

(P-28) POLICY FOR THE ASSESSMENT AND MANAGEMENT OF CONFLICT OF INTEREST

(GB 08-14-09-04), (FBOT 11-16-03-09), (FBOT 05-18)

Code for the Assessment and Management of Conflict of Interest

Purpose and Application:

Complex relationships with **for-profit** and **not-for-profit** organizations and entities may by their existence present a perceived or real conflict with the missions and values of the AASLD FOUNDATION. In as much as the existence of real or perceived conflicts of interest serves to undermine the stature, integrity, creditability and function of the AASLD FOUNDATION, the AASLD FOUNDATION must insure that its membership, leadership and the public-at-large understand the importance it places on identification and resolution of conflicts. The independence and the credibility of AASLD FOUNDATION require implementation of a clear policy that can be enacted in a practical, fair and transparent manner.

Conflicts of interest are defined as **any** circumstances that create a risk that professional judgments or actions regarding a primary interest will be unduly influenced by a secondary interest. ¹Primary interests are those associated with the stated mission of the AASLD FOUNDATION. Secondary interests may be financial or non-financial in nature. (e.g. intellectual conflict of interest,² membership in other organizations, or institutional or corporate associations).

The degree of permitted associations will be regulated in a fashion that is commensurate with the influence that the individual has in the creation, implementation or execution of AASLD FOUNDATION functions. Since the AASLD FOUNDATION plays roles of advocacy for clinical care, education and research in liver diseases, the policy shall cover all individuals who participate at any level in those functions. The definition of conflict, review of disclosures and the adjudication and resolution of conflicts needs to be a multi-layer effort that is charged to the AASLD Ethics committee. The policy outlined will require diligent interpretation in complex cases, with the goal of providing clarity for members as they engage in their functions. The overriding goal is to provide objective conflict management. The application of this Code is not intended to be punitive to the member. The process is by its nature fluid and ongoing reporting and review is necessary.

Definitions ³

The following terms are defined for purposes of this Code:

Company: A Company is an entity that develops, produces, markets, or distributes drugs, devices, services or therapies used to diagnose, treat, monitor, manage, and alleviate health conditions and whose interests could reasonably be seen to overlap with the interests, missions and values of the AASLD FOUNDATION. This definition is not intended to include entities outside of the healthcare sector, or entities through which physicians provide clinical services directly to patients.

Direct Financial Relationship: A Direct Financial Relationship is a compensated relationship with a Company held by an individual that should generate an IRS Form W-2, 1099 or equivalent income report.

Educational Grant: An Educational Grant is a sum awarded by a Company, typically through its grants

¹ Conflict of interest in medical research, education and practices. <http://www.nap.edu/catalog/12598.html>

² Guyatt G, Aki EA, Hirsh J, et al. The vexing problem of guidelines and conflict of interest: a potential solution: Ann Intern Med 2010;152:738-41

³ Modified from Council of Medical Specialty Societies, 230 E Ohio St. Suite 400 | Chicago, IL 60611

office, for the specific purpose of supporting an educational or scientific activity offered by the recipient. Educational Grants awarded by a Company to support a CME activity are referred to in the ACCME Standards for Commercial Support as “Commercial Support” of CME. An Educational Grant may also be “in-kind.”

Gifts “in kind”: Compensation in goods or services rather than money; non-monetary gifts of valued consideration (e.g. access to advisory or consultant services, specific resource allocation or access).

Research Grant: For purposes of this Code, a Research Grant is an award that is given by a Company or other funding agency to an individual, institution, or practice to fund the conduct of scientific research. Companies may provide an individual, institution, or practice with programmatic support (e.g., an Educational Grant) designated for the specific purpose of funding Research Grants.

Principles and Practice

1. Independence

AASLD FOUNDATION will develop educational activities, products, services and advocacy positions aligned with the mission of the AASLD and the AASLD FOUNDATION, independent of external influence, and will develop and adopt policies and procedures that foster this independence. The AASLD FOUNDATION will separate their efforts to seek Educational Grants, Corporate Sponsorships, Charitable Contributions, and support for Research Grants from their programmatic decisions. The initial step in program development is the independent assessment by the AASLD FOUNDATION that a program is needed (e.g., to address gaps in care or knowledge). Once the AASLD FOUNDATION determines that a program is needed, it is permissible to assess the availability of funds.

- A.** AASLD FOUNDATION Governing Board Member Trustee representatives must follow the policies established for AASLD as outlined in the **AASLD Code for the Assessment and Management of Conflict of Interest.**
- B.** The Ethics Committee of AASLD will be responsible for evaluating and adjudicating conflicts of interest and guiding the interactions of the AASLD FOUNDATION, and its Members, and monitoring the compliance with this Code by the Covered Individuals (as found in the **AASLD Code for the Assessment and Management of Conflict of Interest.**)
- C.** The COI process for Ethics Committee action includes approval of a motion involving identification or management of a conflict of interest by two-thirds majority of voting Trustee members.
- D.** AASLD FOUNDATION Trustees are permitted to have Direct Financial Relationships with Companies and must disclose any such Relationship and indicate whether it is in excess of \$10,000 per year. Disclosure should be collected annually.
- E.** Research support, uncompensated services and other permitted relationships must be disclosed to the AASLD Foundation, regardless of any monetary value or its equivalent.
- F.** Trustees may provide uncompensated service to Companies and accept reasonable travel reimbursement in connection with those services.

- G. Trustees may accept research support as long as grant money is paid to the institution (e.g., academic medical center) or practice where the research is conducted, not to the individual.
- H. Covered Individuals will use written agreements with Companies for Educational Grants, Corporate Sponsorships, Charitable Contributions, Business Transactions, and support of Research Grants. Written agreements should specify what the funds are for, the amount given, and the roles of the Company and the Covered Individual. These agreements may be reviewed by the AASLD Ethics Committee.
- I. Membership as an officer or member of the governing board of a related professional association/society or foundation maybe allowed, but must be declared and adjudicated for direct competition with the AASLD FOUNDATION.
- J. The Foundation Trustees who are appointed prior to the time the Foundation approves this Code are able to maintain existing relationships with Companies for the duration of their terms.
- K. AASLD FOUNDATION Trustees should NOT participate in:
 - a. Industry-sponsored satellite symposia at DDW or The Liver Meeting®
 - b. Programs conducted by vendors contracted by AASLD FOUNDATION. (Based on the policy of AASLD GB 02-26-2009)

2. Transparency

The AASLD FOUNDATION will make their conflict of interest policies available to the public. The AASLD FOUNDATION, through the Ethics Committee, will manage conflicts of interest in a variety of ways. This may include disclosure alone, or other conflict of interest management mechanisms such as recusal, divestiture or AASLD FOUNDATION-independent review. The Ethics Committee will select conflict of interest management mechanisms that are appropriate for the activity, type of relationship and role of the individual under consideration (as found in the **AASLD Code for the Assessment and Management of Conflict of Interest**).

- A. The AASLD FOUNDATION, through the Ethics Committee, will provide written disclosure forms to individuals who serve on behalf of the AASLD FOUNDATION, and will use the disclosed information to manage conflicts of interest in decision-making. AASLD FOUNDATION will require volunteers to update disclosure information at least annually and when material changes occur.
- B. The AASLD FOUNDATION leadership will disclose all Direct Financial Relationships in excess of \$10,000 per year and uncompensated relationships with an equivalent monetary value held by the Trustees, making this information available to their members and the public.
- C. Disclosure forms obtained during any nominating process shall not be included as part of the review of the candidate by the Nominating Committee. The disclosures of the finalists selected by the Nominating Committee shall be reviewed by the Ethics Committee prior to review by the AASLD Governing Board and the Foundation Board of Trustees.

3. Adherence to the Code

Adherence to this Code will be promulgated by the AASLD FOUNDATION. All Trustees of the AASLD FOUNDATION will be encouraged to adopt the principles of this Code and their application.

Appendix A

CONFLICT OF INTEREST: SPECIAL CONSIDERATIONS FOR AASLD FOUNDATION BOARD OF TRUSTEES AND COMMITTEES (RESEARCH AWARDS AND DEVELOPMENT)

Disclosures

Disclosures must be made at least annually and when material changes occur.

Position	Review By	Made Public
Chair	AASLD Foundation Board of Trustees & Ethics Committee	Yes-Required (website)
Trustees	AASLD Foundation Board of Trustees & Ethics Committee	Yes-Required (website)
AASLD Governing Board Member Representatives	Follows the AASLD Code for the Assessment and Management of Conflict of Interest	Follows the AASLD Code for the Assessment and Management of Conflict of Interest
Committee Chairs and Vice-Chairs	Committee (as delegated by the Ethics Committee)	Not required
Committee Members	Committee (as delegated by the Ethics Committee)	Not required
Nominees for AASLD Foundation Board Service	AASLD Governing Board & Ethics Committee	Not required