



North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) Policy on Conflict of Interest and Relationships with Industry and Other Organizations.

NASPGHAN Mission Statement.

The mission of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition is to be a world leader in advancing the science and clinical practice of Pediatric Gastroenterology, Hepatology and Nutrition in health and disease.

Preamble.

NASPGHAN was established to advance the understanding of the normal development and physiology of diseases of the gastrointestinal tract and liver in infants, children and adolescents, and to foster dissemination of this knowledge through scientific meetings, professional education, public education, and interaction with other organizations concerned with Pediatric Gastroenterology and Nutrition. Since being founded in 1972, NASPGHAN has gained considerable respect as a leading authority in the field of pediatric gastroenterology, hepatology and nutrition from other scientific and professional organizations, the health care industry and governmental organizations involved in health care, and has gained public trust in the promotion of the health and well being of infants, children and adolescents with disorders of the digestive system and nutrition. The maintenance of this respect and the public trust in NASPGHAN's integrity, credibility and ethical standards are of paramount importance to the Society in order for it to continue to accomplish its mission. This policy document is designed to serve as a general guide to avoid conflicts of interest and ensure appropriate relationships with industry and other organizations are maintained at all times. In developing this document the Society affirms its commitment to adhering to the American Medical Association's "Principles of Medical Ethics" (<http://www.ama-assn.org/ama/pub/category/2512.html>), the "Code of Ethics of the Canadian Medical Association" (http://www.cma.ca/index.cfm/ci_id/2419/la_id/1.htm), the Canadian Medical Association's policy statement "Physicians and the Pharmaceutical Industry" (http://www.cma.ca/staticContent/HTML/N0/12/where_we_stand/physicians_and_the_pharmaceutical_industry.pdf) and the ACCME's recommendations on "Standards for Commercial Support of Continuing Medical Education" (<http://www.bu.edu/cme/accreditation/stdcommsupport.html>).

1. Policy on Conflict of Interest and Disclosure.

Introduction.

NASPGHAN uses many methods to accomplish the society's mission of advancing the science and clinical practice of the subspecialty, including professional education, public education and research. In order to fund such activities NASPGHAN and its members collaborate with industry (including manufacturers of devices, pharmaceuticals, products, formulas or equipment) and other organizations such as foundations, government agencies and corporations. While NASPGHAN accepts that without such collaborations it would not be possible to adequately fulfill its mission, the society realizes that these relationships can create both potential and real

conflicts of interest that may affect an individual's opinion, may appear to make that opinion self serving, or might not allow for impartial objective determinations.

NASPGHAN does not wish to exclude individuals who are expert in a given field from participation in the activities of the society merely because they have a conflict of interest. However the validity of policy statements and recommendations that emanate from the society are dependent on confidence in its integrity, and the belief by members of the society, the scientific community and the public at large, that these are unbiased and based only on concerns for the health of the patients and their families and are in the best interests of continuing education for health care professionals and the lay public. Therefore, NASPGHAN accepts the principle that it is not wrong to have a conflict of interest, but that failure to disclose such a conflict, and if necessary take steps to resolve such a conflict, is wrong and will not be tolerated by the Society. The policy outlined in this document is designed to serve as a general guide for all members of NASPGHAN to define potential conflicts of interest and address how they may affect the participation by members in the activities of the society.

1.1. Definition of Conflict of Interest.

A conflict of interest is defined as a relationship with a business or agency that may result in a financial, fiduciary or otherwise rewarding arrangement for the individual or any member of his/her immediate family, which may influence subsequent deliberations or actions, whether perceived or factual. It is incumbent on the individual to disclose any such relationship that may be perceived as establishing a conflict of interest and, when necessary, take remedial action to resolve the conflict by removing oneself from any action (e.g. discussions or voting) that may be influenced by such conflict.

1.2. Examples of Potential Conflict of Interest.

- A. A conflict of interest may exist when an individual, his/her spouse, child, parent or business partner, is involved with a commercial firm or organization (for profit or otherwise) in the health care field that includes one or more of the following circumstances:
 - i) Consultant, scientific advisory committee member, scientific program organizer or faculty member for which an honorarium, stipend, research grant or any other form of remuneration is derived or expected within a 12 month period. An honorarium paid by a university, hospital or medical society which extends the invitation does not require disclosure. For an honorarium paid directly by a commercial firm or organization, or paid by a third party organization contracted by the commercial firm or organization to arrange the activity, disclosure is required.
 - ii) Officer, board member, trustee, owner or employee of a commercial firm or organization.
 - iii) A significant* financial interest as a stock or bond holder in a commercial firm or organization. (* Refer to appendix 1).
 - iv) Stock options held in a commercial firm or organization.
 - v) A patent is held or impending for a medically health related device, technology or drug with the expectation of personal economic gain.

A conflict of interest does not include a relationship with the individual's own private practice unless that practice is doing business with NASPGHAN.

- B. A conflict of interest may exist when an individual serves as program director, moderator or faculty member at an educational event funded by a commercial firm or organization (for profit or otherwise) and the individual also participates in the design or conduct of studies involving products manufactured or distributed by the firm or organization.
- C. A conflict of interest may exist when an individual serves on the Governing Board of another national medical organization or society whose interests overlap with those of NASPGHAN, even if no financial benefits accrue to the individual.

The above examples do not include all possible scenarios that may lead to a conflict of interest. It is the responsibility of each individual to use their best judgment in making a decision involving a situation that may require disclosure. When in doubt, the individual should consider seeking advice from the NASPGHAN Ethics committee or err on the side of declaring a possible conflict of interest.

1.3. Disclosure.

It is required that NASPGHAN officers, committee chairs and members, task force members, CME organizers, course directors, moderators and faculty, employees and others acting on behalf of NASPGHAN adhere to the policies outlined above and openly disclose any real or potential conflicts of interest. Candidates for any of these positions must be informed of the NASPGHAN conflict of interest policy and procedures, and agree to abide by them, before they are appointed, hired or placed on a ballot.

Procedure.

- It is required that the NASPGHAN conflict of interest disclosure statement be signed at the beginning of any term of service and that this be updated whenever there is a change in circumstances that give rise to a potential conflict of interest, for the duration of the individual's term of service. Even if there is no perceived change during the term of service, it is required that each individual complete a conflict of interest disclosure on an annual basis.
- A disclosure statement must be completed whether or not a conflict of interest is perceived.
- It is the individual's duty to disclose a potential conflict of interest. If the individual knowingly fails to disclose a conflict of interest which is subsequently discovered, the Society will take action as deemed appropriate.
- All disclosure statements will be reviewed by the Executive Director of NASPGHAN.

- Disclosure statements of candidates running for elected office within NASPGHAN will be included in the candidate's biographical information for review by the membership of the society prior to the elections.
- Disclosure statements of the NASPGHAN Officers and Council members will be made available for review by the society membership through a posting on the “Members Only” section of the NASPGHAN website for the duration of their tenure. In all other cases a potential conflict of interest will be disclosed on a "need to know" basis only.
- When a potential or real conflict of interest exists that may affect objectivity, the Executive Director of NASPGHAN will notify the President, committee chairperson, course director or leader of the relevant NASPGHAN entity. A determination will then be made whether the individual who has a perceived conflict may participate in the discussion after making full disclosure of the potential conflict of interest. Any individual who has been determined to have a conflict of interest is disqualified from voting on recommendations or any NASPGHAN matter pertaining to that conflict.
- In the event the President, chairperson, course director or leader believes a conflict exists, but the individual does not agree to reveal this to the other members of the committee or entity, participation by that individual in the activity concerned is not allowed.
- In all cases where there is a dispute between the interested party and the President, chairperson, course director or leader as to whether a perceived conflict is relevant to the individual’s participation, the matter will be referred to the Ethics Committee for review. Following review, the Ethics Committee will make a recommendation to the NASPGHAN Council who shall have the final say in the matter.
- Any transgressions of the NASPGHAN Disclosure of Conflict of Interest Policy will be referred to a subcommittee of the Ethics Committee for review. This subcommittee will be responsible for meeting with member(s) under review and thoroughly investigating the facts pertaining to the alleged transgression. The findings of the subcommittee will be presented to the Ethics Committee for deliberation and recommendations for any action to be taken in the event a transgression is deemed to be valid. The findings and recommendations will then be referred to the NASPGHAN Council who shall have the final say in the matter. (See NASPGHAN Policy on Due Process for Ethics Violations).

2. Policy on Receiving Gifts from Industry.

Receipt of a gift from manufacturers of medical devices, pharmaceuticals, products, formulas or equipment can create perception of a conflict of interest. For this reason NASPGHAN suggests adherence to the guidelines on “Gifts to Physicians from Industry” as described in the AMA Code of Medical Ethics, Opinion 8.061. (www.ama-assn.org/go/ethicalgifts). (See appendix 2)

.3. Policy on Industry Support for CME Activities.

Introduction.

As a CME provider accredited by the Accreditation Council for Continuing Medical Education (ACCME), NASPGHAN must adhere to the ACCME's "Essential Areas and their Elements" by ensuring balance, independence, objectivity, and scientific rigor in all its individually sponsored and jointly sponsored educational activities and must abide by the ACCME's "Standards for Commercial Support of Continuing Medical Education".
(<http://www.bu.edu/cme/accreditation/stdcommsupport.html>).

NASPGHAN recognizes that it has many positive and beneficial relationships and collaborations with the pharmaceutical, formula and medical device industries that further the Society's educational mission. Accordingly, NASPGHAN adopts the following guidelines that should be interpreted to be in concert with similar requirements of the ACCME
(http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf), which we adopt in their entirety.

3.1. Principles of Corporate Sponsorship and Partnership for NASPHGAN endorsed CME activities.

- NASPGHAN will accept support from industry and from other outside sources for educational, professional and scientific activities and publications. This support is subject to the standards and conditions outlined in this document and by the ACCME.
- NASPGHAN, or the course/program director appointed by NASPGHAN, is responsible for the organization and content of all educational activities endorsed by the Society and there can be no control of content by any sponsoring agent.
- NASPGHAN requires that the organizer, course director, moderator, faculty members or any individual directly involved in an educational activity endorsed by the Society, complete a conflict of interest disclosure statement, and that any potential conflict of interest be declared beforehand to the participants in the educational activity or be resolved prior to the event.
- Under no circumstances will NASPGHAN explicitly endorse any product, brand, or company. The NASPGHAN logo may not be used in conjunction with the name of the product or brand and may not be used in a manner that would express or imply a NASPGHAN endorsement of the corporation or its policies unless explicit consent is given by NASPGHAN.
- Participation in a specific corporate arrangement does not imply that NASPGHAN will exert its influence to advance the corporation's interests outside the substance of the arrangement itself.
- Any project or program involving commercial support must have a clear, stated scientific or educational purpose that is consistent with the mission of NASPGHAN to promote child health, advocacy, and education of physicians, health care providers and the public.

- According to the AMA and CMA guidelines, physicians cannot accept subsidies from corporate supporters to attend an educational program. Scholarships or payments by corporate supporters for attendance of medical students, residents, fellows and graduate students at NASPGHAN educational programs is permissible if based on objective criteria approved by NASPGHAN, and in no case on prescribing practices, device usage or other similar economic factors. Selection of awardees for these scholarships will be made by NASPGHAN or the academic/training institutions of its members.
- All applicable requirements of the ACCME, American Medical Association and FDA guidelines must be adhered to.
- All principal parties must sign a Letter of Agreement that defines the relationship, its duration, and respective responsibilities.
- All publicity related to a commercially-supported event or program must be reviewed and approved by NASPGHAN prior to its distribution or dissemination. It is acceptable to acknowledge receipt of commercial support providing only the name of the sponsoring agent is listed without reference to any brand name product or device manufactured or distributed by the sponsor.
- NASPGHAN prefers multiple sources of commercial support for its educational, professional and scientific activities. Exclusivity will be by mutual agreement.
- Only individuals authorized by the NASPGHAN Executive Council may solicit funding for NASPGHAN programs or projects.
- NASPGHAN adopts the principle that it will not accept any support from industry specifically allocated for the development of a NASPGHAN endorsed Clinical Practice Guideline. It is acceptable to use funds received in the form of an unrestricted grant from multiple sources of commercial support for this purpose.

3.1.2. Policy and Procedure.

Honoraria and Reimbursement for Expenses

- Honoraria will be provided only as agreed upon in advance by NASPGHAN and the speaker, teacher or author. The honorarium will be disbursed only by NASPGHAN. Any Sponsor must give the payment as an unrestricted educational grant to NASPGHAN, who will then be responsible for direct payment to the speaker, teacher or author.
- Reimbursement for reasonable out-of-pocket expenses will be made directly by NASPGHAN. This may include payment for travel, hotel and meals, and registration as well as other designated sundry fees and costs. Documentation of expenses must be provided by the planner, speaker, teacher, or author who then may be reimbursed.

- Subsidies for hospitality should not be accepted outside of modest social events and meals that are held as part of the conference or meeting.

3.2. Policy on Corporate Sponsorship of non-NASPGHAN endorsed CME activities.

NASPGHAN accepts there are many industry sponsored CME activities available to physicians, and while these are not endorsed by NASPGHAN they may be of educational benefit to the members of the Society. Accordingly, NASPGHAN is open to the policy of allowing industry to sponsor CME activities, such as topic symposia, during the period the Society holds its annual scientific meeting. Although this arrangement should not imply that NASPGHAN endorses the content of any such activity, the Society fully accepts that this perception may exist because the event is held in conjunction with the meeting of the Society. Accordingly NASPGHAN requires that a corporate sponsor of any non-NASPGHAN endorsed or organized CME activity held in conjunction with any meeting of the Society agrees to abide by the following principles.

3.2.1. Principles of Corporate Sponsorship of non-NASPGHAN endorsed CME activities.

- The event organizer/director must ensure there is balance, independence, objectivity and scientific rigor of the educational activity.
- The event organizer/director may be appointed by the sponsoring company but may not be an employee of the company.
- The event organizer/director is responsible for the content of the educational activity and there can be no control by the sponsoring company.
- There must be a clear stated scientific or educational purpose for the event that promotes health care or education.
- The event organizer/director, moderator, faculty member or any other individual directly involved in the educational activity must fully disclose any potential conflicts of interest beforehand to the participants.
- There may not be promotion of any specific product, brand or device manufactured or distributed by the sponsoring company. Wherever possible only generic names of drugs should be used, or when brand names are used, mention must also be made of competing products from other companies.
- Publicity related to the event may make mention of the sponsoring company by name but not of any brand name product or device manufactured or distributed by the sponsor.

3.2.2. Policy and Procedure.

- Participant CME evaluations of the event will be reviewed by the NASPGHAN Executive Council, or a designee appointed by the Executive Council, to ensure the principles outlined above are adhered to. If any participant expresses a concern for non-adherence to these principles, or believes the event was unacceptably biased, this will be thoroughly investigated.
- Potential Corporate sponsors of non-NASPGHAN sponsored events must be made aware of these principles beforehand. Failure to adhere to these principles will result in punitive action, including the possibility of prohibiting the corporate entity from sponsoring future events in conjunction with other NASPGHAN activities.

Honoraria and Reimbursement for Expenses.

- The event organizer/director and faculty members may receive a reasonable honorarium for their work and be reimbursed for travel and out-of-pocket expenses by the sponsor.
- There should be no payment to participants who attend the event.
- It is acceptable for the sponsoring company to provide subsidies for a modest social event or meal as part of the event.
- Participants should not receive gifts as an enticement to attend the event. The sponsor should adhere to the AMA policy on gifts to physicians.

4. Policy on Ethics for Industry Sponsored Research Activities.

Introduction.

The primary responsibility of all physicians is the physical and mental well-being of their patients and their families. Physician members of NASPGHAN who choose to participate in research activities must be able to demonstrate that their activities are ethically defensible, socially responsible, and scientifically valid. NASPGHAN opposes the testing of medication or products that would further scientific knowledge but not improve the overall health or quality of life of the research subjects after completion of the study. NASPGHAN also opposes exploitation of people as research subjects in developing countries based on poverty, or by accepting a higher benefit to risk ratio than would be tolerated in North America.

4.1. Industry Funding to NASPGHAN.

NASPGHAN recognizes that corporate industrial research and product development are important components in the overall advance of scientific knowledge to understand and treat digestive diseases in children. NASPGHAN also recognizes that non-profit funding does not fully fund non-corporate, academic research. Therefore, NASPGHAN is open to accepting

unrestricted funding from corporate industrial sources to further academic research related to digestive diseases in children.

4.1.1. Policy and Procedure.

- An independent committee of NASPGHAN members with no ties to the corporate donor will decide how to best distribute any funds collected. The President of NASPGHAN will be responsible for delegating this task to an existing committee within the organization (e.g. Research Committee) or for appointing an ad hoc committee of NASPGHAN members specifically appointed for this purpose
- If the distribution is based on a competitive basis, the designated independent committee of NASPGHAN members will choose recipients based on the scientific merits of their submitted work.
- The name of the research award may include the name of the corporate donor but may not make mention of any particular product or device associated with that donor.

4.2. Industry Funding to NASPGHAN Members.

NASPGHAN members may accept funds directly from industry to do research. All industry-sponsored research activities should be formally reviewed and approved by an appropriate Institutional Review Board whose goal is to ensure that the rights and welfare of human subjects are protected. The research should be carried out based on ethical principles, namely respect for persons, beneficence, non-maleficence, and justice. Such research should be conducted according to the standards and procedures which apply to individual jurisdictions.

4.2.1. Policy and Procedure.

- The design of a given study may be a collaboration between physician investigator and corporate sponsor; however, it must be based on sound scientific evidence and be socially responsible and ethically defensible.
- Patient enrollment and participation in industry-sponsored research studies shall commence only after obtaining full, open, informed, competent, and voluntary consent from a patient or the parent/legal guardian, and an assent to participate in research by a minor when appropriate, unless the Institutional Review Board authorizes an exemption to the requirement for consent. Research subjects must be informed before enrolling in the study if their physician will receive any fee, in excess of the normal practice fee, to enroll a patient in a study. The standards and procedures which apply to the jurisdiction where the research will be conducted must be observed. The principal investigator is responsible for the implementation of these standards and procedures.

- Any additional costs directly related to the research study should be paid by the industry sponsor, not by health care institutions or other insurance agencies regardless of whether these costs involve diagnostic procedures or direct patient services.
- Any NASPGHAN physician member with a significant financial interest in a corporate entity, which is also sponsoring the research project, is restricted from enrolling patients, managing a study, or obtaining informed consent for that research project. Violation of this rule represents a conflict of interest and will result in disciplinary action.
- Physician investigators engaging in clinical research on their own inventions, where no other researcher could do the study, must have Institutional Review Board approval and independent oversight to ensure patient safety, minimize undue patient risk, and maximize patient benefit from the study.
- Practicing physicians should not participate in studies unless they are assured by the industrial sponsors that the results will be made public within a specified, reasonable period.

4.3. Physician Responsibility for Disclosure in Industry Sponsored Research.

NASPGHAN members have a responsibility to be open, honest, and fair in disclosing all associations, agreements, and contracts to avoid even the perception of falsehood, manipulation, bias, or dishonesty in matters of research, education, and patient care associated with this organization.

4.3.1. Policy and Procedure.

- All industry-related associations, agreements, contracts, and sponsorships related to any presented research must be disclosed at public meetings.
- When submitting manuscripts for publication in medical journals, physician members should disclose any relationship they share with companies providing funding or products for studies whether or not a given journal requires such disclosure. (See also NASPGHAN policy on Ethics in Journalism)

Appendix 1.

The definition of what constitutes a “significant” financial interest is problematical and subject to change. In the USA, the Public Health Service (PHS) currently defines this as annual income or equity interests in excess of \$10 000, or 5% ownership in a company (42 CFR 50-603, 45 CFR 94.3). In contrast, the ACCME refers to “relevant financial relationships” and defines this as a financial relationship in any amount occurring within the past 12 months that create a conflict of interest. Because the field of ethics in medicine is in a constant state of evolution, the NASPGHAN Ethics Committee has chosen not to quantify the definition of “significant” and recommends that individuals exercise good judgment and, when in doubt, rather err on the side of disclosure.

Appendix 2.

AMA Guidelines on Receiving Gifts from Industry.

1. Any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value. Accordingly, textbooks, modest meals, and other gifts are appropriate if they serve a genuine educational function. Cash payments should not be accepted. The use of drug samples for personal or family use is permissible as long as these practices do not interfere with patient access to drug samples. It would not be acceptable for non-retired physicians to request free pharmaceuticals for personal use or use by family members.
2. Individual gifts of minimal value are permissible as long as the gifts are related to the physician's work (e.g., pens and notepads).
3. The Council on Ethical and Judicial Affairs defines a legitimate "conference" or "meeting" as any activity, held at an appropriate location, where (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation (s) should be the highlight of the gathering), and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented. An appropriate disclosure of financial support or conflict of interest should be made.
4. Subsidies to underwrite the costs of continuing medical education conferences or professional meetings can contribute to the improvement of patient care and therefore are permissible. Since the giving of a subsidy directly to a physician by a company's representative may create a relationship that could influence the use of the company's products, any subsidy should be accepted by the conference's sponsor, who in turn can use the money to reduce the conference's registration fee. Payments to defray the costs of a conference should not be accepted directly from the company by the physicians attending the conference.
5. Subsidies from industry should not be accepted directly or indirectly to pay for the costs of travel, lodging, or other personal expenses of physicians attending conferences or meetings, nor should subsidies be accepted to compensate for the physicians' time. Subsidies for hospitality should not be accepted outside of modest meals or social events held as a part of a conference or meeting. It is appropriate for faculty at conferences or meetings to accept reasonable honoraria and to accept reimbursement for reasonable travel, lodging, and meal expenses. It is also appropriate for consultants who provide genuine services to receive reasonable compensation and to accept reimbursement for reasonable travel, lodging, and meal expenses. Token consulting or advisory arrangements cannot be used to justify the compensation of physicians for their time or their travel, lodging, and other out-of-pocket expenses.
6. Scholarship or other special funds to permit medical students, residents, and fellows to attend carefully selected educational conferences may be permissible as long as the selection of students, residents, or fellows who will receive the funds is made by the academic or training institution. Carefully selected educational conferences are generally defined as the major educational, scientific, or policy-making meetings of national, regional, or specialty medical associations.

7. No gifts should be accepted if there are strings attached. For example, physicians should not accept gifts if they are given in relation to the physician's prescribing practices. In addition, when companies underwrite medical conferences or lectures other than their own, responsibility for and control over the selection of content, faculty, educational methods, and materials should belong to the organizers of the conferences or lectures.