



**Jefferson**<sup>™</sup>  
HEALTH IS ALL WE DO

Sidney Kimmel Medical College at  
Thomas Jefferson University  
Office of Continuing Medical Education

## *CME Conflict Of Interest Policy*

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## ➤ 1.0 Rationale

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The ACCME defines a conflict of interest as existing in the presence of any financial benefit to an individual who is in a position to control the content of a CME activity. They have delegated responsibility for defining implementation policy and procedures for this to the accredited providers. Providers, such as TJU, are free to establish their own policies and procedures to implement the ACCME Standards of Commercial Support as they relate to conflict of interest. Recent statements by the ACCME encourage the use of procedures that stratify levels of conflict of interest in order to appropriately manage these incidents.

## ➤ 2.0 Policy Statement

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2.1 Intent to provide scientifically rigorous and balanced CME activities  
TJU CME activities are designed to be valid, scientifically rigorous and commercially unbiased events. They are designed to provide ongoing education to practicing physicians, to improve the public health.

### 2.2 Compliance with ACCME through review of Conflict of Interest statements

In accordance with the national Standards for Commercial Support, TJU policies and procedures for certification of CME activities include review and management of conflict of interest statements from all individuals involved in the educational planning and delivery of each activity.

### 2.3 Jefferson University Counsel's COI Policy Thresholds

Jefferson's University policy sets a threshold for significant conflict of interest at a personal financial benefit of >\$10,000 from a single commercial source OR >5% interest in a single commercial organization. The OCME recommends utilizing these same figures as the threshold to trigger a conflict of interest review process.

## 2.4 CME COI Stratified Using Same Thresholds as Jefferson University Counsel

In keeping with ACCME Standards, all individuals indicating a conflict of interest will have the conflict resolved prior to the start of the activity. However, CME COI resolution actions are stratified based upon Jefferson University Counsel definitions. For the purpose of the CME Policy on Conflict of Interest, a personal conflict of interest of >\$10,000 from a single commercial source OR >5% interest in a single commercial organization will trigger a specified Conflict of Interest Resolution process to seek additional information and assurances about the bases for content development, topic/speaker selection, and other issues that may affect the balance and/or scientific rigor of any CME activity sponsored by Jefferson.

## ➤ 3.0 Who Must Provide Disclosure Information

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### 3.1 PLANNERS of CME Activities

All individuals in a position to control the CONTENT of a Jefferson certified CME activity (hereafter called "PLANNERS") are required to submit a Conflict of Interest Disclosure statement to the OCME at the time of initial application for credit for the activity. An activity cannot be reviewed for certification until all such statements have been received.

### 3.2 FACULTY of CME Activities

All activity faculty [presenters (moderators and speakers, for example), authors/editors, etc.]) [hereafter called "FACULTY"] are required to submit a Conflict of Interest Disclosure statement to the OCME no later than 60 days prior to the start of the activity.

### 3.3 Collection of COI data from individuals

The OCME will provide a mechanism to collect COI information for the purposes of CME certification. Information should be provided by the activity faculty no later than 60 days of the start of the activity.

*\* Every effort will be made by the OCME to accommodate COI reviews of Planner and Faculty Information should exceptional circumstances arise.*



## ➤ 4.0 Conflict of Interest Management Process

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*Jefferson's Conflict of Interest Management Process requires an attestation on the part of all CME Faculty that their contributions to the CME activity will be free from commercial bias or influence, that any clinical practice recommendations relating to their contribution will be supported by the best available evidence, that absent evidence, will be consistent with generally accepted medical practice and scientific method, and that they will present a balanced view of reasonable clinical alternative, keeping the public health's interest at the center of their educational contribution. The attestation is included in the required CME Faculty Disclosure Form.*

*Disclosure and conflict of interest information received will be reviewed through the Jefferson CME process. The OCME will be responsible to review COI statements from CME Faculty and take appropriate action when a relevant conflict of interest is identified.*

*Consistent with TJU existing policies for faculty conflict of interest, the CME Conflict of Interest Review process will stratify conflict of interest based on the same criteria specified by TJU University Counsel Office.*

*Conflict of interest information will be made available to participants at Jefferson sponsored CME activities, regardless of whether or not the CME Faculty has a conflict of interest.*

*Management of an identified conflict of interest below University Counsel indicators will be accomplished through attestation, disclosure of the information to participants and evaluation of CME Faculty contribution to the CME activity specific to freedom from commercial influence. OCME review of evaluation data will identify those CME Faculty whose contributions are rated at an unacceptable level. CME Faculty whose evaluation rating is below this will be referred to the program director of the activity, and flagged for future involvement in Jefferson sponsored CME activities. Future involvement of CME faculty*

*thus flagged will automatically increase the level of conflict management utilized for that individual.*

*Management of an identified conflict of interest above University Counsel indicators will be accomplished through attestation, disclosure to the audience, faculty evaluation and a “guided interview.” Jefferson CME will contact the individual to conduct a “Guided Interview.” The outcome of the guided interview will determine the course of action to be taken.*

### The Guided Interview

The guided interview process is designed to improve communication with CME Planners and Faculty to proactively manage those with identified conflicts of interest. *The process incorporates a professional discussion between appropriate individuals* (usually physician to physician, through in some instances the Associate Dean or Director of CME will initiate the conversation).

The Committee is committed to meaningful implementation of the conflict of interest resolution process, and developed the guided interview as a response that meets the spirit of the requirement, in a way that recognizes the time constraints normally found in producing CME activities. *The guided interview will utilize a standard set of questions to form the basis for discussion, and seek to identify levels of evidence\* for proposed content. It will document the outcome of the discussion and actions needed, if any.*

### 4.1 Conflict Resolution Process For PLANNERS

When a conflict of interest is identified for a planner, the OCME will work with the Committee on CME members to conduct interviews and to resolve and document planner conflict of interests. A guided interview process consisting of a series of questions will be utilized to resolve conflict of interest.

These may include but are not limited to:

- How were the topics/faculty for the activity decided upon



- How are these topics relevant to the target audience for THIS activity?
- What evidence can you provide that these topics represent a balanced, EBM approach?

#### 4.2 Conflict Resolution Process for FACULTY above CME COI Thresholds

When this type of conflict of interest is identified, the OCME will initiate contact with the faculty member to complete the COI Resolution Form (attached) no later than 30 days prior to the activity. The OCME will work with the CME Committee chair, members, program director, or other Jefferson faculty as appropriate, to accomplish this task. The COI Resolution Form will include questions such as:

- Please describe what you expect to include in your presentation.
- Will you be making clinical recommendations
- Please identify the sources of evidence that currently support your anticipated presentation
- What information would need to be included in this presentation to demonstrate balance on the topic you are presenting?

The OCME will work with the Committee on CME members to conduct interviews and to resolve faculty conflict of interests.

#### 4.3 Resolution conversation

It is anticipated that the guided interview form discussion for both planners and faculty will lead to compliance with the balance and scientific rigor aspects of CME. The COI Form is intended to create the proper documentation of compliance as required by ACCME.

#### 4.4 Activity Content Review

If indicated from the COI Resolution process, the OCME will review slides and other activity materials prior to production for distribution and, in conjunction with the program director or CME Committee, take appropriate action, as needed.



## ➤ 5.0 Unresolved Conflict of Interest Actions

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### 5.1 PLANNER

If it is determined that the Planner's conflict of interest cannot be resolved, the program director will either remove the planner from the planning process, or withdraw the application for CME credit. The CME Committee cannot certify the activity in the presence of unresolved planner conflict of interest. If the Program Director is identified as having a conflict of interest, and the reviewer is uncertain as to its satisfactory resolution, the CME Committee will review the information and make a decision as to certification of the activity.

### 5.2 FACULTY

If it is determined that the Faculty's conflict of interest may not be resolved through the COI Resolution Process, the possible actions are

- A detailed content review of slides or other material prior to distribution by CME Committee designee, with intent to require revisions if necessary
- Replacement of faculty with conflict with individual without conflict.
- Withdraw credit for that portion of the activity, if feasible
- Not certify the activity for CME

## ➤ 6.0 Implications of this Policy on final credits awarded, promotional materials, monitoring of activities, and timing of receipt of information

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### 6.1 Final Credit Determinations

If required, reviews of identified presentations will be completed by the OCME no later than 2 workdays prior to the activity, at which time the program director will receive official notification of certified sessions within the activity. Only sessions whose faculty have satisfactorily completed the conflict resolution process can be certified. Final credit awarded the activity may be less than initially intended.





### 6.2 PROMOTIONAL MATERIALS

In order to be clear about the potential for number of credits awarded at an activity to be less than advertised, promotional materials must include a statement, to be provided by the OCME/approved by CME Committee, to the effect that

*“Credit certification for individual sessions may vary, dependent upon compliance with ACCME Conflict of Interest resolution. The final number of credits certified may vary from the maximum number indicated above”*

### 6.3 ADDITIONAL MONITORING

An activity where >50% of the faculty have identified conflicts of interest will require a CME audit while it is being conducted. In any case, an activity may be credited at the discretion of the CME Committee, Associate Dean, and the Director of CME. The OCME, at its discretion and with the approval of the Committee Chair and/or Associate Dean for CME, may require audits for conflict of interest review in other circumstance. Any direct costs associated with such an audit will be charged to the activity (i.e., travel off campus)

### 6.4 TIMING and IMPLICATIONS OF TIMING

In order to allow time for the Conflict Resolution Process to occur, planners and faculty must provide their COI information in a timely manner. Every effort will be made to accommodate planner and faculty schedules; however, the ACCME requires that COI materials be reviewed and acted upon prior to award of credit for any activity. Therefore, the OCME will utilize the following guidelines for receipt of COI Information.

See table, below

Planners	Provide COI disclosure at first planning session. Review of an activity for CME credit cannot begin until all planning committee members with control of content have been reviewed for COI.
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	All planner information should be submitted a minimum of 60 days prior to the start of the anticipated activity.
Faculty	Provide COI disclosure as soon as identified by planning committee. Must be submitted to OCME no later than 60 days prior to an activity. If faculty do not submit their content for conflict of interest review in a timely fashion, their individual session may not be certified for credit.

- Applications for CME credit must be submitted to OCME a minimum of 60 days prior to the anticipated start date of an activity in order to be considered for Jefferson CME credit.

## ➤ 7.0 Activity content and presentation guidelines

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To aid planners and faculty in developing their activities, the CME Committee will provide guidance for materials to be utilized in the certified activity (i.e., slides, handouts, other written materials). These will include but are not limited to:

Appropriate use of generic and brand names; inclusion of all /most agents within the same therapeutic class to maintain balance in presentations; citations and indications of levels of evidence of material presented; clear identification of preliminary data and sources of data.



## ➤ 8.0 Monitoring

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A variety of monitoring efforts will be implemented as part of this policy.

1. Review of COI statements and actions taken in accordance with this policy
2. OCME review of materials to be presented, as appropriate, involving the CME Committee, program director, and/or Associate Dean for CME as needed.
3. On site auditing of activities, as indicated above. Significant variation from initially approved sessions may affect future requests for certification.
4. Review of evaluation data for presence of bias. Indications of >20% of participants indicating bias in a presentation or in the overall activity will trigger a retroactive review of all materials presented to the participants, discussion with the program director and/or the CME Committee. Individuals whose ratings consistently indicate presence of bias may be precluded from future Jefferson CME activity planning or presentation.