CASL Guidelines Development and Endorsement Policy

1.0 Purpose of this document

The field of Hepatology is dynamic and constantly evolving as new scientific evidence emerges that may substantially impact best practices in the delivery of patient care to Canadians living with liver disease. The Canadian Association for the Study of the Liver (CASL) Executive - or their designates on the CASL Guidelines Committee - therefore may authorize the development of new or revised clinical practice guidelines or related CASL documents. The wealth of evolving clinical knowledge in the fields of both adult and pediatric hepatology necessitates that CASL regularly consider subject matter that may be appropriate for the creation of documents bearing the CASL name.

All published manuscripts officially developed or endorsed by CASL will conform to a well-defined review and approval process. Publication will occur in peer-reviewed journals which may include an official journal of CASL. Industry grants will not be utilized to directly fund guideline preparation and membership of the document working groups will aim to minimize any potential or perceived conflicts of interest. This current document defines how these endorsed manuscripts shall be proposed, budgeted, approved, developed, reviewed, and revised.

2.0 What types of CASL manuscripts will be considered:

2.1 *Clinical practice guideline*: A clinical practice guideline is a scientific-based decision-making tool that addresses specific clinical questions and abides by the rules of evidence-based medicine for guideline development. They should be developed using 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. It is strongly advised that working groups incorporate a checklist for best practices in clinical practice guidelines (i.e. AGREE, RIGHT, CheckUp checklists) in the development of their document, which are available at www.equator-network.org.

2.2 *Position paper or guidance document*: A position paper or guidance document is a CASL manuscript that addresses a topic for which guidance is necessary but due to limited scientific evidence, the recommendations are based mostly on expert consensus. A position paper presents an extensive review of a clinical problem and the available literature for an important clinical topic where high levels of scientific evidence are not available. It is not prepared with the rigorous methodology applied to development of a clinical practice guideline due to the lack of extensive scientific

evidence. There are no or few specific recommendations although generally accepted best practices can be described and are encouraged.

2.3 *Canadian Context and Impact Statement on International Guidelines*: Frequently, comprehensive international guidelines are written that would conform to CASL CPG methodologies. Duplicating all this effort at a national level is not always necessary, but there may be a benefit to an evidence-informed statement on the impact of the guidelines on Canadian practice (considering, for example, Canadian sociopolitical factors, funding environment) with appropriate context given. These statements can be brief but should include clear recommendations for Canadian healthcare providers.

2.4 Update to previously published CASL-endorsed Guideline: It is assumed that previously endorsed and published guidelines will require an update once either a certain period has passed where anther review/update of the data is required (ie: every 5 years) or when there is a significant advance in disease management that should be incorporated into guidelines. In this instance, as opposed to drafting an entirely new guideline, the working group may choose to provide an update to a previous CASL guideline which focuses on: 1) changes to existing guidelines statement(s) and/or 2) addition of new key questions.

3.0. Development and approval process for proposed CASL endorsed documents

3.1 *Topic identification*: Topics should be pertinent and of high relevance for clinical practice, policy, or research in the field of hepatology 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 CASL manuscript unless substantial important new evidence has been published on the topic since the last guideline publication or there is specific relevance to the Canadian context.

3.2 *Document proposal*: Any CASL member may submit a proposed topic to be considered by the CASL Guidelines Committee and Executive. Proposals are required to include a copy of the current application form and a summary which includes the following information:

1) *Manuscript type* - Indication of type of manuscript as per Section 2.0 above
2) *Rationale for the topic* - The initial proposal should include a brief rationale for the proposed manuscript. In determining the feasibility and desirability of the manuscript, favourable criteria may include, but not be limited to:
    a. Common disorders for which the standard of care is poorly defined;
    b. Common problems with widespread clinical/social consequences;
    c. The availability of new diagnostic and/or new treatment modalities;

d. Controversial, complex, and/or challenging diagnostic, treatment, or policy issues;
e. If guideline documents from societies outside of CASL have been published on the same/similar topic, how the working group will address aspects of particular importance/relevance to Canadians (which may not have been addressed in previous work) should be highlighted.

3.3 *Proposed working group members*: Along with the topic proposal summary, proposed members of the writing group must be identified and submitted for review. Writing groups should consist of a Chair and 2 to 7 additional members to be submitted to the CASL Guidelines Committee for review and approval, with final approval provided by the CASL Executive.

Members should include representation from subspecialties comprising the target audience of the guidelines, methodology experts if necessary, and patient partners. Furthermore, writing committees should be proposed that are diverse based on ethnocultural identities, geography, gender, disability and sexual identity where possible.

Each individual writing group member should have expertise that will contribute to the effort and justification for inclusion of each member should be outlined in the proposal.

Where a member of the CASL Guidelines Committee or Executive is proposed as a working group member or Chair, they shall recuse themselves from all review and decisions regarding the proposal, as well as the final review of the document manuscript prior to approval of endorsement and publication.

3.3.1 *Conflicts of interest of the working group members*. The writing group designated to author these documents is charged to review and recommend therapeutic and/or procedural protocols in areas that may impact standard-of-care and/or influence healthcare policy. If it is not possible to confirm a Chair with no conflicts, Guidelines Working Groups may propose co-chairs, where at least one of the co-chairs shall have no conflicts. These writing groups shall be constituted such that:

a. Financial disclosures from the last two years of all members of the writing group including the Chair must be submitted at time of proposal submission to the committee, using the standard CASL Conflict of Interest Disclosure Form. Members of the CASL Guidelines Committee and CASL Executive must recuse themselves from any decisions about the development of a Guideline or Position Paper if they have conflicts.

b. The working group Chair shall have no direct financial relationships to disclose with an affected company, 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 CASL-sponsored guideline or recommendation.
c. It is strongly recommended that the majority (>50%) of the writing group members have no direct and significant financial relationships with an affected company to disclose, in the judgement of the Guidelines Committee. If more than 50% of the members of the writing group have identified conflicts of interest in their disclosure, it shall be left to the discretion of the Guidelines Committee to determine whether the potential or real conflicts could reasonably be perceived to impact document recommendations, and therefore provide an exemption or request that the composition of the proposed working group be revised to meet this requirement.
d. All decisions rendered by the committee that impact clinical management recommendations should ideally be approved only upon receipt of a supermajority vote (>67%) of committee members. When a supermajority vote is not able to be obtained, the dissenting minority opinion should be outlined and discussed in the document.
e. The author numbers above are for proposal writers to be considerate of and be able to justify International Committee of Medical Journal Editors (ICJME) authorship guidelines. Guidelines and position papers involve contributions to conception of idea, design of paper, review of existing data, important intellectual work etc. 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.

3.4 *Budget/in-kind support*: A proposed budget for development and publication of the document, and request for in-kind support from CASL to a maximum of $10,000 per document, must be included in the proposal. Acceptable expenses include costs relating to writing group meetings, writing or editing services, open access publication costs or other similar expenditures. Direct financial support from industry partners will not be permitted for any aspect of document development or publication including travel or accommodations, nor is any in-kind support from

industry permitted, including the provision of medical writing assistance, research, or other administrative support.

4.0 Submission of the proposal to CASL for review

4.1 *Step 1: Review of the proposal by the CASL Guidelines Committee*. Proposals for CASL manuscripts may be submitted to the Guidelines Committee twice per year, with submission deadlines of April 30th and October 31st. The CASL Guidelines Committee Chair will review the proposed documents and send it out to three members of the Guidelines Committee for review and comments, with feedback completed typically within 4 weeks.

The reviewers will be asked to specifically evaluate the proposal on the merits of:

1) importance of the topic;
2) the need for guidance to membership on the issue;
3) scientific merits/grounds; and
4) appropriateness of the requested manuscript to be a Clinical Practice Guideline or Position Paper.

The identity of the reviewers will be kept confidential. Reviews will be forwarded back to the Guidelines Committee Chair, with recommendations for approval or suggested feedback for a revision. If there is significant disagreement/concern within the Guidelines Committee membership regarding the appropriateness of the proposal for endorsement by CASL, the Guidelines Committee Chair will make the final recommendation.

If a revision is requested, the authors can then either revise their proposal in accordance with the reviews or decide not to proceed. Calls and emails between the working group Chair and the Guidelines Committee Chair are permissible.

4.2 *Step 2: Review of the proposal by the CASL Executive*. Once the proposal has been approved by the Guidelines Committee, the proposal and results of the confidential reviews by the Guidelines Committee will be evaluated by the CASL Executive. The CASL Executive shall review the Committee's recommendation and vote for final approval for the project, including the proposal and members of the working group. Such approval can either occur by email, conference/virtual call, or at the in-person leadership meetings.

4.3 *Step 3: Notification of Proposal Approval.* A letter of approval of the proposed document will be sent to the identified working group Chair and members of the approved writing group by the CASL Office signed by the Guidelines Committee Chair. The letter will include the following information/instructions to the authors:

1) Instructions and links to update conflict of interest disclosures for the Chair and all writing group members.
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.
3) All manuscripts endorsed by CASL should include the Society name in the title. (i.e. CASL Clinical Practice Guideline…, The CASL XX Committee Position Paper on…)
4) Timetable for Completion of CASL Manuscripts: CASL manuscripts should be ideally published within 12 to 18 months of approval. The CASL Office will periodically (3 months) request a status update from working group Chair. The Office will assist the Guidelines Chair in these tasks by keeping track of proposals and completed manuscripts.

5.0 Proposal appeal process

At times, the CASL Guidelines Committee or Executive may decide to reject a CASL manuscript proposal based on lack of importance, priority ranking for resource utilization, lack of evidence, or lack of scientific merit. If the proposer wishes to appeal the decision, they can request an appeal review. In such a case, the CASL President will identify 2 reviewers from the CASL Board of Directors and their decision will be final.

6.0 Final document submission and approval

Once the working group has completed the final document, the working group Chair shall submit it to the CASL Office for the following review stages:

6.1) Review of the final draft document by the Guidelines Committee;

6.2) Request for Community input, via the CASL Community Advisory Board or other similar body, which will be provided with 4 weeks to review the document and provide comments;

6.3) Simultaneously with 6.2), Request for CASL Member Commentary: the CASL Office will facilitate sending the document to the CASL membership for commentary at the same time that community input is sought from the Community Advisory Board. The membership will be provided with 4 weeks to review the document and provide comments. Following community and member review, all comments will be anonymized, collated and sent back to the working group Chair for consideration of incorporation.

6.4) Before the document is submitted for peer review and publication, and after any recommended member or Guidelines Committee revisions are incorporated, the CASL Executive will be provided with a copy of the final document for review and approval of CASL endorsement.