

## **Faculty Disclosure and Conflict Resolution Policy**

In order to ensure the continued success and reputation for integrity of our education programs, the University of North Texas Health Science Center at Fort Worth Office of Professional and Continuing Education (PACE) has adopted a Full Disclosure and Conflict Resolution Policy.

It is proper and likely that faculty members maintain relationships with industry and corporations. This involvement in many instances brings recognition and prestige to the health science center and PACE's educational initiatives. Support from industry can contribute significantly to the quality of continuing education activities and healthcare, in general. There is nothing inherently improper with commercial support for a continuing education activity.

On occasion, situations may arise in which an individual faculty member has a relationship that could be perceived as a conflict of interest. When these situations arise, PACE makes attempts to resolve the conflict(s) so as not to preclude any faculty member from participating in any continuing education activity. It is our responsibility to disclose to participants in any educational activity the nature of the faculty relationship so those learners may form their own judgments about the presentation.

With the increased involvement of industry in continuing education, several organizations have issued statements and taken positions regarding the proper behavior of both individuals and organizations regarding involvement in commercially supported continuing education. The American Medical Association has issued a statement regarding Gifts to Physicians from Industry; the Accreditation Council for Continuing Medical Education has issued Standards for Commercial Support of Continuing Medical Education; and the Association of American Medical Colleges has adopted Guidelines for Faculty Involvement in Commercially Supported Continuing Medical Education. PACE agrees with the principles expressed in these documents.

The University of North Texas Health Science Center at Fort Worth Office of Professional & Continuing Education (PACE) requires everyone who is in a position to control the content of an accredited educational activity to disclose all relevant financial relationships with any commercial interest (see below for definitions). PACE reviews information provided by presenters and determines if a conflict of interest exists and, if so, what steps should be taken to resolve the conflict. Refusing to disclose relevant financial relationships will preclude presenters, planning committee members and/or others who could potentially influence content from participating in the planning and implementation of this accredited continuing education activity.

**Each faculty member must disclose “off-label” uses of substances or products** included in the presentation which fall into any of these three categories:

<b>Off Label:</b>	The use of an FDA approved drug or device for an indication, treatment regimen, or patient population that is not included in the FDA approved labeling of the drug.
<b>Investigational:</b>	Any drug or device which is not approved by the FDA for use in humans.
<b>Study:</b>	Any FDA approved drug or device prescribed for human research, possibly outside of FDA approved labeling.

An **unapproved** or **unlabeled use** of a drug can range from a completely unstudied use to a thoroughly investigated drug use but where the FDA has not been asked for approval. A drug, device, treatment or procedure is considered non-standard or unevaluated when it meets one or more of the following criteria:

- It cannot be lawfully marketed without the approval of the FDA and such approval has not been granted at the time of its use or proposed use;
- It is the subject of a current investigational new drug or new device application currently on file with the FDA;
- It is being provided pursuant to a Phase I or Phase II clinical trial or as the experimental or research arm of a Phase III clinical trial;
- It is being provided pursuant to a written protocol which describes among its objectives, determinations of safety, efficacy, or efficacy in comparison to conventional alternatives or toxicity;
- The predominant opinion among experts as expressed in the published peer-reviewed literature is that further research is necessary in order to define safety, toxicity, effectiveness or effectiveness compared with conventional alternatives; and/or
- It is not non-standard or unevaluated in itself pursuant to the above and would not be medically necessary, but when used in conjunction with a drug, device, treatment, or procedure which is non standard or unevaluated.

If you have any questions or need clarification regarding commercial support, conflict of interest, or off-label drug usage, please contact Andrew Crim at the UNT Health Science Center Office of Professional and Continuing Education at (817) 735-2644 or via e-mail at [andrew.crim@unthsc.edu](mailto:andrew.crim@unthsc.edu).

(For office use only)  
**How was disclosure made to participants?**

PACE signature: \_\_\_\_\_

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**Faculty Disclosure**

The University of North Texas Health Science Center at Fort Worth Office of Professional & Continuing Education (PACE) requires everyone who is in a position to control the content of an accredited educational activity to disclose all relevant financial relationships with any commercial interest (see below for definitions). PACE will review the information you provide and determine if a conflict of interest exists and, if so, what steps should be taken to resolve the conflict. If you refuse to disclose relevant financial relationships, you will not be able to participate in the planning and implementation of this accredited continuing education activity.

**This form must be completed and returned by *each* presenter**

<b>Name:</b>	
<b>Activity:</b>	
<b>Date(s):</b>	

**Please complete Sections A, C & D  
or Sections B, C & D and sign below:**

**SECTION A: No Conflict of Interest**

(Please check if true, then skip to sections C and D)

I have no financial conflict of interest or other relationship with any proprietary entity (commercial, for-profit) producing health care goods or services (NOTE: relationships with non-profit, governmental organizations and non-health care related companies **are not** required to be disclosed).

**SECTION B: Financial and Scientific Disclosures**

(Please check if true)

I have (or have had in the last 12 months) a financial interest/arrangement/or affiliation with one or more proprietary entities that could be perceived as a real or apparent conflict of interest, regardless of the context of the subject of my presentation(s). **For this purpose, relevant financial relationships of your spouse or partner of which you are aware should be considered yours, as well.**

(In order to maintain scientific balance and integrity, the disclosures recorded below, as well as any steps taken to resolve conflict of interest, will be provided to activity attendees.)

**Instructions for Disclosure:**

On the following page, list the names of proprietary entities (**excluding non-profit, governmental agencies and non-health care related companies/organizations**) that produce health care goods or services with which you or your spouse/partner have (or have had in the last 12 months) a relevant financial relationship. The nature of the relevant financial relationship should also be disclosed.

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### Disclosure of Financial Relationships

<b>Name:</b>	
<b>Activity:</b>	
<b>Date(s):</b>	

Please list the names of proprietary entities **(excluding non-profit, governmental agencies and non-health care related companies/organizations)** that produce health care goods or services with which you or your spouse/partner have (or have had in the last 12 months) a relevant financial relationship. The nature of the relevant financial relationship should also be disclosed.

<b>Name of Commercial Interest</b> <small>(use back of this form if more space is needed)</small>	Nature of Relevant Financial Relationship	
	<b>What was received?</b> <small>(Salary, royalty, intellectual property rights, consulting fee, research support, honoraria, ownership interest (e.g., stocks, stock options or other ownership interest, excluding diversified mutual funds), or other financial benefit)</small>	<b>For what role?</b> <small>Employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and other activities.)</small>
Example: Pharma Co, Inc.	Honorarium	Non-CME Speaker
Example: Pharma Co, Inc.	Research Support	Clinical Trial

#### Glossary of Terms

**Commercial Interest**

A “commercial interest” is any proprietary entity producing health care goods or services, with the exception of non-profit or governmental organizations and non-health care related companies.

**Financial relationships**

Financial relationships are those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest or other financial benefit. Financial benefits are usually associated with roles such as employment, management position, independent contractor (including contracted research), consulting, speaking, membership on advisory committees or review panels, board membership, and other activities from which remuneration is received or expected. Relationships of the person involved in the activity and those of a spouse or partner should be considered.

**Relevant financial relationships**

Financial relationships with commercial interests in the 12-month period preceding the time from the activity are considered. ACCME has not set a minimal dollar amount for relationships to be significant. Inherent in any amount is the incentive to maintain or increase the value of the relationship.

**Conflict of Interest**

Circumstances create a 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.

**SECTION C: Off-Label Discussion**

My presentation(s)  **Does** or  **Does Not** include discussion of “off-label” substance(s)/product(s) not approved by the FDA for use under discussion or of substance(s)/product(s) that are being investigated for such use.

**If your presentation DOES contain off-label discussion, please complete the off-label declaration. If it DOES NOT, please continue to section D.**

**Off-label Declaration**

**Describe the substance(s) or products(s) to be disclosed, including off-label uses.**

**Please provide contraindications, if any, of off-label discussion of use of substance(s) or product(s).**

**SECTION D: Scientific Integrity and Commercial Support**

By signature at the end of this disclosure declaration, I attest that I have carefully complied with PACE’s Standards for Commercial Support and policies regarding content and presentation of educational material, specifically, that my presentation will ...

- be for scientific and/or educational purposes only and will not promote a company’s products or services directly or indirectly;
- reflect total control of content by me;
- include no “scripting,” emphasis, or influence on content by a company or its agents;
- adhere strictly to principles of the highest quality, scientific integrity, and selection of content;
- disclose when off-label, investigational, study or non-FDA approved drug or device use is mentioned, encouraged or implied, even if contained in a question from an audience member;
- be free of commercial influence of bias in my comments, audiovisuals, and handout materials;
- ensure that the content of slides, reference materials, and handouts in print, electronic, or other media will not enhance the specific proprietary interests of any commercial entity;
- ensure delivery of my presentation free of the participation of industry representatives who may be in the session room.

**By signing below, you agree to accept no payment for participation in this activity from any source other than UNTHSC/PACE.**

Signature	Date

**Please return to:**  
 UNTHSC-PACE  
 3500 Camp Bowie Blvd.  
 Fort Worth, Texas 76107-2699  
 Or FAX to (817) 735-2598