



National Association of Epilepsy Centers

Policy on Conflicts of Interest for Guidelines

A major challenge in this era of significant scrutiny from the media, Congress, and states' Attorneys General is to produce balanced, independent, objective, and scientifically rigorous products without bias but with the most knowledgeable and respected experts in the field. Having conflict-of-interest policies and review processes protect the organization, guidelines, and the panelists.

Standards

National¹ and international standards² for guidelines require careful reviews and approvals of guideline panelists relative to their conflicts of interest (COI). Rigorous COI reviews are a major criterion upon which guidelines are judged.³ The National Association of Epilepsy Centers (NAEC) Guidelines Oversight Committee (GOC) acknowledged the importance of having a defined policy on conflicts of interest that will apply to the guidelines panel with oversight by the members of the GOC.

Recommended NAEC Guideline Conflicts-of-Interest Policy

The Guidelines Oversight Committee approved the following COI policy:

- This COI Policy will be followed and all decisions will be documented.
- There will be no funding from industry to support guideline development.
- There will be no honoraria or remuneration to panelists.
- The goal is that all chairs are unconflicted. If chairs have any financial conflicts of interest (COI), they will be managed and a non-conflicted co-chair will be added and will assume leadership on the affected recommendations.
- The goal will be to have no more than 50% of the panel with COIs, but the aim will be considerably less. No recommendation should have greater than 49% of the panelists with terms of management precluding them from authoring or voting on that recommendation. Secondary or intellectual COIs do not count toward these percentages.
- Non-conflicted individuals representing appropriate stakeholder perspectives will be assigned to the panel to offset and dilute the volume of conflicted individuals.

- The COI review process will be conducted for each applicant deemed to be otherwise appropriate for the panel (*i.e.*, they meet the appropriate stakeholder types). This includes patients/consumers. All final determinations will be documented.
- The COI disclosure form will require applicants to be specific about the details of their disclosures, including the following:
 - Specific topics and complete explanations for grants and consultancies
 - For medical directors and administrators, whether the portion of their salaries based on serving in this role and their bonus incentives are dependent on the revenues and/or accreditation levels of the epilepsy centers.
 - Dollar amounts for personal compensation or benefits if at or above \$5000
 - Disclosures must include the applicant, their spouse, domestic or life partner, dependent children, and minors living in the same household. Adult children, those living outside the household of the applicant, and other relatives are not included.
 - Disclosures apply to the previous 24 months.
- EBQ Consulting will perform the initial COI disclosure reviews and make initial recommendations to the GOC. All final decisions will be made by the GOC, including terms of management, when appropriate.
- All applicants will receive either letters of acceptance or letters of rejection.
- Letters of acceptance must be signed and returned confirming the applicant agrees to the specified terms. These terms might include management of their COIs, when applicable.
- “Terms of management” means that for specific content areas related to that individual’s conflict(s), they will be allowed to share their expertise in the panel calls/discussions but they will not draft or vote on those specific recommendations, nor will they draft those portions of the manuscript. Full participation for those without conflicts or only secondary/intellectual conflicts means they will not have those limitations. Those with secondary/intellectual conflicts will only need to disclose their conflicts but they will have no voting or writing restrictions.
- Approved panelists should refrain from future COIs until 1 year past the date of the guideline publication.
- At designated times during the guideline development process (*e.g.*, before the mDelphis and at the time of submission for publication), panelists must agree to updated disclosures of any new COIs or affirmation that their previous list has not changed. New COIs will be reviewed and final decisions might result in new terms of management or possibly disqualification from the panel, only for COIs determined to reach that level. Therefore, all approved panelists will be encouraged to refrain from incurring additional COIs or request review of any new offers before accepting them.

- All panelists with Primary COIs will be mapped on the COI grid (below) according to the topics of recommendations within the larger topic areas. This COI grid will determine who can vote and who cannot vote on each recommendation.
- Some panelists will have intellectual or secondary COIs, which should be disclosed to the panelists at the time of the panel conference and before the voting, but these do not disqualify a panelist from drafting or voting on the recommendations. These will also be mapped on the COI grid.

Example COI Grid:

Recommendation	Chair		Co-Chair		Co-author 1		Co-author 2		Co-author 3		Co-author 4	
	Type	Details	Type	Details	Type	Details	Type	Details	Type	Details	Type	Details
Rec 1												
Rec 2			2ry	Gdln Author								
Rec 3			2ry	PI							2ry	Gdln Author
Rec 4			1ry	Consult							1ry	Speaker
Rec 5			1ry	Advisor	1ry	Patent Rights						
Rec 6			2ry	PI								

This COI policy should be available for guideline readers upon request but a summary should be written into the methods section of the guideline.

Definitions

The following definitions are based on those of the American College of Chest Physicians:⁴

Commercial interest/entity is any for-profit entity producing, marketing, re-selling, or distributing healthcare goods to be consumed by or used on patients (*e.g.*, pharmaceutical or device companies).

Conflict of Interest (COI) refers to any relationship or other set of known circumstances that has the potential to bias, or that might be reasonably perceived by others to bias an individual’s judgement, conduct, or other work.

Financial COIs include any relationship for which one receives remuneration or in-kind benefits that could be perceived to affect one’s judgment in the evaluation of specific recommendations. These include holdings in individual investments (e.g., holdings in stocks, stock options, warrants, bonds, or any form of direct investment of pharmaceutical or device companies), and patents associated with licensing, and/or financial or in-kind benefit; and these include such holdings held by the guideline participant, their spouse, domestic or life partner, dependent children, and minors living in the same household (per IRS definition). Mutual fund holdings are not included.

Intellectual COIs include any activities that create the potential for attachment to a specific predetermined point of view that could be perceived to affect one’s judgment in the evaluation of specific recommendations or suggestions.

Related content areas are those that are aligned with the clinical questions and/or PICO elements (patient-intervention-comparator-outcomes) to be addressed within the guideline.

COI review outcomes:

Level of Conflict	Required Action
Significant COI (Financial)	Disqualification
Primary COI (Financial)	Disclosures and terms of management*
Secondary COI (Intellectual)	Disclosure only
No COI	None

*Management means individuals with primary conflicts can participate in all activities except those that are directly relevant to the specific topics of their conflicts. They will not be allowed to draft or vote on the recommendations in those areas and they will not write those portions of the manuscript. However, we will seek their expertise and knowledge through discussions with the Chair(s) and the full panel. The Chair(s) may draft those recommendations and portions of the manuscript or they may ask someone else to do so. All nonconflicted panelists and those with only secondary conflicts will vote on all recommendations.

Types of COIs and Recommended Determinations

The following is a list of types of conflicts of interest (COIs) and what kind of conflicts they represent *specific to this project*, per the GOC’s determinations.

Type of COI	Relevant Criteria and Comments	Level of Conflict	Required Action
RESEARCH AND GRANTS			
Nonprofit (NIH, AHA) or University grant <i>only if specific to epilepsy centers’ administration, structural design and</i>	Relevance of topic to design, administration, management	Primary COI	Disclosures and terms of management

<i>management, or process design and management</i>	of epilepsy centers		
	Other	Not a COI	None
Pharmaceutical/device company grant (<i>e.g., educational</i>) <i>only if specific to epilepsy centers' administration, structural design and management, or process design and management</i>	Relevance of topic to design, administration, and management of epilepsy centers	Primary COI	Disclosures and terms of management
Pharmaceutical/device company grant (<i>e.g., educational</i>), other	Potential for vested interest now or in future even though not explicitly on target topic	Primary COI	Disclosures and terms of management
<i>Other grants only if specific to epilepsy centers' administration, structural design and management, or process design and management</i>	Relevance of topic to design, administration, management of epilepsy centers	Primary COI	Disclosures and terms of management
	Other	Not a COI	None
Remuneration for patient enrollment or other aspect of research	Centers are compensated, not individuals	Not a COI	None
OTHER BENEFITS			
Receive in-kind benefits (<i>e.g., travel, accommodations</i>) from a commercial entity	Relevance of topic to design, administration, management of epilepsy centers	Primary COI	Disclosures and terms of management
	Not relevant to topic area	Not a COI	None
CONSULTING AND LEADERSHIP ROLES			
Consultant to a pharmaceutical or device company, <i>only if specific</i>	Potential for vested interest now or in	Primary COI	Disclosures and terms of management

<p><i>to epilepsy centers' administration, structural design and management, or process design and management (if unpaid or through employment and does not add additional salary, then this is not a conflict)</i></p>	<p>future explicitly if specific to target topic (design, administration, management of epilepsy centers).</p>		
	<p>If unpaid or through employment and does not add additional salary, then this is not a conflict</p>	<p>Secondary COI</p>	<p>Disclose only</p>
<p>Employee, officer, or director of a pharmaceutical or device company</p>	<p>Potential for vested interest now or in future even though not explicitly on target topic</p>	<p>Significant COI</p>	<p>Disqualification</p>
<p>Employee, officer or director of an institution or employer that has a financial relationship with a commercial entity having interest in <i>epilepsy centers' equipment, personnel, or other administration, structural design and management, or process design and management</i></p>	<p>Potential for vested interest of commercial entity now or in future even though not explicitly on target topic</p>	<p>Significant COI</p>	<p>Disqualification</p>
<p>Administrator or officer of an epilepsy center</p>	<p>Assumption: They are compensated or bonused based on center revenues and/or</p>	<p>Primary COI</p>	<p>Disclosures and terms of management</p>

	accreditation levels		
Medical Director of an epilepsy center	If they are compensated based on accreditation levels or center revenues	Primary COI	Disclosures and terms of management
	Compensation is not tied to accreditation levels or center revenues	Secondary COI	Disclosures only
Other employee of an epilepsy center	Relevance of topic to their decision-making roles at the centers	Secondary COI	Disclosures only
OTHER FINANCIAL ACTIVITIES			
Share (or stock-option holder) of a pharmaceutical or device company not in a mutual fund	Applicants will be offered option to divest	Significant COI	Disqualification unless the applicant agrees to divest
Hold patent rights, receive royalties for research related to <i>epilepsy centers' administration, structural design and management, or process design and management</i>	If sold to another company, then already divested. But if still receiving royalties, then it is disqualifying. Pending patent applications – must let us know as soon as approved.	Significant COI	Disqualification
Other financial activities that might be relevant		TBD	

INTELLECTUAL ACTIVITIES			
Participate in speaking activities, advisory committee, or other activities related to <i>epilepsy centers' administration, structural design and management, or process design and management</i> , with or without receiving honoraria or in-kind benefits		Secondary COI	Disclosure only
Make public statements related to <i>epilepsy centers' administration, structural design and management, or process design and management</i>		Secondary COI	Disclosure only
Provide expert legal assistance related to any litigation related to <i>epilepsy centers' administration, structural design and management, or process design and management</i>		Secondary COI	Disclosure only
Membership on other guideline panels in a related topic area (provide specifics)		Secondary COI	Disclosure only
Leadership roles in professional or advocacy organizations addressing a related topic (provide specifics)		Secondary COI	Disclosure only
ADDITIONAL INFORMATION			
Anything else that could affect the perception by others of my objectivity and independence [Refer to applicant's drafted COI disclosure statement		TBD	

related to and summarizing all answers listed above in general terms (excluding specific monetary amounts)			
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Process for COIs to be Reviewed, Approved, and Documented

The COI review policy and the process for ensuring compliance with the policy is supported by the GOC. The policies and targets listed above should be achieved for the panel.

- For each applicant, the guideline consultant will review the disclosures, perform any relevant research into current or past disclosures (eg, COI disclosures in published manuscripts and searches of ProPublica), and make initial recommendations to the GOC.
- Panelists who are approved but have Primary COIs will be managed according to the terms of participation established by the GOC on an individual basis.
- Additional panelists might need to be added later, requiring monitoring of these voting-eligible percentages.
- COI disclosures will be required at regular intervals or before important milestones in the development process (eg, voting on recommendations, manuscript submission for publication).
- Approved panelists will be advised that they should not accept any additional potential conflicts without requesting reviews and approvals first.

Letters of Agreement. Once nominees have passed the COI reviews and are accepted as panelists, they will be notified and asked to sign a Letter of Agreement. This letter will specify their roles on the panel, terms of participation if they have any COIs that require management, levels of participation, expectations of adherence to COI policies and the duration of this adherence, and expectations for timely completion of their assignments. These letters might also include the potential for panel termination and the infringements that could lead to such terminations. The panelist’s signature and return of these Letters of Agreement will be a requirement for participation.

Importantly, all COI disclosures, review determinations, and letters of agreement will be documented and filed where they can be quickly retrieved.

REFERENCES

1. Committee on Standards for Developing Trustworthy Clinical Practice Guidelines. *Clinical Practice Guidelines We Can Trust* Washington DC: Institute of Medicine 2011.
2. Qaseem A, Forland F, MacBeth F, et.al. Guidelines International Network: Toward International Standards for Clinical Practice Guidelines *Ann Intern Med.* 2012;156:525-531.

3. AGREE Trust. The Appraisal of Guidelines for Research and Evaluation (AGREE) The AGREE Trust. <https://www.agreetrust.org/>. Accessed March 12, 2021.
4. American College of Chest Physicians. CHEST Conflict of Interest Policy: Guideline/Consensus Statements. https://www.chestnet.org/-/media/chesnetorg/Guidelines-and-Resources/Documents/Guidelines-COI-Policy_Approved-January-2021.ashx. Published 2021. Accessed March 10, 2021.