

# Principles, Policies & Procedures for Managing Conflicts of Interest

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### **Principles**

- A. Conflicts of Interest (COIs) are relationships or associations with organizations, persons, corporations or enterprises that may affect or be perceived to affect one's judgment or decision-making.
- B. The American Urological Association and its affiliated entities (collectively "AUA") hereby adopt a policy of universal disclosure of COIs and, where appropriate, divestiture or other resolution or mitigation of COIs on the part of its officers, active members, consultants, senior staff and participants in AUA activities.
- C. AUA recognizes that professionals especially those involved in policy making, research, education, standard setting, fundraising or outreach for a professional organization are subject to COIs. Therefore, AUA considers it unwise to embrace a general policy that would prevent participation in Association affairs by individuals having relationships that may represent COIs. The existence of an actual or apparent COI does not imply fault or wrongdoing on the part of an individual.
- D. The AUA policy requires disclosure of financial or intellectual relationships that may be regarded as possibly influencing actions taken or statements made under the aegis of the organization, by any of AUA's committees or in AUA's publications or presentations. Relevant relationships that may create a conflict of interest must be disclosed regardless of whether or not compensation was received. Specific dollar amounts are not used as a threshold for disclosures because the potential for a conflict arises from the existence of the relationship, not the monetary value.
- E. The AUA recognizes the need to have a policy that ensures proper balance, independence, objectivity and scientific rigor in governance and in educational, research, health policy and all other activities sponsored by the AUA. Careful compliance will inspire confidence, will avoid both actual bias and the appearance of bias, and will comply with legal and regulatory standards.
- F. All actions, statements and decisions regarding management and operation of the organization and, in particular, those involving research or continuing medical education or involving recommendations for patient safety, coding, reimbursement, health policy or related matters, must serve the best interests of the public and our patients rather than serve the economic interests of AUA's leadership, individual members, employees, consultants or commercial supporters.
- G. The AUA requires that prior to participating in AUA programs, all individuals without exception make full and effective disclosure of their relationships related in any way to health care or to their AUA activities, business transactions, presentations or publications.
- H. The AUA requires that all such disclosures should be made and disclosed in a manner that will allow others to make an informed decision about the existence and impact of COIs including bias in opinions or recommendations, or the necessity for the individual to recuse him or herself or to withdraw completely from an AUA responsibility or activity. If a COI has been identified, it will be resolved or mitigated according to the procedures contained in this document.
- I. Duality of Representation. No AUA officer or other individual vested with authority to speak or take a formal position on behalf of AUA shall represent private industry, or any institution or enterprise unaffiliated with AUA, before the same or any related body. Nor shall such individuals make public statements contrary to any position or policy of the AUA.

- J. Conflicting Entities or Organizations. Individuals who are part- or full-time employees of industry (e.g., pharmaceutical and device manufacturers) may not serve on AUA standing councils/committees unless permitted by the AUA Bylaws. No AUA officer, council/committee chair or editor shall assume a role with any competing or unaffiliated organization or entity that may be regarded as in competition with AUA without knowledge and express consent of the AUA Board of Directors.
- K. Commercial Endorsements. No AUA official, representative, employee or those holding themselves out as representing the AUA may endorse any commercial product related to the specialty of urology. However, this policy shall not prevent acceptance of industry advertisements in AUA publications with an express disclaimer of endorsement or acceptance of financial or in-kind support for AUA activities.
- L. Funding of Research or Educational Activities. No funding shall be solicited or accepted by AUA from any private industry, commercial supporter or related source under express conditions or attendant circumstances whereby the source of funds retains an inappropriate control over use of the funds. More specifically, no AUA funding source may impose restrictions on content or publication of research, nor dictate
  - a) the procedures, protocols or identity of individual researchers or institutions by whom or where the research will be conducted,
  - b) conditions of confidentiality or prepublication review, or
  - c) ownership of intellectual property or patentable results of the research.

No individual making a presentation using materials prepared by industry shall do so without disclosing the nature and origin of such materials. Donor-restricted grants will be accepted only after careful scrutiny to avoid imbalance between competing interests and to avoid the fact or appearance of bias.

## **Definition of Conflicting Interests**

#### A. Types of Conflicts of Interests (COIs)

**Financial COIs** exist when an individual is in or may reasonably be perceived to be in a position to gain or suffer financial loss as a result of an action, deliberation or recommendation of the society.

**Intellectual COIs** exist or may exist as a result of competing scientific beliefs, competing academic institutions, societies or publications. Such COIs may be self-declared (e.g., competing beliefs) or be evident upon appropriately executed disclosures (academic affiliation or editorial responsibility).

#### **B.** Conflicting Interest Definitions

Conflicting interests which must in all instances be disclosed (and which may in some instances constitute grounds for disqualification) are the **private or institutional interests** of individuals or their immediate family members, which may under some circumstances compete or conflict with their duties owed to the AUA.

All financial and intellectual COIs must be disclosed in accordance with AUA policy. Individuals must disclose relationships with certain entities regardless of their view of the relevance of the relationship to the individual's AUA position or activities.

Specifically, members must disclose personal or immediate family relationships with the following types of entities:

- any entity researching and developing, producing, marketing, selling, re-selling or distributing health care products used by or on patients or
- health care publications, or
- other medical associations

Moreover, **relationships in the following categories** related to healthcare or AUA activities must be disclosed:

- Consultant or Advisor. Includes service on research, product development, marketing, advisory boards or quality assurance/safety monitoring boards related to health care products or services.
- Meeting Participant or Lecturer. Honoraria, reimbursements or in-kind payments received as
  faculty members, speakers bureau, industry-sponsored lectures, presenters, chairs, proctors,
  preceptor or consultants. Any role beyond meeting attendee should be disclosed.
- Scientific Study or Trial. Includes research as a principal investigator as well as grant support for scientific studies or trials within a member's institution where the member has direct knowledge of these activities.
- Ownership or Investment (Private Company). Ownership of stocks, stock options or other ownership interest in any private entity.
- **Employee.** Wages or salaries received from a healthcare entity, healthcare publication or other medical association. Employment in a urology practice or in the US Military does not need to be disclosed.
- **Investment Interest (Public Company).** Personal or family ownership of stocks or stock options (or dividends or revenue received from the same) issued by publicly traded healthcare company. Passive stock ownership such as mutual funds need not be disclosed.
- Intellectual Property Interest. Owner of any intellectual property interest (e.g., patent, copyright, trademark) for health care products or services, and/or receipt of royalties from such intellectual property interest.
- **Leadership Position.** Board, officer, trustee, editor, or other leadership position in any commercial entity, society or organization relating to health care.
- **Health Publishing.** Includes service on editorial boards, paid authorship or contributorship, service as a paid peer reviewer and/or any publishing royalty arrangements.

#### C. Disclosure Period

Any existing interests within the past 24 months should be disclosed prior to assuming a role with the AUA. Ongoing disclosure of new relationships is also required for the duration of that role.

#### D. Disclosure Review

Intellectual or financial COIs may be judged as grounds for recusal from participation within a committee or other AUA structure. Upon appropriate disclosure by the individual, the committee or task force chair or president of the board shall present the potential COI to the other members of an AUA Board, Council, Committee or Task Force and, in conjunction with the committee member, shall determine whether such COI warrants recusal or exclusion from participation, under all of the attendant circumstances.

Although disclosure must be uniform, resolution of COIs is dependent on and defined by the activities of the individual relative to AUA.

#### Levels of Involvement

The AUA Board of Directors identifies groups of individuals who serve the AUA at various levels of activity juxtaposed to different activities or relationships that may or may not be permitted, or may require specific review for potential COIs. Although all individuals assuming decision-making authority or responsibility within or on behalf of AUA must disclose their actual or apparent COIs, those with the highest level of responsibility must divest themselves of financial relationships giving rise to COIs. The levels of such responsibility have been defined:

#### A. Level I – Officers and Board Consultants

This Level applies to the following AUA offices or roles:

- 1. Officers
  - a. President
  - b. President-elect
  - c. Immediate Past President
  - d. Secretary
  - e. Treasurer
  - f. Secretary-elect
  - g. Treasurer-elect
- 2. Eight Section Representatives to the Board of Directors
- 3. Council Chairs
  - a. Education Chair
  - b. Public Policy Chair
  - c. Research Chair
  - d. Science & Quality Chair
- 4. Key Committee Chairs
  - a. Coding and Reimbursement Committee Chair
  - b. Practice Guidelines Committee Chair
  - c. Data Committee Chair
  - d. Quality Improvement and Patient Safety Committee Chair
  - e. Judicial & Ethics Committee Chair

#### 5. Peer Reviewed Journal Editors

- a. The Journal of Urology® Editor
- b. Urology Practice® Editor
- c. AUANews Editor
- d. JU Open Plus Editor

The disclosure records of these individuals must be updated and reviewed by the appointing authority, or new disclosure record established, <u>prior</u> to the appointment of these positions. Prior to assuming Level I responsibilities, these individuals must promptly disclose and divest themselves of significant relationships, for the term of their position or office, with pharmaceutical and device industries including:

- Any governance role with a pharmaceutical or device company
- Any role as consultant or advisor to a pharmaceutical or device company
- Any role as paid lecturer or paid attendee at a pharmaceutical or device company event.

Upon appropriate disclosure and review, these individuals may be permitted to maintain current investments in pharmaceutical and device stocks or may participate in institutional or individual research. They may also maintain private ownership as an individual or part of a group in ancillary services or may serve as an officer or board member of an affiliated society, unless deemed by the Board of Directors to be a substantial conflict to the AUA. Members of the Board of Directors, and Level 1 Council Chairs and Editors are not allowed to serve as expert witnesses (for either plaintiff or defendant) in medical liability cases. This applies to new cases (after term of service of board commences), and does not apply to providing medical testimony for a member's own patients.

#### **Roles with Accredited Education Responsibilities**

If a Level 1 position has direct responsibility for AUA's accredited activities (Office of Education, annual meeting), additional conflict of interest restrictions are required to align with the ACCME's Standards for Integrity and Independence in Accredited Continuing Education.

Standard 3 of ACCME Standards for Integrity and Independence in Accredited Continuing Education requires that accredited providers exclude owners or employees of ineligible companies to participate in an accredited educational activity, except in limited circumstances including:

- 1. When the content that they are controlling is not relevant to the business lines or products of their employer/company.
- 2. When the content 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.

Because the Office of Education and annual meeting covers all topic areas within urology, those serving in these roles may not have any disclosures which would identify them as an owner or employee of an ineligible organization.

#### B. Level IA – Guidelines Panel Chairs and Members

**Chairs** - All guideline panel chairs are prohibited from participation in a governance role, as a consultant or paid lecture or attendee for any pharmaceutical or device company for which there is specific subject—matter or material overlap for the duration of the guideline development. This prohibition extends for a period of one year after the approval of the guideline by the AUA Board of Directors. In addition, guideline panel chairs must refrain from *giving industry sponsored talks* 

about the recently published guideline for a period of one year from time of approval by the AUA Board of Directors. The chair otherwise is encouraged to talk about the guideline in other forums to benefit the AUA and increase the dissemination of the guideline material.

Consistent with Level 1 COI, and after appropriate disclosure and review, panel chairs may be permitted to maintain current arms-length investments and current Pharma-sponsored research for which there is no specific subject-matter or material overlap with the Guideline under development; however, panel chairs shall not enter into wholly funded Pharma-sponsored research regarding the topic during guideline development and the 12-month period of time as determined above. They may maintain private ownership as an individual or part of a group in ancillary services, or may serve as an officer or board member of an affiliated society.

**Members** - A majority of new guidelines panel members (greater than 50%) should be free of Level 1A conflicts which includes the prohibiting of participation in a governance role, as a consultant or paid lecture or attendee for any pharmaceutical or device company for which there is specific subject—matter or material overlap for the duration of the guideline development and extending for a period of one year after the approval of the guideline by the AUA Board of Directors.

Panel members, regardless of their industry relationships, must NOT present themselves as spokespersons for the guidelines when giving industry talks on topics with significant subject-matter overlap where guideline content may be discussed. Panel members giving industry sponsored talks are required during guideline development, and for the period of one year subsequent to approval of the guideline by the Board of Directors, to disclaim publicly that they "are not an official spokesperson for the AUA guideline panel" if speaking about any material related to the guideline product. This allows the audience to understand that the panel members, whereas participants in the guideline development, are not AUA spokespersons, and AUA copyrighted material is protected.

#### C. Level II – Committee Members

All other committee chairs and members, guideline panel members, editors of and contributors to AUA publications or scientific and/or educational activities, consultants and review team members or abstractors, must make full disclosure of their relevant relationships.

The chair of the committee should review these COIs before each scheduled meeting. The chair is responsible to report to the committee prior to each meeting. Each AUA committee or entity has the responsibility, prior to its meetings or efforts, to review the financial and intellectual COIs of its members and consultants and to mandate disqualification or recusal of individuals whose COIs may have the appearance of affecting the exercise of their duties.

Following disclosure of potential COIs, it shall be the responsibility of each council or committee on which the individual serves to determine whether such potential conflict warrants a) exclusion from discussion of the subject, or b) recusal from any vote, or c) dismissal from the committee. The goal of committee deliberations is to allow transparency of member interests and relationships in context of the planned agenda for those meetings. Such rules for committees should be openly discussed, and it should be made clear that members may participate in the discussions, at the direction of the chair and with agreement of the committee. However if a COI exists, as determined by the committee chair and the committee, the individual with this COI will be required to be excused from the deliberations during development of recommendations or any vote that may be affected by said conflict. Failure of a committee member to adhere to the disclosure policy and

process, or serious breach of confidentiality, may result in a committee member being removed from the committee.

These rules and principles will apply as adapted to the variety of circumstances encountered by AUA participants at this level.

- 1. All individuals participating in AUA activities at this level shall make the general disclosures required by this document and shall renew and update those disclosures directly relevant to all activities in which the individual is engaged.
- 2. No council or committee member shall serve as a paid or unpaid consultant to a company or interest that may profit from information obtained while serving on that entity, nor may such individual disclose such information to any person or interest who (to their knowledge) may profit from that information.
- 3. No council or committee member shall accept compensation in any form from a company or interest seeking the approval or support of AUA for its product, service or technology.
- 4. Any such issue unresolved within the processes of the council or committee in question may be referred to the AUA Judicial & Ethics (J&E) Committee for resolution by notifying the AUA staff or chair of the committee.
- 5. AUA councils or committees whose members are subject to these Level II requirements shall be at liberty to impose additional disclosure or other requirements on their members if warranted due to the nature of the activities of each (refer to Appendix).

#### D. Level III – Other Members/Staff/Consultants

All other individuals, AUA members and senior staff are responsible to make timely disclosure of all relationships giving rise to potential COIs indicated in the computerized AUA Disclosure Record, as it may be revised from time to time.

The COI Level I and Level II requirements of disclosure and disqualification apply equally to all AUA consultants whose roles, duties, or relationships relative to AUA 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. Included also are temporary or incidental consultants to workgroups reporting to standing committees and councils.

For all purposes under this COI Policy, these requirements apply to all individuals whose role entails consideration, analysis, discussion, drafting, or recommendations a) with respect to scientific or technological applications or strategies for use in the education or practice of urology, or b) with respect to modalities or products intended for urological research or training, or c) for patient care or treatment.

Any such consultant employed by or closely affiliated with an institution, medical practice, agency, company, or similar entity must disclose not only his or her own real or potential conflicts, but also known conflicts of the employer and fellow employees, or of the affiliated entity – but only to the extent that the consultant possesses actual knowledge of the existence of such potential COI relationships during the period of consultancy.

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

Specific issues arising within a committee, or otherwise within AUA structures, or disclosure questions facing one or more individuals and involving potential COIs, may be referred to the AUA Judicial and Ethics Committee for consideration and decision or recommendation. Those questions and answers may be posted – without identifying information – on the J&E portion of the AUA website or otherwise made available to guide others under similar circumstances.

#### **Procedures for Disclosure**

#### A. General Procedures

An interactive program on AUA's primary website (AUAnet.org/coi) permits each individual to establish a disclosure record, and to update the record to reflect changes either in one's role at AUA, or in one's disclosable outside interests or commitments. This disclosure should include the nature of the involvement and should be made before undertaking any AUA activity. An individual's online disclosure must be kept current and updated at least annually. It is the responsibility of the member to update his or her disclosure record whenever relationships change related to relevant AUA activity. When an individual edits his/her disclosures to expire an item in his/her disclosure record, the information is nevertheless retained on the website as part of their current record for a period of 24 months.

Although system input is universal and uniform, output will be limited or varied by one's role, audience, activity or program with AUA. Personal information entered by individuals on the web site will not be publicly disclosed beyond the necessities of the AUA role or activity in question. An internal review policy will seek to limit the output to relevant program requirements.

#### B. Process for Submission, Collection and Review of Disclosures

Submissions will be made in accordance with the following procedures:

#### 1. Appointments to Standing Committees

- a. To begin each Association year (June May), individuals serving on the Board of Directors and each of its Councils and committees are sent appointment or reappointment notification emails.
- b. Participants are provided their AUA Membership Identification Number (or email address) and password to access the AUA Disclosure COI program where they can review and update their disclosure information. If a committee member does not have a Membership Identification Number, one will be issued for this process (e.g., non-member consultants). Log-in information and instructions are provided with the notification emails.

- c. Each participant is expected to fully disclose all commercial/other relationships as defined above, and to update that information whenever there is a change in any such relationship.
- d. AUA staff monitors the online compliance for all committee participants and assist as needed to help members establish their online records.
- e. After the third reminder has been sent, a notification letter over the signature of the President will be sent to individuals failing to comply with the disclosure policy, informing them that they will be excluded from participation on the committee as of a specified date. The chair and staff liaison of each committee will be copied on the letter and any subsequent correspondence, as will the section administrator (where applicable to those Bylaws committees requiring sectional representation). Members removed for noncompliance may be restored to committee service upon completing their disclosure record.
- f. If a committee is convened or a committee member added out of this normal cycle period, then the above process will be utilized with an amended timeline. Disclosure records will be considered current if dated as of (or after) April 1 of the current AUA Association year (June 1 May 31).
- g. <u>Board of Directors Meetings</u>. At least one week prior to each meeting of the Board of Directors, Committee Affairs staff will provide the Board Disclosure Compliance Committee with all disclosure information on record for members of the Board. The committee reviews these records in context of the planned Board agenda, to assess where any potential conflicts of interest may require a Board member to recuse himself/herself from discussion and/or vote. A report of this review is then presented orally at the commencement of the Board meeting.
- h. <u>Committee Meetings</u>. Review of disclosure records for each committee is the responsibility of the committee chair and AUA staff liaison. The disclosure report of all committee members will be provided to the committee as part of the meeting agenda. The chair will report the committee's findings to the entire committee at the beginning of each committee meeting, and this disclosure process will be documented in the meeting minutes.

#### 2. Annual Meeting – Abstract Submissions

To submit an abstract to the AUA, the author must fully disclose all financial relationships with any ACCME defined ineligible companies within the prior 24 months. The ACCME defines ineligible companies as, "those whose primary business is producing, marketing, selling, re-selling or distributing health care products used by or on patients.". Disclosure information is collected by AUA's third-party vendor at the time of the abstract submission. Abstracts cannot be submitted without completing the disclosure form on the submission site.

Disclosure information related to abstracts is indexed and published along with the abstract on the Annual Meeting website.

#### 3. Journal Manuscripts

To submit a manuscript to *The Journal of Urology* \*or *Urology Practice*\*, authors are required to complete disclosure information relevant to the manuscript only. Disclosure information is collected at the time of the manuscript submission. Manuscripts cannot be submitted without completing the disclosure form on the submission site. Information stored in the online database is relevant to the journal manuscript only and is not linked to other activity that individual may perform for AUA.

This disclosure information is published along with the manuscript.

#### 4. AUA Accredited Continuing Education (CE) Activities

To participate as a planner, faculty (includes speakers, moderators, panelists and debaters), editor or author of an AUA accredited activity individuals must fully disclose all financial relationships with any ACCME defined ineligible companies within the prior 24 months. The ACCME defines ineligible companies as, "those whose primary business is producing, marketing, selling, re-selling or distributing health care products used by or on patients."

- a. Individuals are notified of their roles/assignments by AUA staff throughout the year based on those activities. Each participant is provided his/her Membership Identification Number (needed to update their disclosure information online) and the URL link to the area on the AUA website where they can review and update their disclosure information. Log-in information and instructions are provided with the notification letters.
- b. AUA staff will monitor online activity for individual participants and assist as needed to help members establish/update their online records.
- c. A notification letter over the signature of the Education Council chair (responsible for oversight of all AUA accredited activities) will be sent to any individual who fails to comply with the disclosure policy, informing them that they will be excluded from participation in the activity. Staff will coordinate the processing of these letters for documenting the enforcement of the policy and cross-checking against potential involvement the individual may have with other AUA activities.

Financial disclosure information is included in all accredited activity material as required by ACCME Standards for Integrity and Independence in Accredited Continuing Education.

## Educational Activities: Mechanism to Prevent, Identify, and Mitigate Conflicts of Interest

All accredited educational activity disclosures are reviewed by the COI Review Workgroup. The workgroup consists of a chair, vice-chair and COI reviewers who do not have any financial relationships with an ineligible company. The COI Review Workgroup Chair or Vice-Chair will select content to review based on the financial disclosures of the faculty. If selected, the content will be reviewed by a COI Reviewer with written instruction from the Office of Education to ensure that it is based on scientific principles that are generally accepted as valid by the medical profession, and free from bias of any kind.

#### A. Prevention of COIs

- 1. All programs shall be designed to be fair, balanced, and free of bias.
- 2. Review of the content by the appointed COI Review Workgroup will ensure a fair and balanced presentation.
- 3. AUA will maintain strict adherence to the signed statement by all faculty to present content for all accredited CE activities that is based on the highest level of evidence available including expert opinion and customary and generally accepted medical practice.
- 4. Unbiased moderators will be appointed to panel discussions to challenge the panelists on salient points of potential bias and/or conflicts of interest.
- 5. Content will be developed that promotes improvements or quality in health care and not a specific proprietary business interest of an ineligible company.
- 6. Content will present a balanced view of therapeutic options. Faculty will use generic names when speaking about technologies, programs, products, devices, drugs, and/or services; trade names will only be used for clarification.
- 7. Statements of individual preferences and use will be limited to scientific evidence including both pro and con statements and discussions of how different uses and/or local settings may influence diagnostic and treatment choices.
- 8. In accredited hands-on training laboratory settings, no commercial supporter or manufacturer in that field of interest shall be excluded. Faculty and participants will use all equipment on a rotation basis to eliminate appearance of bias or favoritism.

#### **B.** Identification of COIs

All disclosures will be reviewed by the COI Review Workgroup Chair and/or Vice-Chair for identification of conflicts of interest. The peer workgroup members, working with the AUA staff, will document the mechanism(s) for management and mitigation of the conflict of interest and final approval of the activity will be documented prior to implementation.

Standard 3 of ACCME Standards for Integrity and Independence in Accredited Continuing Education requires that accredited providers exclude owners or employees of ineligible companies, except in three limited circumstances including:

3. When the content that they are controlling is not relevant to the business lines or products of their employer/company.

4. When the content 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.

#### C. Mitigation of Identified COIs

Recommended methods for mitigating conflicts of interest, which may be recommended by the Educational Council or Office of Education staff, include:

- 1. Peer review for valid, evidence-based content by the AUA COI Review Workgroup
- 2. Limit content to evidence with no recommendation
- 3. Introduce a debate format with an unbiased moderator (point-counterpoint)
- 4. Inclusion of a moderated panel discussion
- 5. Publish a parallel or rebuttal article for an article that is believed to be biased.
- 6. Limit equipment representatives to providing logistics and operation support only in procedural demonstrations
- 7. Divestiture of the relationship by faculty.
- 8. Selection of alternate faculty for specific topics.

The final mechanism for mitigation of conflict of interest will be the decision of the COI Review Workgroup and/or the Education Council Chair.

#### **Enforcement and Sanctions**

- **A. Procedures to Enforce.** The Judicial & Ethics Committee is charged with responsibility to consider alleged violations of the disclosure requirements and other provisions of these Guidelines, to investigate complaints of such violations, and to recommend appropriate sanctions to the AUA Board of Directors.
- **B.** Penalties. Unexcused failure by any individual to comply with the requirements of these COI rules and procedures will disqualify such individual from participation in AUA committee, educational or similar activities until rectified. Repeated or egregious violations including willful failure to disclose relevant information may lead to harsher sanctions, including expulsion from membership in the Association or disqualification from participation in any of its activities.

## **Appendix - Program Specific Requirements**

#### A. Accreditation Council for Continuing Medical Education (ACCME)-Regulated Activities

The AUA adheres to the ACCME <u>Standards for Integrity and Independence in Accredited Continuing</u> <u>Education</u> (Dec 2020). The Office of Education and its planners, faculty, editors and authors must comply strictly with the following policies for disclosure of commercial support, and represent that:

- 1. All of its educational activities are free of commercial bias for or against any product;
- 2. The commercial supporters of such activities have no control over or input into the planning, content, execution, or evaluation of the activity;
- 3. Payment of honoraria and reimbursement of out-of-pocket expenses for faculty is reasonable, customary and proper, and in accordance with the AUA Honoraria Policy;
- 4. Any and all commercial support, including any "in-kind" support, is acknowledged to the learners prior to any activity;
- 5. All relevant financial relationships of everyone who has any control over educational content (including planners, faculty, authors, COI reviewers and staff) will be disclosed to the learners and will include:
  - a. The name of the individual
  - b. The name of the ineligible company (disclosure must never include the use of a trade name or a product-group message)
  - c. The nature of the relationship the person has with each ineligible company
  - d. For an individual with no relevant financial relationship, the learners must be informed that no relevant financial relationship exists
  - e. An individual who refuses to disclose relevant financial relationships or fraudulently discloses such relationships will be disqualified from being a planner, faculty, editor, or an author of Accredited Continuing Education (CE), and cannot have control of, or responsibility for, the development, management, presentation, or evaluation of the CE activity
- 6. No funds originating from commercial sources are used to pay travel, lodging, registration fees, honoraria or personal expenses for non-faculty attendees, and only modest meals or social events held as part of the activity are subsidized.
- 7. All individuals in control of the content of an accredited CE activity developed by AUA's Office of Education must comply with the requirements of the COI Review process.

#### **B.** Journals

To comply with current standards for scientific journals, when relevant, authors submitting manuscripts to *The Journal of Urology*®, *Urology Practice*® or *JU Open Plus* and external peer reviewers of manuscripts are responsible for recognizing and disclosing conflicts relevant to their work or review:

- 1. Authors must describe all sources of financial support for their research, and this information should be published with the manuscript;
- Authors must disclose whether any portion of their research findings were written by persons employed by affected industry;
- 3. Authors must affirm that no funding agreement limits their ability to fairly complete and publish their research, and that they had full control of primary data;
- 4. External peer reviewers must disqualify themselves from any manuscript for which a conflict might arise. Peer reviewers must indicate in "Comments for Editor" if they have reviewed this paper previously for another publication. If previous or present connections with the author(s) and the author(s)' institution (intellectual conflicts), or personal financial interests might be construed as creating a conflict of interest, these issues must be disclosed. If reviewers believe they might have any difficulty writing an objective review, they should not review the paper and report this immediately.
- 5. Reviewers may not use pre-publication knowledge of the work to advance their own interests.

#### C. AUA Guidelines.

To assure that AUA Guidelines are not developed with undue influence, disclosure by panel members, consultants and peer reviewers is required. However, the disclosure needs to be only relevant to a specific Guideline topic.

The breadth of such "topic" shall include any and all products or modalities used in, useful for or undergoing any form of research development or assessment for the care, diagnosis or treatment of the specific disease, stage or condition as will be discussed in the Guideline in question, whether or not the product or modality is itself specifically approved for, used in, promoted for or referred to in the text of the Guideline. The requirement of recusal or disclosure shall continue for the duration of the Guideline development and for one year after approval of the Guideline by the AUA Board of Directors.

- 1. Panel members, consultants or authors must report private or institutional interests that may compete or conflict with their objectivity in guidelines development on the relevant topic. Such COIs may warrant recusal of such individuals from discussion or voting on such topic, or on a complete Guidelines document.
- 2. Peer reviewers must report private or institutional interests that may impact on their review of the guideline and should follow the same procedures outlined for *The Journal of Urology*® peer reviewers above.
- 3. Panel members and peer reviewers may not use pre-publication knowledge of the work to advance their own interests.
- 4. Non-Disclosure Agreement. Members who serve on AUA Guidelines Panels must also complete and comply with a non-disclosure agreement. As a panel member/peer reviewer and/or writer of documents produced by the relevant panel, these members are routinely exposed to certain

confidential and/or proprietary information, materials or data related to the panel's work and final documentation. It is important to the integrity of the writing process and final work that this information should be kept strictly confidential and not disclosed at any time under any circumstances.

#### Panel members therefore agree:

- To not disclose or cause to be disclosed to anyone or any entity outside of the Guideline panel or the appropriate AUA staff and AUA contractor any confidential and/or proprietary information, materials or data related to the Guideline Panel's work.
- To not speak publicly about a guideline or the deliberations regarding the development of the guideline until the embargo is officially lifted from any guidelines report(s).
- To keep all such confidential information in their possession or control in a safe and secure place and take all reasonable steps to protect against inadvertent disclosure or theft of the information.
- To promptly report to AUA any potential breach of this strict confidentiality of which they are aware, by themselves or others, from whatever cause, and assist to the extent possible in avoiding further disclosure and all possible consequences of such breach.
- Upon request from the Guideline Panel Chair or appropriate AUA staff, to promptly destroy all confidential information that they have been sent or acquired relating to the Guideline Panel. Notwithstanding the return or destruction of any confidential information, they will continue to be bound by this obligation.

<u>Penalties/Sanctions</u>. Panel members acknowledge that any violation or breach of this Agreement on their part shall constitute grounds for termination of access to such information and the penalties described as follows:

- A letter of warning from the Practice Guidelines Committee
- Removal from the panel
- Possible disciplinary action (including expulsion from the Association) in accordance with AUA Bylaws.