



Managing Conflicts of Interest (COI)

Principles, Policies and Procedures of the ISSM

DEFINITIONS

ISSM: The International Society for Sexual Medicine

ISSM Entities: ISSM entities are all groups of ISSM members specifically organized within the structure of the organization for a specific (leadership) purpose. They include, but are not limited to, the ISSM Executive Committee, the ISSM Board of Directors, ISSM standing and ad-hoc committees, ISSM Meeting Steering/Program/Local committees, and all other groups within ISSM identified as such.

COI Committee: The ISSM Conflict of Interests Committee, which is appointed by the ISSM Executive Committee and usually consists of three to five senior members (not Officers/Board Members) with the ISSM 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 to produce, market, sell, re-sell, or distribute healthcare products used by patients (including but not limited to pharmaceutical or device manufacturers/distributors).

PRINCIPLES AND POLICIES

1. ISSM 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 ISSM activities.
2. ISSM recognizes that there may be financial conflicts of interests and/or intellectual conflicts of interests.
3. ISSM officers, directors, journal editors, committee members and chairs and persons in certain leadership roles (see Levels of Involvement Level A and Level B) must disclose any and all known or potential financial and non-financial/intellectual conflicts of interests.
4. Prior to participating in ISSM programs other than as a meeting attendee (e.g., speaker, moderator, organizer, exhibitor), all ISSM members must make full and effective disclosure of non-ISSM 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 ISSM activities, presentations, or publications.
5. Non-ISSM 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 directly or indirectly related to ISSM's activities.

- C. Compensation -- Support or income from commercial or other sources, including any publishing, internet, or e-commerce enterprises, related to healthcare or to ISSM 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 any ISSM member who assumes an ISSM leadership position (see Levels of Involvement Level A, B and C), are those private or institutional interests that may under some circumstances compete or conflict with primary duties owed by the member to ISSM. These COIs may include:
 - A. Personal or family financial interests;
 - B. Professional or business interests of a non-ISSM institution;
 - C. Duality of interest from employment, membership on the Board of Directors, or existence of any fiduciary relationship with any non-ISSM 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 the field of sexual medicine/health.
7. All disclosures of COIs should be sufficiently transparent to allow the ISSM COI Committee members and other interested ISSM members to understand the impact on ISSM 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 ISSM responsibility or activity.
8. No individual vested with authority to speak or take formal position on behalf of ISSM shall assume a role with any competing or unaffiliated organization or entity that may be regarded as in competition with ISSM without knowledge and express consent of the ISSM Board of Directors.
9. No individual vested with authority to speak or take formal position on behalf of ISSM, which includes ISSM Officers, Directors and Committee Chairs, may endorse any commercial product related to sexual medicine/health.
10. Any ISSM officer or other individual vested with authority to speak for or otherwise represent ISSM shall not simultaneously represent competing private commercial entities, institutions, or enterprises; shall not make public statements contrary to any position or policy of the ISSM; 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 any other commercial entities identified as such) may not serve on any of the ISSM entities such as, but not limited to, the Executive Committee, Board of Directors, and/or Standing/Ad-hoc/Program Committees, may not attend meetings nor participate in discussions of the ISSM EC/Board of Directors or any other ISSM entity (including Committees), unless permitted by special action of the ISSM Board of Directors.
12. Disclosure Period for Conflicts of Interest: Conflicting interests such as affiliations, ownership, compensations, or other fiduciary positions in non-ISSM organizations which existed in the 12 months prior to a person assuming a role with ISSM must be disclosed.

LEVELS OF INVOLVEMENT

The ISSM COI principles and policies apply to all individuals in any position in any of the ISSM entities. In addition, the ISSM Board of Directors has identified groups of individuals for whom specific (higher) policy levels have been adopted. Although all individuals assuming decision-making authority or responsibility within or on

behalf of ISSM 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 ISSM 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 ISSM Board positions / roles:

- Officers: President, President-Elect, Immediate Past President, Secretary, Treasurer
- Directors: Members-at-large and Representatives of the (Regional) Affiliated Societies
- Editor(s)-in-Chief of the ISSM Journals
- Chairperson(s) of the International Consultation on Sexual Medicine (ICSM)
- Chairperson(s) and members of the ISSM Scientific Committee
- Chairperson(s) and members of the ISSM Education Committee
- Chairperson(s) and members of the ISSM COI Committee

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 a paid consultant or advisor to an ineligible company whereas the total payment exceeds the threshold of US\$ 65,000 (indexed annually based on CPI, base year 2022 = 100) from the ineligible company in a single calendar year.

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;
- act as a paid consultant or advisor (including advisory board) to an ineligible company whereas the total payment does **not** exceed the threshold of US\$ 65,000 (indexed annually based on CPI, base year 2022 = 100) received from an ineligible company in a single calendar year;
- participate in institutional or individual research;
- serve as an officer or board member of an ISSM (Regional) Affiliate Society, unless deemed by the Board of Directors to be a substantial conflict to the ISSM.

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 sexual medicine or which the ISSM Board of Directors has defined as competing (also see 8. Under definitions), including, but not limited to, the World Association on Sexual Health (WAS), the American Sexual Health Association (ASHA), the American and International Societies for Men's Health (ASMHS and ISMH), and the Androgen Society.
- serve as expert witnesses (for either plaintiff or defendant) in medical liability cases if ISSM has a direct and substantial interest, if ISSM is a named party to the litigation or if ISSM 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 ISSM COI Committee and Board.
- serve as an editor-in-chief of a peer-reviewed journal that may be regarded as in competition with ISSM without knowledge and express consent of the ISSM Board.

Level B — Councils, Committees and Groups

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

- Committee Chairs, co-Chairs, Subcommittee Chairs of all ISSM Standing and ad-hoc committees other than the committees defined under Level A (Education and Scientific)
- Advisory Council Members (Past-Presidents serving on the council)
- ICSM Steering Committee 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 ISSM **Affiliate Society**, unless deemed by the Board of Directors to be a substantial conflict to the ISSM;
- 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 serve as committee chairs of related professional associations in which the principal interests include sexual medicine or which the ISSM Board of Directors has defined as competing (also see 8. Under definitions), including, but not limited to, the World Association on Sexual Health (WAS), the American Sexual Health Association (ASHA), the American and International Societies for Men's Health (ASMH and ISMH), and the Androgen Society.
- serve as an editor-in-chief of a peer-reviewed journal that may be regarded as in competition with ISSM without knowledge and express consent of the ISSM Board.

Level C – Committee Members/Staff/Consultants/Advisors

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

- Committee Members
- 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 ISSM whose roles, duties, or relationships relative to ISSM 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 & RESOLUTION OF CONFLICTS OF INTERESTS

Specific issues arising within any of the ISSM entities, or disclosure questions facing one or more individuals and involving potential COIs, should be referred to the ISSM 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 ISSM 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 ISSM entity in which the conflict of interest exists
4. Resignation or termination of ISSM 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, and contributors to and reviewers of ISSM 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 ISSM 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 ISSM role or a change in disclosable outside interests or commitments. The ISSM 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 ISSM entity shall review these COI disclosures and report any actual or potential conflicts of interests to the ISSM COI Committee.
 3. When a new member or chair is proposed for any ISSM entity, a review of the proposed member's COI statement must be performed prior to that member's appointment to an ISSM entity. This initial review shall be performed by the ISSM officer or chair proposing such an appointment.
 4. The ISSM 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 ISSM website or which are brought to its attention by any ISSM 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 ISSM COI committee or that member will be subject to restrictions on or loss of membership in ISSM.

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

1. If a COI exists and the resolution of the conflict of interests required by the ISSM COI Committee is not acceptable to the conflicted ISSM 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 ISSM member fails to take the actions required by the COI Committee within a reasonable period of time, the COI Committee shall then advise the ISSM Board of Directors that an unresolved COI exists.
3. If the ISSM Board of Directors is notified by the ISSM 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 ISSM Board of Directors made up of three members of the Board of Directors appointed by the ISSM 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 ISSM Board of Directors. The ISSM 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.