American Gastroenterological Association (AGA)/AGA Institute Policy on Disclosure of Potential Conflict of Interest

The AGA values its reputation for excellence among clinical, educational and research organizations and practitioners. To help preserve this high reputation for integrity and excellence, the governing board has enacted a policy on Disclosure of Potential Conflict of Interest. In developing this document, the board has attempted to balance the need to protect AGA’s integrity with the need to avoid unnecessary restrictions which might impede one’s ability to participate in activities of the society.

All nominees and all members of the governing board, committees, editorial boards, task forces and educational activities must complete a disclosure statement. The existence of a conflict does not necessarily preclude service on any of these bodies but may require some modification of the individual’s participation in a given activity.

A. Definitions

A disclosable conflict of interest may exist if your professional or personal involvement includes one or more of the following from a commercial enterprise directly related to the broad field of gastroenterology: [The monetary value of these disclosable financial interests is irrelevant.]

1. Direct interest, i.e., personal possession of shares, options, retainers, or consulting fees, patent or intellectual property rights, direct salary support, advisory board or other governance relationships, authors fees, research related finders or completion fees, restricted or unrestricted educational grants, expert testimony, lectures or speakers bureau relationships given under the direct sponsorship of a commercial enterprise. Shares held as part of a mutual fund or where the individual officer has no direct control over the investment shall be excluded from this provision.

2. Indirect interest, i.e., as in (1) except that the holding is in the name of a family member.

3. Membership on governing bodies or committees of other scientific or clinical societies must be disclosed. This includes major digestive disease organizations (specifically AASLD, ACG, ASGE, Crohn’s & Colitis Foundation, DHPA or SSAT).

Items covered under 1-3 should be reported even after the relationship has ended, if occurred within the previous twelve (12) months.

B. Procedures

1. An AGA/AGA Institute COI disclosure form and confidentiality statement is to be completed by all members of the governing board, committees, editorial boards and task forces as a condition precedent to appointment or nomination, and updated at least annually thereafter during tenure of office.

2. The content of the disclosure is the responsibility of each nominee or member; the member is expected to complete the statement, sign and submit it in writing to the Secretary/Treasurer, c/o the National Office. It will then be forwarded to the ethics committee, who will report the existence
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of a conflict, if present, to the President, Secretary/Treasurer, committee or task force chair as appropriate.

3. Disclosures require the member to certify that they have reviewed and disclosed relevant information (i.e. previous twelve months) reported on their most recent CMS.gov Open Payments Report.

4. The ethics committee is authorized to disqualify a candidate who fails to make a disclosure or who does not agree to resolve the conflict upon assumption of an AGA/AGA Institute position.

5. The disclosure statement should be completed **even if no conflict exists**.

6. Disclosure and confidentiality statements will be held in a confidential file maintained by the National Office. Access to the file will be available only to the President, President-Elect, Secretary/Treasurer, and ethics committee. The Nominating Committee will have access to disclosures submitted by candidates under consideration for positions on the governing board (i.e., officers and councillors) only. Committee chairs will be provided a confidential report of annual disclosures by committee members once each year.

7. Members adversely affected by this policy may request the ethics committee review the issue and recommend to the governing board that application of the policy be waived for compelling reasons.

8. Members who feel an improper judgment of conflict has been made by the ethics committee may appeal to the President, through the Secretary/Treasurer. The President will appoint an ad hoc hearing committee as needed in such cases.

9. Governing board and committee members must disclose any agenda related potential conflicts prior to each meeting. When a conflict is found to exist, the member may be asked or required to:

   1. Resolve the conflict to the satisfaction of the ethics committee.
   2. Publicly declare the potential conflict of interest.
   3. Abstain or recuse themselves from participation or voting in such matters.
   4. Resign from the office, committee membership or activity.

C. Governing Board and Committee Guidelines

In addition to the general disclosure guidelines previously delineated, governing board, committee and task force members are also subject to the following policies:

1. From the time an individual assumes the position of Vice President and for four years thereafter (includes service as President-elect, President and immediate Past President/Chair of AGA Governing Board) that person may make no public appearances that are directly paid for by companies in the pharmaceutical, medical device or biotech industries. Further, this intended prohibition includes any event, whether sponsored, supported, or conducted in whole or in part (either directly or through third parties), where there is direct or implied endorsement of a sponsoring/supporting company or any of its products or services. For events in which there may be perceived bias in presentation, expenses, honorarium or any other aspect involving a member, review and counsel from the ethics committee may be requested.
Persons covered by this policy may appear at AGA/AGA Institute events, programs, symposia, etc., which are supported by a company (as defined above).

2. During service on (or regular attendance at meetings of) the governing board, a committee or task force, or as a publication editor-in-chief, individuals must not be:
   - A member of a governing board nor regularly attend meetings of a governing body or finance committee of a major digestive disease organization, as defined in Section A3.
   - A member of a similar* or analogous policy-making committee, or serve as a state governor of a major digestive disease organization.

* A similar committee is defined as one whose scope is analogous to the relevant AGA/AGA Institute committee.

3. If a governing board/committee member or an entity in which a governing board/committee member has a significant financial interest submits a proposal for funding and the governing board/committee normally serves as the initial review group, an independent review group of experts should be established to assess and prioritize the proposal in question together with all competing proposals. If a specific member of the governing board/committee has unique expertise that would be crucial to evaluating the proposal and has no involvement with the proposal, he or she could be asked to join the review group. However, at least two-thirds of the members of the initial review group should be independent of the governing board or the committee.

4. If a member of the governing board or a member of a committee that is evaluating and prioritizing a proposal for funding is from the same institution as the applicant, has mentored or collaborated recently with the applicant, or has any other relationship with the applicant that might be considered as an actual or potential conflict of interest, he or she should leave the room during any evaluation and discussion of the proposal and should not vote on the proposal in question.

5. **Publications Committee only**: A publications committee member may not serve in any capacity for another organization or publisher’s gastroenterology/hepatology-related periodical during his/her appointment that involves manuscript selection, or editorial, financial or strategic decisions. (Serving simply as manuscript reviewer is acceptable.)

Guidelines 3 & 4 above also apply to oversight of ongoing projects and consideration for renewed or extended funding of ongoing projects.

**D. Educational Activities**

It is the policy of the AGA Institute to assure balance, independence, objectivity and scientific rigor in all of its educational activities. The AGA Institute Governing Board has adopted the ACCME Standards for Commercial Support as its minimum standard for all CME related activities.

All faculty, including program committee chairs/course directors and planning members, participating in any AGA Institute sponsored activity are expected to disclose to the participants any relevant financial relationship or other relationship held within the past 12 months that may pose a potential commercial bias.

A conflict of interest may exist when an individual has both a financial relationship and the opportunity to affect the content of CME about the products or services of any related commercial interests. Any conflicts of interest must be identified and resolved prior to the delivery of the CME activity to learners. If potential conflicts cannot be resolved, an individual may be disqualified from participating as a planner or faculty on
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the CME activity. Any individual who refuses to make a disclosure will be disqualified from the CME activity. In most cases, these forms must be submitted six months prior to the activity.

- **CME Course Directors/Planners:** Disclosures will be reviewed by the ethics committee for presidential appointments; all other appointments will be reviewed by the AGA Institute Education and Training Committee. No planning will begin until all activity planning committee members have disclosed all financial relationships with commercial interests (to include that of a spouse or partner), and, if identified, the COI has been resolved.

- **Faculty:** Faculty disclosure information will be reviewed by the Education & Training Committee. The AGA Institute considers relationships of faculty involved in the CME activity to include financial relationships of a spouse or partner.

- **Presenters/Abstracts:** A statement on the AGA Institute abstract form for DDW provides for disclosure of all financial relationships with a commercial interest. All AGA Institute presenters at DDW are required to disclose. This information will be reviewed by the AGA Institute Council and/or session moderator and the participant will be contacted if there is a conflict of interest and further action will be taken.

The intent of the AGA Institute policy is not to prevent a speaker with financial relationships with commercial interests from making a presentation. It is intended only to impart independence and further educational offerings that are aligned with the best interests of the physician learners and their patients. Disclosure information will also be published for participants prior to the delivery of any educational content. A conflict of interest may also be resolved by:

- Having someone else without a related COI make the presentation.
- Changing the focus of the presentation to eliminate the COI.
- Requiring the conflicted participant to present evidence-based content, which will be peer reviewed.

**E. Publications**

The AGA Institute currently publishes several periodicals, books and other resources. Disclosure forms must be filed for all publications by editors, editorialists, reviewers and publication authors.

**Journals:** It is a conflict-of-interest for editors and associate editors of a peer-reviewed journal, currently *Gastroenterology, Clinical Gastroenterology & Hepatology (CGH)*, and *Cellular and Molecular Gastroenterology & Hepatology (CMGH)*, to hold a position of editorial responsibility for a competing publication. Editors-in-chief must also not be a member of a governing board nor regularly attend meetings of a governing board or finance committee of a major digestive disease organization (as defined in Section A3). Associate editors and special section editors must disclose if they are members of a governing board or finance committee of another GI organization, but such conflicts can be managed as follows:

- Such associate/special editors shall not receive financial or confidential business information from AGA; and
- Such associate/special editors shall be recused from discussions involving finances and business decisions of the journals.

The ethics committee will review disclosure statements submitted by editors and will notify either/both the Secretary/Treasurer and Editor of any potential conflicts. If a conflict is found to exist, the procedures contained in Section C of this document will apply.
In addition to this COI Policy, the AGA Institute has developed a *Policy Regarding Conflict of Interest in AGA Institute Journals* (3/09). Please reference this document for further guidance regarding *Gastroenterology* and *CGH*.

**Clinical Practice Guidelines, Medical Position Statements (MPS) and Technical Reviews (TR):** Prior to commencement of work on an MPS or TR, authors and co-authors of these publications are required to disclose any commercial involvements to include the company(s) name, the nature of the work performed (e.g., primary investigator, consultant, paid speaker, etc.) and any specific products involved. Information disclosed will be published with the MPS/TR.

In addition to this COI Policy, the AGA Institute has developed a *Conflict of Interest Disclosure Policy for Clinical Practice Guidelines* (7/13; 7/17). Please reference this document for further guidance regarding guideline development.