ISHLT DOCUMENT DEVELOPMENT POLICIES

TYPES OF DOCUMENTS

- **Professional Guidelines**
  Documents that include strategies, information, and specific, graded recommendations that assist physicians and other healthcare practitioners in making decisions about appropriate measures of care for specific clinical circumstances. Guidelines must include the following components:

  - A comprehensive literature review and expert opinion which provides the evidence for graded recommendations.

  - Specific recommendations which include a formal grading based on the quality of available evidence; such grading formulations to include an evaluation of benefits, harms, burdens, and costs.

- **Consensus Documents**
  Documents that summarize available information and supply general recommendations on complex or controversial areas of patient care. Consensus Documents must include the following components:

  - A comprehensive literature review and expert opinion which provide the evidence for general recommendations.

  - Consensus documents do NOT include individual recommendations that are graded by quality of available evidence.

- **Health Policy Guidance Statements**
  Documents that present ISHLT guidance and/or positions on ethics, public health issues, and the like. Health Policy Guidance Statements are generally developed on topics that required a timely response from the Society.

- **Other Documents**

IDENTIFICATION OF NEED

Professional Guidelines & Consensus Documents

A. In **March** of every other year, ISHLT Staff and the Standards & Guidelines (S&G) Committee will develop the following:

  - A list of the existing and in-development ISHLT Documents, including those in which ISHLT is a joint collaborator or endorser.

- A list of existing and in-development Professional Guidelines and Consensus Documents promulgated by other relevant organizations and in which ISHLT is not involved.
- An assessment of these documents in terms of their relevance to each of the ISHLT Professional Communities and Interdisciplinary Networks.
- An assessment of these document in terms of their relevance from a national or international perspective (international relevance is strongly preferred).
- An assessment of these documents in terms their need for revision to reflect recent changes in practice.
- An assessment of these documents in terms of any areas of overlap and or disagreement between ISHLT documents and those of other organizations.

B. The S&G Committee will issue a request in **June** of every other year to the Professional Community (PC) Leadership to solicit ideas from the full PC and create two lists identifying:

- Any areas of practice where no relevant Professional Guidelines or Consensus Documents exist and for which there is a need for such to be developed.
- Any ISHLT documents that would benefit from revision to reflect recent changes in practice.

C. The first week of **July** of every other year, the Chairs of all four Interdisciplinary Network (IDN) Steering Committees will meet to review the lists provided by the PCs and determine:

- Whether any ideas would benefit from being combined or expanded
- Whether any ideas would benefit from cross-IDN collaboration.

D. Using the materials provided by the S&G Committee, the lists from the PCs, and the results of the IDN Steering Committee Chairs meeting, the IDN Steering Committee will have until **mid-August** of every other year to develop a summary list including:

- What new documents are needed.
  - Listed as proposed topics or draft document titles.
  - These must be listed in rank order of importance, from the perspective of the IDN Steering Committee, based on input from the PC representatives.
- What existing documents require updating in the coming year.
  - List titles of the Professional Guidelines or Consensus Documents in need of revision.

- o Which of the documents would benefit from development in collaboration with other organizations.
    - ▪ Provide a list of the proposed organizations.
    - ▪ Include the rationale for any recommended collaborations, including benefits to ISHLT and to the partner organization(s).
- o Which of the documents would benefit from endorsement by other organizations.
    - ▪ Provide a list of the proposed organizations.
    - ▪ Include the rationale for any recommended endorsements, including benefits to ISHLT and to the endorsing organization(s).

E. The S&G Committee will review the reports from the IDN Steering Committees and develop recommendations regarding the development of new or revised Professional Guidelines and Consensus Documents, including the following information for each document:

- o IDN or PC who will be responsible for overseeing the document.
- o Type of document needed (Professional Guideline or Consensus Statement).
- o Desired collaborative organizations, if any.
- o Desired endorsing organizations, if any.

These recommendations will be presented to the Statements & Publications Oversight Committee (SPOC) by **1 September** of every other year.

F. The SPOC will review the list from the IDN Steering Committees and the recommendations from the S&G Committee in light of the Society's goals, objectives, and strategies and will develop a final list of priority Professional Guidelines and Consensus Documents to be developed or revised in the coming year.

Health Policy Guidance Statements

A. The need for Health Policy Guidance Statements may be identified by communicating to the Chair of the SPOC at any time. Such communications must occur before development begins and may originate from the Board of Directors, Chairs of Committees or other representative groups, or leadership from a related society.

Other Documents

A. The need for all other types of documents may be identified by communicating to the Chair of the S&G Committee at any time. Such communications must occur before development begins and may originate from working groups, task forces, committees, the Board of Directors, or members of the Society. All proposals will be reviewed by

the S&G Committee at the earliest opportunity and will follow the review and approval procedures described in this document.

PROPOSALS OUTSIDE THE IDENTIFICATION OF NEEDS PROCESS

Professional Guidelines, Consensus Documents, and Other Documents

A. Individual ISHLT members may make recommendations to the Professional Community (PC) Leadership and Interdisciplinary Network (IDN) Steering Committees throughout the year regarding the development of documents relevant to the interests of the Society. These recommendations can be made either directly to the PC or IDN or submitted via the **online submission form**. The decision to submit such recommendations to the S&G Committee for consideration is at the discretion of the IDN Steering Committees.

B. An IDN Steering Committee may submit recommendations to the S&G Committee at times during the year other than those described in the above Statement of Need process. The S&G Committee may choose to approve such documents for development or to hold the recommendation for processing in accordance with the standard annual process and timeline described above.

Health Policy Guidance Statements

A. ISHLT-developed Health Policy Guidance Statements, either those developed individually or jointly with a related organization, may be proposed by:

   a. A member of the Board of Directors
   b. CEO of ISHLT
   c. Chair of the Statements & Publications Oversight Committee (SPOC) or Standards & Guidelines (S&G) Committee
   d. Chair of an Interdisciplinary Network (IDN) Steering Committee
   e. Chair of a Professional Community (PC)
   f. Chair of the Leadership Advisory Forum
   g. A member of the leadership of a related organization

B. The leadership of the relevant IDN(s) and/or PC(s) must be consulted during the development of such proposals.

C. Proposals for such Statements will be reviewed and approved by the SPOC.

APPLICATIONS

Professional Guidelines, Consensus Statements, and Other Documents

A. **Initial Applications**

1. Following approval by the Statements & Publications Oversight Committee (SPOC) of the Standards & Guidelines (S&G) Committee's recommendations, staff will communicate the decision and associated expectations to the responsible Interdisciplinary Network (IDN) Steering Committee and/or Professional Community (PC) Leadership for each approved Professional Guideline, Consensus Document, or other document and request that they submit an Initial Application for the development/revision of the specified document.

2. The IDN Steering Committee and/or PC Leadership is then responsible for the following:

    - Consulting with members of the Network and relevant Professional Communities as needed to identify Project Leads.
    - Completing the Initial Application, taking care to ensure that the document will be maximally relevant to the various PCs.
    - Submitting the Initial Application to ISHLT staff for review and approval by the Standards and Guidelines (S&G) Committee.

3. Project Leads must be current ISHLT members at the time of appointment and throughout the duration of the project and may not be current members of the ISHLT Board of Directors, SPOC, IDN Steering Committees, or the S&G Committee. Exemptions to this rule may be granted by the SPOC in exceptional circumstances where there is limited expertise within the Society. The proposed Project Leads must also reflect the diversity of the Society.

4. The S&G Committee will review the Initial Application and vote to approve it, return it for revisions, or not approve it.

5. Review of the Initial Application will be conducted at the first opportunity. 2-3 weeks will be allowed for the S&G Committee to complete their review.

6. Staff will communicate the S&G Committee's decisions to the responsible IDN Steering Committee and/or PC Leadership. If revisions are required, the feedback from the committee must be addressed and a response from the IDN Steering Committee and/or PC Leadership must be provided when the revised application is submitted for review.

    - In cases where the proposal was submitted via the online submission form, the submitter will also be notified of the S&G Committee's decision. Should revisions be required, the submitter may collaborate

with the responsible IDN Steering Committee and/or PC Leadership to develop a revised application and response.

7. Following approval of the Application, staff will issue invitations to the Project Leads, provide details of the proposed project, and collect Conflict of Interest Disclosure information.

8. Once the Project Leads have accepted their invitations, staff will request that the Project Leads complete and submit the Follow-up Application within 6 weeks.

B. Follow-Up Application

1. The Project Leads are responsible for working with the leaders of the relevant Interdisciplinary Network (IDN) Steering Committees and Professional Community (PC) Leadership to complete and submit the Follow-up Application to the ISHLT staff for review and approval by the Standards and Guidelines (S&G) Committee.

2. Writing Committees must be composed to ensure that the interests of the relevant IDN and PCs are adequately represented, that a broad geographic perspective will be achieved, and that gender diversity is adequately represented. Writing Committees must also include Early Career Professionals (<6 years out of formal training). Project Leads are encouraged to pair them with senior or mid-career mentors.

3. Industry Representatives are not permitted to participate on the Writing Committee of any ISHLT document. Should insight on certain industry-related topics be necessary, Project Leads can communicate with Industry Representatives and cite those conversations within the document.

4. **Methodology:** The methodology used to develop an ISHLT document will depend on the document type and will be decided by the Project leads in conjunction with the responsible IDN Steering Committee and/or Professional Community Leadership with oversight from S&G. It is expected that, irrespective of the overall methodology chosen, a comprehensive literature review will be undertaken to underpin the project.

   ▪ If a consensus methodology is used, the methodology should be outlined in detail, and it is expected that the full writing group has the opportunity to vote on/abstain from each statement.

   ▪ Completed ISHLT documents should focus on providing expert guidance, rather than repeating information compiled during the literature review. Documents should provide recommendations,

supported by evidence from the literature review. If a recommendation cannot be made, this too should be supported by evidence from the literature review.

5. Members of the Writing Committee must be ISHLT members at the time of appointment and throughout the duration of the project. Non-members will be considered in exceptional circumstances where the necessary expertise does not exist among the membership.

6. Expert Reviewers are not required to be ISHLT members at the time of application submission but MUST be ISHLT members at the time the document is complete and ready to undergo review.

7. The Standards & Guidelines (S&G) Committee will review the Follow-up Application to ensure that the scope is appropriate for the topic and can be accomplished within the 25,000-word limit, the content contributors are reflective of the identified relevant IDN and PCs and provide geographic, gender, and generational diversity, the timeline for development is suitable and the methodology is appropriate.

   - If these conditions are not met, the S&G Committee may return the application to the project leads for revision. If revisions are required, the feedback from the committee must be addressed and a response from the Project Leads must be provided when the revised application is submitted for review.
   - Once these conditions are met, the S&G Committee will vote to approve the Follow-up Application and will submit it to the Statements & Publications Oversight Committee (SPOC) for final approval.

8. Review of the Follow-up Application will be conducted at the first opportunity. 2-3 weeks will be allowed for the S&G Committee to complete their review.

9. The SPOC will be allowed 1-2 weeks to review the S&G Committee's decision regarding the Follow-up Application and provide final recommendations regarding publication plans and endorsement (if any).

10. Staff will communicate the decision of the SPOC to the S&G Committee and to the Project Leads and will provide instructions regarding next steps.

Health Policy Guidance Statements

A. Proposals to develop Health Policy Guidance Statements must include:
   a. The issue which the statement will address.
   b. The urgency of the issue.

c. A summary of the need for the statement and reasoning for urgency.

d. The audience for the statement (regulatory bodies, health care providers, patients, etc.).

e. A list of the Society's Professional Communities and Interdisciplinary Networks to which the issue is relevant.

f. Existing statements by other organizations on the same or a closely related topic.

g. Organizations with whom collaboration on a statement would be valuable.

B. The Statements & Publications Oversight Committee (SPOC), along with invited representatives from the Standards & Guidelines (S&G) Committee with relevant expertise, will review the proposal and the need for a rapid response on behalf of the Society. If the issue is not determined to be urgent, the document should go through the traditional approval pathway described above.

C. If it is determined that the statement is warranted with urgency, the SPOC will make a recommendation to the ISHLT Board (or Executive Committee) for its development. Such recommendation must include:

a. Summary of issue and need for statement.

b. Recommended scope of statement.

c. Recommended collaborating organizations (if any)

d. Level of urgency and recommended date for completion of the document.

e. Recommended Project Leads, selected with collaboration with the relevant Interdisciplinary Network (IDN) Steering Committee(s).

i. Recommended Project Leads must be current ISHLT members at the time of appointment and throughout the duration of the project and must also reflect the diversity of the Society.

f. Recommended publication/dissemination vehicles.

D. If the Board of Directors or Executive Committee approves the recommendation, Staff will communicate the decision to the submitter and will provide instructions regarding next steps.

WRITING COMMITTEE INVITATIONS / CONFLICT OF INTEREST MANAGEMENT

A. Following approval of the Follow-up Application or proposal, staff will issue invitations to the Writing Committee members. Invitations will be drafted by project leads and should include details of the proposed project, writing assignments,

planned author credit, publication/endorsement plans and instructions on submitting a Conflict of Interest (COI) Disclosure form.

B. All individuals involved in the development of ISHLT Documents are required to adhere to ISHLT's conflict of interest policies.

C. Once all Section Leaders, Sub-Section Leaders, and Writing Committee members have accepted their invitations, staff will notify the Project Leads.

D. Staff will work with the Project Leads to schedule a kick-off meeting with all invited collaborators, during which Project Leads will communicate detailed instructions, including policies and deadlines for document development. The writing process (or method of consensus, if applicable) will begin after that meeting.

E. Leads may not invite replacement authors without review by S&G. Once approval is granted, staff will issue the invitation to the replacement author(s).

DOCUMENT WRITING POLICIES

A. All ISHLT Documents should be created as a single manuscript rather than multiple papers.

   o If multiple papers are strongly preferred by the Project Leads, the rationale for such must be outlined in writing and in detail and provided to the Standards & Guidelines (S&G) Committee and Statements & Publications Oversight Committee (SPOC) for approval. Approval must be received from both committees before writing begins.

B. All documents should not exceed 25,000 words. This limit excludes tables and references and will be enforced by the S&G Committee and the SPOC. Documents that are more narrowly focused or have a limited scope should be considerably shorter.

C. All ISHLT Documents will be accompanied by a Perspectives Document for print publication in *JHLT*, which should highlight the key takeaways from the document and encourage readers to seek the full document online. Development of the Perspectives Document should be conducted by the Project Leaders after Expert and Peer Review processes have been completed to best reflect the final version of the full manuscript.

D. It is strongly recommended, but not required, that documents include Tables/Figures to graphically present high yield points and recommendations.

E. All documents must be developed using the ISHLT S&G Document Writing Template and Instructions provided by ISHLT staff.

F. Project Leads are responsible for overseeing and managing the engagement of the Writing Committee members, and monitoring their adherence to the policies and procedures and to the established deadlines and timetable.

G. All work on ISHLT Documents shall take place via telephone, virtual meetings, and email. Upon request, ISHLT staff will arrange for conference calls and ISHLTconnect discussion forums for the Writing Committees.

H. A face-to-face meeting of the Writing Committee members or project leadership at the ISHLT Annual Meeting may be arranged upon request. Meeting space will be provided *if available*, but no AV equipment/labor or food and beverage will be provided. No travel expenses associated with such a meeting will be reimbursed by ISHLT.

I. Staff will check in with the Project Leads once a month to ensure that work is progressing in accordance with the approved timetable.

   o If a **Professional Guideline or Consensus Document** is falling behind schedule, staff will notify the Chair of the Standards and Guidelines (S&G) Committee. If the project is falling more than 3 months behind, staff will notify the Chair of the Statements & Publications Oversight Committee (SPOC). At that time, a revised timetable, an explanation for the delay, and a plan for preventing further delays must be submitted by the Project Leaders to the S&G Committee and the SPOC for review and, if necessary, intervention and course correction. Such intervention may include, but is not limited to, direct oversight of remaining development stages, the institution of periodic check-ins with the Project Leaders, or replacement of Project Leaders.

DOCUMENT REVIEW AND APPROVAL PROCESS

A. Internal Review

   1. Initial drafts will be submitted by the Writing Committee members for review and comment by the Section/Sub-Section Leaders.

   2. Revised drafts incorporating comments/revisions from Section/Sub-Section Leaders will be developed by the Writing Committee members and will be submitted for further review/editing by the Section/Sub-Section Leaders.

   3. Once the revised drafts have been finalized by the Section/Sub-Section Leaders, the drafts will be provided to the Project Leaders for collation and final editing.

B. Expert, *JHLT*, and Peer Review

1. While the document is undergoing final collation and editing by the Project Leads, staff will invite the approved Expert Reviewers and collect their Conflict-of-Interest (COI) Disclosures.

2. Staff will notify the *JHLT* Editor-in-Chief and/or Executive Managing Editor of the document status and request an editor be assigned as a *JHLT* Reviewer. When selecting reviewers, preference should be given for an editor familiar with the science being presented.

3. Staff will coordinate the expert review of the draft document by the assigned Expert and *JHLT* Reviewers – Project Leads should not send the draft document directly to the Expert or *JHLT* Reviewers.

4. Concurrently with Step 3, the draft will be distributed to members of the appropriate Interdisciplinary Network (IDN) Steering Committee(s), Professional Community (PC) Leadership, and members of the relevant IDN(s) and PC(s) for Peer Review.

5. The review and comment period for all reviews at this stage shall not exceed 3 weeks except under unusual circumstances.

6. Once the review and comment period has ended, staff will collate the comments received during the Expert, *JHLT*, and Peer Review processes and provide them to the Project Leads.

7. Project Leaders, with assistance from the Section Leaders if desired, will incorporate feedback from Expert, *JHLT* and Peer Reviewers, create a Revised Final Draft of the document, and develop a response to each of the individual reviewer comments.

8. Staff will submit the Revised Final Draft and comment responses to anyone who participated in Expert, *JHLT*, or Peer Review for their approval. 1-2 weeks shall be allowed for this review.

9. If there is any additional feedback from the reviewers, Staff will collate the comments and submit them to the Project Leads for consideration and, if warranted, incorporation into a Final Draft of the document.

10. The Final Draft of the document must be approved by all members of the Writing Committee prior to submission to the Standards & Guidelines (S&G) for review.

C. Final Review

1. Staff will submit the approved Final Draft of all documents to the Standards & Guidelines (S&G) Committee for review.

2. Upon approval by the S&G Committee, staff will submit the Final Draft and Perspectives Document to the Statements & Publications Oversight Committee (SPOC) for review.

3. Should revisions to either the Final Draft or the Perspectives Document be required by the S&G Committee or the SPOC, Project Leads will be required to complete the necessary revisions and resubmit the Revised Final Draft and Perspectives Document, along with a response to the feedback from the Committee(s).

4. Upon approval by the SPOC, staff will submit the Final Draft to the Board of Directors for approval.

5. Once approved by the Board, staff will notify the Project Leads and the *JHLT* Editor-in-Chief of the Board's decision and direct the Project Leads to submit the manuscript and accompanying Perspectives Document to *JHLT* for publication.

Health Policy Guidance Statements

A. **Expert/Peer Review**, and **Final Review** will be conducted as outlined above except in cases where time is of the essence. In those circumstances, the Standards & Guidelines (S&G) Committee and Statements & Publications Oversight Committee (SPOC) will conduct their Final Reviews simultaneously.

PUBLICATION

A. All ISHLT Documents are to be published in full in the digital version of *JHLT*, with accompanying Perspectives Documents published in print issues of *JHLT*. ISHLT Documents may be selected for full print publication at the discretion of the *JHLT* Editor-in-Chief.

B. The Project Leads are responsible for submitting the final approved ISHLT Document and final approved Perspectives Document to *JHLT* in accordance with the process and standards established by the publisher.

C. ISHLT Staff will provide a list of document contributors and their Conflict of Interest (COI) Disclosures to the Project Leads for submission with the final approved manuscript to the *JHLT*.

D. Board of Director-approved ISHLT Documents and accompanying Perspectives Documents will not undergo additional peer / editorial review by the *JHLT* Editorial team. Copy editing and medical editing will be provided by the publisher.

E. All ISHLT Documents will be formatted for publication by the publisher using the Standard & Guidelines (S&G) Publication Template. All Perspectives Documents will

be formatted using the Perspectives Publication Template and will include a QR code for easy access to the online publication of the full manuscript.

F. Publication dates for all ISHLT Documents will be determined by ISHLT Staff. Documents will be placed under embargo by the publisher until the selected date.

G. All ISHLT Documents published in *JHLT* will be made available for free access to the general public on the *JHLT* website. A copy of the document and the accompanying Perspectives Document, links to the published article in *JHLT,* and any associated materials, including those developed for promotional purposes, will be made available on the ISHLT website.

H. The *JHLT* Editor-in-Chief reserves the right to make the final decision regarding publication and associated specifics of all ISHLT Documents. In the event of a disagreement, the Editor-in-Chief will discuss his/her thoughts with the Statements & Publications Oversight Committee (SPOC) prior to reaching a decision.

PUBLICATION ANNOUNCEMENT AND PROMOTION

Professional Guidelines and Consensus Documents

A. ISHLT Staff will work with the Project Leads to create promotional content related to the Professional Guidelines and Consensus Documents. This content may include, but is not limited to graphics, top takeaways, interviews with contributors, and/or Q&A sessions with Project Leads.

B. Prior to publication, staff will work to collect the social media handles of all Project Leads so that they may be tagged in social media posts.

C. Upon publication, Professional Guidelines and Consensus Documents will be announced and promoted as determined by ISHLT Staff. Such announcements may include, but are not limited to announcement on social media, publication on the ISHLT website, posts on ISHLTconnect in the appropriate forums, and inclusion in the next issue of ISHLTaccess.

D. Upon publication, ISHLT Staff will notify all document contributors that the Professional Guideline or Consensus Document is available on the *JHLT* and ISHLT websites.

Health Policy Guidance Statements and Other Documents

A. Announcement and publication of Health Policy Guidance Statements and other documents that are not Professional Guidelines or Consensus Documents, will be conducted at the discretion of ISHLT Staff with input from the Statements & Publications Oversight Committee, Board of Directors (as needed) and ISHLT CEO.