

American Thoracic Society

POLICY ON MANAGEMENT OF CONFLICT OF INTEREST IN OFFICIAL ATS DOCUMENTS, PROJECTS, AND CONFERENCES

I. INTRODUCTION:

The purpose of this document (“ATS COI Policy”) is to establish a fair and transparent framework for individuals with conflicts of interest to continue to participate as valued members or partners of the Society. This document is a result of a review, analysis and discussion of existing COI documents, policies and procedures of the ATS and other professional organizations. It was prepared originally by an ad hoc committee of the ATS Ethics and Conflict of Interest Committee, the ATS Documents Development and Implementation Committee and ATS staff.

II. GOALS:

- 1) To enhance the objectivity, scientific rigor and transparency of official ATS activities by providing an explicit methodology for individuals who prepare an official ATS document (statement), or participate in a project, conference or other official ATS activity, to (a) identify and disclose all personal or institutional “competing interests” that may cause or be perceived as causing a “conflict of interest” (COI) affecting the individual’s participation in the activity, and (b) resolve all conflicts of interest.
- 2) To provide for disclosure and resolution of conflicts of interest in a manner that is respectful of the ATS members and other individuals essential to ATS activities and respectful of confidentiality to the extent appropriate.

III. PRINCIPLES:

- 1) The American Thoracic Society (ATS) has confidence in the integrity of its members and others who participate in official ATS activities.
- 2) The American Thoracic Society’s (ATS) membership is diverse. ATS members can have their primary work affiliations in academic institutions, industry, patient care, government, research, and administration. Regardless of affiliation, the ATS values the contributions of all of its members and affirms the value of different experiences and points of view. Because of the diversity of our members’ affiliations their interests may compete with the interests of the ATS and represent a conflict of interest when participating in ATS activities.
- 3) Physicians and scientists employed or directly affiliated with the pharmaceutical and/or medical device industries make important and often unique contributions to official ATS activities. Researchers and “content experts” are often involved in activities on behalf of professional organizations. In many cases, these same experts receive

industry funding to consult, lecture, participate in industry scientific advisory boards, conduct research, or provide other services. Some researchers and content experts or their institutions have proprietary interests in a substance, technology, or process that has resulted from their work. Some experts serve as paid witnesses in legal proceedings or as consultants in litigation. Practicing clinicians can be involved in activities such as clinical research studies and public speaking that can affect revenue streams and community standing. Such relationships produce conflicts of interest (COI) that may compete with activities performed on behalf of a professional organization (see references: Campbell, JAMA 2007). As they are directly involved in commercial goals by the nature of their existence, disclosure of such involvements must be transparent and be guided by the highest ethical standards and codes of conduct.

- 4) Conscious or subconscious influence as a result of COI, or the perception by others that such influence exists, may impact the balance of considerations within institutions and organizations in favor of a particular management option. This topic as it relates to guideline development has been the subject of a recent review by Boyd and Bero (see references: Boyd and Bero, Health Res Policy Syst. 2006). Scientific organizations like the ATS possess a credibility among clinicians, scientists and laypersons that is tied directly to the integrity of its conduct. COI have the potential to compromise the validity of ATS activities. Since the ATS is likely to affect health care, public health and health policy proportional to its credibility, the ATS must preserve its organizational integrity and rigorously safeguard its processes to disclose and resolve COI.
- 5) Many individuals have “competing interests” that may cause conflicts of interest. A conflict of interest depends on the situation, and not on the character or actions of the individual.
- 6) Simple *a priori* declaration of COI is insufficient.
- 7) Chairs and organizers of official ATS activities should evaluate the COI disclosures of potential participants and take steps as recommended by the ATS to resolve relevant conflicts of interest. If necessary, the chair/organizer may require more information from the participant to assess and resolve an identified COI. The ATS Ethics and Conflict of Interest Committee and Board of Directors should at their discretion have the opportunity to review the evaluation and resolution, if required, before final assignments to official ATS activities are made.
- 8) Project committee members and/or conference or workshop participants should be apprised of the declared COI of all other participants before deliberations begin. Fellow participants become one “check” to resolve COI throughout the process of project and conference development and implementation.
- 9) COI should be acknowledged in the final published document or other products of the project or conference, with footnotes that allow users of the document or other products to access the policies that safeguarded COI during the project or conference’s development.

- 10) The Editors of ATS Journals should ensure that COI disclosures are obtained from manuscript authors, reviewed as part of final editorial review, and made available to journal readers.

IV. DEFINITIONS:

- 1) **“Conflict of interest” (COI)** will be defined as:
 - a) A divergence between an individual’s private interests and his or her professional obligations such that an independent observer might reasonably question whether the individual’s professional actions or decisions are motivated by personal gain, such as financial, academic advancement, clinical revenue streams or community standing.
 - b) A financial or intellectual relationship that may impact an individual’s ability to approach a scientific question with an open mind. Examples:
 - i.) All financial relationships including employment, consultancies, known stock holdings or holdings in a sector fund relevant to the subject matter, honoraria, in kind gifts or benefits, endowments, patents, royalties and paid expert testimony. Examples of in-kind gifts or benefits are travel, accommodation, meals, or frequent flier miles.
 - ii.) Personal, intellectual or academic relationships that interfere with an individual’s ability to consider or interpret the full breadth of available data or alternative points of view objectively. Examples include inability to review a grant, manuscript or project proposal objectively due to competition for funding, timing of publication or professional stature.
- 2) **“Official ATS activities”** here refers to service to the society in an official capacity, including but not limited to elected office, appointed office, and employment, as well as the development of official ATS documents or participation in ATS projects, conferences, and manuscripts published in official ATS journals.
- 3) **“Participants”** in official ATS activities here include but are not limited to members of: the ATS Board of Directors; ATS standing and ad hoc committees and task forces; Assembly leadership; the members of writing committees and/or organizing committees for official ATS projects; the chairs, organizers, and/or presenters or panellists at official ATS conferences and workshops; the Editors, authors and reviewers of manuscripts published in official ATS journals; and ATS staff.
- 4) **“Commercial interests” (relationships):**

All ATS continuing medical education (CME) activities must comply fully with Accreditation Council for Continuing Medical Education (ACCME) requirements of accredited providers of CME. This includes disclosure of commercial interests as defined by the ACCME. The ACCME currently defines commercial interest as any entity producing, marketing, re-selling, or distributing health care goods or services

consumed by, or used on, patients. The ACCME excludes providers of clinical service directly to patients.

In addition, the ATS also requires disclosure of commercial relationships with manufacturers of devices or other products used in scientific research relevant to ATS interests and/or manufacturers of products or processes thought to cause **respiratory** disease or disorders, and disclosure of involvement with tobacco entities (as defined by ATS).

V. **PROCEDURES:**

The following process should be used to identify and manage COI for individuals involved in official ATS activities:

1) **SELF-DECLARATION OF COI:**

- a) All participants in official ATS activities should submit written disclosures of all competing interests that may cause a conflict of interest for them in carrying out an official ATS activity. Disclosures should be made prior to being involved in an official capacity, i.e., after the invitation or application to participate in an official ATS activity is made, but before becoming an official participant. The individual should declare in writing: all known current and past interests relevant to the subject and scope of the matter for the period of 3 years prior to the date of declaration; and any conflicts of interest relevant to the subject and scope of the matter that are expected to occur in the near future. The term of disclosure for ATS Journals may differ to conform to standards of the International Committee of Medical Journal Editors (ICMJE).
- b) All reviewers of grants or manuscripts should disclose any competing interests to committee chairs or editors, respectively.
- c) Disclosure should be made through a standard ATS questionnaire and uniform online process approved by the ATS Ethics and Conflict of Interest Committee. All participants in official ATS activities should be asked to complete a disclosure questionnaire, update it as individual circumstances warrant, and attest to its accuracy and currency when requested by the ATS. The means and requirements for disclosure for ATS Journals may differ from the following to conform to standards of the International Committee of Medical Journal Editors (ICMJE).

The disclosure questionnaire should obtain:

i.) **DISCLOSURE OF PERSONAL INTERESTS IN COMMERCIAL ENTITIES:**

Disclosure of any direct financial benefit derived from work performed for industry (per company), or any direct financial interest or investment in industry (per company) in the previous 3 years relevant to the scope of

the official ATS activity for which the person is disclosing. Financial relationships of any amount are relevant. The following categories should be included:

- A. Ownership of or employment by a commercial entity (*disclosure of salary amount for full time employees is not required.*);
 - B. Consultancy (ies);
 - C. Board or Advisory Board;
 - D. Lecture fees (honoraria);
 - E. Expert witness;
 - F. Industry-sponsored grants (received or pending), including contracted research;
 - G. Patents received or pending;
 - H. Royalties;
 - I. Stock ownership or options, including sector mutual funds with areas of concentration in an industry or industries relevant to the activity;
 - J. Other personal financial interests.
- ii.) **DISCLOSURE OF NON-COMMERCIAL, NON-GOVERNMENTAL INTERESTS** (relevant or potentially relevant to the scope of the official ATS activity for which the person is disclosing):

Disclosure of whether or not the individual has received support within the past three years from a *non-commercial (non-profit) source* that has an interest in the scope of the official activities of the ATS (e.g., foundation or other nonprofit source).

- iii.) **FINANCIAL RELATIONSHIPS SHOULD BE DISCLOSED WITHIN DOLLAR AMOUNT RANGES:**

Dollar amount ranges are specified by the ATS Ethics and Conflict of Interest Committee. Dollar ranges will be considered by the chair of the official ATS activity (or other authorized parties involved in the disclosure review process) as one factor in weighing the significance of a conflict, in order to determine the appropriate measures to take to resolve the conflict. Dollar amounts will not be published or reported within ATS conferences or projects or otherwise reported by ATS to the public, with the exception of ATS official documents, where the dollar amount range of each participant's relationship per company (for the 3 years prior to submission of the draft document to the ATS Board of Directors) should be included in the disclosure statement that is published with the document, in the manner determined by the Publications Policy Committee, the Journal Editors, and the Documents Editor.

NOTE: An individual who owns or is employed by a commercial entity relevant to the subject matter must disclose his/her employer, but is not required to disclose his/her compensation.

iv.) TOBACCO INDUSTRY RELATIONSHIPS:

Consistent with the *ATS Policy Governing Relationships Between the Tobacco Industry, ATS Members and Non-Members who Participate in ATS Activities*, disclosure of all financial and non-financial affiliations with tobacco entities, as defined by that policy, held at present and/or during at least the past three years.

- d) Disclosures and conflicts should be re-reviewed by participants in an ongoing manner. Any relevant new developments that may influence or be perceived as influencing an individual's participation in an official ATS activity should be disclosed by the individual and brought to the attention of all decision makers within the activity (e.g., project/conference chairs, organizing or writing committee members, conference session faculty).
- e) All participants (committee/panel members and/or presenters) should be asked and reminded to consider their own conflicts and conflicts of others during discussions and decision making. Participants should abstain from discussion and voting if they or a sizable proportion of the other participants identify a COI.

2) **REVIEW OF POTENTIAL PARTICIPANTS' COI:**

- a) Those choosing participants for official ATS activities should review disclosures before deciding on participants, and exclude participants if there is a non-resolvable conflict of interest.
- b) Chairs, organizers, and others with COI review responsibilities should receive step-by-step procedures that clearly and simply articulate what happens and who is responsible at each stage of disclosure and review, and that provide guidance in evaluating the relevance and significance of the COI and determining appropriate methods of resolution. (See appendix 2, significance scale, and appendix 3, sample resolution guidelines.)

For the following categories of participation in ATS, the step-by-step procedures for COI review should include:

i.) ***Candidates for ATS office:***

The ATS Nominating Committee should receive and review COI disclosures from individuals under consideration as nominees for office and should give consideration to any identified COIs and whether they are resolvable through disclosure or recusal alone, or require additional consideration. The COI disclosures of candidates for Assembly Chair and other potential members of the ATS Board of Directors should also be reviewed by the Assembly's executive committee and by the ATS Nominating Committee before election or appointment.

ii.) ***Candidates for project/conference chair or organizer:***

Appropriate ATS Assembly oversight committees (i.e., planning committees and/or program committees), or appropriate non-Assembly Committees in situations where they have oversight (e.g., the Education Committee for educational activities or the Documents Development and Implementation Committee for official documents), should review the disclosures of those submitting proposals for official ATS activities as part of their vetting of the proposal. If the chairs or organizers of official ATS activities differ from the original proponents of the projects, their disclosures should be reviewed by the relevant Assembly oversight committee.

iii.) ***Project or conference participants:***

Project or conference chairs or organizers should review the disclosures of participants (e.g., members of project committees and presenters at workshops and conferences) and may exclude participants if they conclude that COI are not resolvable. Written confirmation of this review, including a brief report of any COI identified and the means by which the COI will be resolved, should be submitted to designated ATS staff and to the chair of the oversight Assembly or committee.

iv.) ***Individuals employed full-time by a company or industry relevant to the subject matter:***

Careful consideration must be given regarding participation of individuals employed full-time by a company or industry that is relevant to the subject matter of an official ATS activity. For example, as previously noted, physicians and scientists employed by the pharmaceutical and/or medical device industry make important and often unique contributions as ATS members and participants in ATS activities. At times, the commercial interests of their employer can by its nature cause or be perceived as causing a COI that might affect the individual's participation in ATS activities that are relevant to these interests. The relevance and significance of the conflict may require that the individual or organizer take steps beyond disclosure of the relationship, such as recusal or excusal from roles or decision-making in ATS activities seen as relevant to employer interests. In particular, roles within ATS that control or may be perceived as controlling ATS decision-making (e.g., chair of an Assembly responsible for the development of documents and projects on subject matters of commercial interest to an individual's employer, or a member of a writing committee of a document on such subject matters) should be avoided. ATS members and other individuals employed by industry may be consulted by project and conference organizers and committees in a manner consistent with standards to be set by the ATS Ethics and Conflict of Interest Committee and the ATS Documents Editor. ATS members and other individuals employed by industry may chair or present at a conference or session(s) within a conference if the appropriate oversight committee resolves the conflict in a manner that ensures objectivity, scientific rigor, and balance, and if an accredited CME activity, is in accordance with the requirements of the Accreditation Council for Continuing Medical Education and the American Medical Association.

- v.) ***ATS staff:***
Disclosure of COI should be required of ATS staff and made available to the ATS Executive Director for determination of whether any identified conflicts of interest require an individual's recusal or excusal from certain ATS roles or decision making, or other consideration to ensure that staff acts in the best interests of the ATS.

- vi.) ***Assurance by Chairs that the procedures for COI disclosure management have been followed and reasonable decisions made:***
Chairs of the Assemblies or Committees that oversee official ATS activities should assure ATS that all required procedural steps have been taken, and that decisions made during the review process have been in compliance with this policy and are reasonable. Assembly Chairs may delegate this review to the Assembly Program Committee Chair for conference matters or Assembly Planning Committee Chair for project matters, or to another an appropriate Assembly member who does not have COI relevant to the subject matter.

- vii.) ***Involvement of the Ethics and Conflict of Interest Committee (and the Documents Development and Implementation Committee when pertaining to official ATS documents):***
Involvement of the above-noted committees may be requested or required in situations in which either a project chair's own COI require review or resolution, or a project chair or the oversight Assembly or Committee's chair requests consultation or requires help to review or resolve COI.

- viii.) ***Official peer review of ATS documents:***
The disclosures of participants involved in the writing of official ATS documents should also be reviewed as part of the official peer review process for ATS documents that is overseen by the Documents Development and Implementation Committee. Procedural steps for COI disclosure and review in connection with the development of ATS documents/guidelines may differ from other cases such as ATS conferences. ATS should develop a standard format that can be modified to suit varying circumstances.

3) DISCLOSURE OF COI TO PROJECT PARTICIPANTS:

Once the members of a project committee have been assembled, COI of members should be identified and discussed before beginning deliberations. Individual participants (including project chairs and panellists) should label where COI bear on specific recommendations.

4) RECUSAL OR EXCUSAL FROM CERTAIN DECISIONS OR RECOMMENDATIONS WHEN APPROPRIATE:

Chairs and panellists should ensure that committees are reminded of the specific COI before discussion of individual conclusions or recommendations on which those COI bear. If the COI are not resolved, participants should recuse themselves, or chairs should excuse the participants, from discussions or decision-making on particular

recommendations. (For example, as earlier noted, ATS members and other individuals employed by industry may have or be perceived as having conflicts of interest that warrant recusal from policy decision making on subjects of commercial interest to their employer, but can be encouraged to contribute to scientific dialogue and other ATS activities in many other ways.)

5) DISCLOSURE OF COI TO USERS OF DOCUMENTS AND ATTENDEES OF CONFERENCES:

COI in official ATS activities should be minimized and transparent. ATS policies for COI disclosure and resolution should be publicly available for all users of ATS documents and attendees of ATS conferences (e.g., through posting on the ATS website). COI should be published with all ATS-sanctioned documents and made available to participants in all ATS conferences, and reference should be made to the policies (herein described) and processes used to identify and resolve COI during the project or conference's development. For example, for official ATS documents this includes stating the evidence and the decision-making process, and labeling instances of substantial disagreement and the reasons for that disagreement, in printed documents. COI should be disclosed to participants of ATS continuing medical education (CME) activities and other educational activities in accordance with the requirements of the Accreditation Council for Continuing Medical Education and the American Medical Association for accredited CME.

6) RELATIONSHIPS BETWEEN THE TOBACCO INDUSTRY, ATS MEMBERS AND NON-MEMBERS WHO PARTICIPATE IN ATS ACTIVITIES

The ATS has enacted a *Policy Governing Relationships Between the Tobacco Industry, ATS Members and Non-Members who Participate in ATS Activities* ("ATS Tobacco Relationships Policy"), as first approved on March 10, 2007 and last amended on September 27, 2010. The policy regards a current relationship with tobacco entities as a conflict of interest that causes ineligibility from participation in certain ATS activities, including: service in governance roles; publication in ATS journals; presentation at the ATS International Conference; service on a writing committee of an ATS statement or guideline; service as an ATS reviewer; and as a recipient of ATS recognition awards. The ATS "Tobacco Relationships Policy" will be treated as a procedural appendix to this ATS "COI Policy."

7) CODE FOR INTERACTION WITH COMPANIES

The ATS has endorsed the *Code for Interaction with Companies* of the Council of Medical Specialty Societies, as first issued on April 17, 2010 and revised on March 19, 2011. The Code is a "voluntary 'code of conduct' for Medical Specialty Societies to 'enhance professionalism and to disclose, manage and resolve relationships with industry.'" (CMSS Code, March 2011, p. 3) Topics addressed include: independence, transparency, accepting charitable contributions, accepting corporate sponsorships, society meetings, awarding of research grants, clinical practice guidelines, society journals, standards for advertising, and standards for licensing. The Code will be treated as a procedural appendix to this policy.

8) PROCEDURES FOR HANDLING DISPUTES IN COI RESOLUTION:

The ATS Ethics and Conflict of Interest Committee should develop and oversee the procedures and instruments used to disclose, review and resolve COI, and should advise and assist chairs and organizers where necessary. Project chairs should first contact the chair or designee of the ATS Assembly or ATS committee overseeing the project. The project chair or oversight Assembly or Committee chair should then request the assistance of the Ethics and Conflict of Interest Committee if necessary. Appropriate ATS staff should be available to advise and assist chairs and organizers throughout the process.

In instances where determination of COI and actions taken to resolve COI in official ATS activities has been disputed, an ad hoc adjudication committee of members appointed by the ATS President should be convened to address the matter. Such an ad hoc adjudication committee could include the Chair of the Ethics and Conflict of Interest Committee (or designee), Chair of the Documents Development and Implementation Committee (or designee), ATS Past-President (or designee), and Past-Chair of the Council of Chapter Representatives, in consultation with ATS legal counsel. Such an ad-hoc committee could also review COI of individuals choosing project participants or panellists.

ATS implementation of this policy may be modified in event of joint activities with organizations whose conflict of interest policies differ. Conformance with this policy and with the *ATS Policy Governing Relationships Between the Tobacco Industry, ATS Members and Non-Members who Participate in ATS Activities* (“ATS Tobacco Relationships Policy”) and the Council of Medical Specialty Societies *Code for Interaction with Companies* (where endorsed by ATS) will be sought to the fullest extent possible.

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