

## ISHLT CONFLICT OF INTEREST POLICY

The International Society for Heart & Lung Transplantation (“ISHLT”) is committed to complying with ACCME’s Standards for Commercial Support for all its continuing medical education (CME) eligible activities. ISHLT’s CME Conflict of Interest Policy and Disclosure Form is intended to comply with ACCME’s requirements. The responsibility for managing ISHLT’s CME Conflict of Interest Policy is under the control of the COI Management Committee which reports to the Education Oversight Committee reporting to the ISHLT Board of Directors. The COI Management Committee establishes ISHLT’s rules, responsibilities, and processes with respect to compliance with ACCME’s requirements for identification, disclosure, and resolution of COI; and has the authority to implement, apply, and interpret ISHLT’s CME Conflict of Interest Policy as it applies to CME related activities. This policy does not apply to non-CME learning events conducted by the society.

### Disclosure Requirements

Every person who has the potential to affect the content of a CME activity must complete a Disclosure of Relevant Financial Relationships they have/had with [ACCME defined ineligible companies](#) over the previous 24 months. The form must be submitted to ISHLT prior to participation in a CME related activity, and in all cases, as follows:

- For Planners, the CME Financial Disclosure Form must be returned prior to planning the activity.
- For faculty/moderators/presenters/authors, the CME Financial Disclosure Form must be returned prior to developing their course materials.
- For Reviewers, the CME Financial Disclosure Form must be returned prior to the commencement of content review.

Persons who perform CME related duties on a regular and ongoing basis must complete Disclosure Forms annually. All other persons must complete forms during their becoming involved in CME related activity.

Everyone must provide updates if a change in relevant financial relationships has occurred even if it is outside the normal annual reporting cycle. ISHLT provides a mechanism to make this possible.

### Independence

All persons who have the potential to affect the content of a CME activity must ensure that:

- All recommendations involving clinical medicine in a CME activity are based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients.
- All scientific research referred to, reported, or used in a CME activity or in support of a patient care recommendation conform to generally accepted standards or experimental design, data collection and analysis.
- Content is linked to the learning objectives for the activity, pertinent to the target audience and free of commercial bias.

Before planning CME activities, all planners and others who would be in positions to control content must provide information about all their financial relationships with ineligible companies over the previous 24 months. Ineligible companies are those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients. There is no minimum financial threshold; individuals must disclose all financial relationships, regardless of the amount, with

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ineligible companies. Disclosures will be reviewed by the COI Management Committee.

ISHLT does not allow individuals with current/ongoing relationships as owners and/or employees of ineligible companies or healthcare start-up companies if related to the proposed CME topic in question, to participate as planners, reviewers or presenters of CME content.

Anyone who has potential control of content must provide information about all their financial relationships with ineligible companies over the previous 24 months for review by the ISHLT.

### **Resolution of Personal Conflicts of Interest**

- It is ISHLT's intent that all relevant financial relationships with ineligible companies are identified in a timely manner and any resulting conflicts of interest ("COI") are resolved appropriately. or owner/employee of a healthcare startup company, where a financial relationship exists.
- When the content of the accredited activity is limited to basic science research, such as pre-clinical research and drug discovery, or the methodologies of research, and care recommendations are not made.
- When presenters are participating as technicians to teach the safe and proper use of medical devices, and do not recommend whether or when a device is used.

### **Disclosure Review**

All CME Disclosure Forms will be reviewed by ISHLT's COI Management Committee to ensure compliance with ISHLT's CME Conflict of Interest Policy. Resolution of COI consistent with ACCME's requirements occurs as necessary. Any potential COI matters under ISHLT's Conflict of Interest Policy are identified and addressed; and any additional questions or issues requiring follow-up are referred to the COI Management Committee. ISHLT may from time to time adopt additional procedures for implementing this policy and for handling CME related COI matters.

The Director of Education & Research will elevate any concerns regarding a CME Financial Disclosures to the COI Management Committee for their review and guidance on whether a relevant relationship with ineligible company creates a COI that must be resolved.

### *Unresolvable Conflicts*

If the COI Management Committee determines that a conflict for a planner, faculty member, or reviewer cannot be resolved, the person(s) involved will not be allowed to plan or affect the content of an ISHLT CME activity related to that person's relevant financial relationship with a commercial interest. Anyone with such a COI must recuse themselves from participating in the affected activity. In the alternative, ISHLT will not invite them to participate, will preclude them from participating, or, as necessary, will remove them from participation. In special circumstances, persons with unresolvable conflicts may be considered a critical source of expertise for CME planning purposes. In such cases, ISHLT's COI Committee will appoint one of its members to review and oversee the planning process to ensure that the CME activity is fair, balanced, and without commercial bias.

If the planner, faculty member, or reviewer disagrees with the COI Management committees' determination of ineligibility, the decision may be appealed to the Chair of the Education Oversight

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Committee for final determination.

### *Mitigate Conflicts*

Where COI can reasonably and appropriately be mitigated, ISHLT will work with the affected parties to take steps to resolve their conflicts. For example:

- Planners/reviewers will not be allowed to plan/review the content relevant to their reported COI or another planner/reviewer will be required to participate to ensure fair balance.
- Planners/reviewers should not have any relevant COI. Where relevant COI is present, another reviewer should be selected with no relevant COI and/or a member of the COI Committee shall perform the review.
- Faculty/presenters will have their CME content independently reviewed to ensure that the faculty presenter: (i) does not make recommendations or topics related to their COI; (ii) makes any recommendations for patient care on peer reviewed data; or (iii) re-submits and limits the scope of their presentation as needed to resolve the COI as determined by ISHLT's COI Management Committee.
- Faculty/presenters who have a relevant COI with any grantors of the CME activity, or with content to be discussed during their presentation that is related to their COI, will have their content reviewed prior to presentation by the assigned non-conflicted reviewer for the activity and/or a member of the COI Management Committee. Any content determined by the reviewer to have commercial bias, lack of fair balance or other concerns, may not be presented until it is limited/corrected and re-reviewed by the COI Management Committee.

To avoid having the process for managing resolvable conflicts interfere with the timely development and implementation of CME activities, all persons with a resolvable conflict must present their relevant presentation/materials to ISHLT for review no later than three weeks prior to the CME activity. Whenever corrections or changes are required, the affected person must make those changes/corrections within three business days and re-submit their presentation/materials to the assigned reviewer for final approval. A person with a resolvable conflict can only participate in the affected CME activity after review and final approval by the ISHLT under this policy.

### **Documentation, Interpretation and Final Adjudication**

All actions and decisions implementing this policy will be documented and made a part of the CME activity file. Any questions concerning whether a COI exists, whether it is unresolvable, or whether it is properly resolved and/or otherwise managed will be determined at the sole discretion of the COI Management Committee Chair.

### **Transparency**

ISHLT provides all learners (i.e., CME Participants) with information about the relevant financial relationships of all persons that affect the content of CME related activities pursuant to this policy and with other information that ISHLT determines should be disclosed. All such information will be positioned in course materials and/or opening slides such that it is easily seen by learners prior to the commencement of the CME activity (e.g., at the beginning of course handouts or the beginning of each presentation).