

Manual of Operations NASPGHAN Societal Manuscripts

I. Introduction

Pediatric gastroenterology is a constantly evolving, dynamic field. As evidence emerges that substantially impacts patient care, the NASPGHAN Executive Council will authorize the development of new or revised clinical practice guidelines or position papers. A wealth of evolving clinical knowledge in pediatric gastroenterology, hepatology, pancreatology, and nutrition demands that NASPGHAN regularly consider subject matter that may be appropriate for the creation of manuscripts bearing the NASPGHAN name.

All published societal manuscripts officially developed by or endorsed by NASPGHAN must conform to rigorous standards and a well-defined review and approval process. Publication will occur in the *Journal of Pediatric Gastroenterology and Nutrition (JPGN)* or, with prior approval of NASPGHAN Council, an alternate peer-reviewed journal. Industry or institutional funds/grants shall not be utilized to fund societal manuscripts preparation which include clinical practice guidelines and position papers.

This Manual of Operations defines how NASPGHAN-endorsed societal manuscripts shall be proposed, budgeted, approved, developed, reviewed and revised.

II. Types of Societal Manuscripts

There are two types of societal manuscripts: **Clinical Practice Guidelines** and **Position Papers** to match the types of societal manuscripts of ESPGHAN and to encourage the production of joint societal manuscripts. Proposals submitted for society endorsed papers other than Clinical Practice Guidelines or Position Papers will not be considered.

- 1) ***Clinical Practice Guideline***: This is a scientific-based decision-making tool that addresses specific clinical research questions and abides by the rules of evidence-based medicine for guideline development (www.guideline.gov and www.ncbi.nlm.nih.gov/books/NBK209538/) Guidelines should be developed using a methodology that meets the criteria of the Agency for Health Care Research and Quality (www.guideline.gov). Guideline development includes a thorough systematic literature review, synthesis of the evidence, data analysis, formalized consensus development, recommendations and algorithms for clinical management and internal and external critique.
- 2) ***Position Paper***: This societal manuscript addresses a topic for which guidance is necessary but due to limited scientific evidence, the recommendations are based on the available state-of-the-art medical literature as well as expert consensus with a synthesis of guidance on accepted best practices.

A Position Paper:

- a) Presents an extensive review of the state-of-the-art care for an important clinical topic. It may not be prepared with the rigorous methodology applied to the

development of a Clinical Practice Guideline due to the paucity of existing level 1 robust clinical evidence

(https://www.elsevier.com/data/promis_misc/Levels_of_Evidence.pdf). There should be no or few recommendations although generally accepted “best practices” can be described. It is expected that while rigorous methodology may not be applicable to a position paper, there should be some amount of peer-reviewed literature to inform the writing of the position paper.

- b) Is meant to be a document based on existing literature, data and experience by recognized experts in the field that will likely have sustained relevance over 5 years.
- c) Although a Position Paper may represent a report from a NASPGHAN committee, Special Interest Group (SIG) or task force regarding a specific issue of importance to the field of pediatric gastroenterology, hepatology and nutrition that is not directly related to clinical care (e.g., research agenda; workforce survey; model of care such as aerodigestive center components or pediatric endoscopy services), not all papers written by members of these society groups are Society papers.
- d) May also be a Policy statement, representing an organizational principle to guide and define the child health care system and/or improve the health of children and may contain recommendations based on interpretation of fact, values and opinions.

Rejection of a Position Paper proposal may be based on, but not limited to, reviews that lack clinical impact, are not supported by significant quality evidence, are too heavily based on expert opinion etc.

Please note: If a proposed Clinical Practice Guideline or Position Paper is not accepted by NASPGHAN Council and/or the Clinical Care and Quality (CCQ) Committee for completion, the writing group could consider submitting the manuscript directly to JPGN as a Review Article or other suitable manuscript form. Typically, but not always, the journal’s Editorial Board solicits Review Articles; the authors may self-contact JPGN at <http://edmgr.ovid.com/jpgn/accounts/ifaauth.htm>.

III. Development I Process

- 1) **Topic Identification:** The individual with a proposal for a NASPGHAN or joint NASPGHAN/ESPGHAN societal manuscript must contact the appropriate committee chair (e.g. IBD, motility, hepatology) with the idea. Topics should be pertinent and of high relevance for clinical practice, policy, advocacy or research and should aim to arrive at conclusions with strong evidence-based support that are helpful for practice. Repetition of previously published information will not justify publication of a societal manuscript, unless there is an urgent need to update the prior recommendations with new data. Proposal forms are available on the NASPGHAN website (<https://naspghan.org/professional-resources/clinical-guidelines/>).
- 2) **Conflict of Interest:** The Writing Group Chair shall have no financial or other relationship with an affected company to disclose, where an affected company is defined as a commercial entity with a reasonable likelihood of experiencing a direct or indirect regulatory or fiscal impact as the result of a NASPGHAN- sponsored guideline or recommendation.

- a. A majority (>50%) of the writing group members shall have no financial or other relationships with an affected company to disclose. The first and last authors on the manuscript should also have no conflicts.
- b. Conflict of interest disclosures of all members of the writing group including the chair **must be submitted at time of proposal submission to the CCQ committee** and members of CCQ should recuse themselves from any decisions about development of societal papers if they have conflicts. (<https://naspghan.org/professional-resources/clinical-guidelines/>)
- c. See NASPGHAN Policy on Ethics: (www.naspghan.org/files/documents/pdfs/policies/Final%20COI.pdf)
- d. If one is unsure what constitutes a significant industry tie, the member's disclosures should be reviewed by the NASPGHAN Ethics Committee.

3) **Concept Proposal**: The proposal must include the following information:

- a. **Manuscript Type**: Indication of type of societal manuscript (Clinical Practice Guideline or Position Paper which will determine the submission form used).
- b. **Rationale for the Topic**: The initial proposal should include a brief rationale for the proposed societal manuscript including, but not limited to, common disorders for which the standard of care is poorly defined; problems of widespread clinical/social consequences; availability of new diagnostic and/or treatment modalities; controversial, complex and /or challenging diagnostic, treatment or policy issue.
- c. **Proposed Writing Group Members**: Information should include name, affiliation, one line on area of expertise and expected contribution of each writing group member to the societal manuscript.
 - Writing groups should consist of a Chair and up to 7 additional members to be submitted to the CCQ Committee and NASPGHAN Council for approval for a total of no more than 8 authors. For joint societal manuscripts, a total of 16 authors with a maximum of 8 authors from each society will be allowed to encourage collaboration from both societies with one NASPGHAN member and one ESPGHAN member sharing first/senior authorship. Joint manuscript Writing Groups should be representative of both organizations. Members may include representation from subspecialties other than pediatric gastroenterology, hepatology, nutrition and transplantation. Individuals with expertise in general pediatrics, pediatric surgery, nursing, psychology, epidemiology, etc., and/or other disciplines from whom their clinical and/or research perspective are paramount to the disease state are encouraged whenever possible and reasonable. No fellows, doctoral or postdoctoral trainees, or students shall be included as part of the writing group. The writing group members should be acknowledged experts in the area to be addressed and should include geographic, and gender, and if feasible, racial and ethnic representation nationally or internationally, with inclusion of an

author from Canada and Mexico. There shall be no more than 1 author per institution. Exceptions to the above must be presented and justified with declaration of authorship at time of initial CCQ proposal for approval.

- i. **Once the proposal is accepted by NASPGHAN Executive Council, the author list CANNOT BE CHANGED except by written request with subsequent approval by CCQ Committee and NASPGHAN Executive Council**
 - ii. The author numbers above are for proposal writers to be considerate of and be able to justify ICJME authorship guidelines (below). Guidelines and position papers involve contributions to conception of idea, design of paper, review of existing data, important intellectual work etc. *Please consider these as you design your authorship list to justify inclusion into author list.* ICJME guidelines recommend authorship be based on the following 4 criteria:
 - Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; **AND**
 - Drafting the work or revising it critically for important intellectual content; **AND**
 - Final approval of the version to be published; **AND**
 - Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.
- d. Outline: Brief outline of the proposed societal manuscript
- e. Budget: For most societal manuscripts, a limited budget (maximum allowable amount of \$1,500 [USD], limited to conference calls and minor administrative assistance) should suffice. For Clinical Practice Guidelines, a higher budget may be necessary (maximum allowable amount \$10,000, including needed travel and one face-to-face meeting), but this budget will be reviewed and must be approved by NASPGHAN Executive Council. Phone and teleconference meetings are recommended in place of face-to-face meetings, if possible.
- The need for a face-to-face meeting must be justified as to why a virtual meeting will not suffice.
 - All expenditures must be submitted to the NASPGHAN National Office with receipts for approval and payment and any approved budget must be used for the proposed position or guideline paper.
 - NASPGHAN guidelines or position papers should ideally be funded by NASPGHAN. An exception is that not-for-profit, non-institutional groups can be a funding source. For example, Cyclic Vomiting Syndrome Association, Crohn's & Colitis Foundation, and other patient advocacy groups can be a source of funding. However, single institutions "xxx

Children's Hospital" or "University of xxx" or "xxx Health System" or their foundations, even if not-for-profit, cannot be a funding source.

IV. **Review and Approval Process**

- 1) The CCQ Chair identifies a minimum of 2 reviewers to assess the proposal with reviews typically completed within 4-6 weeks. They will evaluate the proposal based on the criteria outlined in Section II, based on what type of societal manuscript is submitted. The identity of the reviewers will be kept confidential.
- 2) Reviews will be forwarded back to the CCQ chair, with recommendations for approval, rejection or suggested feedback for revision. The authors can either revise their proposal in accordance with the CCQ reviews or decide not to proceed. Communication between the lead author(s) and the CCQ Committee Chair (or designee) are permissible. Please note, the CCQ committee may reject an initial proposal if it does not meet recommended criteria and if rejected, the proposal will not be sent to Council. There is an appeal process (see below, section VII).
- 3) Once the CCQ committee has reviewed the proposal and any indicated revisions are completed, the CCQ chair submits the recommendations and reviews to the NASPGHAN National Office. The National Office will disseminate to the NASPGHAN Council for its consideration and final decision. The Council review can occur by email, conference call, or at the NASPGHAN in-person leadership meetings. The Council's decision (approved, denied or requested changes in the proposal) will be communicated to the corresponding author by the NASPGHAN office. It is strongly recommended that the lead author(s) do not finalize/commit to the final writing group until they receive final approval from the NASPGHAN Executive Council.
- 4) Clinical Practice Guidelines have wider impact and are more costly to our Society. Therefore, in addition to initial review by the CCQ, these proposals will undergo a second review by the NASPGHAN President and two Executive Council members (Council sub-committee) prior to full Executive Council review and approval. In addition to scientific merit, the budget and long-term impact of the proposal will be assessed by the Executive Council.
- 5) The NASPGHAN Executive Council shall review the Council sub-committee's recommendation and vote for final approval of the project. Review of the budget, secondary review (if needed) and approval of the proposal is the responsibility of the NASPGHAN Executive Council. The NASPGHAN President will notify the authors of the final approval.
- 6) **Once a proposal has been accepted by the NASPGHAN Executive Council, no changes shall be made without written approval from the NASPGHAN Executive Council to ensure that there is preservation of the rules of the organization.**

V. Instruction to Authors

- 1) Council's decision on the proposal will be sent to the corresponding author(s) by the NASPGHAN National Office, signed by the Societal Manuscript Editor (SME) and NASPGHAN President. The letter will include the following information/instructions to the authors:
 - a. The suggested page length of a Position Paper is 15-20 double spaced typewritten pages (5-10 journal pages), with approximately 50-75 references.
 - b. The suggested page length of a Clinical Practice Guideline is 20-30 double spaced typewritten pages (10-15 journal pages), with 50-150 references.
 - i. Due to space constraints in *JPGN*, the authors must notify the President, the SME and the Journal Editor if they anticipate the societal manuscript will exceed these page limits.
- 2) All societal manuscripts funded and endorsed by NASPGHAN should include the Society name in the title. (i.e. NASPGHAN Clinical Practice Guideline..., The NASPGHAN xx Committee Position Paper on...)
- 3) Timetable for Completion of NASPGHAN Societal Manuscripts: NASPGHAN societal manuscripts should be submitted for publication within 12 months of NASPGHAN Executive Council approval. If the timetable will be extended past the 12 months, the writing group will need to submit an update and summary of the current state of the manuscript along with the planned date of manuscript submission to be reviewed by Executive Council for approval. The NASPGHAN National Office will periodically (3 months) request a status update from Corresponding Author. The NASPGHAN National Office will assist the CCQ chair and the SME in these tasks by keeping track of proposals and completed manuscripts.
 - a. Please note that any changes in scope, authors, etc. from initial approval at any time during the manuscript development must be submitted in writing and approved by CCQ and Executive Council.
 - b. If the timetable extends beyond 24 months the Executive Council and/or CCQ has the right to withdraw approval of the current manuscript, and request a revised/new proposal for the project to proceed.

VI. Peer review of NASPGHAN Societal Manuscripts

- 1) NASPGHAN societal manuscripts are to be uploaded on the *JPGN* Editorial Manager platform when completed (<https://www.editorialmanager.com/jpgn/default.aspx>) The NASPGHAN National Office should be notified when the upload has been completed. Peer review of these societal manuscripts will be overseen by the SME who (in consultation with the NASPGHAN President) oversees the peer review process by appointing peer reviewers, communicates with the societal manuscript authors, and decides when the revised completed societal manuscript is ready to be forwarded to NASPGHAN Executive Council for final review.
- 2) The SME appoints a minimum of 2-3 reviewers for the manuscript. The reviewers will be known content experts in the field and not necessarily Council members. If the SME is in any way involved with the manuscript development (i.e. the chair of the committee where the

- guideline was proposed, co-author), an alternate SME will be named at the discretion of the President and *JPGN* Editor-in-Chief. At all times, the names of peer reviewers are kept confidential.
- 3) The *JPGN* Editorial Manager platform tracks the time the societal manuscript was provided to the reviewers, following similar processes and practices as all *JPGN* original manuscript submissions. The ideal time for manuscript review will be two weeks, although in selected instances, a longer time may be allowed at the discretion of the SME.
 - 4) Each societal manuscript typically undergoes two rounds of revisions, and once suggestions of the peer reviewers have been adequately addressed, the final version is reviewed via the Editorial Manager platform by the NASPGHAN Executive Council and the *JPGN* Editor-in-Chief.
 - a. For Clinical Practice Guidelines, in addition to the peer review process above, the document is posted on the NASPGHAN website, and forwarded to Society members for commentary.
 - b. For joint societal manuscripts, NASPGHAN Executive Council and ESPGHAN Executive Council will be invited to review after the initial round of revisions by the chosen peer reviewers and will be involved in all subsequent rounds of revision as well as reviewing the final version.
 - 5) Prior to publication of joint Guidelines, the manuscript will be posted on NASPGHAN and ESPGHAN websites for comments from membership of both societies.
 - 6) The *JPGN* Editor-in-Chief will make final editorial changes to the revised manuscript prior to anticipated publication.
 - 7) Publication in *JPGN* will take place without further peer review and the document will be acknowledged as having undergone peer validation and be the expressed position of NASPGHAN.

VII. Appeal process

If a societal manuscript proposal is rejected, the proposer of the topic (either within NASPGHAN or within ESPGHAN if a joint guideline) may appeal the decision by requesting an “appeal review”. In this case, the President will identify two reviewers from the NASPGHAN Executive Council. If the Council reviewers have a differing opinion from earlier recommendations, then a final consensus decision should be made by conference call between CCQ and Council.

VIII. NASPGHAN Endorsement of Guidelines Prepared by Other Societies

Periodically, NASPGHAN is contacted by other societies asking for endorsement of a manuscript under development. The decision to endorse another society’s manuscript

should be made by the NASPGHAN Executive Council, with consultation from the Chair(s) of relevant NASPGHAN committee(s) and CCQ Chair.

In general, NASPGHAN should only endorse other societal manuscripts if contacted during the early course of development of the manuscript and not after the manuscript's completion.

Criteria and procedure for endorsement of another society's manuscript:

- The document needs to be developed by a reputable society with a long track record of professional education. Examples include but are not limited to the American College of Gastroenterology, Crohn's and Colitis Foundation, American Association for the Study of Liver Diseases, and American Gastroenterological Association.
- At least one NASPGHAN member must participate in development and be an author of the document.
- The NASPGHAN President or designee must review the clinical practice guideline or position paper policy of the other society, to make sure it is similarly rigorous to the NASPGHAN process.
- The final document should be reviewed by 2 NASPGHAN members (a member of Executive Council, and a member of the relevant committee). The President or their designee will identify the reviewers.
- The reviewers will recommend that NASPGHAN endorse the document or decline to endorse.
- If both reviewers agree with endorsement, the NASPGHAN Executive Council must vote to provide final endorsement.
- The NASPGHAN President or designee (including NASPGHAN Executive Director) will contact the entity/person seeking endorsement, stating why NASPGHAN endorsed or declined to endorse the document.