

# Policy and Procedure Manual



ENTITY <b>American Epilepsy Society</b>	NUMBER <b>AES-COI</b>
MANUAL <b>Policy and Procedure</b>	EFFECTIVE DATE <b>11.2006; another year beginning 11.30.07</b>
SUBJECT <b>Collection and Resolution of Conflicts of Interest</b>	REVISED <b>Council approved on 11.20.06; Board approved on 11.30.06; Policy to be reviewed again in one year; Council approved again on 11.30.07. Approved by BOD 3.28.2008</b>

## I. PURPOSE

In accordance with the ACCME's *Standards for Commercial Support of Continuing Medical Education* updated on September 27, 2004, the Policy on Collection and Management of Conflict of Interest exists to provide guidance for staff, instructors, planners and managers of CME activities sponsored by American Epilepsy Society (and applicable educational partners). This policy addresses the underlying philosophy of disclosure to learners, mechanisms to collect disclosure information and the parties from which COI shall be collected, the mechanisms to resolve COI, and requirements to make actual disclosure to learners.

## II. GUIDING PRINCIPLES RELATING TO COI AND ITS DISCLOSURE

American Epilepsy Society is guided by what is in the best interest of the public, always deferring to independence from commercial interests, independence and keeping CME separate from product promotion. It is also recognized that instructors come with certain biases that are unique to their perspective. These inherent biases *may* be acceptable in the context of an educational presentation so long as that bias is disclosed to learners. Complex issues of COI, therefore, must be resolved by an established committee within the structure of the AES considering all of the available information collected. These are the basic guiding principles for the collection and management of COI.

## III. POLICY

### a. Identifying Conflict Of Interest

- i. Conflict of Interest Disclosure shall be completed on line by individuals involved with a CME activity that have the following roles:
  - I. Instructor/Faculty

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2. Planner/Course Director
  3. Council on Education Reviewers, who review the content/development of the CME activity
  4. Faculty and planners must submit the COI online survey by the given deadline as a condition for participation in the role of faculty/instructor for the CME activity
- ii. Reporting guidance is as follows:
1. Any personal financial relationship during the previous 12-month period represents a potential conflict of interest, and therefore must be reported. This also includes spouses with significant relationships with applicable industry (e.g., spouse is marketing director at an applicable pharmaceutical company).
  2. A COI is present when both (a) the relationship is financial and occurred within the past 12 months and (b) the individual has the opportunity to affect the content of CME about the products or services of that commercial interest.

### **b. Guidelines for Interpreting COI**

The COI Online Survey will generate a COI Score, which will be used as a predictor for potential Conflict of Interest potential. Based upon established thresholds, remedies such as interviews by course liaison and/or chair may be suggested or required.

### **c. Processing COI Reports**

- i. Staff has primary responsibility for initial processing of COI reports and publishing relationship disclosures where appropriate.
- ii. In addition, will provide COI documentation for established levels of concern and inform the CME Program liaison for resolution when necessary.
- iii. The Activity Chair will be consulted with cases in which the resolution is unclear or where disqualification is the option.
- iv. The Conflict of Interest Committee of the Council on Education is an additional resource for resolution of COI when the Activity Chair is not available or in cases when he recuses him/herself.
  1. The chair of the Council on Liaison shall appoint a COI Committee with three members, each one of which shall have staggered three year terms.
- v. Options for resolution of COI include:
  1. Substitution of a person with no COI or minimal levels of COI
  2. Utilization of AES' stringent Peer Review Process in which content is validated
  3. Referencing the best available evidence in all CME activities in which potential conflicts exist

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4. Requesting the instructor or planner to sever financial relationships with the commercial interest
5. Relegating the person with significant COI to a role in which therapeutic options will not be recommended
6. Excluding that part of the instruction or disqualification of the presenter

### **d. Documenting Resolution of COI**

- i. Completed COI Disclosure Reports will be maintained in the activity file
- ii. The resolution of COI by staff, liaison, course chair, activity chair or COI Advisory Board will be documented on the Resolution of COI Form.

## **IV. IMPLEMENTATION**

### **a. For Instructors**

- i. COI Disclosure instructions will be included in the Faculty Letter with clear instructions on due date process for planning

### **b. For Planners and Managers**

- i. As soon as external physician planners and reviewers for the activity are identified, they must be instructed on how and when to complete the submission
- ii. Liaisons will complete a disclosure annually and that information shall be transparent to the learners
- iii. COI Advisory Board members will complete a COI disclosure annually

## **V. Transparency to Learners**

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<b>Disclosure of Conflicts of Interest</b>	
<p>The American Epilepsy Society (AES) assesses conflict of interest with its faculty, planners and managers of CME activities. Conflicts of interest that are identified are thoroughly vetted by management and the Council on Education for fair balance, scientific objectivity of studies utilized in this activity, and patient care recommendations. AES is committed to providing its learners with high quality, unbiased and state-of-the-art education.</p> <p>The following faculty has reported real or apparent conflict of interest that has been resolve through a peer review process:</p>	
<i>Name of Faculty or Presenter</i>	<i>Reported Areas of Conflict</i>
<p>Planners and managers have reported real or apparent conflicts of interest:</p>	
<i>Name of Planner or Manager</i>	<i>Reported Areas of Conflict</i>
<p>In addition, the AES &lt;and name of joint sponsor, if applicable&gt; report the following relationships with commercial interests associated with this activity:</p>	
<i>Name of Commercial Interest</i>	<i>Type of Financial Relationship</i>
<p style="color: red;">&lt;NOTE: If no relationships are reported in any of the above categories, state that in the block and delete this note.&gt;</p>	

- a. Learners will be provided with disclosure information in the following format:

In addition, AES will utilize a Learner’s Bill of Rights to communicate this policy to them.

The Learner’s Bill of Rights is as follows:



### LEARNER BILL OF RIGHTS

The American Epilepsy Society (AES) recognizes that you are a life-long learner who has chosen to engage in continuing medical education to identify or fill a gap in knowledge or skill; and to attain or enhance a desired competency. As part of AES' duty to you as a learner, you have the right to expect that your continuing medical education experience with AES includes:

- Content that:
  - ♦ Is driven and based on independent survey and analysis of learner needs
  - ♦ Promotes improvements or quality in healthcare
  - ♦ Is current, valid, reliable, accurate and evidence-based
  - ♦ Offers balanced presentations that are free of commercial bias
  - ♦ Is vetted through a process that resolves any conflicts of interests of planners and faculty
  - ♦ Is driven and based on learning needs, not commercial interests
  - ♦ Addresses the stated objectives or purpose
  - ♦ Is evaluated for its effectiveness in meeting the identified educational need
- A learning environment that:
  - ♦ Is based on adult learning principles that support the use of various modalities
  - ♦ Supports learners' ability to meet their individual needs
  - ♦ Respects and attends to any special needs of the learners
  - ♦ Respects the diversity of groups of learners
  - ♦ Is free of promotional, commercial, and/or sales activities
- Disclosure of:
  - ♦ Relevant financial relationships that planners, teachers, and authors have with commercial interests related to the content of the activity
  - ♦ Commercial support (funding or in-kind resources) of the activity

## VI. Continuous Quality Improvement Briefing to the Council on Education

- i. A summarization of COI actions shall be provided to the Council on Education as a part of American Epilepsy Society's periodic CQI review
- ii. The results of the discussion shall be documented for the files and include:
  1. Issue identified
  2. Actions taken
  3. Changes to the system that were implemented