

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.

The manual of operations (MOO) further outlines the precise mechanisms by which:

1. A proposal is submitted to NASPGHAN, reviewed by the Clinical Care and Quality Committee, and approved by Council.
2. How completed manuscripts undergo peer review and NASPGHAN Executive Council approval prior to publication in *JPGN*
3. How published societal manuscripts are periodically reviewed by the NASPGHAN Clinical Care and Quality (CCQ) Committee.
4. NASPGHAN endorsement of guidelines prepared by other societies
5. The process for development of joint NASPGHAN/ESPGHAN societal manuscripts.

II. 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 societal manuscript is encouraged to contact the appropriate NASPGHAN committee chair (e.g. IBD, motility, hepatology) with their idea. The author, together with the NASPGHAN committee chair 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 NASPGHAN Official Statement proposal form (Appendix A) to the NASPGHAN National Office, which will

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:

1. **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
2. **Proposed Writing Group Members** - Information should include affiliated institution, one line on area of expertise and expected contribution of each writing group member to the societal manuscript.

Writing groups will consist of a Chair and 2 to 7 additional members and will 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 and epidemiology are encouraged whenever possible and reasonable. The writing group members are to be acknowledged experts in the clinical area to be pursued.

The committees 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 committees shall be constituted such that:

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

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.

3. **Outline** - Brief outline of the proposed societal manuscript.
4. **Manuscript Type** - Indication of type of societal manuscript (i.e. Clinical Practice Guideline, Clinical Report, etc)

5. **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 formal 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 closely scrutinized by NASPGHAN Executive Council.

All expenditures must be submitted to the NASPGHAN National Office with receipts for approval and payment.

III. Review of Proposal

1. The CCQ Chair identifies at least 2 reviewers to assess the proposal (Appendix B - "Reviewer Form for Application for NASPGHAN Official Statement"). Reviewers identified by the CCQ Chair may be CCQ members, NASPGHAN council 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 one of a Clinical Practice Guideline (CPG), clinical report, or other.
2. The identity of the reviewers will be kept confidential. Reviews should 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.

IV. Instructions to Authors

A letter of approval will be sent to the selected Chair and members of the approved writing group (Appendix C) 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 Clinical Report 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. The NASPGHAN Guideline..., The NASPGHAN xx Committee Clinical Report 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.

V. 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 SME who (in consultation with the NASPGHAN President) oversees the peer review process by appointing peer reviewers, communicates with the guideline 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 2-3 reviewers for the manuscript. The reviewers are most commonly 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 *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 two 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.
5. The *JPGN* Editor-in-Chief will make final editorial changes to the manuscript at this time in anticipation of impending publication

6. Brief society position statements should be reviewed by three individuals: the president, president-elect, and one member of Executive Council chosen by the president. If all three recommend approval without revision, the statement is considered approved by Executive Council and submitted to the *JPGN*.

Following NASPGHAN Executive Council approval, the document may be sent to external societies interested in endorsing it.

7. Publication in the *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.
- VI. **Tracking of published guidelines** will be done by the CCQ Committee. This committee will perform an annual review and evaluation of the published NASPGHAN guidelines and clinical reports, beginning three years after publication. The committee will suggest whether they should be allowed to stand as is, be revised, or retired.
- 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, either 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 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 as to whether or not to endorse another society’s guideline should be made by the NASPGHAN Executive Council, with consultation from the Chair of relevant NASPGHAN committees.

In general, NASPGHAN should only endorse guidelines if contacted prior to the time the final manuscript is written. The correspondence between the other society and NASPGHAN should be saved by the Executive Director or their designee, and the date of correspondence logged in the guideline tracking sheet.

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

1. 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 of America, Infectious Disease Society of America and American Association for the Study of Liver Diseases. (e.g. AASLD, CCFA, AGA, etc).
2. At least one NASPGHAN member needs to have been a coauthor on the document.

3. 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.
4. 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.
5. The reviewers will simply recommend that NASPGHAN endorse the document or to decline to endorse.
6. If both reviewers agree with endorsing, the NASPGHAN Executive Council must vote to provide final endorsement.
7. 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.



Application for a New NASPGHAN Official Statement Proposal

Date:

Name of Proposer:

Affiliated NASPGHAN Committee:

Date idea discussed with NASPGHAN President/CCQ Committee Chair:

1. Proposed Title:

2. Rationale for the Topic:

3. Writing Group Members:

Please list the names of proposed writing group members, affiliated institution, and include one line on area of expertise and expected contribution of each writing group member to the written document. All members of the writing group must complete conflict of interest disclosure information before work on the document is started (see NASPGHAN Policy of Conflict of Interest Policy). Please See Attachment A for summary of requirements regarding writing groups.

4. Please indicate which of the following you would envision for your proposed idea:

☐ Clinical Practice Guideline

☐ Clinical Report

☐ Consensus Statement

☐ Position Statement

☐ Technical Report

☐ Other (please elaborate):

5. Brief outline of the proposed manuscript:

6. Please provide a brief Budget Proposal

For most societal manuscripts, a limited budget (suggested amount under \$1,500 [USD], limited to conference calls and minor administrative assistance) should suffice. For formal 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 closely scrutinized by NASPGHAN Executive Council. All expenditures must be submitted to the NASPGHAN National Office with receipts for approval and payment.

*Attachment A

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

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

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

For potential or standing committee members, financial disclosures in Category III under Criteria 1, 3 and 4, above, as well as disclosures under Criteria 5 may represent disqualifying conflicts of interest. Pending review by the COI Subcommittee, such relationships may prohibit these individuals from proposed or continued participation in the preparation of Clinical Practice Guidelines, Position Statement, Clinical and Technical Reports. Disclosure of individual-industry associations is not a static process, and must be reported on an ongoing basis before and during the development and generation of all guidelines and reports. This disclosure protocol shall follow the reporting algorithm: (see <http://www.naspghan.org/files/documents/pdfs/policies/COI%20flowchart.pdf>)

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



CCQ Proposal Review

Title of Proposal:

Review Date:

Type of Report:

- ☐ Clinical Practice Guideline
- ☐ Clinical Report
- ☐ Consensus Statement
- ☐ Position Statement
- ☐ Technical Report
- ☐ Other (please elaborate):

Author:

Budget:

Conflicts of Interest:

Suggested Response:

- ☐ Approval:
- ☐ Approval with conditions/suggestions:

1.

2.

3.

☐ Denial:

Reasons:

1.

2.

3.