



Alzheimer's Association Rules for the Disclosure and Management of Clinical Guidance Panel Conflicts of Interest (COIs)

The Alzheimer's Association is committed to the development of trustworthy clinical practice guidelines and other types of evidence-based guidance informing clinical decision-making at the individual, health system, and population levels. A core criterion for trustworthy guidelines, as defined by the National Academy of Medicine, involves collaboration between an organizing body and panels of clinical and subject-matter experts who are minimally conflicted both intellectually and financially.

To that end, the Association established rules for collecting conflict of interest (COI) disclosures from guideline panel nominees, our criteria for evaluating these forms and selecting panel members, and our process for managing conflicts during and after the guideline development process. All disclosures, both financial and intellectual, are publicly reported in our published guideline manuscripts.

Definitions and key terms used throughout can be found at the end of this document.

Rules and Procedures During Clinical Guidance Development

Sponsorship and Funding

The Alzheimer's Association does not accept direct support from for-profit healthcare companies for the development of guidelines or for the initial printing, publication, or distribution of Alzheimer's Association guidelines. After guideline development and initial printing, publication, and distribution is complete, such company funding may be accepted to support further distribution, translation, or repurposing of the guideline content.

Governmental or external nonprofit funding for guideline development and publication may occasionally be accepted. In such cases, the role of the funder in the development of the guideline is determined on a case by case basis by the Alzheimer's Association. External sources of funding and the role of the funding organizations or individuals are described in the published guideline.

Eligibility for Appointment to an Alzheimer's Association Guideline Panel



Eligibility: Eligibility will be determined through a variety of approaches, including interview, disclosure collection, and checking of public records. For all roles on an Alzheimer's Association guideline panel, individuals' eligibility is determined based on disclosures indicating that in the past 36 months, individuals have not:

- Received direct financial conflicts of interest of >\$20,000 USD over past 3 years from any relevant single for-profit healthcare company or in aggregate from two or more for-profit healthcare companies
- Made public statements (presentations, media, editorial) expressing a strong intellectual position on any of the guideline's (i.e., the one in development) potential (i.e., new guideline) or previously established (i.e., in case of an update) clinical questions
- Served in paid leadership or advisory role (e.g., board member or director) for: (a) any for-profit healthcare company; or (b) a non-profit organization that reasonably could be directly affected by the guideline
- Benefited from relevant patents (or other intellectual property rights like copyrights, royalties) or other ownership interests (equity, stock options, or other ownership interests) in products that could be affected by the guidelines
- Spoken on behalf of a relevant for-profit healthcare company (e.g., speaker bureaus, but not including accredited CME)
- Participated in guideline efforts by other organizations on the same topic

Please note that on a case-by-case basis, any conflict of interest judged to be important or relevant by the organization may disqualify a nominee from a guideline panel.

Other eligibility considerations:

Individuals who have had such interests within the past 36 months, but do not currently hold them, may be considered for appointment if they offer crucial expertise, are willing to comply with this process, and the nature of their past interest(s) is such that the interest(s) can be appropriately mitigated given the make-up of the remainder of the panel.

Chairs are additionally should not have a current leadership role (e.g., principal investigator) for a research study that addresses a guideline question. If by special exception a chair is allowed to have any of the conflicts described above, a co-chair and a vice-chair must not have the same or similar conflict.

Individuals considered for a guideline panel often have *indirect* financial interests in for-profit healthcare companies, e.g., research funding, as well as intellectual, professional, or reputational interests in the guideline topic. Guideline panels will be intentionally composed with the goal of avoiding a majority (<49%) of the panel having the same or similar conflict of interest, including conflicts that are *indirectly* financial or not mainly financial.



Self-disclosure, assessment of disclosures, and final panel invitation rules and processes

Upon email submission of an electronically-completed application for appointment to an Alzheimer's Association guideline panel, individuals must disclose: (a) for themselves and their partner or spouse/children all direct financial interests in for-profit healthcare companies held currently and/or within the past 36 months; (b) for themselves/spouse/dependent children, all indirect financial interests in for-profit healthcare companies held currently and/or within the past 36 months; and (c) for themselves/spouse/children, all other current financial interests (i.e., in other entities, patents, etc.) that may be affected by the subject matter of the guidelines, and any relevant non-financial interests.

Disclosure: Individuals must **disclose** any financial conflicts that individually or in aggregate amount to over \$5000 USD/past 3 years as part of the application for guideline panel members. Any interests held by the panel nominee's spouse/dependent children should also be reported for assessment.

Once disclosure forms are received, association staff and advisors will review the forms using the criteria outlined in this process document. If criteria are met, panelists will receive formal invitations to be on the guideline panel. Panelists who do not meet the criteria will be notified.

Panelists must maintain disclosures throughout the guideline development process and should notify staff immediately of any changes. Organizational staff will also prompt the panel for COI updates before all major panel meetings. All disclosures are ultimately published in the guideline manuscript.

New Conflict Avoidance

The Association prioritizes the timely conduct and publication of our guidance deliverables (i.e., under 2 years from initiation to submission of manuscripts for publication). From time of appointment to one year after publication of these deliverables, individuals on the panel, regardless of role, must:

- Not accept directly conflicting payments or transfers of value >\$5,000 USD/year in aggregate from for-profit healthcare companies.
- Not accept paid speaking ("speaker bureaus") positions from for-profit healthcare companies.
- Disclose any new direct and indirect financial interests with for-profit healthcare companies and any new relationships with other entities that reasonably could be expected to be relevant to the guidelines.
- Check disclosure form submitted as part of the panel invitation process against publicly available information such as Open Payments and explain discrepancies.



- Panelists should avoid simultaneous or post-publication participation in guideline efforts (for 2 years) by other organizations on the same topic and notify association staff of any such engagement.
- Attest compliance with the above when requested by organization.

Management of Allowed Conflicts

Any financial or intellectual conflicts that panel members have (i.e., those that have not met these criteria for panelist's exclusion from participating on the panel), are allowed conflicts that either don't need to be managed (i.e., they are not significant enough to potentially bias recommendations) or they need to be managed (i.e., they are significant enough to potentially bias recommendations).

- Disclosure forms will be kept updated throughout the project with timely prompts from organizational staff to panel members
- All allowed conflicts are managed through disclosure and group discussion.
- A senior member of the guideline panel who is not a chair and who has no direct financial or intellectual conflicts will serve as the COI Compliance Officer. Throughout the development process, the COI Compliance Officer will review disclosures, facilitate discussions by the panel about conflicts before each call or meeting, and facilitate recusal or other mitigation methods when required as described below.
- On a recommendation by recommendation basis, certain conflicts also may be managed through recusal:
 - Current direct payments or transfers of value >\$20,000 USD/over 3 years from a single for-profit company or in aggregate from two or more for-profit companies that could be directly affected by that recommendation
 - Leadership role (e.g., principal investigator) for a research study relevant to the guideline question
 - Other important conflicts at the discretion of panelists, chairs, or the Association's scientific leadership team
- Final decisions about recusal (e.g., in the case of disagreements) are made by the organization.
- Recused individuals may participate in question formulation, review and discussion of evidence, and manuscript writing but are recused from making judgments about evidence or decisions about the direction or strength of recommendations.
- Recused individuals may be asked to leave the room. This will be decided by Alzheimer's Association staff and advisors on the basis of risk of influence.
- If >49% of the panel must be recused for a guideline question, the panel may not address the question. The organization may appoint a different panel to address the question.

Deviations from these procedural criteria



- Panelists who do not substantially abide by the above procedures will be dismissed from the guideline panel. Upon guideline publication, the participation of dismissed individuals will be described or acknowledged, but dismissed panelists will not be listed as authors.
- Panelists who do not substantially abide by the above procedures will not be invited to participate in future Alzheimer's Association guideline efforts.
- Dismissed individuals will generally not be replaced with new panelists.
 - Instead, guideline panels will be initially composed with the expectation that during the development process, some panelists will drop out, be recused, or be dismissed. For example, *usually* at least 18 people will be initially appointed to the panel, with the goal of retaining at least 13-15.
- Decisions about how to manage deviations from these procedures, including through dismissal, will be made by the Alzheimer's Association as an internal conversation with scientific leadership.

On a case-by-case basis, minor deviations from this process may be managed through disclosure or other means, including by describing the deviation within the guideline publication. The Alzheimer's Association will judge if a deviation is "minor." In general, a "minor deviation" must meet all of the following conditions: (1) occur unintentionally, (2) be unlikely to have influenced any recommendations, and (3) be unlikely to be perceived by guideline users as important.

Guideline Publication

- A section of the published guidelines, "Guideline Funding and Management of Conflicts of Interest," describes how conflicts were managed.
- Complete disclosure forms are published as a supplement to the guidelines.
- For 1 year after publication, all panelists are cautioned from establishing/re-establishing conflicted financial/intellectual relationships and/or speaking on behalf of for-profit healthcare companies that could be affected by the guidelines.

Definitions

Conflict of interest A situation in which a reasonable person would consider that an individual's judgments or actions regarding any aspect of the guideline development process is, or could be perceived to be, influenced by an outside interest.

Financial interest A position or relationship held by an individual (or spouse or dependent child) that offers potential gain or loss of monetary value, such as employment, stock ownership, payment for services, travel, or gifts given with the expectation of reciprocity.



Direct financial interest A financial interest that is owned by the individual or received directly by the individual (or spouse or dependent child).

Indirect financial interest A financial interest that is owned or received to the nominee (or spouse or dependent child) via an intermediary, e.g., research funding to an individual received through the individual's academic institution.

For-profit healthcare company "A for-profit entity that develops, produces, markets, or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, and alleviate health conditions.

- This definition is not intended to include non-profit entities, entities outside of the healthcare sector, or entities through which physicians provide clinical services directly to patients" (Council of Medical Specialty Societies' "Code for Interactions With Industry" 2015).
- For the purpose of this document, this definition is furthermore not viewed by the Alzheimer's Association to include companies that provide accredited continuing medical education or that publish scientific or educational content.

Please email Malavika Tampi, Director, Guideline Development at mptampi@alz.org with any questions or comments about this document/process.

Please note that these rules include language originally drafted by the American Society of Hematology.

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