



UNIVERSITY of NORTH TEXAS
HEALTH SCIENCE CENTER *at Fort Worth*

★
Education, Research,
Patient Care *and* Service

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:

Off Label:	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.
Investigational:	any drug or device which is not approved by the FDA for use in humans.
Study:	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 **Error! Reference source not found.** at the UNT Health Science Center Office of Professional and Continuing Education at 817-735-2539 or via e-mail at **Error! Reference source not found.**@hsc.unt.edu.

RETURN THIS PAGE



UNIVERSITY of NORTH TEXAS
HEALTH SCIENCE CENTER at Fort Worth
★
Education, Research,
Patient Care and Service

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

PACE signature: _____

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

Name:	
Activity:	
Date(s):	

**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.

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 following section. If it DOES NOT, please continue to section D.

1. 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

RETURN THIS PAGE



UNIVERSITY of NORTH TEXAS
HEALTH SCIENCE CENTER at Fort Worth
Education, Research, Patient Care and Service
Professional and Continuing Education
3500 Camp Bowie Boulevard
Fort Worth, Texas 76107-2699

Statement of Evidence-Based Content

Activity Title	
Activity Date	
Faculty Member	

I am a presenter for this CME activity and I have reviewed the proposed content and find that (please check to indicate agreement):

- This activity is based on scientific principles that are generally accepted as valid by the scientific community;
- The content is based on conclusions or inferences from evidence that is accepted in the general medical community as valid and sound;
- Scientific research cited conforms to generally accepted standards of experimental design, data collection, and analysis;
- The content of this activity does not recommend treatments or methods that are (1) not within the ACCME Definition of CME, (2) known to have risks or dangers that outweigh benefits, or (3) known to be ineffective;

The source(s) of evidence upon which this activity has been developed is/are as follows:

- Agents or treatments that are approved by the US Food and Drug Administration (FDA);
- Treatments that may be unlabeled or unapproved by the FDA but that have been found safe and efficacious through clinical application and are based on current practice standards in the medical community;

Please List:

ACCME Definition of CME

“Continuing medical education consists of educational activities which serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships that a physician uses to provide services for patients, the public, or the profession. The content of CME is that body of knowledge and skills generally recognized and accepted by the profession as within the basic medical sciences, the discipline of clinical medicine, and the provision of health care to the public.”

Printed Name: _____

Signature: _____ Date: _____

FAX COMPLETED FORM To: 817-735-2598