



## **The International Society on Thrombosis and Haemostasis Conflict of Interest and Disclosure Policy and Process**

### **I. GENERAL**

The International Society on Thrombosis and Haemostasis (ISTH) is a global not-for-profit membership organization advancing the understanding, prevention, diagnosis and treatment of thrombotic and bleeding disorders.

The Society is dedicated to transformative scientific discoveries and clinical practices, the development of young professionals and the education of physicians, scientists and allied health professionals wherever they may live.

The International Society on Thrombosis and Haemostasis (“ISTH” or “Society”) is committed to ensuring the integrity of its medical, scientific, educational, and research activities. ISTH’s policy requires its elected and/or appointed organizational and scientific leaders as well as senior staff to deal with a variety of issues that may have far reaching implications.

The Society is well served by the fact that many of those involved in its programs and activities and in policy development and implementation have diverse interests and are involved in a number of activities outside the ISTH. These interests enhance the expertise that these individuals bring to the various roles that they fill in representing the Society.

On occasion, situations may exist in which an individual serving the Society in an elected, appointed, or volunteer position or as an employee has some outside interest that could constitute a “conflict of interest”, as defined herein, or that could be perceived as constituting a conflict of interest. The ISTH’s position is to actively seek to address such issues, preferably before they arise, or, at a minimum, when they become known to the individual and/or the Society.

Generally, a conflict of interest could be said to exist when individuals have material or intellectual interests outside the Society specifically in the fields of thrombosis and hemostasis, hematology or cardiology that could influence or could be perceived as influencing their decisions or actions not to be in the best interest of the Society.

The intent of this policy is not to prevent ISTH leaders with relevant relationship(s) with commercial interest(s) or other interests from involvement in the activities of the Society but rather to ensure that ISTH activities promote quality and safety, are effective in improving education, science and medical practice, are based on valid content, and are independent of control from commercial interests and free of commercial bias. In addition, all covered individuals under this policy are required to act in the best interest of the Society at all times and to uphold its scientific and organizational reputation.



**The atmosphere ISTH wishes to create is one in which individuals are comfortable asking questions relating to conflict of interest without feeling awkward or accusatorial and where recusing one's self from participation in discussions that might be perceived as constituting a conflict is the norm rather than the exception**

## **II. TYPES OF CONFLICT OF INTERESTS**

Most often, the type of outside interest resulting in a conflict could be financial, such as when an individual has a "commercial interest" (as defined herein), an association with a third party through receipt of a research or other type of grant or stipend, an ownership interest (e.g., stock ownership, investment in), an employment relationship, or a consultative or advisory arrangement.

However, a conflict of interest may exist even though the issue does not arise out of financial considerations. For example, a member of the ISTH, in a leadership role or who has the opportunity to influence outcomes within the ISTH, may have a fiduciary responsibility as a member of the Board of Directors or Executive Committee of some other organization. If the interests of that organization were in conflict with the interests of the Society or represented potential competition with the activities and interests of the Society, a situation could exist in which the individual could not fulfill his or her responsibilities to both organizations in an impartial manner. A conflict of interest would exist, even though it might not be related to personal financial or other gain.

### **II.a. Commercial and Financial Interests**

A 'commercial interest' is with any entity producing, marketing, selling, re-selling, or distributing health care goods or services consumed by healthcare professionals. organizations (such as hospitals or laboratories) and/or used on patients.

Financial interests are defined as those relationships that are ongoing or have occurred within the past 12 months in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest (like stocks, stock options or other ownership interest, excluding diversified mutual funds), or other financial benefit.

Financial benefits are usually (but not always) associated with such roles as those of employee, manager, independent contractor (including contracted research), consultant, speaker/lecturer, faculty, membership on advisory committees or review panels, board membership, or involvement in other activities for which remuneration is received or expected. The Society considers relationships of any person required under this policy to include financial relationships of a spouse or life partner.

Only such interests need to be disclosed as pertain to entities with products or activities in the medical/scientific fields covered by the activities of the Society.

ISTH considers certain types of academic consulting and fees exempt from its definition of reportable financial interests, e.g., fees received for serving on independent grant application review groups (study sections) and fees given as honoraria by another academic institution for an academic activity, such as seminars and grand rounds. Where these activities are sponsored from a source with a potential conflict of interest, this exemption does not apply and the activity should be declared.



## **II.b. Other Interests**

The Society expects that each individual required by this policy to file a disclosure statement will also disclose situations which include other interests that may compromise the individual's ability to act in the best interest of the Society.

These other interests may include, but are not limited to, the following situations: leadership position (voluntary or compensated) in another organization involved in the fields of thrombosis and hemostasis, hematology or cardiology; non-compensated consultancy; and leadership position (voluntary or compensated) in foundations/fundraising organizations in thrombosis and hemostasis, hematology or cardiology.

The Society has determined that a conflict of interest would exist if an individual serving as an Officer, Council member, Editor of any of the Society's publications or Congress President were simultaneously serving in a similar or otherwise significant leadership position with another organization (profit or nonprofit) having a mission that substantially overlaps with that of the Society.

The Society, therefore, requires that individuals who are currently serving or are candidates for positions as Officers or members of the Council of the Society, or the other positions listed in the previous paragraph, disclose whether they currently hold a similar leadership position with another relevant entity and that, if they do, they agree to disclose such information and work with the Society, and its Board, to find a way to avoid any potential conflicts by excluding themselves partially or completely from their designated ISTH activity where they are judged to have a conflict of interest. Further, such individuals agree that for the duration of time during which persons serve in an ISTH leadership positions defined above, should they consider accepting positions with organizations, which may result in a conflict of interest, they will immediately inform the ISTH and work with the Society, and its Board, to find a way to avoid any potential conflicts by excluding themselves partially or completely from their designated ISTH activity where a conflict of interest may develop.

## **III. DISCLOSURE OF CONFLICTS OF INTEREST**

A key element in transparently dealing with and avoiding conflicts of interest is to ensure that a system is in place under which those serving the Society are well aware of what constitutes a conflict of interest, are open and willing to deal with conflicts for the benefit of the integrity of the Society and its programs and provide full disclosure of any relevant interest.

Accordingly, ISTH has developed a disclosure policy and form which is to be followed by those individuals serving the Society in elected and/or appointed organizational, scientific and educational leadership positions as well as senior staff (please see the disclosure form for a full list) on an annual basis.

To ensure transparency, the ISTH expects that each individual required by this policy to file a disclosure statement will disclose - in the requested timely matter - any/all relationships (financial and other interests).

The Society commits itself to hold the disclosures in confidentiality and that they will be reviewed by the Secretary General and may only be shared with relevant Board, committee or program chairs to be aware of and can manage any possible conflicts of interest.

The Society will only share disclosures outside the organization should this become legally required or otherwise necessarily as determined by the Council of the ISTH and after first notifying the individual.

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Additionally, every individual who is covered by this disclosure policy is expected to notify the ISTH Secretary General in writing if a conflict of interest arises that has not previously been noted on the current disclosure form. ISTH will update these forms on an annual basis.

In addition to the ISTH Society disclosure, separate and different disclosure statements may be required to fulfill the disclosure requirements of different accrediting entities (such as for specific CME activities).

Failure to return a completed disclosure form or provide complete disclosure information to ISTH is equivalent to a refusal.

## **IV. ASSESSING, MANAGING, REPORTING & RESOLVING CONFLICTS OF INTEREST**

### **IV.a. Assessing the Existence of a Conflict**

The process of determining if a conflict exists, what level of risk it may present, and the kind and level of management is needed for a given conflict of interest is an exercise in risk assessment.

The process by which any individual's disclosed information is assessed, and the evaluation as to any level of "conflict", begins with the prompt and full disclosure by the individual involved.

On an annual basis, disclosures will be collected by ISTH staff via electronic means and shared with the Secretary General. In the context of known, or prospective, ISTH activity, the Secretary General shall perform an initial due diligence assessment of any possibly conflicts of interest.

The Secretary General, with the support of ISTH staff, will then share all relevant disclosures with the Chairs of the relevant deliberative bodies (such as a committee, subcommittee, task force, etc.) so that Chairs of these bodies can be informed about the disclosed interest and consider as well as address them in their respective activities.

The Chairs and/or Secretary General shall consider the different areas of responsibilities at risk from biased conduct and action resulting from a conflict of interest that may damage the scientific, scholarly, professional and organizational integrity/reputation of the Society.

When an individual covered by this policy has a conflict of interest, determined per the forgoing process, on a particular subject of known interest or importance to the ISTH, this individual should not

1. Take any action on behalf of ISTH concerning the subject in conflict or any issue relevant to the subject in conflict;
2. Participate in discussions on the subject without full disclosure;
3. Participate in decision-making discussions or cast a vote;
4. Imply that he/she is acting on behalf of ISTH when discussing the relevant subject with third parties;
5. Fail to clarify with third parties with whom he/she deals on the relevant subject that he/she is not acting on behalf of ISTH; or
6. Share confidential information, including disclosure of embargoed abstract data which would break laws relating to insider trading.



## **IV.b. Managing Conflicts of Interest**

The Society, via the Chairs of its deliberative bodies and/or Secretary General, is responsible for identifying and resolving all disclosed interests and those that should arise without disclosure, prior to its acting on organizational, medical/scientific, programmatic and/or educational matters.

Each year the committee chairs receive a report of the declared conflicts for each committee member so that he/she can facilitate the proper management of conflicts.

Every meeting of a deliberative body should begin with a review of the ISTH Conflict of Interest Policy and processes for managing conflicts.

Members should be reminded of their duty of care to avoid conflicts of interest as part of their participation in the work of the respective committee.

For the relevant meetings, deliberations and decision making it is critical for participants to be aware of conflicts so decisions can be made without bias. When a subject comes up that presents a potential conflict, the member must state the conflict, refrain from participating in decision-making or voting on that particular issue by leaving the room.

It is upon the Chair of the committee to monitor that no member exhibits biased behavior or action.

In situations in which individuals exhibit biased behavior or action and/or situations the Chairs (or members) of a deliberative body may recommend the following actions:

1. Requiring an individual to choose between the competing activities.
2. Prohibiting an individual from participating in the deliberations about the subject relevant to the conflict.
3. Prohibiting an individual from playing a decision-making role in ISTH relevant to the conflict.
4. Prohibiting an individual from presenting at ISTH-sponsored events.
5. Exclusion from publishing in ISTH publications.
6. Exclusion from participating in ISTH deliberative bodies (such as committees).
7. Revocation of membership in ISTH.

After the appropriate due diligence is applied, and a dialogue with the member who may have a conflict of interest sought, the Chair shall issue a decision to the potential conflict, related risk, and any proposed action and inform the deliberative body and the Secretary General.

Such decisions should be reflected in the minutes of the relevant meeting.

In case the individual alleged to have a conflict does not agree, the ISTH has adopted the following policy:

“When the question of a conflict continues to exist, the Chair of the respective deliberative body and the individual with a conflict will be given the opportunity to state why they believe a conflict does or does not exist with the final decision on whether the individual has a conflict of interest be made by a majority vote of the deliberative body at issue.”



If there is continued disagreement and need for further deliberation, the matter will be referred to the ISTH Ethics Committee for review. The ISTH Ethics Committee will make a recommendation to Council for final decision.

It again must be emphasized that ISTH's Policy on Conflict of Interest and the required disclosure are not intended to dissuade qualified candidates from service to the Society.

Indeed, each individual's special interests and involvements can enhance his or her ability to better serve the organization. In many instances, those interests and involvements clearly do not constitute a potential or actual conflict of interest. However, when the potential for a conflict of interest exists, it is appropriate that the relevant facts be fully disclosed.

#### **IV.d. Continuing Nature of Obligation**

It is understood by all who are covered by this policy that their obligation hereunder, and the submission of the disclosure form, is on-going; it is not satisfied merely by the annual submission of the requisite form. If a covered individual is subject to changed circumstances that would otherwise require disclosure or some ISTH consideration, the covered individual is obligated to make such disclosure, in accordance with this policy, as soon as practically possible.

#### **V. ISTH COVERED ACTIVITIES AND POSITIONS/INDIVIDUALS**

An individual is a "covered individual" when he/she assumes a role contributing to, influencing or controlling content of, or direction or decision making regarding an ISTH activity. Such "activity" includes, but is not limited to: research, education (development and/or scheduling), publications, editorial roles, participation on committees (or any related grouping thereof), and participation in governance, on organizational leadership.

All members of the ISTH functions and positions below are currently covered:

- ISTH Council
- ISTH Council appointed Committees
- ISTH's World Thrombosis Day Steering Committee
- ISTH SSC Executive Committee
- ISTH SSC Subcommittees Chairs and Co-Chairs
- Editors, Associate Editors, Subject Editors, and the Editorial Board of ISTH publications (Applicable official publishing disclosure requirements may supersede these ISTH disclosure requirements)
- Organizing Committees (Local and Program) of ISTH Congresses, Meetings, Training and Educational Courses, Webinars \*
- Faculty/presenters of ISTH Congresses, Meetings, Training and Educational Courses and Webinars
- Scientific Content Experts working on ISTH Education Programs \*
- ISTH Senior Staff (Directors and Managers) and content specialists

\* Applicable official CME disclosure requirements shall supersede these ISTH disclosure requirements.

