

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 may authorize the development of new or revised clinical practice guidelines or related societal papers. A wealth of evolving clinical knowledge in pediatric gastroenterology, hepatology 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 will 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, an alternate peer-reviewed journal. Industry grants will not be utilized to fund guideline preparation.

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**. This has been changed from the previous list of options approved in 2003 which included guidelines, clinical reports, technical reports, committee and/or task force reports and policy statements. This has been streamlined to match the types of societal manuscripts of ESPGHAN and to encourage the production of joint societal manuscripts.

- 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. They should be developed using a methodology that meets the criteria of the Agency for Health Care Research and Quality for posting on 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 expert consensus. A position paper presents an extensive review of the state-of-the-art care for an important clinical topic. It is not prepared with the rigorous methodology applied to development of a Guideline. There are no or few recommendations although generally accepted best practices can be described. A position paper may also represent a report from a NASPGHAN committee, special interest group 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). In addition, a position paper 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.

III. Development and Approval Process

Proposals for all NASPGHAN societal manuscripts can be submitted to the CCQ Committee at any time. The CCQ Committee Chair will arrange for reviewers, with reviews completed typically within 4-6 weeks. The proposal and results of the reviews will be reviewed by the NASPGHAN Executive Council. Final approval of the proposal and writing committee must be approved by the NASPGHAN Executive Council. Such approval can either occur by email, conference call, or at the NASPGHAN in person leadership meetings.

- 1) **Topic Identification** - The individual with a proposal for a NASPGHAN or joint NASPGHAN/ESPGHAN societal manuscript is encouraged to contact the appropriate NASPGHAN committee chair (e.g. IBD, motility, hepatology) or Special Interest Group (SIG) with his/her idea. Topics should be pertinent and of high relevance for clinical practice, policy 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 usually not justify publication of a societal manuscript. The author, together with the NASPGHAN committee chair or SIG Chair for which the topic is relevant should then contact the NASPGHAN President or Chair of the Clinical Care and Quality (CCQ) Committee with the topic and suggested writing committee chair.
- 2) **Concept Proposal** - The author then submits their completed proposal on the submission form (Guideline or Position Paper) to the NASPGHAN National Office, which will then forward the proposal to the Chair of the CCQ Committee for review. Proposal forms are available on the NASPGHAN website or can be requested from the National Office.

The proposal must include the following information:

- **Manuscript Type** - Indication of type of societal manuscript (Guideline or Position Paper) which will determine the submission form used
- **Rationale for the Topic** - The initial proposal should include a brief rationale for the proposed societal manuscript. In determining the feasibility and desirability of this societal manuscript, favorable criteria may include, but not be limited to:
 - Common disorders for which the standard of care is poorly defined
 - Common problems with widespread clinical/social consequences
 - The availability of new diagnostic and/or new treatment modalities
 - Controversial, complex, and/or challenging diagnostic, treatment or policy issue
- **Proposed Writing Group Members** - Information should include name, affiliated institution, 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 2 to 7 additional members to be submitted to the CCQ Committee and NASPGHAN Council for approval. Members may include representation from subspecialties other than pediatric

gastroenterology, hepatology, nutrition, and transplantation, if appropriate, and individuals with expertise in general pediatrics, pediatric surgery, nursing, psychology, and epidemiology are encouraged whenever possible and reasonable. When a joint manuscript is being proposed, members of the writing group should be representative of both organizations. The writing group members should be acknowledged experts in the clinical area to be addressed.

- The writing group designated to author these documents are charged to review and recommend therapeutic and/or procedural protocols, as well as to present official NASPGHAN or joint NASPGHAN/ESPGHAN positions in areas that may impact standard-of-care and/or influence healthcare policy. These writing groups shall be constituted such that:
- Financial 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 Guideline or Position papers if they have conflicts.
- The Chair shall have no financial relationships with an affected company to disclose, where 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*.
- A majority of the writing group members 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.
- 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:
 1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
 2. Drafting the work or revising it critically for important intellectual content; AND
 3. Final approval of the version to be published; AND
 4. 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.

**See NASPGHAN Policy on Ethics –*

<http://www.naspghan.org/content/12/en/about/ethics-statements>

(If one is unsure what constitutes a significant industry tie, the member's disclosures should be reviewed by the NASPGHAN Ethics Committee.)

- **Outline** - Brief outline of the proposed societal manuscript.
- **Budget** - For most societal manuscripts, a limited budget (suggested amount under \$1,500 [USD], limited to conference calls and minor administrative assistance) should suffice. For Clinical Practice Guidelines, a higher budget may be necessary (suggested amount \$10,000, including travel and one face to face meeting), but this budget will be reviewed and must be approved by NASPGHAN Executive Council.
 - All expenditures must be submitted to the NASPGHAN National Office with receipts for approval and payment.

NASPGHAN societal papers - 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 of Proposal

- 1) The CCQ Chair identifies a minimum of 2 reviewers to assess the proposal. Reviewers identified by the CCQ Chair may be CCQ members, NASPGHAN council members, NASPGHAN committee or SIG members, or other experts in the field. Reviewers will be asked to evaluate the proposal on the merits of the importance of the topic, the need for guidance to NASPGHAN membership on the issue, scientific merits/grounds, as well as appropriateness of the requested societal manuscript to be a Clinical Practice Guideline (CPG) or Position Paper.
- 2) The identity of the reviewers will be kept confidential. Reviews will be forwarded back to the CCQ chair, with recommendations for approval or suggested feedback for revision. The authors can then either revise their proposal in accordance with the CCQ reviews, or decide not to proceed. Calls and emails between the Author and the CCQ Committee are permissible.
- 3) Once the CCQ has approved the proposal, the CCQ chair submits the recommendations for approval to the NASPGHAN National Office. The National Office will disseminate to the NASPGHAN Council for its consideration.
- 4) Clinical Practice Guidelines (CPGs) have wider impact, greater legal ramifications, and are more costly to the society. Therefore, in addition to initial review by CCQ, these proposals will undergo a second review by the NASPGHAN President and two Executive Council members. In addition to scientific merit, the budget and long term impact of the proposal will be assessed by the Executive Council. The NASPGHAN President will notify the authors of the final approval.

- 5) The NASPGHAN Executive Council shall review the Committee's recommendation and vote for final approval for the project. Review of the budget, secondary review (if needed), and approval of the proposal is the responsibility of the NASPGHAN Executive Council.

V. Instructions to Authors

A letter of approval will be sent to the selected Chair and members of the approved writing group by the NASPGHAN National Office signed by the Societal Manuscript Editor (SME). The letter will include the following information/instructions to the authors:

- 1) Instructions and links to complete conflict of interest disclosure
- 2) The suggested page length of a Position Paper is 15-20 double spaced typewritten pages (5-10 journal pages), with approximately 50-75 references. The suggested page length of a Clinical Practice Guideline is 20-30 double spaced typewritten pages (10-15 journal pages), with 50-150 references. 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.
- 3) 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...)
- 4) Timetable for Completion of NASPGHAN Societal Manuscripts: NASPGHAN societal manuscripts should be ideally published within 12 to 18 months of NASPGHAN Executive Council approval. The NASPGHAN National Office will periodically (3 months) request a status update from Principal Author. The NASPGHAN National Office will assist the CCQ chair and the SME in these tasks by keeping track of proposals and completed manuscripts.

VI. Peer review of NASPGHAN Societal Manuscripts

- 1) NASPGHAN Societal manuscripts are to be uploaded on the *JPGN* Editorial Manager platform when completed. The NASPGHAN National Office should be notified when the upload has been completed. Peer review of these societal manuscripts will be overseen by the Societal Manuscript Editor 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 and revisions and subsequent approval to move forward to *JPGN* publication.
- 2) The SME appoints a minimum of 2-3 reviewers for the manuscript. The reviewers will be known content experts in the field. 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. 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.
 - 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) The *JPGN* Editor-in-Chief will make final editorial changes to the revised manuscript prior anticipated impending publication
- 6) 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.
- 7) Prior to publication, Guidelines will be posted to NASPGHAN membership and ESPGHAN membership as well for joint guidelines.

VII. Appeal process

At times, the NASPGHAN leadership or CCQ committee may decide to reject a societal manuscript proposal on the basis of lack of importance, priority ranking for resource utilization, lack of evidence, or lack of scientific merit.

If the proposer of the topic (either within NASPGHAN or within ESPGHAN if a joint guideline) wishes to appeal the decision, they may request 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 the recommendation of the Clinical Care and Quality Committee, then a final consensus decision should be made by the Executive Council conference call.

VIII. NASPGHAN Endorsement of Guidelines Prepared by Other Societies

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

be made by the NASPGHAN Executive Council, with consultation from the Chair(s) of relevant NASPGHAN committee(s) or SIGs.

In general, NASPGHAN should only endorse guidelines if contacted during the course of development of the final manuscript.

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

- 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 needs to participate in development and author the document.
- The NASPGHAN President or designee needs to review the guideline 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 simply recommend that NASPGHAN endorse the document or to decline to endorse.
- If both reviewers agree with endorsing, the NASPGHAN Executive Council must vote to provide final endorsement.
- The NASPGHAN President or designee contacts the appropriate medical contact in the other society, stating why NASPGHAN endorsed or declined to endorse the document. The Executive Director of NASPGHAN can formally notify the other society of the Executive Council's decision