

Managing Conflicts of Interest (COI): Principles, Policies and Procedures of the IUGA

APPLICATION

This Policy applies to all IUGA Directors & Officers (Board) as well as to all International & Regional Advisory Board Members, Committee Chairs, Committee Members, Special Interest Group Chairs and Steering Group Members, Editors-in-Chief and Editors of the IUJ, IUGA key staff, IUC Chairs and Members.

DEFINITIONS

IUGA: The International Urogynecological Association

IUGA Entities: IUGA entities are any and all groups of IUGA members specifically organized within the structure of the organization for a specific (leadership) purpose. They include but are not limited to: the IUGA Board, IUGA Committees and other groups within IUGA such as the International Advisory Board, ad hoc committees, Special Interest Groups, IUJ Editorial Board, task forces, guideline panels and all other ad hoc IUGA (writing) groups.

COI Committee: The IUGA Conflict of Interests Committee, which is appointed by the IUGA President and usually consists of three to five senior members (not Board Members) with the IUGA Past-President serving as an ex-officio (non-voting) member.

Conflicts of Interests: Conflicts of Interests (COI) are circumstances which require incompatible loyalties from an individual or organization to one or more competing individuals or organizations in a manner which produces or may produce detriment to one of the competing individuals or organizations.

Ineligible Company: any company whose primary purpose is the producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients (including but not limited to pharmaceutical or device manufacturers/ distributors).

PRINCIPLES AND POLICIES

1. IUGA recognizes that professionals involved in policymaking, research, education, standard-setting, fund-raising, outreach and other activities for a professional organization may be subject to COIs. The existence of an actual or apparent COI does not imply fault or wrongdoing on the part of an individual and does not necessarily disqualify an individual from participation in IUGA activities.
2. IUGA recognizes that there may be financial conflicts of interests and/or intellectual conflicts of interests.
3. IUGA members must disclose any and all known or potential financial and intellectual conflicts of interests.
4. Prior to participating in IUGA programs, all IUGA members must make full and effective disclosure of non-IUGA relationships that may be related in any way to the healthcare industry, and which may in any way create, or may be perceived to create in any, way COIs with their IUGA activities, presentations or publications.
5. Non-IUGA interests are defined as follows:
 - A. Affiliation -- Membership on the Board of Directors, holding an office, chairing a committee, editorial position, or status as a paid employee or paid or non-paid consultant in any proprietary interest producing health goods or services, including health publishing, internet or e-commerce.

- B. Ownership – Personal or family holdings in any commercial entity, including any publishing, internet, e-commerce or other business enterprise that provides healthcare products or services related to IUGA activities.
 - C. Compensation -- Support or income from commercial or other sources, including any publishing, internet or e-commerce enterprises, related to healthcare or to IUGA activities. Income includes stock options in, royalty arrangements with, dividends from the commercial entity, honoraria for speaking engagements (exclusive of reimbursable travel costs), or in-kind payments within the past twelve months.
6. Conflicts of interest, which must in all instances be disclosed by an IUGA member, are those private or institutional interests that may under some circumstances compete or conflict with primary duties owed by the member to IUGA. These COIs may include:
 - A. Personal or family financial interests;
 - B. Professional or business interests of a non-IUGA institution;
 - C. Duality of interest from employment, membership on the Board of Directors, or existence of any fiduciary relationship with any non-IUGA entity. Such interest may include: membership on a scientific advisory panel or other scientific or medical committee; ownership of stock; receipt of honoraria or consulting fees; receipt of financial support or grants for research or for travel on behalf of the other entity; or ownership of a patent or another intellectual property rights in any drug, device or product related to urogynecology.
7. All disclosures of COIs should be sufficiently transparent to allow IUGA members to understand the impact on IUGA of such conflicts of interests, the presence of bias in opinions or recommendations, or the necessity for the conflicted individual to recuse himself or herself from an IUGA responsibility or activity.
8. No individual vested with authority to speak or take formal position on behalf of IUGA shall assume a role with any competing or unaffiliated organization or entity that may be regarded as in competition with IUGA without knowledge and express consent of the IUGA Board.
9. No individual vested with authority to speak or take formal position on behalf of IUGA may endorse any commercial product related to urogynecology.
10. Any IUGA officer or other individual vested with authority to speak for or otherwise represent IUGA shall not simultaneously represent competing private commercial entities, institutions or enterprises; shall not make public statements contrary to any position or policy of the IUGA; and shall divest themselves of any duality of interests or representation.
11. Individuals who are part-time or full-time employees of ineligible companies (pharmaceutical or device manufacturers or other commercial entities) may not serve on any of the IUGA entities (including the Board, Committees and SIGS), may not attend meetings nor participate in discussions of the IUGA Board of Directors or any other IUGA entity (including Committees and SIGs), unless permitted by special action of the IUGA Board of Directors.
12. Disclosure Period for Conflicts of Interest: Conflicting interests such as affiliations, ownership, compensations or other fiduciary positions in non-IUGA organizations which existed in the 12 months prior to a person assuming a role with IUGA must be disclosed.

LEVELS OF INVOLVEMENT

The IUGA COI principles and policies apply to all individuals in any position in any of the IUGA entities. In addition, the IUGA Board of Directors has identified groups of individuals for who specific (higher) policy levels have been adopted. Although all individuals assuming decision-making authority or responsibility within or on behalf of IUGA must disclose their actual or potential COIs, those with the highest level (A) of responsibility must divest themselves of financial relationships giving rise to COIs.

The disclosure records of all individuals in any position in any IUGA entity must be provided and reviewed prior to the appointment of the position. Disclosures must be updated annually for the duration of the position.

Level A — Board & Editorial Leadership

This is the highest level of responsibility and applies to the following IUGA Board positions / roles:

- President
- Vice President
- Immediate Past President
- Secretary
- Treasurer
- Editor(s)-in-Chief of the IUJ

Prior to assuming Level A responsibilities and for the term of their position or office, these individuals must promptly disclose **and divest themselves** of significant relationships with ineligible companies (see definition above), including:

- Any governance role (e.g. President, CEO, CMO, etc.) or direct employment with an ineligible company;
- Any role as consultant or advisor (including advisory board) to an ineligible company;
- Any role as paid lecturer or paid attendee at an ineligible company event.

Upon appropriate disclosure and review, these individuals may, during their term of office, be allowed to:

- maintain current investments in pharmaceutical and/or device stocks;
- participate in institutional or individual research;
- serve as an officer or board member of an IUGA **Affiliate Society**, unless deemed by the Board of Directors to be a substantial conflict to the IUGA;

These individuals may NOT, during their term of office:

- in any way officially represent or serve as officers or members of the governing board or serve as committee chairs of related professional associations in which the principal interests include urogynecology, such as (but not limited to) the International Continence Society (ICS), the American Association of Gynecologic Laparoscopists (AAGL), the American Urogynecologic Association (AUGS), and the European Urogynecological Association (EUGA).
- serve as expert witnesses (for either plaintiff or defendant) in medical liability cases if IUGA has a direct and substantial interest, if IUGA is a named party to the litigation or if IUGA may be adversely impacted by the outcome of the litigation (this applies to new cases only, after term of service commences) unless the participation is specifically authorized or requested by the IUGA COI Committee and Board.
- serve as an editor-in-chief of a peer-reviewed journal that may be regarded as in competition with IUGA without knowledge and express consent of the IUGA Board.

Level B — Councils, Committees and Groups

This is the second highest level of responsibility and applies to the following IUGA positions / roles:

- Committee Chairs, co-Chairs, Subcommittee Chairs
- International Advisory Board Members
- Special Interest Group Chairs and Steering Committee Members
- Editors of the IUJ
- IUC Steering Committee Chairs
- Writing Group Members

Upon appropriate disclosure and review, these individuals may, during their term of office:

- act as a consultant or advisor (including advisory board) to an ineligible company;
- act as a paid lecturer or paid attendee at an ineligible company event.
- be permitted to maintain current investments in pharmaceutical and device stocks;
- participate in institutional or individual research;
- serve as an officer or board member of an IUGA **Affiliate Society**, unless deemed by the Board of Directors to be a substantial conflict to the IUGA;
- serve as expert witnesses (for either plaintiff or defendant) in medical liability.

However, these individuals may NOT, during their term of office:

- serve as officers or members of the governing board or as Committee Chairs of related professional associations in which the principal interests include urogynecology, such as (but not limited to) the International Continence Society (ICS), the American Association of Gynecologic Laparoscopists (AAGL), the American Urogynecologic Association (AUGS), and the European Urogynecological Association (EUGA).
- serve as an editor-in-chief of a peer-reviewed journal that may be regarded as in competition with IUGA without knowledge and express consent of the IUGA Board.

Level C – Committee Members/Staff/Consultants/Advisors

This level of responsibility applies to the following IUGA positions / roles:

- Committee Members
- Regional Advisory Board Members
- IUGA Staff
- Consultants
- Advisors

Please note that COI Level A and Level B requirements of disclosure and disqualification apply equally to all consultants active for or within IUGA whose roles, duties, or relationships relative to IUGA activities are significant in education, research, or formulation of guidelines or treatment options, or who may otherwise be (or assumed by others to be) in a position to affect or influence medical care, product selection or use, health policy, coding or reimbursement.

Note: Any individual who participates in activities at more than one level is required to comply with the COI Guidelines of the higher level.

PROCEDURES FOR DISCLOSURE AND RESOLUTION OF CONFLICTS OF INTERESTS

Specific issues arising within any of the IUGA entities, or disclosure questions facing one or more individuals and involving potential COIs, should be referred to the IUGA COI Committee for consideration and decision or recommendation. Those questions and answers may be posted – without identifying information – on the members only section of the IUGA website or otherwise made available to guide others under similar circumstances.

A. Options for Resolution of Conflicts of Interests

1. Recusal of conflicted individual from committee discussion and vote on conflicting item
2. Divestiture by conflicted individual of financial or intellectual interest in conflicted item
3. Dismissal or resignation of conflicted individual from membership in the IUGA entity in which the conflict of interest exists
4. Resignation or termination of IUGA membership
5. Any one or combinations these resolutions may be used to eliminate a conflict of interests

B. Routine Procedures.

1. All elected members of the Board of Directors; chairs and members of standing and ad hoc committees; editors, sub-editors and contributors to and reviewers of IUGA publications and educational activities; and consultants must:
 - a. disclose their actual or apparent COIs by establishing a disclosure record in the COI section of the IUGA website;
 - b. divest themselves of financial and intellectual relationships giving rise to COIs;
 - c. update the disclosure record annually or when there is a change in IUGA role or a change in disclosable outside interests or commitments. The IUGA COI Committee will review these COI disclosures annually or at more frequent intervals at the discretion of the COI Committee.
2. The chair of each IUGA entity shall review these COI disclosures and report any actual or potential conflicts of interests to the IUGA COI Committee.
3. When a new member or chair is proposed for any IUGA entity, a review of the proposed member's COI statement must be performed prior to that member's appointment to an IUGA entity. This initial review shall be performed by the IUGA officer or chair proposing such an appointment.
4. The IUGA COI Committee shall review in detail possible conflicts of interests which are discovered through its annual review of COI disclosures that are registered on the IUGA website or which are brought to its attention by any IUGA member, officer or entity chair.
5. After careful review, the COI Committee shall then render its opinion as to whether a COI exists and, if present, define the methods required to resolve the COI.
6. The conflicted member will be required to take the action prescribed by the IUGA COI committee or that member will be subject to restrictions on or loss of membership in IUGA.

C. Appeal of the Decision of the IUGA Conflict of Interests Committee

1. If a COI exists and the resolution of the conflict of interests required by the IUGA COI Committee is not acceptable to the conflicted IUGA member, that member may appeal for a review, with or without a hearing, by the COI Committee. After such review, the COI Committee will then render its final opinion as to whether a COI exists and, if present, identify methods to resolve the COI.
2. If the conflicted IUGA member fails to take the actions required by the COI Committee within a reasonable period of time, the COI Committee shall then advise the IUGA Board of Directors that an unresolved COI exists.
3. If the IUGA Board of Directors is notified by the IUGA COI committee that an unresolved COI exists, the Board of Directors will determine the final resolution of that COI. The conflicted member may appeal for an additional hearing with an ad hoc committee of the IUGA Board of Directors made up of three members of the Board of Directors appointed by the IUGA President. The Board of Directors may or may not grant the conflicted member this additional hearing. If such a hearing occurs, the ad hoc committee of the Board of Directors which conducts the hearing will present its findings to the IUGA Board of Directors. The IUGA Board of Directors will determine the final resolution of the conflict of interests, with or without a hearing, and the decision of the Board of Directors will be final.