

Conflict of Interest Policy for Officers, Committee Chairs and Committee Members of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN)

I. Purpose and Background

The NASPGHAN Conflict of Interest (COI) Policy describes a mechanism for full disclosure of all financial relationships between private industry and individual society members and representatives. This policy also seeks to prevent such relationships from influencing the unbiased development of NASPGHAN clinical practice and healthcare policy recommendations. This policy is also intended to prevent such relationships from influencing evidence-based educational offerings, materials and programs. By educating society members and other stakeholders with respect to associations that represent a potential COI, the policy assures that all NASPGHAN position statements, clinical practice guidelines, clinical and technical reports reflect the best interests of patients, families and practitioners. And, following the principle of full disclosure, this policy defines those situations in which a COI may prevent an individual's participating in the creation of these documents.

Guidelines and reports developed under NASPGHAN auspices, that impact patient management (often through the generation of clinical practice guidelines and clinical reports), must reflect the impartial and unbiased review and analysis of available evidence. Every attempt must be made to insure that resulting recommendations are free from outside influences and competing interests including, but not limited to the industry sponsorship of guideline development as well as other financial relationships between commercial entities and individual committee members. Public confidence in the veracity of these reports depends upon obtaining expert opinions based upon the best available evidence, in a manner designed to eliminate both actual and perceived COI. Such a COI exists when financial incentives have the potential to compete with the impartial evaluation of evidence. The integrity of NASPGHAN policies and recommendations may be compromised by a COI when committee members have personal financial interests in companies developing or marketing products under review. The perception that a commercial entity influenced patient care recommendations only serves to undermine the credibility of NASPGHAN as the sponsor of such reports.

II. Principles

The objectives of NASPGHAN's COI Policy are to:

- Describe those situations for which a real or perceived COI may exist.
- Develop a mechanism for disclosure of relationships that may create a COI.

- Assure that all NASPGHAN officers, committee chairs and committee members fully disclose all relevant commercial relationships (i.e. other than governmental or educational associations), including the nature and amount of compensation received.
- Based upon these commercial relationships, determine an individual NASPGHAN member's ability to impartially stand for or serve as a society officer, committee chair or committee member.
- Determine the nature of public reporting of these commercial relationships.
- Apply the COI Policy to all initiatives that may be influenced by or may affect a commercial entity, from either a regulatory (e.g. achieving FDA approval) or direct financial (e.g. increasing product sales) perspective.

An effective COI Policy ensures that all society-generated recommendations are guided by the needs of patients, are independent from funding sources; and, are monitored by an oversight committee that serves as NASPGHAN's "institutional firewall". A COI arises as a consequence of a divergence between an individual's private interests and her/his professional obligations. If an independent observer reasonably questions whether recommendations arising from a NASPGHAN-sponsored initiative are motivated by considerations of personal gain, such a perceived COI is deemed to be an impediment to the impartial evaluation of evidence. Thus, all recommendations produced by this initiative may reasonably be considered suspect. An important corollary to the principle of full disclosure is the fact that the NASPGHAN policy and its application inform solely on the integrity of the disclosure process and not directly on the character of any one individual. Clearly, relationships that may represent potential conflicts are common among NASPGHAN members. Commercial sponsorship of research and education programs, including direct payments to individuals, divisions, departments and institutions help support our clinical and academic missions. Such relationships must manifest complete transparency. And, while compensation by industry for these activities may be appropriate, considerations of financial gain must not be allowed to influence the decision making process when formulating policy.

In accordance with the following NASPGHAN disclosure protocol, all proposed NASPGHAN officers, committee chairs and committee members must fully report the status of all financial relationships with commercial entities that may, potentially, influence or be influenced by any NASPGHAN-sponsored recommendation. For purposes of full disclosure, all categories listed in the **Policy** section, below, must be reported. When an individual-industry relationship exists outside of these criteria, this relationship and its nature must also be disclosed. Furthermore, all potential conflicts of interest must be appropriately managed, so that any NASPGHAN committee member, committee chair or elected officer reporting such a relationship must recuse

herself/himself from any and all discussions that may influence a commercial entity or be influenced by association with a commercial entity (see, also, **Special Requirements for Clinical Practice Guidelines, Clinical Reports, Technical Reports and Position Statements**, below).

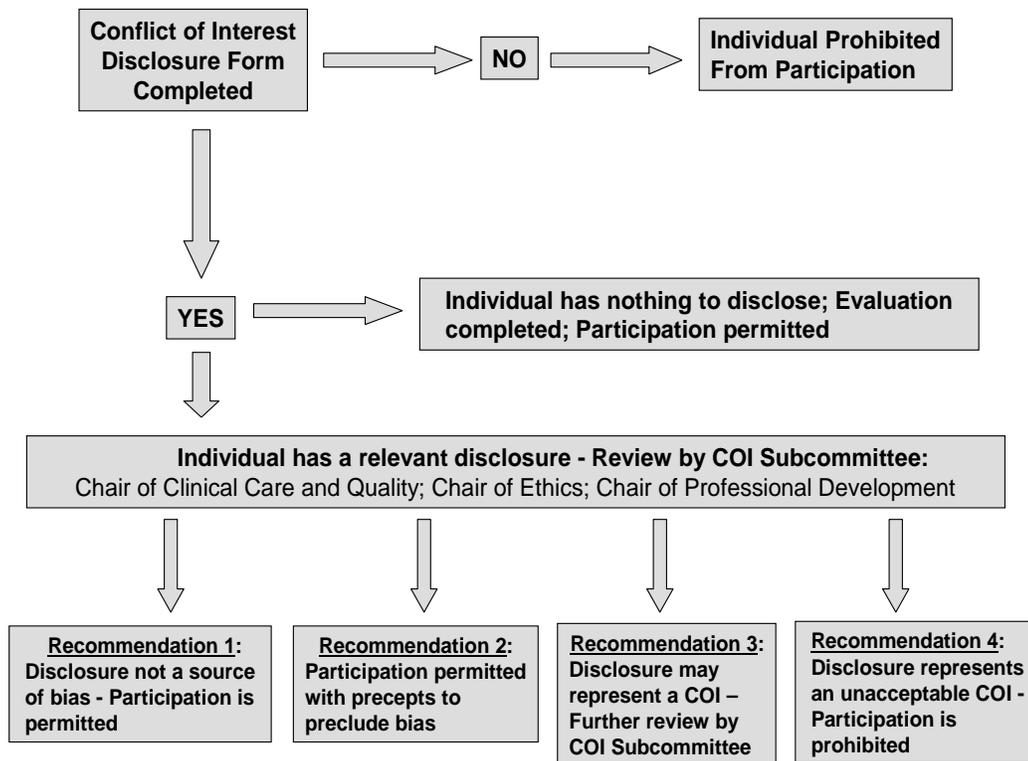
III. Policy

The following categories represent the most common (but not all) of those situations for which a real or potential COI may exist:

- A research grant or contract from an affected company* supports salary and/or provides per capita payments for clinical trials subjects.
- A grant or contract from an affected company supports educational programs.
- Consulting or other activities (CME or non-CME) on behalf of or sponsored directly by an affected company, generate personal income, including honoraria.
- Receipt of product royalties from an affected company.
- Personal or immediate family equity holdings in an affected company.

* *Note: Disclosures by standing or proposed NASPGHAN officers, committee chairs and committee members must list financial relationships with all commercial entities (i.e. non-governmental, non-educational organizations) that produce, provide or promote medically-related services and products. Selection of a member to participate in development of clinical practice guidelines, position statements, clinical and technical reports (see IV., below) will be based upon such relationships with affected companies where, in these cases, an affected company is defined as a commercial entity with a reasonable likelihood of experiencing a direct regulatory or fiscal impact as the result of a NASPGHAN-sponsored guideline or recommendation.*

The following procedure will be followed for the disclosure of individual-industry relationships by all proposed NASPGHAN officers, committee chairs and committee members:



In disclosing financial relationships with commercial entities, all proposed NASPGHAN officers, committee chairs and committee members will complete a “disclosure grid” based upon the following criteria:

1. **A research grant from an affected company supports my salary, or I receive *per capita* payments for clinical trials research:**
 - Category I - <\$1,000. annually
 - Category II - \$1,000. - \$9,999. annually
 - Category III - ≥\$10,000. annually

2. **A research or educational grant from an affected company supports my professional activities, with no direct payments or salary support to me:**
 - Category II - <\$10,000. annually
 - Category III - ≥\$10,000. annually

3. **I provide consulting services for, or participate in CME activities sponsored by an affected company, that generate personal income as direct payments to me, in the form of either salary or honoraria.**
 - Category I - <\$1,000. annually
 - Category II - \$1,000. - \$9999. annually
 - Category III - ≥\$10,000. annually

4. I receive personal royalties from an affected company.

Category I - <\$1,000. annually

Category II - \$1,000. - \$9,999. annually

Category III - ≥\$10,000. annually

5. I or a member of my immediate family has an equity interest in an affected company.*

Category I - <\$1,000. annually

Category II - \$1,000. - \$9,999. annually

Category III - ≥\$10,000. annually

* **Note:**

Individual holdings in pooled financial instruments, such as diversified mutual funds, generate equity that is sufficiently remote so as to reasonably preclude any relevant conflicts of interest; and, as such, these investments may be exempt from disclosure.

This disclosure grid must be completed and submitted, as follows, prior to one's candidacy (elected NASPGHAN officers) or appointment (committee chairs, committee members). All NASPGHAN officers, chairs and committee members must provide this information annually and whenever a new, relevant individual-industry relationship is established:

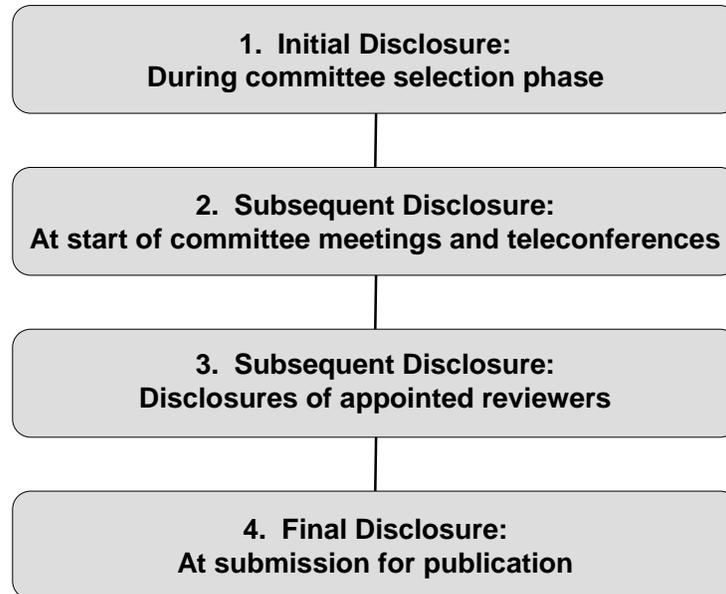
Criteria	Disclosure	Category		
		I	II	III
1	A research grant from an affected company supports my salary, or I receive <i>per capita</i> payments for clinical trials research.			
2	A research or educational grant from an affected company supports my professional activities, with no direct payments or salary support to me.			
3	I provide consulting services for, or participate in CME activities sponsored by and affected company, that generate personal income as direct payments to me, in the form of either salary or honoraria.			
4	I receive personal royalties from an affected company.			
5	I or a member of my immediate family has an equity interest in an affected company.			

IV. Special requirements for Clinical Practice Guidelines, Clinical Reports, Technical Reports and Position Statements

Apart from these disclosure principles, special attention must be paid to the generation of NASPGHAN Clinical Practice Guidelines, Clinical Reports, Technical Reports and Position Statements. The committees designated to author these documents are charged to review and recommend therapeutic and/or procedural protocols, as well as to present NASPGHAN's official position in areas that may impact standard-of-care and/or influence healthcare policy. These committees shall be constituted such that:

- **The Committee Chair shall have no financial relationships with an affected company to disclose.**
- **A majority of committee members (to include the Chair) shall have no financial relationships with an affected company to disclose.**
- **All decisions rendered by the committee that impact clinical management recommendations shall be approved only upon receipt of a supermajority vote ($\geq 67\%$) of committee members.**

For potential or standing committee members, financial disclosures in Category III under Criteria 1, 3 and 4, above, as well as disclosures under Criteria 5 may represent disqualifying conflicts of interest. Pending review by the COI Subcommittee, such relationships may prohibit these individuals from proposed or continued participation in the preparation of Clinical Practice Guidelines, Position Statement, Clinical and Technical Reports. Disclosure of individual-industry associations is not a static process, and must be reported on an ongoing basis before and during the development and generation of all guidelines and reports. This disclosure protocol shall follow the following reporting algorithm:



Periodically during preparation of these reports, the appointed NASPGHAN COI Subcommittee will review all disclosures for potential COI, and provide oversight of these relationships, including identifying possible disqualifying associations of committee members. The names of all committee members and the identity of their relevant relationships with affected commercial entities, if any, will be reported in the published Clinical Practice Guideline, Clinical Report, Technical Report or Position Statement. These disclosures will also be published, along with the associated document, on the NASPGHAN website.