

CONFLICT OF INTEREST (COI) DISCLOSURE & MANAGEMENT REQUIREMENTS FOR 2011 “OFFICIAL ATS PROJECTS”¹

¹ **Including:**

- **All ATS guideline development projects** (guideline panels) operating during 2011, whether or not:
 - New or initiated in a prior year;
 - Approved through the annual Assembly /Committee/Program Review Subcommittee process;
 - Otherwise approved by the ATS Executive Committee;
 - A joint activity with another organization.
 - **All other ATS projects operating during 2011 that are intended to result in an official ATS document:**
 - **All other “official ATS projects” operating during 2011**, whether or not:
 - New or initiated in a prior year;
 - Approved through the annual Assembly /Committee/Program Review Subcommittee process;
 - Otherwise approved by the ATS Executive Committee;
 - A joint activity with another organization.
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(1) UNDERLYING POLICIES:

These requirements are based on the:

- **ATS POLICY ON MANAGEMENT OF CONFLICT OF INTEREST IN OFFICIAL ATS DOCUMENTS, PROJECTS, AND CONFERENCES**, as approved by the ATS Board of Directors, March 14, 2008, and amended May 14, 2008 and September 27, 2010.
- **ATS POLICY GOVERNING RELATIONSHIPS BETWEEN THE TOBACCO INDUSTRY, ATS MEMBERS, AND NON-MEMBERS WHO PARTICIPATE IN ATS ACTIVITIES**, as approved by the ATS Board of Directors on March 10, 2007, and amended on December 14, 2007 and September 27, 2010;
- **COUNCIL OF MEDICAL SPECIALTY SOCIETIES CODE FOR INTERACTION WITH COMPANIES**, as adopted by the ATS Board of Directors on September 27, 2010.

Copies of above policies are available at <http://www.thoracic.org/about/coi-management/index.php>.

(2) PROJECT-SPECIFIC DISCLOSURE²:

- A. **Disclosure of potential conflicts of interest relevant to project subject matter is now required of project participants annually during the life of an official ATS project – not only** at time of initial project application and/or ATS publication of project outcomes. **Project participants include members of the project’s “ad-hoc project committee”, “writing committee” or “guideline panel”**, and are those individuals who are in a position to control the outcome of an official ATS project (in part or in whole), from the point of application for ATS recognition as an official project through the point of project completion, including review and approval of project documents by the ATS Board of Directors.

² Note: ATS project disclosure requirements comply with the Council of Medical Specialty Societies (CMSS) *Code of Interaction with Companies*, as adopted by the ATS Board of Directors in September 2010, including: (7.2) Societies will follow a transparent Guideline development process that is not subject to Company influence. For Guidelines and Guideline Updates published after adoption of the Code, Societies will publish a description of their Guideline development process, including their process for identifying and managing conflicts of interest, in Society Journals or on Society websites. (7.5) Societies will require all Guideline development panel members to disclose relevant relationships prior to panel deliberations, and to update their disclosure throughout the Guideline development process. (7.6) Societies will develop procedures for determining whether financial or other relationships between Guideline development panel members and Companies constitute conflicts of interest relevant to the subject matter of the guideline, as well as management strategies that minimize the risk of actual and perceived bias if panel members do have conflicts.

B. All project committee members (panelists) are required to make a project-specific disclosure to ATS BEFORE they start project activity.

- 1) Project applicants, who typically also are the proposed project chair(s), first make a project – specific disclosure at the time of application for approval as a new or renewed official ATS project. The deadline for project applications submitted through the annual ATS project approval process is typically a date in July. (Note: respective ATS assemblies and committees, and the ATS Program Review Subcommittee (PRS) evaluate and rank proposed projects on the basis of scientific need/appropriateness and planning quality. The existence of any real or potential conflict of interest(s) of the project applicant is not formally vetted as part of this scientific review. However, the Program Review Subcommittee is informed by the ATS COI Office of any COI issues (e.g., cases where a proposed chair doesn't meet CMSS/ATS requirements) as part of its discussions during its deliberations, so that it can take these into account as part of its final decisions.)
- 2) After proposed projects' "approval-in-concept", project chairs are instructed to ask all members of their project committee to make a project-specific disclosure to ATS by the ATS-determined deadline. Again, this typically occurs as part of the annual ATS project approval process held each summer and fall. ("Approval-in-concept" as part of the annual project approval process typically occurs in September.) For 2011 official ATS projects (new or renewal) that were approved in fall 2010, project members should have made a project-specific disclosure at that time, and do not need to disclose again in regard to this project until required as part of annual project renewal in the fall of 2011, unless an earlier update is warranted; for example, because there are new commercial interests relevant to project subject matter. (Note: due to ATS conversion to an improved online disclosure process, any updating of previous project-related disclosures now requires completion of the "Supplemental COI Questionnaire for Other 2011 ATS Activities" through the ATS COI-SMART website.)
- 3) **Any members of 2011 official ATS projects that had not made a project-specific disclosure as of April 2011 must do so before they start project activity, by completing or updating the ATS "Supplemental COI Questionnaire for Other 2011 ATS Activities" that is accessed online through the ATS COI-SMART website.** (See next paragraph.)

C. ATS COI disclosure is "activity-specific." Effective April 2011, there are three methods of disclosure within ATS :

- 1) For ATS Journals contributions (manuscript submission), disclosures are made on a manuscript-specific basis using the International Committee of Medical Journal Editors (ICMJE) Conflict of Interest Reporting Form;
- 2) For ATS International Conference planners and presenters, disclosures are made annually by completing and submitting the ATS "COI Questionnaire for Conference Faculty" that is accessed online through the ATS COI-SMART website;
- 3) **For all ATS official activities other than the International Conference or contributions to the ATS Journals, activity-specific disclosures are now made by completing or updating the ATS "Supplemental COI Questionnaire for Other 2011 ATS Activities" that is accessed online through the ATS COI-SMART website.**

D. To make a project-specific COI disclosure to ATS, you must first be "invited" (registered by the ATS COI Office as a participant in that project) and be issued an ATS COI-SMART website "user name." The ATS staff assigned to the respective ATS project (typically ATS Assembly Programs staff) must first notify the ATS COI Office of the project and its participants, so that participant names and email addresses can be registered within the ATS COI-SMART system accordingly. (Note: Previous users of the ATS COI-SMART disclosure site do not need a new User name, but will be reminded of their User Name as part of notification.) Individuals in need of an ATS COI-SMART User Name, or who have questions about an ATS request to disclose, can contact ATS COI Office staff at coioffice@thoracic.org or Liz Guzman at 212-315-

8627. (Note: Assembly/Committee Project committee members may also contact Jessica Wisk for assistance at jwisk@thoracic.org or 212-315-8611.)

(3) REVIEW/ASSESSMENT OF PROJECT MEMBER DISCLOSURES³:

- A. **Review and assessment of project applicant's disclosures** (i.e., typically the prospective project chair[s]) is shared by the respective Assembly Planning Committee, the ATS Program Review Subcommittee, and the ATS COI Office (in consultation with the ATS Ethics and COI Committee as needed). This typically occurs during July and/or August as part of the formal, annual project approval application process.
- B. Upon a project's "approval-in-concept", the project's Chair(s) are responsible for **review and assessment of project-specific disclosures made to ATS by project committee members**. This review and assessment typically occurs during November, and is now conducted through the ATS COI-SMART website. Instructions are issued to Project Chairs by the ATS COI Office. ATS definitions of COI are provided as guidance in assessment (see below). Consultation may be provided by ATS COI staff, respective Assembly Planning Committee members, and the ATS Ethics & COI Committee when needed.

³**Please note: As earlier noted, in September 2010 the ATS Board of Directors adopted the Council of Medical Specialty Societies (CMSS) Code of Interaction with Companies as ATS policy.** This CMSS code includes several provisions pertaining to the development of official society Guidelines. Some of these are current ATS practice, but some will be new to ATS. Since the planning and vetting of 2011 official ATS projects (including new and renewed guideline projects) pre-dated ATS Board adoption of the CMSS code, ATS is not requiring these new provisions of 2011 official ATS projects (with exception of some projects conducted jointly with other organizations). **However, Project Chairs, Project Committee Members, Assembly Planning Committee members are others involved in ATS project management should be aware of these future requirements, including in particular:**

- (7.7) Societies will *require that a majority of Guideline development panel members are free of conflicts of interest relevant to the subject matter of the Guideline.*
- (7.8) Societies will *require the panel chair (or at least one chair if there are co-chairs) to be free of conflicts of interest relevant to the subject matter of the Guideline, and to remain free of such conflicts of interest for at least one year after Guideline publication.*
- (7.14) Societies will recommend that Guideline development *panel members decline offers from affected Companies to speak about the Guideline on behalf of the Company for a reasonable period after publication. (Annotation: A period of at least one year is recommended. An affected company is one that is reasonably likely to be positively or negatively affected by care delivered in accordance with the Guideline.)*
- (7.15) Societies will *not permit Guideline development panel members or staff to discuss a Guideline's development with Company employees or representatives, will not accept unpublished data from Companies, and will not permit Companies to review Guidelines in draft form.*

ATS will determine and announce plans for implementation of these new requirements for 2012 projects later this year.

(4) ONGOING “COI MANAGEMENT” OF 2011 OFFICIAL ATS PROJECTS:

Ongoing COI management of official projects, including guideline development, is **a shared responsibility** of Project Chairs, project committee members (including guideline panelists), and others involved in project management and review and approval of project outcomes, including the ATS Document Editor, relevant ATS staff (Assembly unit, Document unit, COI office), the ATS Program Review Subcommittee (in event of renewal), and the ATS Board of Directors and its Document Review Subcommittee. **Project Chairs must take primary responsibility for ensuring that ATS standards are met**, as the person most in control of project deliberations and decisions.

The following are regarded by ATS as appropriate methods of resolving COI affecting 2011 ATS Assembly/Committee projects. Circumstances may warrant more than one of the following:

1. ENSURE A BALANCE OF OPINION

Projects should be designed to reflect a balance of opinion. However, structuring the format of an activity to be “balanced” does not alone resolve an identified conflict of interest. Other methods of resolution as recommended here should also be used.

2. ORAL DISCLOSURE OF COI TO PROJECT PARTICIPANTS; RECUSAL FROM PARTICULAR RECOMMENDATIONS WHEN APPROPRIATE

In addition to project-specific disclosure to ATS via the online ATS COI-SMART process, before deliberations begin, **project committee members should be required to orally report to the rest of the committee any conflict of interest relevant to project subject matter**, to allow full committee knowledge and consideration as it proceeds. Individual participants (including project chairs and panelists) should label where COI bear on specific recommendations. Chairs and panelists should ensure that committees are reminded of specific conflicts of interest before action on conclusions or recommendations on which those COI bear. **If the COI are excessive, participants should recuse themselves, or chairs should recuse the participants, from discussions or decision-making on particular recommendations.**

3. PEER REVIEW TO ENSURE RECOMMENDATIONS REFLECT THE BEST AVAILABLE EVIDENCE

Recommendations should always reflect the best available evidence, or when absent of evidence, be consistent with generally accepted medical practice. All research reported should conform to generally accepted standards. Where COI has been identified, peer review of content by the project chair, committee as a whole, and/or outside peer reviewers can attest that the content is evidence-based.

4. DISCLOSURE TO CONSUMERS OF ATS DOCUMENTS AND ATTENDEES OF ATS CONFERENCES

The perception of COI in ATS activities should be minimized. Though it is likely impossible to have ATS activities without any potential COI, the process for declaring and resolving COI can be made transparent. A Summary of Financial Disclosures, drafted by ATS COI staff based on the project-specific disclosures made to ATS by project participants, must accompany the document as it receives final review and is published once approved. In addition, document authors are encouraged to make reference within the document to policies and processes used to manage COI during document development. Project chairs will have opportunity to review the Summary of Financial Disclosures in draft form as part of proofing.

5. AN INDIVIDUAL DOESN'T PARTICIPATE IN THE PROJECT

At times, the ATS (i.e., chairs of ATS projects, Assembly/Committee Chairs or their designees, and/or other authorized ATS officials) may judge that an individual's conflict of interest cannot be adequately resolved through the above methods, and it would be in the best interests of the ATS for the individual not to participate in the project. For example:

- Individuals employed by an industry relevant to the subject matter are generally regarded as inappropriate for roles that may control decision-making affecting ATS policies in that subject area - such as chair or member of the writing committee for a document involving that subject matter. Individuals employed by industry relevant to the subject matter may be consulted by writing committees in a manner acceptable to standards to be set by the ATS Documents Editor.
- Individuals whose financial livelihood is principally as an independent contractor providing consultation/recommendations on a specific medical procedure would generally be regarded as inappropriate to chair an ATS project on that topic, and may be judged as inappropriate to participate on a project committee (writing committee) on that topic, due to the potential that it would be perceived that he/she has direct financial benefit from ATS recommendations on that topic.

(5) ATS DEFINITIONS OF CONFLICT OF INTEREST⁴:

⁴ The following are drawn from the ATS Policy on Management of COI and the ATS Tobacco Relationships Policy. Full policies are available at the COI Management section of the ATS website: <http://www.thoracic.org/sections/about-ats/coi-management/index.html>.

- 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.
- 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 by a commercial entity; consultancy (ies); Board or Advisory Board [membership]; lecture fees (honoraria); [serving as an] expert witness; industry-sponsored grants (received or pending) including contracted research; patents received or pending; royalties; stock ownership or options, including sector mutual funds with areas of concentration in an industry or industries relevant to the activity; other personal financial interests...;
 - 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 proposal objectively due to competition for funding, timing of publication or professional stature.
- In addition, specific to relationships with the tobacco industry, ATS policy now regards individuals who have a current relationship (or within past 12 months) with a tobacco entity to be ineligible for certain ATS roles including the following relevant to ATS Assembly/Committee projects: "serve as a planner (organizer) or chair of ATS scientific and educational programs", "serve on the writing committee of an ATS statement or guideline." If the relationship is limited to personal holdings, divestiture is permitted. Details available within the ATS Tobacco Relationship Policy available at the COI Management section of the ATS website:

<http://www.thoracic.org/about/coi-management/index.php>

(5) ADDITIONAL RESOURCES:

- For staff assistance and to request consultation with the ATS Ethics & COI Committee or ATS Documents Editor about project COI management, contact Shane McDermott, Senior Director, Ethics & COI Management at smcdermott@thoracic.org or 212.315.8650. (In his absence, contact Elizabeth Guzman, Coordinator at eguzman@thoracic.org or 212-315-8627, or Jessica Wisk, Manager, Documents and Ad-Hoc Projects at jwisk@thoracic.org or 212-315-8611.)
- General information about ATS COI management, including ATS policies, is also available at the COI Management section of the ATS website:
<http://www.thoracic.org/about/coi-management/index.php>