

I. PURPOSE & OVERVIEW

The gastroenterology and endoscopy community rely on transparency and, where needed, the management of conflicts of interest (COI) to advance the practice of endoscopy, conform to standards of care, and improve patient outcomes. The American Society for Gastrointestinal Endoscopy (ASGE) and its scientific journals, *GIE* and *VideoGIE*, continuously review and strengthen processes for disclosure and management of actual and perceived conflicts of interest. Any COI caused by financial, intellectual or competing professional interests relevant to scientific publications, society volunteers, clinical practice guidelines (CPG), other review documents, and clinical or non-clinical educational activities are collected, managed where needed, and made available to the public.

In 2011, the Institute of Medicine (IOM) issued an updated report that specifically addressed the issue of transparency and management of financial conflicts of interest (FCOI). The IOM called for organizations to develop policies regarding FCOI.

The International Committee for Medical Journal Editors (ICMJE) also has recommendations to review best practice and ethical standards in the conduct and reporting of research and other material published in medical journals. The ICMJE suggests that all authors should disclose interactions with ANY entity that could be considered broadly relevant to the work. ICMJE has proposed updates to its existing policy in 2020 and ASGE will update and adjust its policies as needed.

ASGE and *GIE* use a combined COI policy. Disclosures listed on Center for Medicare and Medicaid Open Payment system (CMS) is another COI data source that is required to be provided to *GIE* and/or ASGE. ASGE and *GIE* recognize that just because there are financial ties does not mean that anyone is doing anything wrong. Transparency will shed light on the nature and extent of these financial relationships and, where necessary, management of disclosed conflicts of interest will be conducted. At a minimum, ASGE and *GIE* require fully disclosed relationships.

II. DEFINITION OF CONFLICT OF INTEREST

ASGE defines a conflict of interest (COI) as involvement in a business, partnership, consulting position, professional society, or a rewarding arrangement that could influence the deliberations or actions of the individual involved with ASGE and/or its designated activities or publications within three years of the start date of serving in a role for ASGE, during the term of service and/or at the time of submission for a publication and, if known, any upcoming conflicts.

III. WHO SHOULD DISCLOSE?

1. ASGE Governing Board members
2. ASGE Foundation Trustees
3. Committee or Task Force Chairs
4. Committee or Task Force Members
5. Special Interest Groups (SIG)
6. Education faculty or Planning member
7. Education enduring product authors or planning members
8. Authors and reviewers of *GIE* and *VideoGIE* manuscripts
9. *GIE* and *VideoGIE* editorial and review boards
10. Clinical Practice Guideline authors and reviewers
11. ASGE Society Publication Technology Reviews and Other Related Documents authors and reviewers
12. ASGE Staff

IV. RELATIONSHIPS REQUIRING DISCLOSURE

Potential conflicts of interest are to be collected by all leadership, committee members, education planners, faculty, and others in control of content about all their financial relationships with ineligible companies within the prior 36 months.

- a. There is no minimum financial threshold; individuals must disclose all financial relationships, regardless of the amount, with ineligible companies.
- b. Individuals must disclose regardless of their view of the relevance of the relationship to the project, activity or educational program. Disclosure information must include:
 - The name of the ineligible company with which the person has a financial relationship
 - The nature of the financial relationship.

Examples of financial relationships include employee, researcher, consultant, advisor, speaker, independent contractor (including contracted research), royalties or patent beneficiary, executive role, and ownership interest. Individual stocks and stock options should be disclosed; diversified mutual funds do not need to be disclosed. Research funding from ineligible companies should be disclosed by the principal or named investigator even if that individual's institution receives the research grant and manages the funds.

- c. Owners or Employees of "ineligible companies": Financial relationships identified of those individuals who are owners or employees of ineligible companies require further detailed peer-review. These individuals must be excluded from controlling content or participating as planners or faculty in accredited education. There are three exceptions to this exclusion whereby employees of ineligible companies can participate as planners or faculty in these specific situations:

ASGE & JOURNAL POLICY FOR MANAGING DECLARED CONFLICTS OF INTEREST (COI)

- When the content of the activity is not related to the business lines or products of their employer/company.
 - When the content of the accredited activity is limited to basic science research, such as pre-clinical research and drug discovery, or the methodologies of research, and they do not make care recommendations.
 - When they are participating as technicians to teach the safe and proper use of medical devices, and do not recommend whether or when a device is used.
- d. ASGE staff are also required to provide any potential conflict of interest disclosures for review.
- e. ASGE's Governing Board members and Foundation Trustees should disclose professional conflict of interest for any individual who holds or anticipates accepting a leadership position in another professional national or international gastroenterology society.
- f. If there are no conflicts of interest, individuals must state that there are none.
- g. Although it is not possible to define all situations, a conflict of interest may be deemed to exist if an independent observer might reasonably question a posed conflict. All ASGE Governing Board, Committee, and Task Force members, are expected to avoid any activity performed on behalf of the Society that has the potential to result in personal gain for themselves except for paid activities approved by the Governing Board such as speaker or officer honoraria.

V. CONFLICT OF INTEREST DISCLOSURE PROCESS

ASGE has developed a checklist, provided in the appendix at the end of this document, as a quick reference and practical tool to be used by any ASGE committee, task force, faculty of an accredited ACCME educational activity, author of a publication, or governing board to reference when developing or reviewing a document that falls within the scope of this policy.

A. For all ASGE Society Leadership, Volunteer and *GIE/VideoGIE*

1. All conflicts of interest are to be listed and updated in the ASGE COI Planstone system (<https://asge.planion.com/Z?D48449035>).
2. If there are no conflicts of interest, ASGE leadership and/or volunteers must state that there are none in the ASGE COI Planstone system.
3. All must confirm any disclosures at a minimum, matching what is currently listed for the previous 3 years in Centers for Medicare and Medicaid Services (CMS) Open Payment at time of submission (<https://openpaymentsdata.cms.gov/>).
4. When in doubt, disclose.
5. Time period for reporting any potential conflicts is during a three-year period prior to the date of assuming an ASGE role or society publication and, if known, any upcoming conflicts.
6. Any disclosures or the declaration of no disclosures will appear in print and online.
7. *GIE/VideoGIE* only: Associate Editors and Reviewers will recuse themselves from involvement in processing manuscripts when they identify a conflict of interest.

B. ASGE Clinical Practice Guideline Disclosures

1. Must follow indications above listed in A 1-6.
2. All individuals who are invited to participate in a guideline development panel must disclose to ASGE all COI and, if the guideline is co-sponsored by another society, to that society, if requested. Ideally, the chair of a clinical practice guideline has no conflicts of interest related to the topic area.
3. Disclosures must be made prior to the commencement of guideline development and then updated annually, as well as anytime the panel convenes. If a potential COI arises during guideline development, it must be disclosed immediately. Approved panelists need to review and update the ASGE COI Planstone system throughout the development process. All COI will be listed with other panel members at the beginning of each meeting. Panelists must allow ASGE to review their declared COI and determine whether these conflicts are manageable for the panel and, if manageable, how they should be managed.
4. Authors must confirm all disclosures during development and at time of submission to *GIE* for publication.

C. ASGE Accredited Continuing Medical Education (CME) Disclosures

1. Must follow indications above listed.
2. All individuals who are invited to participate in the development of an ASGE accredited continuing medical education activity must disclose to ASGE all COI.
3. Disclosures must be made prior to the commencement of planning and then updated annually. If a potential COI arises during planning of an activity, it must be disclosed immediately.
4. Approved planners, faculty, authors, and/or staff need to review and update the ASGE COI platform system throughout the development process. All COI will be listed at the beginning of each meeting.
5. Any member participating in an ASGE-sponsored CME educational activity, including faculty, planning committee, staff, or review group, must complete an Attestation Form during the planning stages of the activity.
6. Members refusing to provide disclosure will not be allowed to participate in the educational activity. Relevant conflicts will be presented to participants prior to the CME activity.
7. For the ASGE Annual Scientific Meeting (DDW®), every attempt will be made to achieve fairness and impartiality in the selection process for abstracts, oral and audiovisual presentations, and posters. Submitting authors will not be allowed to submit disclosures on behalf of a co-author.
8. Selection committee voting members will score and select presentations without knowledge of the authors or institution. A committee member should neither discuss nor vote upon his/her own abstract nor vote upon a competing presentation.
9. ASGE Publications and Educational Product Development must be disclosed and mitigated for all individuals involved with the development of educational products or ASGE publications in accordance with the ASGE policy Conflicts of Interest.

VI. MANAGEMENT OF DISCLOSED CONFLICTS OF INTEREST

A. ASGE Society Leadership & Volunteer Disclosure Management

1. If the member fails to disclose a conflict of interest that is subsequently discovered and deemed relevant, the Society may take disciplinary action.
2. The disclosure should reveal the nature of all possible conflicts of interest.
3. Potential conflicts of interest will be forwarded for review by the appropriate chairperson, Secretary, or President, as detailed below.
4. The following are general mechanisms to mitigate potential conflicts of interest:
 - a. Disclosure of conflicts prior to relevant decisions, presentations, activities, or discussions.
 - b. Recusal from the discussion and decision-making process.
 - c. Inclusion in the discussion but recusal from the decision-making process.
 - d. Removal of the individual from the decision-making body or activity.
5. When a conflict of interest is thought to exist by both the Secretary and President, the member will not be permitted to vote on any actions related to this conflict.
6. The President will determine whether the individual may participate in discussion on matters related to the conflict and will notify the Secretary of this determination.
7. After appointment, all members of committees and task forces must submit a disclosure form at least annually.
8. It is incumbent upon committee members to inform the chairperson of any new potential conflicts that arise subsequent to written disclosures.
9. When a conflict of interest of a committee or task force member is thought to exist by the chairperson, the member will not be permitted to vote on any actions related to this conflict.

B. *GIE* and *VideoGIE* Author Disclosure & Management

***includes technology reviews and other society document publications**

1. Authors must complete the COI disclosure in an ASGE platform system, irrespective of whether a conflict of interest is perceived.
2. If the member fails to disclose a conflict of interest that is subsequently discovered and deemed relevant, the Editor-in-Chief of *GIE* or *VideoGIE* can take necessary action with the article at their discretion.
3. The following are general mechanisms to mitigate potential conflicts of interest:
 - a. The primary method of mitigation is disclosure.
 - b. In cases of major COI, such as a corporate employee who authors a paper, the Editor may request independent data analysis or revisions to the manuscript to reduce the appearance of bias.
 - c. Manuscripts that cannot avoid the appearance of major bias may be rejected by the Editor. In cases where the Editor or Associate Editor has a major COI with the manuscript, the paper will be reviewed by the independent Editorial Board.

- d. The Editor has final authority on accepting or declining manuscripts on potential issues related to COI of authors.
10. The disclosure should reveal the nature of all possible conflicts of interest.
11. Actual or perceived conflicts of interest may compromise all aspects of scientific publication, including research validity, interpretation and presentation of data and results, and editorial review. All Editors and Editorial Board members, authors, and reviewers for *GIE* must disclose actual or potential COI.

C. ASGE Clinical Practice Guideline Disclosure Management

1. Ideally, the chair or co-chairs and the majority of guideline development panel members (>50%) should be free from relevant conflicts of interest related to the specific topic area of the guideline.
2. Financial disclosures that pose a conflict for individuals who are invited to participate in an ASGE guideline development panel are reviewed by the staff prior to the individual being accepted as a panel member.
3. Based on their disclosures, proposed panelists are considered as either free from relevant COI, having manageable COI that requires management, or having disqualifying COI that must be terminated in order to serve as a member of the guideline panel.
4. Individuals with no relevant COI are approved for full participation. Research funding that is free of direct or indirect industry funding or control is not regarded to be a conflict of interest. Service on a data and safety monitoring board for such research is also not regarded as a conflict of interest.
5. For information on what constitutes a manageable COI, see the full document at www.xxx. Individuals with manageable conflicts must disclose their conflicts to the whole guideline panel.
6. Individuals with manageable conflicts as defined will be permitted to participate in discussions about the evidence but must excuse themselves or be recused from decision-making. They must attest that the intellectual conflict will not bias their participation in the panel and may be required by ASGE to excuse themselves or be recused from decision-making on relevant recommendations.
7. For an explanation of disqualifying COI, see the full document at www.xxx.
8. Proposed panelists with disqualifying COI will be notified by ASGE staff.
9. ASGE recognizes that experts in the subject matter of a guideline may be unable to serve as ASGE guideline panelists due to financial relationships that cause disqualification.
10. Confidentiality: All discussions and work by the guideline development panel must remain strictly confidential. Every member of a guideline development panel will be required to sign a confidentiality agreement to participate in the project. Further information on confidentiality and penalties for violation can be found in the full document at www.xxx.
11. Publication of disclosures: All relevant COI of guideline panel members that were in existence during guideline development and the previous three years, and known by ASGE, will be published together with the ASGE clinical practice guideline or review documents. All ASGE guideline documents should include a Methods section describing in enough detail the processes used to identify and manage conflicts of interest during guideline development.

12. Speaking related to the guideline topic: All guideline panel members, irrespective of conflicts of interest, should refrain from speaking activities related to the guideline's subject matter that involve payments by industry directly to the speaker during the period of guideline development and for one year after publication. Panelists should also decline offers to speak about the guideline on behalf of an entity with an actual, perceived, and/or potential vested interest in guideline subject matter for a reasonable period (at least one year is recommended) after guideline publication.
13. Implementation of this policy may be modified for joint guideline development with organizations whose conflict of interest policies differ from that of ASGE only if the importance of the collaborative guideline justifies departing from ASGE's policy. For a full explanation of how to handle those cases, see the full document at www.xxx.

Any guideline panel member who is suspected of having failed to disclose a relevant COI at the time of disclosure to ASGE or having failed to disclose to ASGE a new COI acquired during the time since they were appointed to the panel will be contacted by the staff of ASGE and asked to update their disclosures. Previously undisclosed COI that are confirmed will be categorized as manageable or disqualifying as described above. For further information on the process that follows failure to disclose, see the full document at www.xxx.

D. ASGE Accredited Continuing Medical Education (CME) Disclosure Management

ASGE follows the accreditation council for continuing medical education (ACCME) requirements related to Standards to Ensure the Independence of CME Activities. The following is a guide used in managing potential conflicts of interest as well as validating CME content.

- a. ASGE supports education and research in diagnostic and therapeutic endoscopy and uses where appropriate, collaborations between the society, academia and industry that ultimately benefit patients. To avoid any potential conflicts of interest, each individual and staff who are involved in planning efforts, are required to adhere to evidence-based, scientific only, unbiased content. Any recommendations included in the content must be based upon evidence that is accepted within the profession of medicine and gastroenterology as adequate justification for indication and contraindications in the care of patients.
- b. Content of ASGE's CME activities 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 healthcare to the public.
- c. All planning of educational content is independent from any communications with the ineligible companies.
- d. All faculty's, staff's and planning members' potential conflicts of interest are disclosed and reviewed to determine relevance to the content and managed accordingly.
- e. Hands-on courses do not rely on vendors to demonstrate use of any device used in accredited CME activities.

- f. Any vendor representatives at ASGE accredited CME activities are required to sign an agreement that they will not promote their product in any way.
- g. ASGE continuously audits for commercial bias to determine whether its processes and measures remain effective.
- h. In the ASGE COI platform system, all educational faculty, planning members and staff are required to sign an attestation form stating that all clinical recommendations will be based upon evidence that is accepted within the profession of medicine, gastroenterology and all scientific research referred to or reported will conform to the generally accepted standards of experimental design, data collection and analysis.

VII. REFERENCES

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APPENDIX COI STEPS

STEP 1: Review ASGE COI policy located at <https://www.asge.org/home/about-asge/mission-governance#governing-policies-and-forms>

STEP 2: Review ASGE and confirm what is currently listed in Centers for Medicare and Medicaid Services (CMS) Open Payment at time of submission (<https://openpaymentsdata.cms.gov/>). Make sure what is listed in CMS Open Payment matches what you provide to ASGE.

STEP 3: Log into ASGE's online platform system. If your first time, you will need to create an account. The ASGE online platform system can be found at <https://asge.planion.com/Z?D48449035>. Please log into the platform system periodically and review your listed disclosures, especially prior to any ASGE education CME accredited activity, document or guideline review under development, committee, task force and/or governing board meeting.