

AUGS Conflict of Interest Policy – Overview

Purpose and Application: Complex relationships with for-profit and non-profit organizations and entities may, by their existence, present a perceived or real conflict with the missions and values of AUGS. Inasmuch as the existence of real or perceived conflicts of interest serves to undermine the stature, integrity, creditability and function of AUGS, AUGS must ensure that its membership, leadership and the public-at-large understand the importance it places on identification and resolution of conflicts. The independence and the credibility of AUGS require implementation of a clear policy that promotes professionalism and trust and can be enacted in a practical, fair and transparent manner. The AUGS Conflict of Interest Policy has been adapted from the Council of Medical Specialty Societies Code for Interactions with Companies. Note, the AUGS COI Policy includes limitations related to volunteer engagement with for-profit companies and non-profit organizations.

What defines a relevant relationship that requires disclosure? AUGS Board of Directors, Committee Chairs and Committee members will report relationships with commercial entities that could be perceived to influence, or that give appearance of potentially influencing the programs, products or services provided by AUGS. A financial relationship includes any exchange of items of value, ex. meals, travel support, lodging expenses, or donated materials from commercial and non-commercial entities. Disclosure should include ANY entity that could be considered broadly relevant to the work of AUGS. All sources of revenue paid or promised to be paid directly to the physician or their Institution on the physician's behalf over the prior 12 months (regardless of amount) should be disclosed.

Examples of items that need to be disclosed include but may not be limited to:

- A joint industry-society research award or industry-sponsored competitive award, in which the company does not have primary or sole input in choosing the awardee
- An “unrestricted educational grant” or investigator-initiated industry-funded research given to an individual (including CME activities) in a non-competitive fashion is considered a financial conflict
- If a spouse or domestic partner has a significant financial relationship with a commercial interest that makes a product or device currently used in the field of Female Pelvic Medicine and Reconstructive Surgery
- Participation in legal consulting (for either defense or plaintiff) in class action or product liability cases.
- A consultant for educational for-profit educational company's Educational collaboration like the International Academy of Pelvic surgery (IAPS) or Up-To-Date® are also companies with a product
- Grants or consulting role outside of AUGS (public funding i.e., NIDDK, NICHD, NIA supported grant pertaining to PFD issues; consulting role FDA, AHRQ)
- Payments including honoraria (e.g., serving on a scientific advisory board, providing continuing professional education lectures or serving as an expert witness in class action or product liability cases)
- Equity holdings (including stock options and grants) in a company that, to your knowledge, conducts or plans to conduct business related to your field of discipline

Failure to Disclose: Failure to disclose is viewed as a breach of trust and will be investigated and managed as deemed appropriate by the AUGS Governance Committee.

Specific COI Policy Statements: In addition to this general COI Policy, AUGS has adopted specific COI policies for:

- AUGS Board of Directors
- Volunteers
- Corporate Support

Conflict of Interest – Board of Directors Policy

AUGS depends on volunteers for governance and the initiatives that provide value to members. The membership includes a wide spectrum of women's healthcare and AUGS strives to provide value to all members. Many members, including Board members, have multiple relationships with other health care entities whose interests and goals may be incongruous with those of AUGS.

AUGS is cultivating a culture of transparency and disclosure within the Board to manage these different relationships. In reality, most Board members will have some relationship that might be perceived as conflicting with the Societies goals, and rather than limiting the Board to a subset of membership without relationships, the Board is cultivating a culture where members are aware of their own relationships that pose potential conflicts and voice these relationship and possible conflict during pertinent related Board business.

To ensure ethical decision making and avoid conflicts of interest, or the appearance thereof, AUGS has adopted the following Conflict of Interest Policy for the AUGS Board of Directors.

General Principles

- Presidential line and the Treasurer may not have Direct Financial Relationships with Companies during their term of office.
 - Nominees for Key Leadership positions will be notified that they will be required to terminate any Direct Financial Relationship with Companies within six (6) months of being elected to office.
- Board Members at large, Foundation Chair and Vice Chair are permitted to have Direct Financial Relationships with Companies but must disclose any such Relationship and indicate whether it is in excess of \$5,000 per year when requested.
- Members of the Board of Directors may not participate as leaders or presenters in a Company Industry Expert Theater, Product Theater or promotional/marketing event held in the exhibit hall or associated with AUGS' annual meeting.
- All Board members are required to complete a COI Disclosure Form when they begin their service on the Board. Updates to the COI Disclosure Form will be requested two weeks prior to each Board meeting to ensure accurate disclosures are provided for each Board meeting.
- Disclosures will be stored in the member's online profile contained in the AUGS membership database. Volunteer disclosures will be made publicly available if a specific request is made to AUGS.
- Failure to disclose is viewed as a breach of trust and will be investigated and managed as deemed appropriate by the AUGS Governance Committee.
- These guidelines will apply to AUGS and the PFD Research Foundation.

Transparency

- AUGS will disclose on its website all financial and uncompensated industry relationships that officers and Board of Directors have reported to AUGS.
- AUGS will make its conflict of interest policies known to its members and the public and will make individual disclosures available upon request.

Service on Boards/Committees

- Members of the Board of Directors cannot serve as officers or members of the governing board or as Committee Chairs of related professional associations during their term of office. Related professional societies include national and international professional societies whose principal interests include Female Pelvic Medicine and Reconstructive Surgery including but not limited to Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU), International Continence Society (ICS), International Urogynecological Association (IUGA), Society of Gynecologic Surgeons (SGS), and American Association of Gynecologic Laparoscopists (AAGL). This also includes national and international

organizations in women's health such as, The American College of Obstetricians and Gynecologists (ACOG), International Federation of Gynecology and Obstetrics (FIGO) and the American Urological Association (AUA). It does not include national certifying organizations like American Board of Obstetrics and Gynecology (ABOG), and American Board of Urology (ABU).

- The PFD Research Foundation Chair and Vice Chair may not serve as officers or members of the governing board of related foundations during their term of office.

Direct Financial Relationships with Companies

A Direct Financial Relationship is a relationship held by an individual that results in wages, consulting fees, honoraria, or other compensation (in cash, in stock or stock options, or in kind), whether paid to the individual or another entity at the direction of the individual, for the individual's services or expertise. As used in this policy, the term Direct Financial Relationship does not mean stock ownership or intellectual property licensing arrangements.

Key Society Leaders may:

- Provide uncompensated service to companies and accept reasonable travel reimbursement in connection with services
- Accept research support as long as grant money is paid to the institution or practice where the research is conducted, not to the individual
- Receive wages or other compensation from a company in exchange for providing or overseeing the provision of health services to company personnel
- Accept reasonable compensation for serving on an independent data safety monitoring board in a company study
- Own stock or stock options in a company
- Receive royalties or similar fees relating to patents or other intellectual property

Conflict of Interest Policy – Volunteers

AUGS depends on volunteers for governance and the initiatives that provide value to members. The membership includes a wide spectrum of women's healthcare and AUGS strives to provide value to all members. Many members, including Committee and Task Force members, have multiple relationships with other health care entities whose interests and goals may be incongruous with those of AUGS. To ensure ethical decision making and avoid conflicts of interest, or the appearance thereof, AUGS has adopted the following Conflict of Interest Policy for AUGS Volunteers.

General Principles

- Volunteers are permitted to have Direct Financial Relationships with Companies, unless otherwise noted, but must disclose any such Relationship and indicate whether it is in excess of \$5,000 per year when requested. Exceptions to this principle are outlined below.
- All volunteers are required to complete a COI Disclosure Form when they begin their volunteer role. Updates to their COI Disclosure Form are required annually.
- Volunteer Disclosures will be stored in the member's online profile contained in the AUGS membership database. Volunteer disclosures will be made publicly available if a specific request is made to AUGS.
- Failure to disclose is viewed as a breach of trust and will be investigated and managed as deemed appropriate by the AUGS Governance Committee.
- These guidelines will apply to AUGS and the PFD Research Foundation.

Transparency

- AUGS is cultivating a culture of transparency and disclosure within our governance structure to manage these different relationships. In reality, most volunteers will have some relationship that might be perceived as conflicting with the Society's goals, and rather than limiting volunteer service to a subset of membership without relationships, AUGS is cultivating a culture where members are aware of their own relationships that pose potential conflicts and voice these relationship and possible conflict during pertinent related society business.
- AUGS will make its conflict of interest policies known to its members and the public and will make individual disclosures available upon request.

Direct Relationship with Companies

A Direct Financial Relationship is a relationship held by an individual that results in wages, consulting fees, honoraria, or other compensation (in cash, in stock or stock options, or in kind), whether paid to the individual or another entity at the direction of the individual, for the individual's services or expertise. As used in this policy, the term Direct Financial Relationship does not mean stock ownership or intellectual property licensing arrangements.

Clinical Guidance Documents

- Members of any committees or writing groups related to document development/oversight, performance measures or outcomes will disclose all financial or uncompensated relationships with industry.
- The chairs and co-chairs of these writing groups and committees may not have Direct Financial Relationships with Companies and must remain free of conflicts of interest for at least one year after publication.
- All committee and writing group members are required to complete an annual disclosure form and disclose all relationships prior to panel deliberations, as well as update their disclosures throughout the development process. All disclosure information will be posted along with the published document. It is recommended that at least 50% of the writing group members are free of conflicts of interest.

- Committee members, writing group members and staff may not discuss a guidance document's development with Company employees or representatives, will not accept unpublished data from Companies, and will not permit Companies to review documents in draft form.
- Committee members are not permitted to speak on behalf of any guidance document at a Company meeting or Company-sponsored meeting for a period of one year after publication.
- All contributors, including expert advisors or reviewers who are not officially part of the committee, are required to disclose financial or other substantive relationships that may constitute a conflict of interest.
- Individuals who are employed by or engaged to represent a Company are not eligible to serve on a clinical guidance document writing group or serve as an expert advisor or reviewer.
- Since health care providers, payors and patients look to clinical guidance documents as an important resource from experts in the field, it is important that they are free from commercial bias and influence.
- A transparent development process that is free of company influence will be followed in the development of all clinical guidance documents and related products.
- Prior to publication clinical guidance documents will be subject to multiple levels of review, including rigorous peer-review by a range of experts. The AUGS Board of Directors will review and approve all documents prior to being submitted to the Journal, Female Pelvic Medicine and Reconstructive Surgery. It is expected that the Journal will submit the guideline document to an independent editorial review like any other manuscript submitted for publication.

Journal

- *Female Pelvic Medicine and Reconstructive Surgery*, the Society's official Journal, shall maintain editorial independence from the Society and its advertisers. The Journal may have its own conflict of interest policy, which should at a minimum include:
 - All authors are required to disclose financial and other relationships with Companies for the past year. This disclosure information will be published with the article/issue.
 - All editors and reviewers are also required to disclose financial and other relationships with Companies. These disclosures will be published on the Journal's Web site.
 - The Editor-in-Chief has the ultimate responsibility for determining when a conflict of interest should disqualify an editor or reviewer from reviewing a manuscript, according to established policies.
 - The Journal will develop a policy prohibiting the submission of "ghost-written" manuscripts prepared by or on behalf of Industry.
- The FPMRS Editor-in-Chief may not have Direct Financial Relationships with Companies during their term.

AUGS Registries

1. The Chair and Vice Chair of the PFDR Registry Committee may not have Direct Financial Relationships with Companies during their term.
2. The PFD Research Registry Committee will be responsible for ensuring that transparent processes exist for access, use, analyses and publication of data from the PFDR.
3. The selection of data elements may include input from Companies, but all decisions regarding data elements must go through the formal peer review process and approval by an AUGS Committee.

PFD Week

- The PFD Week Program Chair may not have Direct Financial Relationships with Companies during their term.
- PFD Week Program Committee members may not participate as leaders or presenters in a Company Industry Expert Theater, Product Theater or promotional/marketing event held in the exhibit hall or associated with AUGS' annual meeting during their term on the Committee.

Conflict of Interest Policy – Corporate Support

To ensure ethical decision making and avoid conflicts of interest, or the appearance thereof, AUGS has adopted the following Policy on Corporate Support.

General Principles

- AUGS will develop all programs, products, services, and clinical guidance documents independent of industry influence.
- AUGS will separate its fundraising efforts and business transactions from programmatic decisions.
- AUGS will use written agreements with companies for grants, sponsorship, charitable donations and business transactions that will specify what the funds are for, the amount given, and the separate roles of the company and the Society.
- These guidelines will apply to AUGS and the PFD Research Foundation.

Transparency

- AUGS will disclose industry support for activities to include company name, category of support (e.g., monetary support, in-kind support, and charitable donations) and dollar amount. This will be updated annually.
- AUGS will disclose on its website all financial and uncompensated industry relationships that officers and Board of Directors have reported to AUGS.
- AUGS will make its conflict of interest policies known to its members and the public and will make individual disclosures available upon request.

General Corporate Support

- AUGS will accept corporate support only for activities that are consistent with our mission.
- AUGS will not accept corporate support in a form or manner that could be interpreted as an endorsement of a corporate supporter, its products, or services, and will take steps to avoid such appearances.
- AUGS shall always make decisions with respect to its policies, programs and publications independent of corporate support and shall avoid actions which would give the appearance that corporate support had any influence on, or was a factor in making, such decisions.

Educational Programs (including Annual Meeting)

- AUGS will conduct its educational programs in a manner consistent with the Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support of Continuing Medical Education and in compliance with all applicable federal, state, and local rules and regulations.
- AUGS will accept funds for educational programs provided that:
 - We will have responsibility for the criteria, objectives, content, quality, and scientific integrity of such programs and publications.
 - We will avoid the appearance that corporate supporters have authority to make decisions regarding program or publication content, program development, speaker/author selection, or the like.
 - All decisions with respect to programs will be made by AUGS staff, members, or agents who have no conflict of interest with the funding source.
- AUGS will not accept funds for, nor will it sponsor or co-sponsor, any programs that are tied to the products or services of a corporate supporter unless such program clearly discloses such corporate support.
- The receipt and use of corporate support will be subject to a written agreement.

- For purposes of this policy, “corporate support” does not include paid advertising by corporate supporters for AUGS programs or publications or payment for goods or services provided to the corporate supporter by AUGS (e.g., exhibitor fees; annual meeting registration fees).

Clinical Guidance Documents and Outcome Measures

- AUGS will not permit industry support of the development of clinical guidance documents, performance measures or outcomes measures.
- Corporate support may be solicited to assist with the distribution of clinical guidelines to AUGS members and other interested parties.

Research and Registries

- Companies are not permitted to select (or influence the selection of) recipients of Research Grants. Companies have no control or influence over manuscripts that arise from grant-funded research.
- AUGS will appoint an independent review committee to select recipients of research grants, based on a peer-review process.
- AUGS will not name a research grant or endowment after a corporate entity. Instead recognition will be provided to all corporate/foundation donors to the research grants program.
- AUGS will not permit Companies that support research grants to receive intellectual property rights or royalties arising out of the grant-funded research
Companies will not be allowed to participate in the direct management or development of AUGS registries. Unless the registry is serving as a public/private partnership for device/drug surveillance. In this circumstance, AUGS will ensure the appropriate governance structures are in place and will not allow Companies to have a collective majority representation.