitted to COM Development for review with the Dean's Office.

## **9. COM Partnerships and Business Arrangements with Industry**

The COM may enter into a variety of business arrangements and partnerships with Industry when such arrangements advance the COM missions. These are relationships that extend beyond purchasing the standard Industry product or service and may include, for example, shared research, development, and/or ownership of a health care product or service. As in purchasing, any individuals with a conflicting personal financial relationship or interest must disclose such interests and may not vote on adopting by the COM of a proposed Industry partnership or business arrangement. Each proposed partnership or business arrangement will be reviewed in accordance with this policy and any additional standards that may be developed by the COM Industry Relations Committee and approved by the Dean. The COM Industry Relations Committee may recommend to the Dean any steps needed in structuring the partnership or business arrangement to avoid or minimize conflicts of interest or the appearance of conflicts.



COM Industry partners and vendors shall be provided copies of this policy and an acknowledgement of receipt and review must be obtained prior to commencement of a partnership or vendor relationship.

#### **10. Research with Human Subjects**

COM Personnel may not conduct research with human participants if such personnel have a Significant Financial Interest in an existing or potential product or a company that could be affected by the outcome of the research. Any exceptions to this policy must be reviewed by the COM Industry Relations Committee and the responsible Institutional Review Board (IRB) and be approved by the Dean. Exceptions to this policy may be permitted only if (a) the individual's participation is essential for the conduct of the research and (b) an effective mechanism is established for managing the conflict and protecting the integrity of the research.

#### **11. Ghostwriting**

COM Personnel may not publish articles or materials under an individual's own name that are written in material part by Industry representatives. Specifically, COM Personnel shall not accept writing or editorial assistance; manuscript preparation, revision, production, or submission services; slide preparation or revision; or other services from Industry, either directly or indirectly, unless such materials provided by Industry are specifically attributed to the author (i.e., each slide of a presentation must be appropriately attributed). "Guest" authorship or "ghostwriting" is prohibited. All persons who make a substantial contribution to a manuscript, presentation, or other writing meeting the International Committee of Medical Journal Editors (ICMJE) standards/criteria ([http://www.icmje.org/ethical\\_1author.html](http://www.icmje.org/ethical_1author.html)) or other accepted scientific standards for authorship should be listed as authors and their affiliations listed as either academic, Industry or other.

#### **12. Enforcement**

Suspected violations of this policy shall be referred to the individual's Supervisor, Chair, Director or Associate Dean or Associate Vice President, who shall review the matter and if warranted, refer the matter to the COM Compliance for investigation. COM Compliance may consult the COM Industry Relations Committee before advising the Dean or other senior management on proposed enforcement actions, as appropriate. Violations of this policy by COM Personnel may result in the following actions (or in any combination), depending upon the seriousness of the violation, whether the violation is a first or repeat offense, whether the violator knowingly violated the policy or attempted to hide the violation and other appropriate considerations: (a) counseling of the individual involved; (b) written reprimand, entered into the violator's employment or faculty record; (c) banning the violator from any further outside engagements for a period of time; (d) requiring that the violator return any monies received from the improper outside relationship; (e) requiring the violator to complete additional training on conflicts of interest; (f) removing the violator from supervision of trainees or students; (g) revoking the individual's Pegasus Health clinical privileges; (h) fines; and/or (i) termination for cause.

#### **13. COM Industry Relations Committee**

The Dean shall appoint an advisory COM Industry Relations Committee to assist in implementation of this policy and management of COM Industry relations. The COM Industry Relations Committee shall include faculty members representative of COM. *Ex officio* voting COM Industry Relations Committee members shall consist of the Associate Vice President for Medical Affairs and COM Chief Legal Officer, the COM Associate Dean for Clinical Affairs, the COM Associate Vice President for Administration, Finance and Operations, and the COM Associate Dean for Research. COM Industry Relations Committee members, other than the *ex officio* members, and a chair or co-chairs shall be appointed by the Dean for three-year terms. An *ex officio* member may be appointed as a chair or co-chair for three-year terms. The COM Industry Relations Committee shall meet at least two times per year, or more often as needed, to review, monitor, and advise the Dean regarding implementation and enforcement of this policy and the financial and business arrangements that require review. The COM Industry Relations Committee shall

keep minutes and records of its reviews and recommendations. The COM Industry Relations Committee shall review the policy regularly and propose updates as appropriate.

#### **14. Continuing Evolution of COM Industry Relations Policy**

The COM recognizes that oversight, guidance and debate around Industry relationships and conflicts of interest must continue to evolve at local and national levels. This policy will continue to evolve as issues are considered further by the COM and the COM Industry Relations Committee.

#### **Approved and Adopted**

Deborah C. German, M.D.  
Vice President for Medical Affairs  
Dean, College of Medicine  
August 16, 2010

#### **Revisions Approved and Adopted:**

March 1, 2012  
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