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. 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, AASLD 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 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. Primary interests are those associated with the stated mission of the AASLD. Secondary interests may be financial or non-financial in nature. (e.g. intellectual conflict of interest, membership in other organizations, or institutional or corporate associations).

Application of this policy is to be temporally phased in with addition of new members and reappointments (see for example, Section 1G). Further, 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 functions. Since the AASLD 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 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.

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

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. 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 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 will develop all educational activities, scientific programs, products, services and advocacy positions aligned with the mission of the Association, independent of external influence, and will develop and adopt policies and procedures that foster this independence. AASLD 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 AASLD that a program is needed (e.g., to address gaps in care or treatment).

3 Modified from Council of Medical Specialty Societies, 230 E Ohio St. Suite 400 | Chicago, IL 60611
knowledge). Once AASLD determines that a program is needed, it is permissible to assess the availability of funds.

A. The Ethics Committee of AASLD will be responsible for evaluating and adjudicating conflicts of interest and guiding the interactions of AASLD, and its Members, and monitoring the compliance with this Code by the Covered Individuals (See Appendix C).

B. Approval of a motion involving identification or management of a conflict of interest by the Ethics Committee requires a two-thirds majority of voting members.

C. The President, President-elect and the Editors-in-Chief of AASLD journals may not have Direct Financial Relationships with Companies during his or her term of service.

D. Other AASLD Members are permitted to have Direct Financial Relationships with Companies and must disclose any such Relationship and indicate whether it is in excess of $5000 per year when requested.

E. Governing Board members and journal editors (a) should not serve on industry speakers’ bureaus, (b) should not participate in industry-sponsored satellite symposia at DDW or The Liver Meeting®, and (c) should not participate in programs conducted by vendors contracted by AASLD. (GB 02-26-2009)

F. Nominees for Councilor will be informed that they will be required to terminate any Direct Financial Relationships with Companies prior to their term as President-elect.

G. The President, President-elect and the Editors-in-Chief of AASLD journals may provide uncompensated service to Companies and accept reasonable travel reimbursement in connection with those services. The President, President-elect and the Editors-in-Chief of AASLD journals 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. Research support, uncompensated services and other permitted relationships must be disclosed to the AASLD, regardless of any monetary value or its equivalent. Membership as an officer or member of the governing board of a related professional association is not allowed.
H. AASLD may permit the President, President-elect and the Editors-in-Chief of AASLD journals who are elected or appointed prior to the time the AASLD approves this Code to maintain existing Direct Financial Relationships with Companies for the duration of their terms.

I. 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 Ethics Committee.

2. Transparency

AASLD will make their conflict of interest policies available to their members and the public. AASLD, 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-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 (see Appendix C).

A. AASLD, through the Ethics Committee, will provide written disclosure forms to individuals who serve on behalf of the AASLD (see Appendix D), and will use the disclosed information to manage conflicts of interest in decision-making. AASLD will require volunteers to update disclosure information at least annually and when material changes occur.

B. AASLD will disclose all Direct Financial Relationships in excess of $5000 per year and uncompensated relationships with an equivalent monetary value held by the President, President-elect and the Editors-in-Chief of AASLD journals, making this information available to their members and the public. AASLD is not required to disclose the relationships of other Board members elected prior to the time that AASLD approves this Code.

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 Governing Board.
3. **Clinical Practice Guidelines**

AASLD will base Clinical Practice Guidelines on scientific evidence and will follow a transparent Guideline development process that is not subject to Company or other external influence, including any intellectual conflict of interest. AASLD will publish a description of their Guideline development process, including their process for identifying and managing conflicts of interest, in AASLD Journals or on AASLD websites.

A. AASLD will not permit direct Company support of the development of Clinical Practice Guidelines or Guideline Updates.

B. Permitted relationships and their disclosure for Clinical Practice Guidelines Committee members and Chairs are outlined in Appendix A.

C. AASLD will require that a majority (based on simple numerical majority) of Guideline development panel/writing group members are free of conflicts of interest relevant to the subject matter of the Guideline during the period of Guideline Development. If Guideline development panel/writing group members and chairs have conflicts of interest at the time of adoption of the Code, AASLD may permit these individuals to remain involved in drafting the Guideline without voting privileges. However, each panel/writing group for which this exception is made must meet the requirements of this Code by the time of the next Guideline Update to remain a member of the Guideline development panel/writing group. For the minority of panel/writing group members who are not free of conflicts, AASLD will apply procedures for conflict of interest management developed in accordance with Section 2.

D. AASLD will require the panel/writing group chair (or at least one chair if there are co-chairs) to be free of conflicts of interest and to remain free of conflicts of interest during Guideline development up to the time of publication of the Guideline.

E. AASLD will require that Guideline recommendations be subject to multiple levels of review, including rigorous peer-review by a range of experts. AASLD will not select as reviewers individuals employed by or engaged to represent a Company.
F. AASLD will publish Guideline development panel/writing group members’ disclosure information adjacent to each Guideline and will identify voting members.

G. AASLD will require all Guideline contributors, including expert advisors or reviewers who are not officially part of a Guideline development panel/writing group, to disclose financial or other substantive relationships that may constitute conflicts of interest.

4. **Adherence to the Code**

   Adherence to this Code will be promulgated by AASLD. All Members of the AASLD will be encouraged to adopt the principles of this Code and their application.
### Appendix A

**CONFLICT OF INTEREST: SPECIAL CONSIDERATIONS FOR PRACTICE GUIDELINES COMMITTEE CHAIR, COMMITTEE MEMBERS, AND WRITING GROUP MEMBERS**

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

<table>
<thead>
<tr>
<th>Review By</th>
<th>Made Public</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Practice Guidelines Committee Chair</strong></td>
<td>Ethics Committee</td>
</tr>
<tr>
<td><strong>Practice Guidelines Committee</strong></td>
<td>Practice Guidelines Committee Chair (as delegated by the Ethics Committee)</td>
</tr>
<tr>
<td><strong>Writing Group Members</strong></td>
<td>Practice Guidelines Committee (as delegated by the Ethics Committee)</td>
</tr>
</tbody>
</table>

#### Relationships with commercial entities whose interests may be impacted by guidelines:

<table>
<thead>
<tr>
<th>Stock Ownership or Equity</th>
<th>Disclose and indicate if amount is greater than $5000</th>
<th>No, except in a diversified fund or independently managed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employee, Officer, Director</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Scientific Consultant, Advisory Board</td>
<td>Disclose and indicate if amount is greater than $5000 on an annual basis</td>
<td>No</td>
</tr>
<tr>
<td>Promotional Advisor, Speakers’ Bureau</td>
<td>Disclose and indicate if amount is greater than $5000 on an annual basis</td>
<td>No</td>
</tr>
<tr>
<td>Research Grants</td>
<td>Disclose</td>
<td>Disclose</td>
</tr>
<tr>
<td>Travel Grants</td>
<td>Disclose</td>
<td>No</td>
</tr>
<tr>
<td>Intellectual Property Rights (Patents, Royalties, Licensing fees)</td>
<td>Disclose</td>
<td>No</td>
</tr>
<tr>
<td>Honoraria for CME Activities</td>
<td>Disclose and indicate if amount is greater than $5000 on an annual basis</td>
<td>Disclose and indicate if amount is greater than $5000 on an annual basis</td>
</tr>
</tbody>
</table>
Appendix B

CONFLICT OF INTEREST: SPECIAL CONSIDERATIONS FOR GOVERNING BOARD, JOURNAL EDITORS-IN-CHIEF, COMMITTEES

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

<table>
<thead>
<tr>
<th>Role/Position</th>
<th>Review By</th>
<th>Made Public</th>
</tr>
</thead>
<tbody>
<tr>
<td>President, President-Elect</td>
<td>Governing Board &amp; Ethics Committee</td>
<td>Yes - Required</td>
</tr>
<tr>
<td>Other Governing Board Members</td>
<td>Governing Board &amp; Ethics Committee</td>
<td>Not Required</td>
</tr>
<tr>
<td>Journal Editors-in-Chief</td>
<td>Ethics Committee</td>
<td>Yes - Required</td>
</tr>
<tr>
<td>Committee and SIG Chairs</td>
<td>Committee or SIGs (as delegated by the Ethics Committee)</td>
<td>Not required</td>
</tr>
<tr>
<td>Committee Members and SIG Steering Committee Members</td>
<td>Committee or SIG Steering Committee (as delegated by the Ethics Committee)</td>
<td>Not required</td>
</tr>
<tr>
<td>Finalists in Nominating Process</td>
<td>Governing Board &amp; Ethics Committee</td>
<td>Not required</td>
</tr>
</tbody>
</table>

Relationships with commercial entities whose interests may be impacted

<table>
<thead>
<tr>
<th>Activity</th>
<th>President &amp; President -Elect</th>
<th>Other GB Members</th>
<th>Journal Editors-in-Chief</th>
<th>Committee &amp; SIG Chairs</th>
<th>Committee &amp; SIG Steering Com. Members</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leadership in Related Society: Board, Committee, Journal</td>
<td>Not permitted (Code COI Section 1G)</td>
<td>Not permitted (Bylaws Title 3 Section 3: Nominations (p.6))</td>
<td>Not permitted (Code COI Section 1G)</td>
<td>Disclose &amp; indicate role With 2 exceptions: Journals Publications and Practice Guidelines Committee Chairs may not serve as Editor or Associate Editor of competing journals (Policy 117 B GB03-12-19-12)</td>
<td>Permissible - Disclose and indicate if amount is greater than $5000 on an annual basis</td>
</tr>
<tr>
<td>Scientific Consultant</td>
<td>Permissible if uncompensated except for reasonable travel reimbursement and should be disclosed (Code COI Section 1F)</td>
<td>Permissible - Disclose and indicate if amount is greater than $5000 on an annual basis (Code COI Section 1D)</td>
<td>Permissible if uncompensated except for reasonable travel reimbursement and should be disclosed (Code COI Section 1F)</td>
<td>Permissible - Disclose and indicate if amount is greater than $5000 on an annual basis (Code COI Section 1D)</td>
<td>Permissible - Disclose and indicate if amount is greater than $5000 on an annual basis (Code COI Section 1D)</td>
</tr>
<tr>
<td>Activity</td>
<td>President &amp; President -Elect</td>
<td>Other GB Members</td>
<td>Journal Editors-in-Chief</td>
<td>Committee &amp; SIG Chairs</td>
<td>Committee &amp; SIG Steering Com. Members</td>
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<tr>
<td>Speakers' Bureau</td>
<td>Not permitted (GB Minutes Feb 26-28, 2009, Motion 30, P. 9)</td>
<td>Not permitted (GB Minutes Feb 26-28, 2009, Motion 30, P. 9)</td>
<td>Not permitted (GB Minutes Feb 26-28, 2009, Motion 30, P. 9)</td>
<td>Permissible - Disclose and indicate if amount is greater than $5000 on an annual basis</td>
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</tr>
<tr>
<td>Company: Employee, Officer, Director</td>
<td>Not permitted (Code COI 1.C)</td>
<td>Not permitted (Bylaws Title 3 Section 3: Nominations (p.6)</td>
<td>Not permitted (Code COI 1.C)</td>
<td>Not permitted (Bylaws Title IV: Committees)</td>
<td>Not permitted</td>
</tr>
<tr>
<td>Stock/Stock Options</td>
<td>Not permitted, except in a diversified fund or independently managed Code COI 1.C</td>
<td>Permissible - Disclose and indicate if amount is greater than $5000</td>
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<td>Permissible - Disclose and indicate if amount is greater than $5000</td>
<td>Permissible - Disclose and indicate if amount is greater than $5000</td>
</tr>
<tr>
<td>Grants/Research Support</td>
<td>Permissible - Disclose and indicate if amount is greater than $5000 on an annual basis and whether it was paid to covered individual or their institution (Code COI 1.H)</td>
<td>Permissible - Disclose and indicate if amount is greater than $5000 on an annual basis and whether it was paid to covered individual or their institution (Code COI 1.H)</td>
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<tr>
<td>Intellectual Property Rights</td>
<td>Permissible - Disclose and indicate if amount is greater than $5000 on an annual basis</td>
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<tr>
<td>Other ie: Expert Testimony</td>
<td>Permissible - Disclose and indicate if amount is greater than $5000 on an annual basis (Ethics Com. Min. 11-7-2011 p. 2)</td>
<td>Permissible - Disclose and indicate if amount is greater than $5000 on an annual basis (Ethics Com. Min. 11-7-2011)</td>
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</table>
Appendix C

Policy and Criteria for Assessment of Conflicts of Interest by the Ethics Committee

Policy

The Ethics Committee will employ a policy of evaluating conflicts of interest that embodies the criteria of proportionality, transparency, accountability and fairness. Proportionality requires a policy to address the most important conflicts (i.e. direct financial relationships or financial relationships in-kind); the disclosure forms will reflect this policy. Transparency dictates that the policy be available and understood by the affected parties; this code and the attached appendices (outlining the criteria that will be employed for the assessment of conflicts) will be posted for all members to review and disclosure forms will be accompanied by clear instructions to allow members to understand the specific information required to fulfill full and accurate disclosure. Accountability requires divulging the details of who will be responsible for assessment and enforcement; this is reflected in the code stating that the Ethics Committee will be responsible for the assessment of conflicts and that enforcement of the management of conflicts will be via relevant sections of the Association’s By-laws and the joint actions of the Ethics Committee and the Governing Board. Fairness requires that a policy for the evaluation of conflicts apply to all relevant parties with equal measure; this criterion is met by the statement in this code indicating that the criteria employed to assess conflicts of interest will be independent of the individual or groups to whom they are applied but rather will vary by the set of circumstances around which a conflict arises.

Criteria for Assessment of Conflicts of Interest

Conflicts of interest are rarely, if ever, “absent” or “clearly present”, but rather vary in their severity and relevance to a particular circumstance. Accordingly, the Ethics Committee will assess potential conflicts from the perspectives of the chance that a conflict will impair impartial decision-making and the degree of harm that would arise from such impairment. Based on this Code’s definition of a conflict of interest as any circumstances that create a risk that professional judgments or actions regarding a primary interest will be unduly influenced by a secondary interest, the Ethics Committee will use the following criteria when assessing a conflict:

1. What is the financial value of the secondary interest involved?
2. What is the scope of the relationship(s) of the individual being assessed, with the party or parties associated with the secondary interest?
3. Is the circumstance one involving sole discretion of the particular individual being assessed?
4. What is the value (either direct financial or “in-kind”) to the AASLD of the interest that could be affected by a conflict?
5. What is the scope of the consequence to the AASLD resulting from public disclosure of the conflict?
Questions 1, 2 and 3 evaluate the potential that a conflict could impair impartial decision-making, while questions 4 and 5 assess the degree of harm that could result from an impairment.

After review and discussion of an individual’s potential conflict(s) of interest and its (their) severity, the Ethics Committee will, by voting according to this Code, determine that a conflict exists and that the severity of the conflict rises to the point that management of the conflict requires more than simple disclosure. Based on the criteria outlined above, the Ethics Committee, by a two-thirds majority vote, will request recusal, withdrawal of consideration for a nominated position, AASLD-independent review, divestiture or any other appropriate management of the conflict. The recommendation of the Ethics Committee will be forwarded to the Governing Board for its approval and enforcement. If the matter involves an individual who is a Member of the Governing Board, that Member will recuse themselves from any deliberations involving that matter.

Appendix D

AASLD Conflict of Interest Disclosure Form

AASLD Conflict of Interest Disclosure Form for Practice Guidelines Participants