ENDOCRINE SOCIETY

Hormone Science to Health

CONFLICT OF INTEREST POLICY AND PROCEDURES FOR ENDOCRINE SOCIETY CLINICAL PRACTICE GUIDELINES

INTRODUCTION

There are many sources of guidance on conflict/duality of interest (C/DOI) as it relates to establishing guideline development panels and the production of guidelines themselves. The Endocrine Society's Clinical Guidelines Committee (CGC) finds guidance provided by the Guidelines International Network (G-I-N) to be clear and concise, and a document published by G-I-N in 2015[1] forms the primary basis of this C/DOI policy. Standards from the IOM's *Clinical Practice Guidelines We Can Trust*[2], other similar documents, and the C/DOI policies of other medical societies have also informed the content of this policy.

POLICY

1. Optimally, the Society's Guideline Development Panels (GDPs) would only include members who are free of C/DOIs relevant to the topic of the guideline. The Society will strive to achieve this ideal whenever possible.
2. Acknowledging that establishing a C/DOI-free GDP is particularly challenging in many fields of endocrinology, the Society will meet the following minimum standards.
   a. **GDP Chairs:** The GDP Chair and Co-Chair must be free of relevant C/DOI[3];
   b. **GDP Members:** A majority (>50%) of non-Chair GDP members must be free of relevant C/DOI with a goal of limiting the number of GDP members with relevant C/DOI to a distinct minority (25-30% of the panel membership);
   c. **Expert Reviewer and Publisher's Reviewer:** Individuals asked to review guideline drafts in the capacity of Expert and Publisher's Reviewer must be free of relevant C/DOI;
   d. **Advisors:** Individuals who are not members of the GDP but who are asked to act in a formal advisory capacity to the panel are not required to be C/DOI-free but will be required to disclose all relationships in line with the policies identified herein.
3. When appointed to a GDP, chairs and members must refrain from adding new relevant relationships throughout the guideline development process, until one year after publication.
4. Primary authors of recommendation-related guideline sections (i.e., sections of text pertaining to individual recommendations or topically-organized sections of text pertaining to multiple recommendations) and PICO[4] leads must be individuals without conflicts of interest relevant to that section.

IMPLEMENTATION

C/DOI DISCLOSURE

1. Complete disclosure is the foundation of an effective C/DOI policy and ensures that each GDP complies with the Society's C/DOI policy. Individuals being considered as chair or member of a guideline GDP, as an advisor, or as Expert Reviewer or Publisher's Reviewer must submit details of all their (and all known immediate family member relationships'[5]) relationships, irrespective of whether the candidate considers them to be relevant to the scope of the guideline.
2. When requested, C/DOI information must be provided (or updated) using the Endocrine Society's online Conflict of Interest Form for Guideline Development Panels (accessed from endocrine.org) unless the candidate previously completed this form within the last 90 days *and* the candidate confirms no interim changes in their C/DOI information.
3. When C/DOI information is requested, candidates are required to disclose all relationships for the prior 24-month period. This is consistent with the reporting time-frame for the National Institutes of Health and the Food and Drug Administration.
4. Organizational relationships should be declared including all relationships with commercial, non-commercial, governmental, and patient/advocacy organizations. This includes employment, consultancy, interests in start-up companies and/or in those where stock is not publicly traded, ownership interests in publicly-traded companies such as stock options (excluding indirect investments through mutual funds), research funding directly paid to the individual, research funding paid to employer organization or other research institution with whom the individual is involved, serving as a Principal Investigator, honoraria, royalties, paid or unpaid expert testimony, speaking

[1] Schünemann et al. Guidelines International Network: Principles for Disclosure of Interests and Management of Conflicts in Guidelines. Ann Intern Med. 2015; 163: 548-53.

[2] Committee on Standards for Developing Trustworthy Clinical Practice Guidelines, Board on Health Care Services, Institute of Medicine of the National Academies. Graham R, Mancher M, Wolman DM, Greenfield S, Steinberg E, eds. Clinical Practice Guidelines We Can Trust. Washington, DC: The National Academies Press; 2011.

[3] For the purposes of this policy, a "relevant" COI is defined as a potential COI that could plausibly influence (or could have the appearance of influencing) the direction or strength of one or more guideline recommendations or create a risk of bias.

[4] In guideline development, a PICO (population intervention, comparator, outcome) question is the clinical question that guides systematic reviews and recommendation development.

[5] For the purposes of this policy, "immediate family member" refers to a spouse/partner or a first-degree relative (parent, child, sibling). WC candidates need only disclose relevant family relationships that are already known to the candidate: when the candidate knows of no such relationships, the candidate need not directly solicit such information from family members. However, when a candidate is aware of a potentially-relevant relationship on the part of an immediate family member, but does not know details about said relationship, collection of additional information may be required to establish the relevance (or non-relevance) of such relationships. Note that similar disclosure should also be provided for any person with whom a candidate has a very close personal relationship *if* such could be seen as a plausible conflict of interest on the part of the candidate.

engagements, speaker's bureaus, etc. Leadership positions and memberships in companies, organizations, professional societies, and other entities (paid and unpaid) including Data Standards Monitoring Boards, non-profit or for-profit advisory boards and committees must also be disclosed. Participation in related guidelines, consensus documents, standards of care, or similar efforts withing the past 5 years must be reported.

5. Endocrine Society guidelines staff will use information from Centers for Medicare & Medicaid Services (CMS)'s Open Payments database to provide the CGC Chair with additional information on a candidate's historic C/DOI profile for those candidates to whom this applies.[6]
6. Candidates will be asked for additional and/or clarifying information where this is needed to determine the relevance of specific relationships and the extent of any potential conflict.

C/DOI REVIEW, VETTING AND DECISION-MAKING

Initial C/DOI information requests are sent by Endocrine Society staff who combine the information received from candidates with public information from the Open Payments website. Review of such C/DOI information will be conducted as follows:

1. **GDP Chairs:** Review of the C/DOI information collected is undertaken by the Chair of the CGC who reviews all disclosed relationships and determines whether they represent a potentially relevant conflict of interest. The CGC Chair's final recommendations are reviewed and approved by the CGC, and subsequently submitted to Endocrine Society Board of Directors (BOD) for approval. The CGC chair is encouraged to discuss any concerning C/DOI with the CGC members or Ethics and Professionalism Committee during this process.
2. **GDP Members:** The CGC Chair and GDP chairs review all available details on relationships and determine whether any represents a potentially relevant conflict of interest. Decisions on the relevance of relationships/conflicts to each guideline topic/section—in addition to the overall acceptability of a candidate's C/DOI—will be made by the CGC Chair, with input from the GDP chairs when necessary. The CGC chair is encouraged to discuss any concerning C/DOI with the CGC members or Ethics and Professionalism Committee during this process. The recommendations for the GDP members are reviewed and approved by the CGC.
3. **Expert and Publisher's Reviewer:** Review of the C/DOI information collected is undertaken by the Chair of the CGC who reviews all disclosed relationships and determines whether they represent a potentially relevant conflict of interest. The CGC Chair's decision is final.
4. **Advisors:** C/DOI information will be recorded and shared with the GDP chairs and members and the CGC Chair to ensure transparency.

INFORMATION TO BE CONSIDERED WHEN ESTABLISHING RELEVANCE OF C/DOI RELATIONSHIPS

- **Type of relationship:** Employment, consultancy, interests in start-up companies, stock options, research funding, serving as a Principal Investigator, paid or unpaid expert testimony, speakers bureau, advisory committee, board membership/executive office, guideline panel member, etc.
- **Type of organization with which the relationship exists:** Pharmaceutical company, health care delivery institution, government agency, academia, medical society, association, disease advocacy organization, etc.
- **Time frame of the relationship:** Long-term vs. short-term relationship, previous vs. ongoing relationship, recency of relationship (two years vs. five years), etc.
- **Specific nature of the relationship:** Specific pharmaceutical product or device forming the basis of the relationship, type of research support, leadership role and/or duties within a company or organization, etc.
- **Type of payment:** Food and beverage, travel reimbursement, direct compensation, salary support, honoraria, royalties, stock options, etc.
- **Amount of remuneration received as payment for the relationship:** Dollar amounts received from company or organization for services rendered.

RELEVANT C/DOI

The presence of direct financial relationships with entities that have an investment in products or services directly relevant to the guideline topic—in addition to the potential for indirect C/DOIs relating to issues such as academic advancement/reputation, clinical revenue streams, community standing, etc.—while not inherently indicative of bias, necessitates clear boundaries to preserve the integrity of the guideline development process. The following are examples of relevant conflicts of interest that will disqualify individuals from serving as a GDP Chair or Co-Chair and that must be assessed for all GDP members to ensure that no more than a minority of non-Chair panel members have relevant C/DOIs:

The following activities/relationships are not permitted for Chairs, Co-chairs, or any GDP Members:

1. **Direct Involvement Prohibitions:** Participation in speakers' bureaus, or similar marketing activities for affected companies, and employment within for-profit healthcare or affected companies or organizations within two years preceding or during their panel terms—or a plan for such involvement within a year following their panel terms. Participation on an Endocrine Society guideline precludes both (1) holding a leadership position/executive office with affected companies or organizations during their panel term and for one year following and (2) participation in a guideline/consensus panel on a similar or related topic during the development of the guideline. Patents/products: Patents or other ownership interests in products that could be affected by the guidelines.

[6] CMS's Open Payments only contains information on physicians and certified non-physicians practicing in the United States. Non-US practitioners and some other potentially relevant stakeholders are not required to report to the database.

2. **Ownership and Significant Financial Interests:** Substantial ownership or significant financial interests in any affected company.[7] Significant Financial Interest is any interest in a single company >$10,000 value or > 25% United States Median Average Household Income (USMAHHI) in aggregate (i.e., the total combined value of all such financial interests, rather than each holding considered individually.)

   *Additionally, there are some financial or intellectual relationships with, or fiduciary obligations to, an affected company or organization that could, in the judgment of the Endocrine Society, introduce an unmanageable risk for bias or could otherwise undermine the guideline's credibility, and therefore render an individual ineligible. A bias risk assessment will be conducted and documented by the CGC in these cases. Examples that will be carefully considered as potentially disqualifying include:

   a. participation in another guideline/consensus document on the same topic within 5 years of the initiation of the current project;[8]

   b. public statements expressing a strong intellectual position on a guideline question, including expert testimony and lobbying.

Criteria for Majority Panel Participation

Individuals with relationships judged by The Society to be disqualifying (as described in the Relevant COI section above) will not be further considered for appointment as panel Chairs or Co-Chairs. A majority (at least 51%) of GDP (including Co-Chairs) must be free of COI with affected companies/entities. Relevant disqualifying relationships include the following:

1. They hold any disqualifying relationship with an affected company, as defined in the section on Relevant COI (above).
2. They receive research funding or grants from an affected company in which payments are made directly to the individual, or in which the individual's institution receives research payments that directly support the individual's salary or other personal compensation.
3. They serve as a member of a steering committee for a study funded by an affected company that does not have a designated principal investigator.
4. They serve, whether compensated or uncompensated, as a consultant, or as a member of an advisory board, data safety monitoring board, or similar body for an affected company or organization.

Criteria for Minority Panel Participation

The Minority (≤49%, aiming for 25-30%) of the GDP must not have any more than minimal conflicts of interest. Relevant disqualifying relationships include the following:

1. The individual has any disqualifying relationship with an affected company, as defined in the section on Relevant COI.
2. The individual receives research funding or grants from an affected company that involve:

   a. Direct research-related payments from the company to the individual; or

   b. Research payments made by the company to the individual's institution that directly support the individual's salary or other compensation, when such payments equal or exceed $20,000 in aggregate from any one affected company in a calendar year.

   c. If more than one affected company, the aggregate value of compensation described in (2a) must not exceed 30% of the United States Median Adjusted Household Income (USMAHHI).
3. The individual serves as a member of a steering committee for a study funded by an affected company that does not have a designated principal investigator, regardless of whether salary support is provided.
4. The individual receives consultancy or advisory compensation related to research and development (R&D) activities pertinent to evaluation and management (E&M), including R&D-related advisory board participation, from any affected company in an amount exceeding $10,000 per company per calendar year. Participation in commercial or marketing-directed advisory boards is not permitted under any circumstances.

Additional Considerations: In assembling a guideline panel, the Endocrine Society evaluates all potential C/DOIs among prospective panel members, considering both direct associations with affected companies or organizations and other professional activities. The aim is to mitigate any real or perceived biases that cannot be effectively managed, ensuring the guidelines maintain public trust. Specific categories of professional activities are scrutinized on an individual basis, including but not limited to:

1. **In-Kind Contributions:** Contributions of services or expertise provided instead of financial compensation are treated as direct financial relationships. However, contributions that directly support patient care, such as patient care items, patient samples, and study drugs, are not regarded as financial relationships.
2. **Travel, Lodging, Food, and Beverage:** The Endocrine Society permits the acceptance of reasonable travel reimbursements and meal provisions related to service for an affected company or organization, provided that:

   a. For uncompensated service, such arrangements comply with the Society's conflict of interest policy

   b. For compensated service, the relationship must be considered an acceptable relevant C/DOI under this policy (e.g., ongoing relationships with total compensation less than $10,000 per year and otherwise permissible for minority panel members), and the travel or meal support

[7] This includes individual stocks, stock options, or other direct equity holdings. It does not include diversified holdings such as mutual funds, exchange-traded funds (ETFs), or other investment vehicles where the individual does not directly control the investment decisions for specific companies.

[8] Past participation in related guideline development may create real or perceived bias toward confirming earlier recommendations. Such participation can influence objectivity through anchoring or confirmation bias, limit openness to new evidence, and undermine public confidence in the independence of the guideline process.

must be reasonable and directly related to the scope of the compensated service

3. **Funding from Non-Profit Entities:** Contributions from non-profit organizations, entities beyond the healthcare sector, government agencies, or organizations through which physicians deliver direct clinical services to patients are not considered affiliations with affected companies in the context of panel composition. Nonetheless, foundations associated with or under the influence of an affected company are treated with the same scrutiny as the companies themselves to ensure conflicts of interest are transparently and effectively managed. Panel members and candidates are encouraged to openly discuss any such associations with the Endocrine Society staff for guidance.

PROCESSES

The process of selecting chairs, co-chairs and members of guideline GDPs can be found in the Clinical Guidelines Committee Standard Operating procedure for Guideline Panel Member Selection, and can be summarized as follows:

- The Chair of the CGC seeks nominations for GDP chairs from several sources, including CGC members and Endocrine Society BOD members.
- The Chair of the CGC selects GDP Chairs and Co-Chairs, based on the C/DOI information received, the individuals' clinical expertise, leadership skills, commitment to the Society's guideline development process, and their availability for a long-term project.
- The CGC Chair submits their nominees for Chair and Co-Chair to the Clinical Guidelines Committee for approval. Once approved, the nominations are sent to the Endocrine Society BOD which reviews and endorses the nominees[9] or suggests changes if appropriate.
- Upon confirmation, guideline Chairs and Co-chairs are contacted to determine their willingness to serve and to establish the continued absence of relevant C/DOI.
- The CGC Chair works with the Chairs and Co-Chairs to select non-Chair members of the GDP in addition to other guideline-development participants (e.g., advisors to the GDP). Decisions will be based on the C/DOI status of each candidate, the representation needs of the panel (e.g., involvement in other societies, etc.), the individuals' clinical expertise, commitment to the Society's guideline development process, and their availability for a long-term project.
  - When the GDP Chair and Co-Chair request inclusion of a GDP member with relevant C/DOI, they must carefully describe the reason(s) for proposed inclusion.
  - The CGC must approve all non-Chair members of the GDP (including plans for C/DOI management as appropriate).
  - When the GDP includes members with relevant C/DOI, the following must be carefully documented by GDP Chairs:
    - reasons for inclusion;
    - proposed plans for C/DOI management; and
    - implementation of C/DOI management strategies throughout the guideline development process.
- Following initiation of the panel, C/DOI information will be updated at regular intervals.
  - GDP members will complete the Endocrine Society's online Conflict of Interest Form for Guideline Development Panels (as described above) at least once a year.
  - At the beginning of every in-person meeting and of most conference calls, GDP members will describe all interim changes to their C/DOIs.
    - GDP members with interim changes to their C/DOIs will be required to update their C/DOI information via completion of the Endocrine Society's online Conflict of Interest Form.
    - When a GDP member has interim changes to their C/DOIs, the CGC Chair and GDP Chairs must determine whether the new C/DOI represents a relevant relationship[10] and whether/how that C/DOI should be managed.
  - At periodic intervals post-publication
    - GDP Chairs/members who perform post-publication surveillance (to identify changes in the field that may indicate a need for CPG updating) will update their C/DOI information periodically (e.g., once a year) via completion of the Endocrine Society's online Conflict of Interest Form.

Guideline Development Panel Chairs, members and society staff must be alert for situations which might present a potential or perceived conflict of interest and be ready to act accordingly.

MANAGING CONFLICTS OF INTEREST

The process of managing conflicts of interest is as follows:

- **Disclosure:**
  - All C/DOI of each GDP member should be reported and discussed by the GDP prior to the start of guideline development.
  - If a member is aware of another person who might have a conflict and has not declared it for some reason, they are obliged to bring this to the GDP Chair's attention.
  - Any individuals who are not members of the GDP but who are asked to either review guideline drafts or act in a formal advisory capacity to the panel will be required to disclose all relationships in line with the policies identified above.

[9] Endocrine Society BOD endorsement will indicate agreement that the Chair and Co-Chair are free of relevant COI.

[10] According to this COI policy, new industry relationships relevant to the guideline are prohibited.

- **Divestment:** Members of the GDP (and their immediate family members) must divest themselves of direct financial investments (e.g., direct ownership in stock or other form of equity[11]) with entities that may have a potential financial interest in the contents of the guideline. GDP members must also refrain from participating in the marketing activities and commercial advisory boards of these entities. A candidate's commitment to such divestment will be a requirement for selection as a GDP member.
- **Maintenance:** Members of the GDP must refrain from taking on any new relevant relationships and maintain eligibility over the course of the GDP development and for one year following publication.
- **Recusals:** GDP members who have conflicts that are directly relevant to specific sections/PICOs[4] of the guideline are required to recuse themselves from all formal decision-making processes related to those sections/PICOs.
  - GDP members are prohibited from serving as leads for PICOs directly related to their C/DOI.
  - GDP members are prohibited from drafting guideline sections directly related to their C/DOI.
  - GDP members are prohibited from determining the strength and direction of a recommendation directly related to her/his C/DOI.
  - GDP members are prohibited from voting on matters directly related to her/his C/DOI.
  - Given that a GDP member with relevant C/DOI may have important insights that should be carefully considered, the GDP Chairs may elect to allow the GDP member to participate in discussions related to guideline sections/PICOs directly related to her/his C/DOI. However, at the GDP Chair and Co-Chair's discretion, such members may be required to recuse themselves from all activities (including discussions) related to their C/DOI. Such decisions should be carefully documented and approved by the CGC Chair.
- **Transparency:**
  - The Society will include details of all relevant conflicts of interest of members of the GDP in a detailed appendix of the published guideline. The appendix will include CGC determinations regarding relevance of relationships and a description of the ways that relevant C/DOI was managed throughout the guideline development process.
- **Mitigation**
  - Members who fail to comply with the established policies or procedures will be removed from the panel. Upon the publication of the guideline, the contribution of any removed members may be noted in acknowledgments, but they will not be recognized as authors.
  - Individuals found in significant non-compliance with these policies or procedures will not be considered for involvement in future guideline projects of the Endocrine Society.
  - The Endocrine Society will address minor infractions on a case-by-case basis, potentially through disclosure or other corrective measures. Such deviations may also be noted within the guideline document itself. The determination of what constitutes a "minor deviation" falls under the purview of the CGC, based on the criteria that the deviation was unintentional, did not impact the guideline recommendations, and is unlikely to affect the perception of the guideline by its users.
  - In the event of a member's dismissal, the CGC will typically not seek a replacement. Instead, the guideline panel is structured with the anticipation that some members may not complete their term due to various reasons, including dismissal.
  - The CGC is responsible for determining the appropriate course of action for deviations from the policy, including the decision to dismiss a member.

DEFINITIONS

Conflict/duality 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 plausibly be perceived to be, influenced by an outside interest.

Consultancy and advisory activities: Participation in R&D-related advisory boards pertinent to E&M and/or R&D-related consultation pertinent to E&M can be allowed. Participation in commercial or marketing directed advisory boards are always disallowed .

Financial interest: A position or relationship held by an individual that offers potential gain or loss of monetary value, such as employment, stock ownership[6], payment for services, or gifts given with the expectation of reciprocity.

Direct financial interest: A financial interest held by an individual that results in wages, consulting fees, honoraria, or other compensation (in cash, in stock or stock options, or in kind), whether paid to the individual or to another entity at the direction of the individual, for the individual's services or expertise. Indirect financial interest: A financial interest that is owned or received via an intermediary, e.g., research funding to an individual received through the individual's academic institution.

Intellectual conflicts of interest: Academic, professional, or publicly expressed views, activities, or commitments that create a potential attachment to a particular point of view, which could unduly influence an individual's judgment when making a specific recommendation. Such conflicts may arise from authorship of original studies, prior guideline authorship, advocacy, lobbying, expert testimony, organizational leadership roles, or receipt of peer-reviewed grant funding directly related to the recommendation. Secondary examples include prior

[11] Ownership of managed fund portfolios (e.g., mutual funds) is not prohibited.

participation in related guideline panels or authorship of systematic reviews informing the recommendation.

Company: For-profit health care company means a business that develops, produces, markets or distributes drugs, devices, services, or therapies used to diagnose, treat, monitor, manage, or alleviate health conditions.

Affected Company: Company whose interests could plausibly be affected by guideline as determined by the Endocrine Society.

Affected Organization: Any entity such as patient advocacy groups, professional societies, government agencies, or regulatory bodies whose responsibilities, policies, or interests are likely to be materially influenced by the development or publication of a clinical practice guideline as determined by the Endocrine Society. Entities with little financial interest or a more balanced intellectual interest, such as government agencies or nonprofit organizations not focused on a specific clinical area, are generally considered to pose a lower risk for conflicts of interest, though they may still be "affected" by guideline recommendations. top

POLICY OVERSIGHT

The original Conflict of Interest Policy & Procedures for Endocrine Society Clinical Practice Guidelines was adopted by the Endocrine Society in 2019. This updated edition was reviewed and approved by the Clinical Guidelines Committee (CGC) in August 2025 and provisionally implemented thereafter. Final approval was granted by the Board of Directors (BOD) in November 2025. The revised policy applies to all guideline development panels convened on or after that date.