



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.

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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 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](https://www.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

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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.

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A conflict of interest may exist when an individual has both a financial relationship and the opportunity to affect the content 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 educational/CME activity to learners. If potential conflicts cannot be resolved, an individual may be disqualified from participating as a planner or faculty on 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

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- 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*, *CGH* and *CMGH*.

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.

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POLICY REGARDING CONFLICT OF INTEREST IN AGA INSTITUTE JOURNALS¹

This policy applies to editors, authors, and reviewers of content submitted for publication to the print and electronic versions of the journals *Gastroenterology*, *Clinical Gastroenterology and Hepatology* and *Cellular and Molecular Gastroenterology and Hepatology*. Decisions regarding conflict of interest (COI) are made by the journal editors, with input from the AGA Institute Publications Committee as needed.

A. Potential Conflicts of Interest

The following are examples of COI that may occur with editors, authors (including invited authors), and reviewers. Interactions considered pertinent are from the start of the research activity in a specific program until such time that a submission is anticipated to be published or one year from submission date, whichever is longer.

- a. *Editors*: Editors who make final decisions about manuscripts must have no personal, professional, or financial involvement in any of the issues they might judge. Examples of personal involvement with an author include former student, fellow, mentor, or relative. Examples of professional involvement include academic rivalry, being from the same institution or research group as the author, evaluating a manuscript submitted by a member of the board of editors, or collaborating (e.g., co-authoring research article or grant) with an author. Examples of financial involvement include employment, consultancies, honoraria, stock ownership or options, expert testimony, grants/patents received, and royalties with an entity (or competing entity) discussed in the manuscript.

It is a COI for editors of the AGA Institute journals to hold a position of editorial responsibility for a competing publication. The Ethics Committee reviews disclosure statements submitted by editors and notifies either/both the Secretary/Treasurer and editor of any potential conflicts. The procedures contained in Section B of the “AGA/AGA Institute Policy on Disclosure of Potential Conflict of Interest” apply if a conflict is found to exist.

- b. *Authors*: COI for an author may arise if there exists a financial arrangement (e.g., employment, consultancies, honoraria, stock ownership or options, expert testimony, grants/patents received, and royalties) with a company whose product figures prominently in the submitted manuscript or with a company that makes a competing product.

¹ Approved in principle by the AGA Institute Governing Board, (26) VOTED, Feb. 2009; Approved by the Executive Committee, Mar. 27, 2009. (03/19)

- c. *Reviewers:* COI for reviewers exist when they have had an ongoing collaboration, original publications, or grants with the authors within the previous two years, except when part of a multicenter group from a different site; are from the same institution as the authors; or have any financial arrangements (e.g., employment, consultancies, honoraria, stock ownership or options, expert testimony, grants/patents received, and royalties) with a company whose product figures prominently in the submitted manuscript or with a company that makes a competing product.

B. Process

Potential COI are to be disclosed at the beginning of the peer-review process.

- a. *Editors:* An associate editor having COI with a submitted manuscript must recuse himself from handling the manuscript and request that the manuscript be reassigned. The editor-in-chief having COI with a submitted manuscript must assign review to one of an associate or guest editor for handling. A manuscript submitted by one of the members of the board of editors must be assigned to a guest editor.
- b. *Authors:* The senior or corresponding author assumes full responsibility for supplying the following information on the title page at manuscript submission:
 - i. For each author, disclosure of any financial arrangement with any company whose product figures prominently in the submitted manuscript or that makes a competing product; or a statement for each author that there is no conflict to disclose.
 - ii. A disclosure of all funding sources supporting the work and all institutional or corporate affiliations.
 - iii. A list of individuals who provided writing assistance for the manuscript and the source of funds that supported this assistance.

In addition, at manuscript submission, each author must complete and submit to the editorial office a standardized form that transfers copyright to the AGA Institute, verifies authorship responsibility, states NIH funding (if any), discloses all relevant conflicts of interest, and attests that the research protocol was approved by the author's institution and all experimentation was conducted in conformity with ethical and humane principles of research.

Based on the information provided, the editors will determine whether COI exists and decide to either a) reject the manuscript or b) publish the manuscript with the COI disclosed.

- c. *Reviewers:* When invited, reviewers must decline to review a manuscript if a potential COI exists. After review, all reviewers must agree to and initial one of the following statements, which appear in the journals' manuscript tracking system:
 - i. I, the undersigned Reviewer, certify that I have not had an ongoing collaboration, original publication, or grant with the authors within the previous two years, except in the case of being a part of a multicenter group from a different site, nor am I from the same institution as the authors. I also certify that I do not have any financial arrangements (e.g., employment, consultancies, honoraria, stock ownership or options, expert testimony, grants/patents received, and royalties) with a company whose product figures prominently in the submitted manuscript or with a company that makes a competing product.

- ii. I have listed any potential conflicts on interest in the Comments to Editors field.

If the reviewer discloses a potential COI after the review, the handling associate editor decides if the review should still be used to judge the manuscript.

C. Sanctions

Should an editor, author, or reviewer fail to disclose a potential COI and this is discovered after publication, the following sanctions may be applied according to the severity of the infraction. Editors may consult with the AGA Institute Ethics Committee or Publications Committee at their discretion.

a. *Editors:*

- i. A letter of reprimand and warning as to future conduct from the editor, in the case of an associate editor, or from the Chair of the Publications Committee, in the case of the editor.
- ii. Dismissal from the position.

b. *Authors:*

- i. A letter from the editor of explanation and education where there appears to be a genuine misunderstanding of principles.
- ii. A letter from the editor of reprimand and warning as to future conduct.
- iii. A letter from the editor to the author's institution or funding body.
- iv. Publication of a notice detailing the author's failure to disclose the COI.
- v. Publication of an editorial detailing the full details of the misconduct.
- vi. Refusal to accept future submissions from the author on a sliding scale of one-to-five years.
- vii. Formal retraction or withdrawal of the paper from the scientific literature.
- viii. Reporting the case to the Office of Research Integrity (ORI).

c. *Reviewers:*

- i. A letter from the editor of explanation and education where there appears to be a genuine misunderstanding of principles.
- ii. A letter from the editor of reprimand and warning as to future conduct.
- iii. A letter from the editor to the reviewer's institution.
- iv. Refusal to allow the individual to review for the journal on a sliding scale of one-to-five years.

This policy was developed in accordance with the guidelines set forth by the Committee on Publication Ethics and the International Committee of Medical Journal Editors.

AGA's Conflict of Interest Disclosure Policy for Clinical Practice Guidelines*

AGA is committed to the enhancement of the field via development of evidence-based tools. The development of clinical practice guidelines (CPG) is an important component of AGA's strategic plan. As much as it is important to ensure that rigorous methodology is used in the data presented, it is of utmost importance to maintain integrity for disclosure of potential conflicts of interest (COI). This includes disclosing all potential conflicts and maintaining transparency. To that effect, AGA has adapted IOM recommendations for managing COI disclosures in the development of CPG. 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 this process.

All members of the guideline development group (GDG), defined as technical review authors, methodologist, guideline panel chair, guideline panel members, and external reviewers, must complete a disclosure statement prior to commencing work. 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.

A. General Principles

1. The chair of the guideline panel should not be a person with a potential conflict of interest.
2. Funders should have no role in CPG development.
3. Whenever possible, GDG members should not have potential COIs. In some circumstances, a GDG may not be able to perform its work without members who have COIs, such as relevant clinical specialists who receive a substantial portion of their incomes from services pertinent to the CPG.
4. Members with potential COIs should not represent more than a minority (49%) of the guideline panel.

B. 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

* Approved by the AGA Institute Governing Board, (14) VOTED, July 2013; Revised (8) VOTED, July 2017.

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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 except that the holding is in the name of a family member.
3. Intellectual interest, i.e., strongly held opinions on the clinical topic to be addressed by the guideline or affiliation with an institution that could potentially benefit or be harmed by the recommendations put forth in the guideline.
4. 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 or SSAT).

Items covered under 1-4 should be reported even after the relationship has ended, if occurred **within the previous three (3) years.**

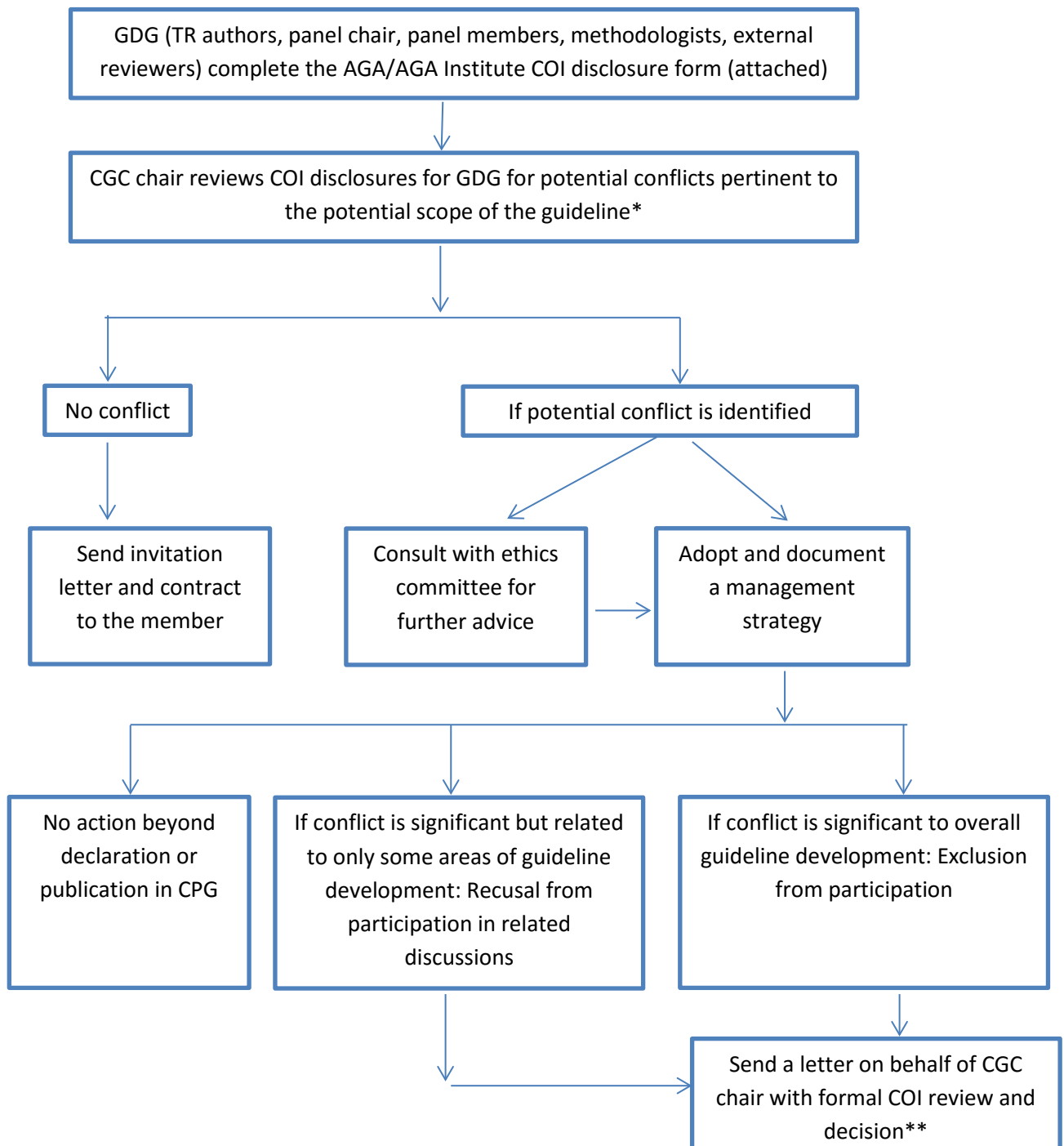
C. Procedure

1. Prior to the selection of the GDG, all individuals being considered for membership should complete an AGA/AGA Institute Clinical Guideline COI disclosure form and confidentiality statement. Disclosures should reflect all recent, current and planned activities as described in Section B.
2. The disclosure statement should be completed **even if no conflict exists.**
3. The content of the disclosure is the responsibility of each member; the member is expected to complete the statement, sign and submit it in writing to the National Office. Disclosure and confidentiality statements will be held in a confidential file maintained by the National Office. Members are responsible for updating their disclosure as changes occur throughout the project.
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. Members who feel an improper judgment of conflict has been made by the chair of the Clinical Guidelines Committee or the Ethics Committee may appeal to the Ethics Committee within 30 days of notice.
6. All potential COI disclosures of each GDG member should be reported and discussed by the prospective development group prior to the onset of work. Each panel member should explain how his or her potential COI could influence the CPG development process or specific recommendations.

All members of the GDG (except the external reviewers) agree to not accept new speaking engagements or consulting arrangements for which an honorarium is paid by a pharmaceutical company (or a direct intermediary) with interest pertinent to the scope of the CPG during the guideline development process, until 12 months after its publication date.

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Step 1: COI disclosure review prior to guideline development



**Decisions will be made on a case-by-case basis and will be guided primarily by the guideline topic.*

***Appeals of decision may be made within 30 days to the AGA Institute Ethics Committee.*

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Step 2: COI disclosure review during guideline development

It is optimal if the members involved in guideline development lack potential conflicts of interest. However, AGA recognizes that there could be circumstances where this would not be feasible. To ensure that the guideline development process is transparent, all declaration of interests made by the guideline development group members will be shared with all the members as a first agenda item for every meeting. In addition, the members will also be provided an opportunity to declare any changes to previously declared interests.

Members are expected to update their disclosures in writing as changes occur throughout the development process.

Step 3: COI disclosure review during guideline publication

A summary of how COIs were collected, any declared potential conflicts and a brief description of how they were managed will be included in the actual guideline document. All COI disclosure forms will be maintained at the AGA National Office in Bethesda, MD.

Examples of COI declaration in guidelines

Conflicts of interest: All members were required to complete a disclosure statement. These statements are maintained at the American Gastroenterological Association (AGA) National Office, and pertinent disclosures are published with the report. Where a potential conflict is detected; remedial measures to address the potential conflict are taken and will be noted in the disclosure statement.

- A) Dr. X has received research grants from MMMM, and serves as a consultant for NNNN. Dr. Y owns stock in ZZZZ. (If a remedy is needed, example: Dr. X terminated his consultancy with NNNN, effective 6/17.)
- B) The chair of AGA's CGC reviewed conflict of interest disclosures from all participants and determined that they were not relevant or influential to the subject matter of this guideline.

There should be a COI statement filed even if there are no specific potential conflicts to report.