



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



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.



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:

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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



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.

Last updated: October, 2023