

International Society for Heart and Lung Transplantation (ISHLT) Principles, Policies, and Process Related to Conflict-of-Interest (COI)

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Principles, Policies, and Process Related to Conflict-of-Interest (COI)

A. Introduction

ISHLT policies concerning the management of conflicts of interest involve all aspects of the Society – from committee meetings to the annual meeting organization and speakers, its journal and other publications, and the development of clinical guidelines, educational advisories, or position statements. As an ACCME-approved provider, ISHLT fully complies with the new continuing medical education rules regarding meeting program design and speaker/planner/chair disclosure. ISHLT has put enforcement mechanisms in place to ensure that scientific presentations fully disclose relevant financial relationships and has developed specific policies to resolve conflicts and prevent bias or the appearance thereof. A centralized system tracks speakers who fail to comply with COI requirements; the system will be expanded to allow Web-based management of the process. Additionally, COI Compliance Officers are assigned for the Board of Directors, the Education Committee, the Registry Steering Committees, the Standards and Guidelines Committee, the Grants and Awards Committee, and the Scientific Program Committee. Finally, formal policies have been developed to guide our interactions with commercial interests. ISHLT's COI oversight and resolution process is outlined in the principles, policies, and procedures set forth below.

B. Definitions

Financial Relationships: Financial relationships are those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fees, honoraria, stipends, gifts, ownership interest (e.g., stocks, stock options or other ownership interest, excluding diversified mutual funds), or other financial benefit. Financial benefits are usually associated with roles such as employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and other activities from which remuneration is received, or expected, including subsidized travel, hotel, and registration fees for any activities. 'Contracted research' refers to research funding in which an institution receives a grant and manages the grant funds and an individual is the principal or named investigator on the grant at that institution. ISHLT agrees generally with the definitions of financial interests in research outlined by the Association of American Medical Colleges (AAMC). Specifically, ISHLT agrees with the AAMC that the following do not represent significant financial interests: (a) Interests in publicly traded diversified mutual funds and (b) salary and other payments for services from the member's institution.

Relevant Financial Relationships: Relevant financial relationships are those in which an individual (including the individual's spouse/domestic partner/business partner) has/had any of the above mentioned financial relationships, in any amount, occurring currently or within the last 12 months with a commercial interest producing health care goods or services. When a person divests themselves of a relationship, it is

immediately not relevant to conflicts of interest but it must be disclosed for an ongoing period of 12 months.

Exemptions: ISHLT considers exempt from its definition of reportable financial interests certain clearly defined types of academic consulting and fees; e.g. fees received for serving on grant application review groups (study sections) and fees given as honoraria by another academic institution or non-profit organization for an academic activity, such as seminars and grand rounds.

Conflict of Interest: Circumstances create a conflict of interest when an individual has an opportunity to affect educational content, scientific content, and/or Society decisions/work products related to the products or services of a commercial interest with which he/she has a financial relationship. A conflict of interest exists when individuals have financial relationships outside ISHLT, regardless of value or cash amount, that could influence or be perceived as influencing their decisions, actions, or presentations. Conflicts of interest may involve either an agent or device as the subject in question or an agent or device that might be in competition with the subject in question. ISHLT considers financial relationships to create actual conflicts of interest when individuals have both a financial relationship with a commercial interest and the opportunity to affect the educational or scientific delivered by the Society that is related to the products or services of that commercial interest.

Commercial Interest: A commercial interest is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. The ACCME does not consider providers of clinical service directly to patients to be commercial interests.

C. Principles

1. The **integrity** of ISHLT, and the scientific, educational, and advocacy activities it undertakes, depends on the avoidance of bias arising from conflicts of interest, or from the appearance of such bias, by the individuals involved with those activities. Continuing medical education (CME) provided by ISHLT must be free of bias arising from financial arrangements or considerations.
2. The **atmosphere** ISHLT desires is one where people are comfortable asking questions (relating to COI) without feeling awkward or accusatorial, and where recusing oneself from participation in discussions that might be perceived as constituting a conflict is the norm rather than the exception.
3. ISHLT subscribes to the view that **research and development** sponsored by the biomedical industry play an important role in biomedical research and that academic-industrial relationships have developed useful and life-saving products.

4. The mission of ISHLT does not include **marketing** of pharmaceutical or biomedical products. To this end, specific policies have been developed to insulate ISHLT from inappropriate commercial influence.

5. ISHLT's policies are congruent with the positions of the Accreditation Council for Continuing Medical Education (**ACCME**).

6. ISHLT agrees with the Association of American Medical Colleges (**AAMC**) that the considerations of conflict-of-interest are relevant not only to clinical research, but also extend to all phases of biomedical research, including pre-clinical research.

D. Policies

The COI policies of ISHLT apply to individuals engaged in the following capacities on behalf of the Society:

Governance: All persons who are employees or staff of ISHLT or who serve on the following governing bodies of the society: Board of Directors, Registry Steering Committees, Grants and Awards Committee, Conflict of Interest Committee.

Publications: All persons who seek to submit scientific material for any ISHLT publication or who are engaged in the reviewing of such material;

Standards and Guidelines: All persons who are engaged in the writing or reviewing of clinical practice guidelines, educational advisories, or position statements;

Educational Programming: All persons who are engaged in the development, planning, selection, chairing, or presenting of any educational activities of the Society, including members of the Scientific Program Committee and the Education Committee.

1. COI Policies Regarding All Individuals Engaged in the Above Capacities:

- All individuals engaged in the above capacities on behalf of ISHLT are required to disclose fully and completely all of their relevant financial relationships. Failure to disclose by the deadline stated or failure to disclose fully may result in the individual being barred from the activity and, potentially, from future activities of the Society. ISHLT has the right to take action regarding individuals who have exhibited biased behavior or action. These actions may include:
 - a. Requiring an individual to choose between the competing activities
 - b. Exclusion from participating in ISHLT committees
- If the Conflict of Interest Committee determines that an individual has a relevant conflict of interest, ISHLT makes a presumption of potential bias, which requires a formal process to identify and manage the potential for bias.
- Individuals engaged in the above capacities on behalf of ISHLT are not permitted to receive any direct or indirect remuneration or gifts, including travel and registration

subsidies, from any commercial interests for any activity in which they are an official representative or a participant on behalf of the Society, nor may they receive or accept direct input from a commercial interest regarding any such activity.

- All individuals who are subject to the ISHLT COI Policy and who are found to be in non-compliance with the policies and processes will be referred to the COI Committee for review and investigation of relevant information. The COI Committee will make recommendations to the Board regarding any actions to be taken. Individuals who are determined by the COI Committee to be in non-compliance will, upon decision of the Board, be placed in a database of ISHLT COI policy violators. These individuals may, upon decision of the Board, be barred from those roles in the future and potentially from other roles in the Society as well.
- With respect to financial relationships with commercial interests, when a person divests themselves of a relationship it is immediately not relevant to conflicts of interest and is considered to be resolved, but it must be disclosed to the learners for 12 months.

2. COI Policies Regarding Individuals Involved in ISHLT Governance Bodies:

The governing bodies of ISHLT consist of the Board of Directors, the Registry Steering Committees, the Grants and Awards Committee, the Conflict of Interest Committee, and employees/staff. The focus of each relates to either a specific mission of ISHLT or to the administration and management of the Society. All members of such bodies must agree to comply with the letter and spirit of the ISHLT COI Policy. All members of such bodies must complete an annual disclosure form that will be kept on file at ISHLT Headquarters and must notify the committee's staff liaison in writing of any changes that occur after the disclosure form has been submitted. All members of such bodies must provide detailed information that will shed light on all actual and potential conflicts of interest. The written COI declarations for all members of governing bodies will be included with the meeting agendas and must be verbally disclosed by each individual prior to the start of each meeting. When any member of a governing body has a conflict of interest, s/he will not:

- a. Participate in discussions on the subject without full disclosure;
- b. Cast a vote;
- c. Imply s/he is acting on behalf of ISHLT when discussing the relevant subject with third parties;
- d. Fail to clarify with third parties with whom s/he deals on the relevant subject that s/he is not acting on behalf of the Society;
- e. Break laws relating to insider trading.

3. COI Policies Regarding Individuals Involved in ISHLT Publications:

The JHLT and ISHLT publication policy follows the recommendations of the International Committee of Medical Journal Editors (ICMJE) and of the Council of Science Editors (White Paper on Promoting Integrity in Scientific Journal Publications). The JHLT provides opportunities for commercial advertising. However, the editorial function of the journal is completely segregated from the advertising function. The

Editor-in-Chief has full authority over the editorial and scientific content of the JHLT, and the Monograph Editor serves this function over this Monograph Series. ISHLT does not interfere in the evaluation, selection, or editing of individual articles, either directly or by creating an environment in which editorial decisions can be influenced. At the time of first submission, authors must disclose any conflicts of interest. At time of submission of final accepted manuscripts, authors must complete a copyright transfer form and a disclosure form. All authors and reviewers must:

- a. Refrain from introducing bias relevant to their COI into any ISHLT publication,
- b. Review the content contributed by all coauthors to ascertain freedom from bias.

4. COI Policies Regarding Individuals Involved in ISHLT Standards and Guidelines, Educational Advisories, and Position Statements:

From time to time, ISHLT will engage in activities designed to develop evidence-based clinical guidelines and professional practice standards, educational advisories, and position statements. All individuals engaged in the writing or reviewing of such documents will be required to disclose their relevant financial relationships. If any such candidate has a relevant financial relationship with a company whose drugs or devices might be included in the guidelines, their written contributions will be subjected to peer review.

5. COI Policies Regarding Individuals Involved in ISHLT Educational Programming:

ISHLT is committed to ensuring that the following decisions will be made free of any influence or control by commercial interests:

- Identification of CME needs
- Determination of educational objectives
- Selection and presentation of content
- Selection of all persons and organizations that will be in a position to control the content of the CME activities
- Selection of educational methods
- Evaluation of the activity

ISHLT is committed to ensuring quality, objective, balanced, and scientifically rigorous continuing medical education activities. ISHLT holds all speakers, chairs, and planners of ISHLT-sponsored educational activities to certain standards of conduct with regard to conflicts of interest and avoidance of bias from financial relationships.

- a. Such individuals must:
 - i. Fully disclose all relevant financial relationships.
 - ii. Safeguard all educational activities from biased influence of industry.
 - iii. Work to create an educational environment that eliminates the perception of inappropriate influence of industry on the Society's educational mission.
- b. No employee of a commercial interest can plan, present, influence, or control any ACCME accredited educational activity content which is related to the commercial interest's product/service or class of products/services.

- c. Anyone who participates as a planner, presenter, or chair at the ISHLT Annual Meeting may, upon approval of the COI Committee, also serve as a planner, invited speaker, or chair of a commercially supported symposium, accredited or not, held in conjunction with the ISHLT Annual Meeting. They may serve as an abstract presenter at the ISHLT Annual Meeting without the need for COI Committee approval.
- d. All conflicts of interest must be resolved prior to the educational activity.
- e. Speakers must disclose the nature of any presentation concerning off-label usage.
- f. Speakers must agree that all research referred to in support of clinical recommendations will conform to generally accepted standards of experimental design, data collection, and analysis, and that they will not promote a proprietary business interest or a commercial interest.
- g. Speakers must reveal whether they have been trained or utilized by a commercial entity or its agent as a speaker and must exclude any promotional aspects from their ISHLT presentation.
- h. Although the abstracts are blinded during the abstract review process, all author conflicts of interest are shared with the Program Committee, which is charged with oversight of the entire abstract review process.
- i. **Industry employees** may serve as abstract co-authors but may not present abstracts.
- j. The financial relationships of all planners, presenters, and chairs are printed and distributed at the Annual Meeting.
- k. **Program committee members** are prohibited from receiving support from a commercial interest (whose product or services/class of products or services is within the scope of interest of ISHLT) for travel, hotel, registration and/or other costs associated with THAT educational activity.
- l. **Abstract reviewers** are prohibited from receiving support from a commercial interest (whose product or services/class of products or services is within the scope of interest of the abstracts they have been assigned to review) for travel, hotel, registration, and/or other costs associated with THAT educational activity IF such support is offered prior to the date of submission of abstract scores. **Invited speakers, abstract presenters, invited discussants, panelists, and session chairs** and all others engaged in an official capacity in the delivery of educational content are prohibited from receiving support from a commercial interest (whose product or services/class of products or services is within the scope of interest of the presentation/session they are engaged in) for travel, hotel, registration and/or other costs associated with THAT educational activity.

E. COI Resolution Process

1. Conflict of Interest Committee

Chair: The COI Compliance Officer for the Board shall serve as Chair of the COI Committee.

Composition: The COI Committee members shall consist of the COI Compliance Officer for the Board, the Chair of the Education Committee, the Chair of the Scientific

Program Committee, the Chair-elect of the Scientific Program Committee, the President, and the President-Elect. .

Responsibilities:

- a. The COI Committee reviews the COI disclosures of all individuals with relevant financial relationships. They formally document and communicate with all such individuals their responsibilities regarding COI policy and bias management, including specific steps to be taken to resolve conflicts of interest.
- b. The COI Committee reviews and investigates instances of non-compliance with and violations of COI Policy and makes recommendations to the Board regarding any corrective and/or punitive action they feel is warranted.
- c. In some instances, the nature of the conflict of interest may be so substantial that the individual will be asked to discontinue the non-ISHLT activity resulting in the conflict or relinquish his/her position with the Society.

2. Process for Resolving Conflict of Interest of Individuals Involved in ISHLT Governance Bodies (Staff, Board of Directors, Registry Steering Committees, Grants and Awards Committee):

A member of the Board of Directors, selected by the President, shall serve as Chair of the COI Committee. S/he must be free of all relevant financial relationships (other than contracted research paid to the chair's institution) during the 1 year term. S/he will act as the COI Compliance Officer for the Board

The Chairs of the Registry Steering Committees and the Grants and Awards Committee shall serve as the COI Compliance Officers for their committees. Verbal disclosure will be made by each staff, Board, and Committee member prior to the start of each meeting or conference call. The COI Compliance Officer will monitor discussions to ensure and enforce absence of biased participation by individuals with conflicts of interest. **In all cases, individuals with relevant financial relationships may not participate in voting on issues related to their areas of conflict.** If appropriate, the COI Compliance Officer may request that the individuals with relevant financial relationships not participate in discussions related to their areas of conflict. While the COI Compliance Officer is the person designated to enforce the COI policy and process, all Committee and Board members are responsible for holding one another accountable for compliance with the policy and must be willing to call on their colleagues to act in accordance with the policy. While it is possible that a committee member may not agree with the perception by others that a conflict of interest exists, all committee members must abide by the policy and recuse themselves from participation as required by the Society's COI policy.

3. Process for Resolving Conflict of Interest of Individuals Involved in ISHLT Publications:

The Editor-in-Chief serves as the COI Compliance Officer for the JHLT and the Monograph Series. S/he evaluates allegations or instances of conflict of interest impropriety on the part of the JHLT and Monograph editors, reviewers, and authors. Instances of documented impropriety may lead to sanctions, including but not limited to dismissal of an editor, barring an author from future JHLT submissions or Monograph contributions, and reporting of infractions to the authors' institutions and to the

JHLT/Monograph readership at large. Ethical breaches and improprieties are dealt with on a case by case basis with respect to the sanctions ordered.

4. Process for Resolving Conflict of Interest of Individuals Involved in ISHLT Standards and Guidelines, Educational Advisories, and Position Statements:

The Chair of the Standards and Guidelines Committee shall serve as the COI Compliance Officer for the committee. The COI Committee will review COI disclosures from all standards and guidelines taskforces and committees and will identify any members who have relevant financial relationships which would require their participation in the writing and/or reviewing process to be peer reviewed. This will be communicated to the Standards and Guidelines Committee Chair and to the leaders of the related Writing Taskforces. The writing committee will apply evidence tests to the information gathered from all participants to determine how much it can be relied upon in formulating the guidelines. The COI Compliance Officer will monitor evolving COI during the deliberative and reportage processes.

5. Process for Resolving Conflict of Interest of Individuals Involved in ISHLT Educational Activities:

The President and the Program Chair-Elect will serve as the Program Committee's COI Compliance Officers. The Chair of the Education Committee will serve as the Education Committee's COI Compliance Officer.

The COI Committee will review disclosure forms from all education committee members, scientific program committee members, abstract reviewers, abstract authors, presenters, session chairs, and any other formal participants in ISHLT educational activities. If a conflict of interest is identified, one or more of the mechanisms below will be used to resolve most situations.

- **Peer Evaluation:**

- a) Abstract Presentations: When selecting abstracts for presentation, the abstract reviewers and the program committee members serve as peer reviewers of the content of the material to be presented and on-site peer review is not required. Program Committee members and abstract reviewers who have a financial relationship with the commercial interest whose product or class of products is the subject of the abstract must recuse themselves from scoring such abstracts and/or from recommending them for inclusion in the scientific program
- b) Invited Speakers: An informed learner or peer will be present at invited lecture presentations for which a relevant financial relationship has been identified by the COI Committee as needing peer evaluation. This individual will usually be the chair of the session. This individual will be asked to complete a formal detailed evaluation of any identified bias in the presentation.

- **Attestation**: All abstract presenters with conflicts of interest will be advised in writing that they must support any clinical recommendations they make with the best available evidence. All invited speakers with conflicts of interest will be asked to attest in writing that they will support any clinical recommendations they make with the best available evidence. All planners (program committee members, abstract reviewers, session chairs) with conflicts of interest will be asked to attest in writing that they will make

unbiased decisions about any content as it relates to their relevant financial relationships and will ensure that the content of the educational activity they have control or influence over does not promote the products or services of any commercial interest.

- **Audience Evaluation:** Attendees will be queried regarding their impressions concerning bias (or absence of bias) within the activity. The results of the evaluation will be shared with appropriate planning personnel and will be used for future planning efforts.
- **Reassignment or Elimination:** Education Committee members, Program Committee members, abstract reviewers, presenters, and session chairs who exhibit bias or who have unresolvable conflicts of interest will, upon the recommendation of the COI Committee, be assigned to an area in which they do not have a conflict of interest or will be eliminated from participation in the educational activity.

Additional resolution mechanisms for individuals serving in specific educational capacities are as follows:

Education Committee:

The Chair of the Education Committee will serve as the COI Compliance officer for the Committee. The COI Committee will review all disclosure forms which include relevant financial relationships. They will formally communicate with all such committee members the specific manner in which the COI must be resolved. In some instances, the nature of the conflict may be so substantial that the individual will be asked to discontinue the problematic financial relationships or relinquish his/her position on the committee. Conflict of interest disclosures will be attached to each meeting agenda and verbal disclosure will be made by each Committee member prior to the start of each meeting or conference call. The COI Compliance Officer will monitor discussions to ensure and enforce absence of biased participation by conflicted individuals. **In all cases, individuals with conflicts of interest may not participate in decision-making discussions or voting on issues related to their areas of conflict.** If appropriate, the COI Compliance Officer may request that the individuals with conflicts of interest not participate in any discussions related to their areas of conflict. Written documentation of all these measures will be made by the COI Compliance Officer. While the COI Compliance Officer is the person designated to enforce the COI policy and process, all committee members are responsible for holding one another accountable for compliance with the policy and must be willing to call on their colleagues to act in accordance with the policy. While it is possible that a committee member may not agree with the perception by others that a conflict exists, all committee members must abide by the policy and recuse themselves from participation as required by the Society's COI policy.

Scientific Program Committee Members:

The President and Program Committee Chair-Elect serve as the COI Compliance Officers for the committee. The COI Committee will review all disclosure forms which include relevant financial relationships. They will formally communicate with all such committee members the specific manner in which the COI must be resolved. In some

instances, the nature of the conflict may be so substantial that the individual will be asked to discontinue the problematic financial relationships or relinquish his/her position on the committee. Conflict of interest disclosures will be attached to the meeting agenda and verbal disclosure will be made by each Committee member prior to the start of each meeting. The COI Compliance Officers will monitor discussions to ensure and enforce absence of biased participation by conflicted individuals. **In all cases, individuals with conflicts of interest may not participate in decision-making discussions or voting on issues related to their areas of conflict.** If appropriate, the COI Compliance Officers may request that the individuals with conflicts of interest not participate in any discussions related to their areas of conflict. Written documentation of all these measures will be made by the COI Compliance Officers. While the COI Compliance Officers are the individuals designated to enforce the COI policy and process, all committee members are responsible for holding one another accountable for compliance with the policy and must be willing to call on their colleagues to act in accordance with the policy. While it is possible that a committee member may not agree with the perception by others that a conflict exists, all committee members must abide by the policy and recuse themselves from participation as required by the Society's COI policy.

To minimize the introduction of bias in the selection of symposia which are developed prior to the Program Committee meeting, the **program committee members may not participate in the pre-program-committee-meeting development of any proposed symposia that pertain to a topic area in which they have a relevant financial relationship.**

Since an important proportion of the symposium and invited speaker program content is developed at the Program Committee meeting (as opposed to specific proposals submitted in advance), an additional layer of monitoring and management of potential bias is needed, as follows:

- a. The COI Committee will review the disclosures for all proposed Program Committee members. If financial relationships relevant to potential meeting content in a given topic Category are present in BOTH Category Chairs, the COI Committee will require either:
 - i. replacement of one or both chairs with other individuals
 - ii. specific steps to resolve potential bias
- b. If one Category Chair has a relevant financial relationship and is permitted to remain on the committee, he/she may, depending upon the nature of the relationships, be instructed to recuse him/herself from any discussions, program development, or decision-making regarding symposia/invited lectures in the specific area in which he/she has a relevant financial relationship. In any event, this will require the participation of the co-chair and/or the other Program Committee members who do not have relevant financial relationships in those topic areas to participate in symposia/invited speaker development in those topic areas or as peer reviewers in those topic areas

- c. If both Category Chairs have relevant financial relationships and are permitted to remain on the Program Committee, they may, depending upon the nature of the relationships, be instructed to both recuse themselves from any discussions, program development, or decision-making regarding symposia/ invited lectures in the specific topic areas in which they have relevant financial relationships. In any event, this will require the participation of the other Program Committee members who do not have relevant financial relationships in those topic areas to participate in symposia/invited speaker development in those topic areas or as peer reviewers in those topic areas

Presenters (Abstract and Invited)

Presenters are informed in writing that a disclosure slide must be included in their presentations that includes all of the relevant financial relationships of themselves and their co-authors, and they must state these relevant financial relationships prior to their presentations. Slide templates are available on the ISHLT Web site. Audiovisual (AV) personnel will screen all presentations to ensure that the required disclosure slide precedes each presentation. If the author has not included this slide, AV personnel will add it to the slide collection in collaboration with the author. No slide presentation will be delivered to the lecture room without this slide. AV personnel assigned to the lecture room will leave the disclosure slide on the screen long enough for the audience to review the information it contains, but no less than five seconds, even for speakers who indicate that they have nothing to disclose.

Speakers with relevant financial relationships will receive written notification from the COI Committee of specific expectations during their presentation designed to avoid bias. Copies of these notifications will be provided to the Session Chairs who are responsible for monitoring COI policy compliance and violations in their sessions. Session Chairs are instructed to ensure that the presenters state conflicts of interest or the lack of same. If the Chair notes that the presentation reflected bias, s/he is required to make a statement to that effect immediately after the bias was communicated by the presenter. The Chair must also submit a written report of the observation to the COI Committee.

Session Chairs

Session Chairs are responsible for monitoring COI policy compliance and violations in their sessions. Session Chairs are instructed to ensure that the presenters state conflicts of interest or the lack of same. If the Chair notes that the presentation reflected bias, s/he is required to make a statement to that effect immediately after the bias was communicated by the presenter. The Chair must also submit a written report of the observation to the COI Committee.

Session Chairs are informed in writing that they must display a disclosure slide at the start of the session they are chairing and that they must state their relevant financial relationships prior to the start of the session. Slide templates are available on the ISHLT Web site. Audiovisual (AV) personnel are instructed to ensure that the required

disclosure slide precedes each session. If the Session Chair has not prepared this slide, AV personnel will add it to the slide collection in collaboration with the Session Chair. No session may begin without the Chairs' disclosure. AV personnel assigned to the lecture room will leave the disclosure slides on the screen long enough for the audience to review the information it contains, but no less than five seconds, even for Chairs who indicate that they have nothing to disclose.

Session Chairs with relevant financial relationships will receive written notification from the COI Committee regarding specific expectations of them designed to avoid bias. Copies of these notifications will be provided to each Chair's co-Chair, who is responsible for monitoring COI policy compliance and violations on the part of their co-Chair. If a Chair notes that his/her co-Chair is exhibiting bias, s/he is required to make a statement to that effect immediately after the bias was noted. The Chair must also submit a written report of the observation to the COI Committee.

Abstract Co-Authors

The relevant financial relationships of Abstract Co-Authors, including co-authors who are industry employees, are resolved by ensuring they do not present the abstract.

Abstract Reviewers

The conflicts of interest of Abstract Reviewers are resolved by the following process:

- a. Abstract reviewers who have relevant financial relationships with a commercial interest whose products/services or class of products/services are addressed in an abstract must recuse themselves from scoring that abstract.
- b. Abstract reviewers must recuse themselves from scoring any abstracts in which their institution was involved.
- c. All abstracts are blinded before being distributed for scoring.
- d. All abstracts are scored by between 5 and 12 reviewers, and a mean score is computed for each abstract to ensure that no one reviewer can overly influence an abstract score.
- e. The selection of abstracts for presentation is performed by the Program Committee and is done primarily on the basis of average score, which serves to insure that no one reviewer can exert undue influence over whether or not an abstract is accepted for presentation.

F. ISHLT Relationship with Commercial Interests

Many ISHLT members, speakers, and other volunteers, as well as their institutions, are involved in pharmaceutical-sponsored clinical trials or have other relationships supported by industry. Recognizing both the importance of collaboration between scientists and industry as well as the conflicts of interest these arrangements present, ISHLT has created clear policies designed to protect the integrity of its core mission from being influenced by industry supporters.

1. Grants and Fellowships Underwritten by non-ISHLT Entities and Administered by ISHLT

No donor, commercial or otherwise, can select or designate grant or fellowship recipients or in any way exert control over how the ISHLT grants and awards program is administered or how the ISHLT grants and awards are distributed.

2. ISHLT-Sponsored Educational Activities

- a. Commercial Interests may not be involved in the following with regard to ISHLT Educational Activities:
 - i. Identification of CME needs;
 - ii. Determination of educational objectives;
 - iii. Selection and presentation of content;
 - iv. Selection of any persons and organizations that will be in a position to control the content of the CME;
 - v. Selection of educational methods;
 - vi. Evaluation of the activity.
- b. Commercial Interests may not set conditions on the use of funds provided to ISHLT for the purpose of supporting ISHLT-sponsored educational activities nor have input into or influence over the disbursement of such funds.
- c. The terms, conditions, and purposes of all support from commercial interests will be documented in a written agreement signed by the commercial interest and ISHLT.
- d. The source of all support from commercial interests will be disclosed to participants of all educational activities prior to the start of the activities.
- e. Product-promotion material or product-specific advertisement of any type is prohibited in or during CME activities. The juxtaposition of editorial and advertising material on the same products or subjects will be avoided. Exhibits and independent non-ACCME accredited industry activities will be kept separate from CME activities.

3. Educational Activities Sponsored by Industry

- a. ISHLT does not offer accreditation for symposia sponsored by commercial interests.
- b. All activities conducted by commercial interests in conjunction with an ISHLT educational activity must be approved in writing by ISHLT. Failure to comply with this requirement may result in the commercial interest being removed from the exhibit hall and being prevented from exhibiting at future meetings.
- c. The scheduling of all activities conducted by commercial interests must be approved by ISHLT.
- d. **Independent ACCME accredited educational activities** that are supported by industry may be conducted during times designated by ISHLT. The complete program for such activities must be submitted to ISHLT no less than 30 days in advance for review and approval and verification of ACCME accreditation. Educational activities whose content is judged to duplicate or otherwise compete with the content offered by ISHLT will not be permitted. Individuals who are invited speakers (not including abstract presenters), planners, or chairs at an ISHLT educational activity may, upon approval of the COI Committee, serve as speakers, planners, or chairs at an independent CME-accredited industry-

supported educational activity held in conjunction with the ISHLT educational activity. Such activities will be included in the ISHLT Final Program in a separate section for CME accredited affiliate programs, and information about them may be distributed from the company's exhibit booth and in the ISHLT delegate bags. Promotional materials and signage regarding such activities must display the following verbiage: "This is an independent activity that is NOT part of the ISHLT Annual Meeting and Scientific Sessions. The content has not been approved or endorsed by ISHLT."

- e. **Independent non-ACCME accredited educational activities and/or non-educational activities** organized by industry may be conducted during times designated by ISHLT. The complete program for such activities must be submitted to ISHLT 30 days in advance for review and approval. Educational activities whose content is judged to duplicate or otherwise compete with the content offered by ISHLT will not be permitted. Individuals who are invited speakers (not including abstract presenters), planners, or chairs at an ISHLT educational activity may, upon approval of the COI Committee, serve as speakers, planners, or chairs at an independent non-accredited industry-supported educational activity held in conjunction with the ISHLT educational activity. Such activities will NOT be included in the ISHLT Final Program. Information about **non-educational activities** may be distributed from the company's exhibit booth and in the ISHLT delegate bags. Information about **non-accredited educational activities** may not be distributed or promoted in the meeting areas or in the ISHLT delegate bags. Promotional materials and signage regarding such activities must display the following verbiage: "This is an independent activity that is NOT part of the ISHLT Annual Meeting and Scientific Sessions. The content has not been approved or endorsed by ISHLT."

4. Advertising by Industry

- a. Exhibitor space will be made available to companies in compliance with the ISHLT COI policies as indicated in this document.
- b. Other advertising techniques such as logo branding of meeting bags, advertisements in the program book, logo-branded room keys and the like are allowed if not prohibited by ACCME.
- c. Funds received for promotional./advertising activities are not considered to be support for ISHLT educational activities.