

**Manual of Operations
NASPGHAN Societal Manuscripts
Table of Contents**

Section I - Introduction	2
Section II – Definition of Societal Manuscripts	2
Section III – Development Process	4
Section IV – Proposal Submission Process	4
Manuscript Proposal Requirements	4
1. Manuscript Type	4
2. Writing Group Composition	5
3. Outline and Rationale	5
4. Methodology	6
5. Budget	6
6. Financial Conflict of Interest	6
Section V - Review and Approval Process	7
Section VI - Appeal Process	8
Section VII - Instructions to Authors	
Manuscript Length	8
Electronic Appendices	8
Title Requirement	8
Timetable for Completion	8
Section VIII - Peer Review of Societal Manuscripts	9
Section IX - NASPGHAN Endorsement of Guidelines Prepared by Other Societies	10



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 NASPGHAN societal manuscripts. A wealth of evolving clinical knowledge 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. As appropriate, collaboration with the European Society of Pediatric Gastroenterology, Hepatology and Nutrition is encouraged to generate joint NASPGHAN/ESPGHAN societal manuscripts.

All published societal manuscripts officially developed by or endorsed by NASPGHAN must conform to rigorous standards and follow a well-defined review and approval process. Publication will occur solely in the *Journal of Pediatric Gastroenterology and Nutrition (JPGN)* or, with prior approval of NASPGHAN Council, an alternate peer-reviewed journal. No industry or institutional funds, including grants, may be used at any stage in the preparation, authorship, or development of NASPGHAN societal manuscripts.

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: **Practice Guidelines** and **Position Statements**. Proposals submitted for other society-endorsed papers will not be considered.

1) **Practice Guideline:**

- A Practice Guideline is a scientific-based decision-making tool that was originally defined in 2011 by the Institute of Medicine (now called National Academy of Medicine) to address specific clinical research questions and that abides by most rules of evidence-based medicine for guideline development (www.ncbi.nlm.nih.gov/books/NBK209538/).

Best practices for NASPGHAN Practice Guideline development include a thorough systematic literature review, synthesis of the evidence, data analysis, formalized consensus development, recommendations and algorithms to facilitate implementation and internal and external critique.

- Current best practices in guideline development encourage the use of:
 - * PICO (Population-Intervention-Comparator-Outcome) questions (<https://training.cochrane.org/handbook/current/chapter-03>).

- * [Appraisal for Guidelines REsearch Evaluation \(AGREE\) II checklist](#), to ensure a structured and rigorous development methodology. The use of specific frameworks such as AGREE II also provides the potential for NASPGHAN and others to conduct internal assessments that ensure that guidelines are methodologically sound and to evaluate guidelines from other groups for potential adaptation to their own context.
- “Grading of Recommendations Assessment, Development and Evaluation” (GRADE) methodology (<https://www.gradeworkinggroup.org/>).
- *Additional information on the development and construction of a practice guideline is described in the document “Guidance for development of NASPGHAN practice guidelines”. This guidance is available on the NASPGHAN website, or can be sent to authors upon request by emailing the guidelines editor or the chair of the Clinical Care and Quality committee.*

2) **Position Statement**

- Position Statements are developed to guide clinicians in practice with respect to a topic for which there may be insufficient evidence to develop a Practice Guideline.
- Position Statements are meant to be documents based on existing literature, data, and experience by recognized experts in the field that will likely have sustained relevance over five years.
- Position Statements may be prepared with a less rigorous methodology than applied to the development of a Practice Guideline, but a clear methodology must be described. A clear methodology for impartially determining expert consensus across the writing group will all be utilized to inform its writing. In particular, a clear process (i.e. Delphi and/or modified Delphi technique) for establishing expert consensus on statements and recommendations with interactive electronic voting on recommendations, will be encouraged.
<https://www.rand.org/topics/delphi-method.html>;
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2550437/>
- Position Statements should have no or few specific recommendations, although authors can describe generally accepted “Best Practices”.
- Position Statements may also represent a report from a NASPGHAN committee, 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 e.g. Aerodigestive Center components or Pediatric Endoscopy services).
- Position Statements 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.

Please note: If a Position Statement or Practice Guideline is not accepted by NASPGHAN Council and/or the Clinical Care and Quality (CCQ) Committee for completion, some suitable manuscripts could be considered as a Review Articles for *JPGN*. Rejection of a proposal for a Position Statement to NASPGHAN Council may be based on, but not limited to reviews of lack of clinical impact, lack of significant quality evidence, concerns for a topic that is too heavily based on expert opinion, etc.

III. Development Process

1) Topic Identification for NASPGHAN societal manuscripts. Proposed topics should:

- Be pertinent and highly relevant and address key issues in clinical practice, policy, advocacy, or research, with the goal of reaching evidence-based conclusions that inform practice.
- Be justified. – Provide new insights rather than duplicate previously published information, unless an update is urgently needed due to new data.
- Be sponsored by a NASPGHAN Committee. Proposals from Special Interest Groups (SIGs) or individual NASPGHAN members must include a letter of sponsorship from the relevant NASPGHAN committee. Sponsorship entails, at a minimum:
 - * The Committee Chair participating in discussions about authorship, recommendations and responses to all reviews (both independent and from NASPGHAN Council).
 - * Support in navigating any sensitive issues or challenges that arise during manuscript development.
- Be discussed with the CCQ Chair. If the proposed topic does not clearly align with the domain of a specific NASPGHAN committee, the proposer should consult the Chair of the CCQ Committee. Additional input may be sought from NASPGHAN leadership, including the JPGN Editor or NASPGHAN Council committee liaison.

IV. Proposal Submission Process

IMPORTANT: All proposals for societal manuscripts need formal review and approval by the Clinical Care and Quality (CCQ) Committee and NASPGHAN Council before work on the manuscript begins. The submission of previously drafted manuscripts will be rejected for review as a societal paper.

Components of a Societal Manuscript Proposal:

A proposal for a NASPGHAN societal manuscript must include the following information:

1. Manuscript Type

- Indicate whether the manuscript is a **Practice Guideline** or a **Position Statement**. This designation determines the appropriate submission form and approval process.

2. Proposed Writing Group Members

For each proposed Writing Group member:

- Name
- Affiliated institution
- One-line description of area of expertise
- Expected contribution to the manuscript
- Conflict of interest disclosures

- Relevant equity, diversity, and inclusion (EDI) considerations

Writing Group Composition Guidelines

- **Practice Guidelines:** 11-13 authors.
- **Position Statements:** 8-9 authors.
- Must include a **Writing Group Lead** (either first or last author) and recognized experts in the field.
- Include representation from relevant disciplines beyond pediatric gastroenterology, hepatology, nutrition, and transplantation (e.g., general pediatrics, pediatric surgery, nursing, psychology, epidemiology) when applicable
- Patient representatives are strongly encouraged for Practice Guidelines (per AGREE II framework)
- Fellows may NOT be included
- Joint societal manuscripts (e.g., ESPGHAN) must have equitable organizational representation
- Writing Groups should reflect geographic, gender, and -where feasible - racial and ethnic diversity. Specific attention to including at least one author from Canada and/or Mexico.
- Limit **one author per institution** (*exceptions must be justified and pre-approved by the CCQ Committee and the NASPGHAN Council*).
- Clinical Practice Guidelines must include at least one coauthor who is a GRADE-trained methodologist.

Authorship Justification

All Writing Group members must meet ICMJE authorship guidelines:

- Substantial contributions to the conception/design of the work or acquisition, analysis, or interpretation of data and,
- Drafting or revising the work critically for important intellectual content and,
- Final approval of the version to be published and,
- Accountability for all aspects of the work

Once the proposal is accepted by the NASPGHAN Executive Council, no changes to authorship are permitted after proposal approval, unless a written request is submitted and approved by both the CCQ Committee and the NASPGHAN Executive Council.

3. Outline and Rationale for the Topic

The proposal should include a **brief rationale (1-2 pages)** outlining the manuscript's significance, including:

- Common disorders with undefined standards of care
- Problems with widespread clinical/social consequences
- New diagnostic/treatment modalities
- Controversial, complex, or challenging diagnostic, treatment, or policy issues
- Practice Guidelines must include clinical questions formulated in g PICO format (Patient/Intervention/Comparison/Outcome)

4. Methodology

Describe the planned methodology, including:

- Literature search strategy
- Evidence summary
- Quality appraisal process
- Recommendation development and strength assessment/rating process

5. Budget

- NASPGHAN societal manuscripts should require minimal funding.
- Virtual meetings (e.g., Zoom) are expected; **in-person meetings are not funded.**
- NASPGHAN issues an annual Request for Applications (RFA); number of accepted proposals depends on budget allocation.
- Practice Guidelines must include at least one coauthor who is a GRADE-trained methodologist.
- Funding requests must be pre-justified in advance and approved by NASPGHAN Executive Council.
- NASPGHAN is the primary funding source; exceptions for support from non-profit, non-institutional organizations only.
- Funding from single institutions (e.g., hospitals, universities) is NOT permitted.

6. Financial Conflict of Interest: In order to preserve the society's integrity, while balancing unnecessary restrictions on participation in societal papers, NASPGHAN has developed the following requirements on disclosure of potential conflict of interest.

- a) All financial and other relationships of the writing group members with an affected company in the past 12 months, shall be disclosed to NASPGHAN at the time of submission of the proposal and yearly thereafter for the duration of the workgroup activities. 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.
- b) No NASPGHAN member of the writing group, nor their immediate family members, shall have a financial relationship in excess of \$5000 USD with an affected company (as outlined in Section 6 a) that requires disclosure. Financial relationships include employment, ownership, speaking fees, honoraria, consulting fees, or any other direct payments to the writing group member or their immediate family (spouse and dependent children). This does not include investment vehicles such as mutual funds where the member or family has no control over the selection of the holdings, or research grants in any amount paid to the writing group member's institution, although research grants should still be disclosed.
- c) All members of the writing group agree to not accept new speaking engagements or consulting arrangements for which an honorarium is paid by an affected company (or a direct intermediary) with interest pertinent to the scope of the societal paper, during the writing group activities until 12 months after manuscript publication date.
- d) If one is unsure what constitutes an affected company, or a prohibitive financial relationship, or if non-financial ties may be perceived as problematic, the member's disclosures should be reviewed by the NASPGHAN Ethics Committee.

- e) Although the preference for NASPGHAN is that no member has a financial conflict of interest above \$5000 USD in a 12 month period, in certain circumstances a Writing Group may not be able to perform its work without members who have conflicts of interest. In that case, the Ethics Committee will be consulted about appropriateness of inclusion of this member and suggest a management plan for the conflict of interest. NASPGHAN retains the right to deny appointment to the Writing Group in such cases. The Lead of the Writing Group, should never have a prohibitive financial relationship with an affected company.
- f) Disclosures require Writing Group members to certify that they have reviewed and disclosed relevant information (i.e. previous twelve months) reported on their most recent CMS.gov Open Payments Report.
- g) Conflict of interest disclosures of all members of the writing group including the Lead **must be submitted at time of proposal submission to the CCQ committee, and annually thereafter until one year after publication date.** Changes in COI, should be reported within 30 days to the CCQ committee. Members of CCQ should recuse themselves from any discussion or decisions about development of societal papers if they have financial conflicts.
(<https://naspghan.org/professional-resources/clinical-guidelines/>)
- h) Funders should have no role in guidelines development.
- i) Writing Group Leads should start every meeting with a disclosure of all members financial and other relationships with affected companies and any management plans.

Also see [NASPGHAN COI Policy: \(www.naspghan.org/files/documents/pdfs/policies/Final%20COI.pdf\)](http://www.naspghan.org/files/documents/pdfs/policies/Final%20COI.pdf)

Submission

- The Writing Group Lead should submit their proposal through [the online submission portal](#). The National Office will then forward the proposal to the Chair of the CCQ Committee for review.

V. Proposal Review and Approval Process

- The CCQ Chair assigns at least two confidential reviewers to evaluate the proposal (typically within 4-6 weeks).
- The CCQ Committee provides a composite review with recommending revision, rejection, or advancement to the NASPGHAN Council. If revisions are suggested, 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).
- The NASPGHAN Council reviews the proposal (via email, conference call, or in-person) and issues a decision (approval, rejection, or request for revisions).
- Practice Guidelines undergo an additional review by the NASPGHAN President and two Executive Council members before full Executive Council review.
- The NASPGHAN Executive Council conducts a final review and vote.
- Approved proposals receive a letter from the NASPGHAN President and JPGN Section Editor for Societal Papers (SESP) including the instructions to authors.

Once a proposal has been accepted by the NASPGHAN Executive Council, no changes shall be made without written approval from the NASPGHAN Executive Council. 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.

VI. Appeal process for Non-Approved Proposals

At times, the NASPGHAN leadership or CCQ committee may 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 earlier recommendations, then a final consensus decision should be made by conference call between CCQ committee and Executive Council.

VII. Societal Manuscript Instructions to Authors

1. Societal Manuscript Length:

- Position Statements: 4,000 words (not including 50-75 references)
- Practice Guidelines: 4,000-5,000 words (not including 50-150 references).

2. Electronic appendices which can be published on line at the time of publication are encouraged for additional methodology details.

The authors must notify the President, the SESP and the Editor-in-Chief if they anticipate the societal manuscript will exceed these limits.

3. Title Requirement: All NASPGHAN-endorsed manuscripts must include NASPGHAN in the title (e.g., “NASPGHAN Practice Guideline on...”).

4. Timetable for Completion of Societal Manuscripts:

- Completed NASPGHAN societal manuscripts should be uploaded on the *JPGN* Editorial Manager platform (<https://www.editorialmanager.com/jpgn/default.aspx>) by the lead author.
- The [NASPGHAN National Office should be notified](#) when the upload has been completed.
- Position Statements: Submitted within 12 months of approval.
- Practice Guidelines: Submitted within 18 months of approval.
- The NASPGHAN National Office will track progress and request updates every 3 months.

Extensions require a written update and Executive Council approval.

Summary of Key Differences

Feature		Practice Guidelines	Position Statements
Author Count		11-13 authors	8-9 authors
Patient Representatives		Encouraged (AGREE II)	Optional
ICMJE Authorship Required		Yes	Yes
PICO Format Required		Yes	No
GRADE-Trained Methodologist Required		Yes	No
Secondary Executive Review		Yes	No
Word Count		4,000-5,000	4,000
Reference Range		50-150	50-75
Submission Deadline		18 months	12 months

VIII. Peer review of NASPGHAN Societal Manuscripts

Oversight: The JPGN Section Editor for Societal Papers (SESP), in consultation with the NASPGHAN President, manages the peer review process, appointing reviewers, communicating with authors, and determining when the manuscript is ready for NASPGHAN Executive Council review.

Reviewer Selection:

- The SESP appoints 2–3 expert reviewers, who may not be Council members.
- If the SESP is involved in manuscript development (e.g., committee chair, co-author), an alternate SESP is designated by the President and JPGN Editor-in-Chief.
- Reviewer identities remain confidential.

Review Timeline and Process

- The **JPGN Editorial Manager** tracks manuscript review timelines, following standard JPGN submission practices.
- Reviews should ideally be completed within **two weeks**, though extensions may be granted at the SESP's discretion.
- Manuscripts typically undergo **two rounds of revisions** before final review by the NASPGHAN Executive Council and JPGN Editor-in-Chief.

Additional Review & Public Feedback:

- Per **AGREE II guidelines**, NASPGHAN guidelines are posted on the NASPGHAN website for member comments before publication.
- **Joint manuscripts** undergo an extra review by **NASPGHAN and ESPGHAN Executive Councils** after the first peer review round.
- Before publication, joint guidelines are posted on both NASPGHAN and ESPGHAN websites for further member input.

Final Steps & JPGN Publication:

- The **JPGN Editor-in-Chief** makes final editorial adjustments.
- The manuscript is published in **JPGN without further peer review**, acknowledged as peer-validated, and representing NASPGHAN's official position.
- 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 SESP.
- 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.
 - 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.
- The *JPGN* Editor-in-Chief will make final editorial changes to the revised manuscript prior anticipated impending publication
- 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.

IX. NASPGHAN Endorsement of Guidelines Prepared by Other Societies

NASPGHAN is periodically invited by other societies to endorse a manuscript under development. Endorsement decisions are made by the NASPGHAN Executive Council, in consultation with the Chair(s) of relevant NASPGHAN committee(s) and the NASPGHAN CCQ Chair.

As a general principle, NASPGHAN should only consider endorsement when approached early in the manuscript development process, not after the document is finalized.

Endorsement Criteria and procedure:

- The document must be developed by a reputable professional society with a strong track record in professional education and guideline development. 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 serve as an author on the document.
- The NASPGHAN President or designee must review the originating society's guideline development policy to ensure it meets standards comparable to NASPGHAN's 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 endorsement or non-endorsement.

- If both reviewers agree with endorsement, the NASPGHAN Executive Council must vote to provide final endorsement.
- The NASPGHAN President or designee (which may include the NASPGHAN Executive Director) will contact the requesting society of NASPGHAN's final decision and rationale.

This Manual of Operations is updated as of March 2025 by Drs. Joseph Picoraro, Athos Bousvaros, Vicky Ng (NASPGHAN President), NASPGHAN guideline task force (appendix 1) and Margaret Stallings. Prior versions of this document (Dr. Melanie Greifer – October 2020, Revised by Dr. Athos Bousvaros 9/5/2021).

Appendix 1 – NASPGHAN Guideline Task Force 2024-2045

Chair: Joseph Picoraro, Columbia University Medical Center, New York, New York

Athos Bousvaros, Boston Children's Hospital

Ben Gold – Children's Healthcare of Atlanta

Sandeep Gupta – University of Alabama at Birmingham

Jeannie Huang – Rady Children's Hospital, San Diego

Ammer Imdad – Stead Children's Hospital, University of Iowa

Jenifer Lightdale, Boston Children's Hospital

Jonathan Moses – Stanford Medicine Children's Health

Vicky Ng – Hospital for Sick Children, Toronto, Ontario

Sharon Tam – Lurie Children's Hospital, Chicago

Catharine Walsh – Hospital for Sick Children, Toronto Ontario

Margaret Stallings, NASPGHAN Executive Director