

**INTERNATIONAL SOCIETY FOR HEART AND LUNG TRANSPLANTATION  
POLICIES AND PROCESSES FOR DEVELOPMENT AND ENDORSEMENT OF**

- **PROFESSIONAL PRACTICE GUIDELINES AND CONSENSUS STATEMENTS**
  - **HEALTH POLICY GUIDANCE STATEMENTS**
    - **STANDARDS DOCUMENTS**
    - **PUBLIC COMMENTS**

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## PREAMBLE

Subjects chosen for ISHLT Professional Practice Guidelines And Consensus Statements, Health Policy Guidance Statements, Standards Documents, and Public Comments (collectively referred to herein as S&G Documents) are usually medical and clinical issues related to topics within ISHLT's discipline and core competencies where there is a clear need for guidance to assist physicians/clinicians in diagnosis and/or clinical management. They can encompass public health issues, epidemiology, prevention, management strategies, health policies, education, ethics, etc.

Efforts to update previously published ISHLT S&G Documents will be given a high priority when new data has emerged in the relevant field.

Duplication of previously existing, high quality S&G Documents issued by other Societies is discouraged unless new data exists which makes existing S&G Documents out of date. In such cases, collaborations with the Societies which published the existing S&G Documents is strongly encouraged before embarking on the development of new and independent ISHLT S&G Documents.

S&G Documents developed under the auspices of ISHLT are copyrighted by ISHLT and may not be published in any forum or format without prior written approval by the Publications Oversight Committee, the ISHLT Board of Directors, and, in some cases, the JHLT publisher.

## DEFINITIONS

- A. Health Policy Guidance Statements:** Documents which present ISHLT guidance and/or positions on ethics, public health issues, and the like
- B. Standards Documents:** Documents which describe standards for training, competency, or nomenclature and incorporate a development process that involves multi-disciplinary and broad geographic representation among the content contributors, as appropriate
- C. Public Comments:** Responses to or comments/assessments of decisions or documents promulgated by **other organizations**, regulatory bodies, etc., on issues of relevance to the field of advanced heart failure and transplantation, advanced lung failure and transplantation, mechanical circulatory support, and/or pulmonary vascular disease.
- D. Professional Practice Guidelines:** Documents which 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 development process that involves multi-disciplinary and broad geographic representation among the content contributors
- A comprehensive literature search 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

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

- A development process that involves multi-disciplinary and broad geographic representation among the content contributors
- A comprehensive literature search 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

**F. Endorsements:** The awarding of approval or support either a) by ISHLT to another organization's S&G Documents or b) by other organizations to ISHLT S&G Documents. **Such organizations are limited to not-for-profit organizations and governmental agencies with similar and/or complementary interests in advanced heart failure and transplantation, advanced lung failure and transplantation, mechanical circulatory support, and/or pulmonary vascular disease.**

**G. Collaborative Documents:** Professional Practice Guidelines, Consensus Documents, Health Policy Guidance Statements, and Standards Documents which are a) developed under the auspices of another organization(s), for which ISHLT has significant input into the content of such documents and rights regarding review, publication, and use of ISHLT's name in association with the document or b) developed under the auspices of ISHLT, for which one or more other organizations has significant input into the content of such documents and rights regarding review, publication, and use of their name in association with the document. **Such organizations are limited to not-for-profit organizations and governmental agencies with similar and/or complementary interests in advanced heart failure and transplantation, advanced lung failure and transplantation, mechanical circulatory support, and/or pulmonary vascular disease.**

**H. Consensus Conferences:** A conference of multidisciplinary experts reflecting broad geographic representation designed to review information related to a specific area of patient care and come to consensus on recommendations regarding the area and/or gaps in information that require further study. A Consensus Conference is not a required precursor to the development of a

Consensus Document. However, a Consensus Document should result from most Consensus Conferences. **A Consensus Conference should only be undertaken when adequate consensus and plans for moving the field forward cannot be accomplished through the usual Consensus Document development process. A separate process for obtaining Board approval and funding for a Consensus Conference is required.**

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## **HEALTH POLICY GUIDANCE STATEMENTS (non-collaborative projects)**

Health Policy Guidance Statements are documents which present ISHLT guidance and/or positions on ethics, public health issues, and the like.

### **IDENTIFICATION OF NEED**

The need for a Health Policy Guidance Statement to be developed by ISHLT, either individually or jointly with a related organization(s), may be brought to the Board by one of the following:

- A member of the Board of Directors
- The CEO
- The Chair of the Publications Oversight Committee
- The Chair of an Interdisciplinary Network Steering Committee
- The Chair of the Standards and Guidelines Committee
- The Chair of the Leadership Advisory Forum
- A member of the leadership of a related organization
- An elected representative of one of the Professional Communities

The identification of need for a Health Policy Guidance Statement must include the following information:

- The issue which the statement will address
- The nature of the guidance requested (ethics, health policy, etc.)
- A summary of the need for the statement
- The audience for the statement (regulatory bodies, health care providers, patients, etc.)
- The urgency of the issue
- The relevance of the issue from a national or international perspective (national relevance is the minimum expected; international relevance is strongly preferred)

- The relevance of the issue to each of the Society's Professional Communities and Interdisciplinary Networks
- Existing statements by other organizations on the same or a closely related topic
- Statements under development by other organizations on the same or a closely related topic
- Organizations with whom collaboration on a statement would be valuable

The Publications Oversight Committee (POC) will review and assess the identification of need document and, if it is determined that the need is warranted, will make a recommendation to the ISHLT Board (or Executive Committee) for its development. Such recommendation must include the following:

- Summary of issue and need for statement
- Recommended scope of statement
- Recommended collaborating organizations, if any
- Level of urgency and recommended date for completion of the document
- Recommended Project Leads (input may be sought from relevant Interdisciplinary Network Steering Committees)
- Recommended publication/dissemination vehicles

## **WRITING AND APPROVAL**

Once approved by the Board (such approval must include details regarding publication/dissemination expectations and diversity expectations among the content developers), the selection of Writing Committee members, the collection of COI disclosures, and the development and approval of the content shall proceed in accordance with the processes in place for S&G document development. The need for disciplinary and geographic diversity among the content developers will be dependent upon the issue at hand, the relevant audience, and the scope of the statement.

In instances where time is of the essence, the responsibilities of the IDN Steering Committees may be handled by the Standards and Guidelines (S&G) Committee, the responsibilities of the S&G Committee may be handled by the Publications Oversight Committee (POC), and the Peer Review process may be replaced by a more robust Expert Review process. POC approval and Board approval of the final document are required.

## **PUBLICATION**

Publication options for Health Policy Guidance Statements include publication in the JHLT, on the ISHLT website, and publication/presentation in other forums as appropriate. Details and decisions regarding publication/presentation are to be agreed upon by the Publications Oversight Committee (POC), Board of Directors, and JHLT Editor at the time of approval of the final statement.

## **ASSESSMENT OF ONGOING RELEVANCE**

Staff will engage the Publications Oversight Committee (POC) in a review of the relevance of the Society's existing Health Policy Guidance Statements no less than every five (5) years. Health Policy Guidance Statements identified as in need up updating will be presented to the Board via the above Identification of Need process. Health Policy Statements identified by the POC and Board as no longer relevant or valid will be removed from the ISHLT website.

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## **STANDARDS DOCUMENTS (non-collaborative projects)**

Standards Documents are documents which describe standards for training, competency, or nomenclature and incorporate a development process that involves multi-disciplinary and broad geographic representation among the content contributors, as appropriate. **Because of their strong connection to professional education, these will generally be developed in close collaboration with the Education Oversight Committee (EOC).**

### **IDENTIFICATION OF NEED**

The need for a Standards Documents to be developed by ISHLT may be brought to the POC by one of the following:

- A member of the Publications Oversight Committee
- The Chair of the Education Oversight Committee
- The Chair of the Research Oversight Committee
- The Chair of an Interdisciplinary Network Steering Committee
- The Chair of the Standards and Guidelines Committee
- The Chair of the Leadership Advisory Forum
- The Chair of the Early Career and Trainee Committee
- An elected representative of one of the Professional Communities

The identification of need for a Standards Documents must include the following information:

- The topic which the Standard will address
- The nature of the Standard (training, competency, nomenclature, etc.)
- A summary of the need for the Standard
- The Professional Communities and/or Interdisciplinary Networks for which the Standards should be developed
- The relevance of the issue from a national or international perspective (national relevance is the minimum expected; international relevance is strongly preferred)
- A list of existing Standards promulgated by other organizations on the same or a closely related topic
- A list of Standards under development by other organizations on the same or a closely related topic
- A summary of why these existing Standards are not sufficient

The Publications Oversight Committee (POC) and the Education Oversight Committee (EOC) will jointly review and assess the identification of need document and, if it is determined that the need is warranted, will make a recommendation to the ISHLT Board (or Executive Committee) for the development of the proposed Standard.

## **WRITING AND APPROVAL**

Once approved by the Board (such approval must include details regarding diversity expectations among the content developers), the Education Oversight Committee (EOC) will lead the content development process.

The EOC may develop specific policies regarding the content, structure, and format of Standards Documents. These policies will be attached as Appendices to this document and must be adhered to.

Unless otherwise specified in the specific content policies developed by the EOC, the selection of content developers, the collection of COI disclosures, and the development and approval of the content shall proceed in accordance with the processes in place for S&G document development, modified as follows:

- The responsibilities of the Interdisciplinary Network (IDN) Steering Committees may be handled by the elected leaders of the Professional Communities or by the EOC, as appropriate
- The responsibilities of the Standards and Guidelines (S&G) Committee will be handled by the EOC
- The Peer Review process may be replaced by a more robust Expert Review process, as appropriate
- The need for disciplinary and geographic diversity among the content developers will be dependent upon the issue at hand, the relevant audience, and the scope of the Standard.

EOC, Publications Oversight Committee (POC), and Board approval of the final Standards are required.

## **PUBLICATION**

Publication options for Standards Documents include publication in the JHLT, on the ISHLT website, and publication/presentation in other forums as appropriate. Details and decisions regarding publication/presentation are to be agreed upon by the Education Oversight Committee (EOC), Publications Oversight Committee (POC), Board of Directors, and JHLT Editor at the time of approval of the final document.

## **ASSESSMENT OF ONGOING RELEVANCE**

Staff will engage the Education Oversight Committee (EOC) in a review of the relevance of the Society's existing Standards Documents no less than every five (5) years. Standards Documents identified as in need of updating will be presented to the Publications Oversight Committee (POC) via the above Identification of Need process. Standards Documents identified by the EOC and POC as no longer relevant or valid will be removed from the ISHLT website.

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## **PUBLIC COMMENTS (non-collaborative projects)**

From time to time ISHLT may be invited to develop a public comment on an issue of relevance in the field of advanced heart failure and transplantation, advanced lung failure and transplantation, mechanical circulatory support, and/or pulmonary vascular disease. Public Comments are responses to decisions or documents promulgated by others and are in that sense distinct from Health Policy Guidance Statements.

### **IDENTIFICATION OF NEED**

The impetus to develop a Public Comment may originate from or be brought to the Board by one of the following:

- A member of the leadership of a related organization/regulatory body
- A member of the Board of Directors
- The CEO
- A member of the Publications Oversight Committee
- The Chair of the Education Oversight Committee
- The Chair of the Research Oversight Committee
- The Chair of an Interdisciplinary Network Steering Committee
- The Chair of the Standards and Guidelines Committee
- The Chair of the Leadership Advisory Forum
- The Chair of the Early Career and Trainee Committee
- An elected representative of one of the Professional Communities

The Board will determine whether or not to respond to a request to develop a Public Comment based upon the following information:

- A summary of the issue (with supporting documentation) on which ISHLT's comment is requested
- The nature and legitimacy of the organization(s) associated with the issue
- The relevance of the issue to ISHLT members and the patients they serve
- The relevance of the issue from a national or international perspective (national relevance is the minimum expected; international relevance is strongly preferred).
- The value of ISHLT's contribution to the public discussion
- The presence of sufficient consensus among the profession to merit the development of an ISHLT contribution to the public discussion

Once the Board has decided to develop a Public Comment, the Publications Oversight Committee (POC) will lead the process with support from staff. Such process will consist primarily of:

- Identifying the Professional Communities (PC) and Interdisciplinary Networks whose expert input is needed to draft the Public Comment
- Working with the elected PC leaders and Interdisciplinary Network (IDN) Steering Committees to identify individuals to draft the Public Comment
- Subjecting the draft Public Comment to peer review conducted by the relevant elected PC leaders, the members of the relevant IDN Steering Committees, and the members of the Standards and Guidelines (S&G) Committee.

The structure of Public Comments must adhere to the ISHLT S&G Document Writing Policies. These policies are under development.

The final draft Public Comment will be presented to the POC and then the Board for final review and approval.

Staff will submit the Public Comment by the deadline and in the format required.

The decision to publish or disseminate Public Comments on the ISHLT website or in other forums will be decided by the POC and staff.

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# PROFESSIONAL PRACTICE GUIDELINES AND CONSENSUS DOCUMENTS

(non-collaborative projects)

## IDENTIFICATION OF NEED

- A.** The Standards and Guidelines (S&G) Committee will issue a request every **March 1** to the Interdisciplinary Network (IDN) Steering Committees to consult with the members of their relevant Professional Communities and develop the following for presentation to the S&G Committee by **June 1**:
- A list of the existing and in-development ISHLT S&G Documents, including those in which ISHLT is a joint collaborator or endorser
  - A list of existing and in-development S&G 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
  - An assessment of any areas of practice where no relevant S&G Documents exist and for which there is a need for such to be developed
  - A summary list including:
    - What new documents are needed (these must be listed in rank order of importance, from the perspective of the IDN Steering Committee, based on input from the Professional Communities)
    - What existing documents are in need of revision
    - Which of the documents would benefit from development in collaboration with other organizations (such organizations are to be listed)
    - The rationale for any recommended collaborations, including benefits to ISHLT and to the partner organization(s)
    - Which of the documents would benefit from endorsement by other organizations (such organizations are to be listed)
    - The rationale for any recommended endorsements, including benefits to ISHLT and to the endorsing organization(s)
- B.** The S&G Committee will review the reports from the IDN Steering Committees and develop a list of recommendations regarding the development of new or revised S&G Documents in the coming 12-18 months, listed in priority order and including the following information for each document:

- IDN Steering Committee recommending the document
- Type of document needed (Guideline, Consensus Statement, Standards Document)
- Desired collaborative organizations, if any
- Desired endorsing organizations, if any
- Geographic areas of the world to which the document is relevant
- Professional Communities to which the document is relevant
- Recommended publication plan (see publication section for options)

These recommendations will be presented to the Publications Oversight Committee (POC) by **July 1**.

**C.** The POC will review the list of recommendations from the S&G Committee and the reports from the IDN Steering Committees in light of the Society's goals, objectives, and strategies and will develop a final list of priority S&G Documents to be developed or revised in the coming year to include:

- Expectations regarding collaboration with / endorsement from other organizations
- The intentions of the JHLT Editor regarding the publication of the document (see publication section for options).
- Languages into which each document should be translated (if any)

**D.** This list will be finalized and presented to the Board of Directors by **August 1** for approval. Such approval must include approval of intended collaborations with / endorsements from other organizations, intended publication plans, and intended translations, along with appropriate funding for the latter.

**E.** Individual ISHLT members may make recommendations to the Professional Community leaders and IDN Steering Committees throughout the year regarding the development of S&G Documents. The decision to submit such recommendations to the S&G Committee for consideration is at the discretion of the IDN Steering Committees.

**F.** 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 recommend such documents to the POC for approval or may choose to hold the recommendation for processing in accordance with the standard annual process and timeline described above.

Any such recommendations to the POC for approval must include the following information:

- The rank order of importance of the proposed document in comparison with the rank order of documents presented in the most recent list of recommendations submitted to the POC
- Whether the document would benefit from development in collaboration with other organizations (such organizations are to be listed)

- The rationale for any recommended collaborations, including benefits to ISHLT and to the partner organization(s)
- Whether the documents would benefit from endorsement by other organizations (such organizations are to be listed)
- The rationale for any recommended endorsements, including benefits to ISHLT and to the endorsing organization(s)

## **APPLICATIONS**

### **A. Initial Application**

1. Following approval by the Board of the Publications Oversight Committee's (POC) recommendations, staff will communicate the decision and associated expectations to the relevant Interdisciplinary Network (IDN) Steering Committee and request that they submit an Initial Application for the development / revision of the specified S&G document.
2. The IDN Steering Committee is then responsible for the following:
  - Consulting with members of the Network and relevant Professional Communities as needed, including for the identification of Project Leaders and Section Leaders
  - Completing the Initial Application, taking care to ensure that the document will be maximally relevant to the various Professional Communities
  - Submitting the Initial Application to ISHLT staff for review and approval by the Standards and Guidelines (S&G) Committee
3. Project Leaders and Section Leaders 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, POC, IDN Steering Committees, or the S&G Committee.
4. The S&G Committee will review the Initial Application and vote to approve it, return it for revisions, or not approve it.
5. Two (2) weeks should be allowed for the Initial Application review and decision process.
6. Staff will communicate the S&G Committee decision to the IDN Steering Committee.
7. Staff will then issue invitations to the Project Leaders and Section Leaders, provide details of the proposed project, and collect Conflict of Interest Disclosure information.

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

## **B. Follow-up Application**

1. The Project Leaders and the Section Leaders are responsible for working with the leaders of the relevant Professional Communities 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. Six (6) weeks should be allowed for the development of the Follow-up Application and its submission to ISHLT staff.
3. Writing Committees must be composed to ensure that the interests of the relevant Professional Communities are adequately represented, that a broad geographic perspective will be achieved, and that genders and generations are adequately represented. The Society strongly encourages the inclusion of Early Career Professionals (<6 years out of formal training) in the S&G Document writing process, especially if they are paired with senior or mid-career mentors.
4. Members of the Writing Committee and Expert Reviewers 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 members, however, in such circumstances, the better approach would likely be to develop the document jointly with an organization whose members possess the necessary expertise.
5. The S&G Committee will review the Follow-up Application to ensure that the table of contents and the content contributors are reflective of the identified relevant Professional Communities and provide geographic, gender, and generational diversity.
6. Once these conditions are met, the S&G Committee will vote to approve the Follow-up Application and will submit it to the Publications Oversight Committee (POC) for final approval.
7. Two (2) weeks shall be allowed for review and approval of the Follow-up Application by the S&G Committee.
8. The POC will review the S&G Committee's decision regarding the Follow-up Application and will provide final instructions regarding publication plans and endorsement (if any).

9. One (1) week shall be allowed for POC review and approval of the Follow-up Application.
10. Staff will communicate the decision of the POC to the S&G Committee and to the Project Leaders and Section Leaders and will provide instructions regarding next steps and publication / endorsement plans.

## **WRITING COMMITTEE INVITATIONS / CONFLICT OF INTEREST MANAGEMENT**

- A.** Following approval of the Follow-up Application by the Publications Oversight Committee (POC), staff will issue invitations to the Sub-Section Leaders, Writing Committee members, and Expert Reviewers, including details of the proposed project, writing assignments, the approved timeline, and publication / endorsement plans, and will collect Conflict of Interest Disclosure information.
- B.** All individuals involved in the development of the S&G document are required to adhere to ISHLT's conflict of interest policies.
- C.** Staff will work with the POC to ensure that no more than 49% of all individuals involved in the development of the S&G Document have current conflicts of interest relevant to the subject matter of the S&G Document. If more than 49% have relevant COI, the Project Leader will identify alternate Writing Committee members/Expert Reviewers to be invited.
- D.** Once all Sub-Section Leaders, Writing Committee members, and Expert Reviewers have accepted, staff will notify the Project Leaders and Section Leaders.
- E.** In collaboration with staff, Project Leaders and Section Leaders will then communicate detailed instructions, including Policies for the writing of S&G Documents and the deadlines for document development, to the Writing Committee members and the writing process will begin. Staff will also distribute the master COI spreadsheet and COI policies to all individuals.

## **DOCUMENT WRITING POLICIES**

- A.** S&G Documents should be created as a single manuscript rather than multiple papers.
- B.** If multiple papers are strongly preferred by the Project Leads, the rationale for such must be outlined in writing and in detail to the JHLT Editor and must be agreed to by the JHLT Editor at the time the Follow-up Application is approved.
- C.** The typical length of a full S&G Document should not exceed 25,000 words, and an Executive Summary should not exceed 5,000 words.

- D. Approval for documents exceeding the above limits must be obtained from the JHLT Editor in advance.
- E. The structure of full S&G Documents must adhere to the ISHLT S&G Document Writing Policies. These policies are under development.
- F. The structure of the Executive Summary must adhere to the ISHLT S&G Document Writing Policies. These policies are under development.

## **DOCUMENT WRITING PROCESS**

- A. The Project Leaders and Section Leaders are responsible for overseeing and managing the engagement of the Sub-Section Leaders and Writing Committee members and monitoring their adherence to the policies and procedures and to the established deadlines and timetable.
- B. All work on the development of S&G Documents shall take place via telephone, email, and online ISHLTconnect discussion forums. ISHLT staff will arrange for conference calls and ISHLTconnect discussion forums for the Writing Committees.
- C. A face to face meeting of the Writing Committee members or Project Leaders/Section Leaders/Sub-Section Leaders at the ISHLT Annual Meeting will be arranged upon request. Meeting space will be provided, 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.
- D. Staff will check in with the Project Leaders once a month to ensure that work is progressing in accordance with the approved timetable. If the project is falling behind, 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 Publications Oversight Committee (POC). 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 POC for review and, if necessary, intervention and course correction.
- E. **IMPORTANT NOTE:** If the publication decision made at the time of approval of the Follow-up Application is for an Executive Summary to be published in JHLT, the Executive Summary **MUST** be submitted for review and approval at the same time that the full document is submitted for such.

## **DOCUMENT REVIEW AND APPROVAL**

- A. Staff will monitor and track the flow of documents through the review and editing process and will notify responsible parties when deadlines have not been met.

- B.** The review and comment period for each step shall not exceed 2 weeks except under unusual circumstances.
- C.** Initial drafts will be submitted by the Writing Committee members for review and comment by the Section/Sub-Section Leaders.
- D.** Revised drafts incorporating comments/revisions from Section/Sub-Section Leaders will be developed by the Writing Committee members and will be submitted for review/editing by the Section/Sub-Section Leaders. At this time, staff will also notify the Expert Reviewers to be prepared for the forthcoming document.
- E.** 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 and for the development of the Executive Summary, if relevant.
- F.** Staff will coordinate the review of the draft document (and Executive Summary) by the assigned Expert Reviewers and the members of the appropriate Interdisciplinary Network (IDN) Steering Committee.
- G.** Staff will collate the comments from the Expert Reviewers and the IDN Steering Committee members and provide them to the Project Leaders.
- H.** The Project Leaders, with assistance from the Section Leaders if desired, will create a Revised Final Draft of the document (and the Executive Summary), incorporating comments from Expert Reviewers and IDN Steering Committee members.
- I.** Staff will then submit the Revised Final Draft (and Executive Summary) to the members of the relevant Interdisciplinary Networks for peer review.
- J.** Staff will collate the comments from the peer review process and submit them to the Project Leaders for consideration and, if warranted, incorporation into a FINAL Final Draft of the document (and Executive Summary). The FINAL Final Draft of the document must have been approved by all members of the Writing Committee prior to submission to the Standards and Guidelines (S&G) Committee and Publications Oversight Committee (POC) for review and approval.
- K.** Staff will submit the FINAL Final Draft (and Executive Summary) to the S&G Committee and the POC simultaneously for review and approval.
- L.** Staff will submit the POC-approved document (and Executive Summary) to the Board of Directors for approval.

- M.** Once approved by the Board, staff will notify the Project Leaders and the JHLT Editor of the Board's decision and direct the Project Leaders to submit the manuscript (and the Executive Summary, as appropriate) to the JHLT for publication.

## **PUBLICATION**

- A.** Publication options for Professional Practice Guidelines and Consensus are as follows:
1. Publication of the full S&G Document in the print and digital JHLT
  2. Publication of an Executive Summary only in the print and digital JHLT with the full S&G Document published as supplementary e-only files (requires Board approval of a budget for professional medical editing of the supplementary e-files) Supplementary e-only files must include a table of contents and must be tagged to the main components of the Executive Summary. If the supplementary e-only files contain separate "task force" documents authored by a distinct set of authors, these will not be credited separately as de novo papers and those authors will not receive publishable credit.
- B.** The JHLT has the right of first refusal for publication of the full S&G Document and/or the Executive Summary.
- C.** Board-approved S&G Documents will not undergo peer / editorial review by the JHLT Editorial team (copy editing and medical editing will be provided by the publisher), however, the following specifications must be adhered to for all documents published in the JHLT:
- S&G Documents should be created as a single manuscript rather than multiple papers.
  - If multiple papers are strongly preferred by the Project Leads, the rationale for such must be outlined in writing and in detail to the JHLT Editor and must be agreed to by the JHLT Editor at the time the Follow-up Application is approved.
  - The typical length of a full S&G Document should not exceed 25,000 words, and an Executive Summary should not exceed 5,000 words.
  - If a longer document is deemed necessary by the Project Leads, it will likely be necessary to pursue publication option #2 above. Approval for documents

exceeding the above limits must be obtained from the JHLT Editor in advance.

- Staff will provide a list of the Writing Committee members and Expert Reviewers and their Conflict of Interest Disclosures to the Project Lead for submission with the final, approved manuscript to the JHLT.

**D.** The structure of full S&G Documents must adhere to the ISHLT S&G Document Writing Policies. These policies are under development.

**E.** The structure of the Executive Summary must adhere to the ISHLT S&G Document Writing Policies. These policies are under development.

**F.** The Project Lead is responsible for submitting the final approved document (and Executive Summary) to the JHLT in accordance with the process and standards established by the publisher. Such document must have been approved by all members of the Writing Committee prior to submission.

**G.** All ISHLT S&G Documents published in the JHLT will be made available for free access to the general public on the JHLT website, with links to them created by staff on the S&G pages of the ISHLT website.

**H.** The JHLT Editor reserves the right to make the final decision regarding publication and associated specifics of all S&G Documents. In the event of a disagreement, the Editor will discuss his/her thoughts with the POC and the ISHLT Executive Committee prior to reaching a decision.

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## ENDORSEMENT OF ISHLT S&G DOCUMENTS BY OTHER ORGANIZATIONS

When warranted due to the need for common patient care approaches among the memberships of related organizations, ISHLT may desire endorsement of ISHLT S&G Documents by other organizations. **Such organizations are limited to not-for-profit organizations and governmental agencies with similar and/or complementary interests in advanced heart failure and transplantation, advanced lung failure and transplantation, mechanical circulatory support, and/or pulmonary vascular disease.**

Plans for endorsement of ISHLT S&G Documents by other organizations will ideally be considered and approved by the Publications Oversight Committee (POC) and Board during the annual S&G Document planning process. If not, a decision to seek endorsement may be made by the POC and Board at any time prior to or after publication of the document, with the understanding that endorsements made after the final document has been approved by the Board for publication will not be acknowledged in the final published document.

Once an S&G Document is ready for Expert Review, staff will communicate with the Executive Director(s) of the organizations whose endorsement is sought to:

- Invite their consideration of the document for endorsement
- Advise them that no changes may be made to the document as a condition of endorsement
- Advise them that they will be acknowledged as having endorsed the document
- Advise them that they may provide a link to the document from their website (joint or subsequent publication of the document is not permitted)
- Advise them that a maximum of three (3) weeks will be provided for their decision to be made.

For those organizations who agree to consider the document for endorsement, staff will send the Executive Director a clean word version of the final Board-approved document, accompanied by an **Endorsement Acknowledgment Form** and a deadline for response. Endorsement will not be considered final until the completed Endorsement Acknowledgment Form is received by ISHLT staff.

Information regarding formal endorsements by other organizations will be provided by staff to the Project Lead and JHLT Editor for incorporation into the final published manuscript. Endorsing organizations will be acknowledged beneath the title of the document and above the author list as follows, "Endorsed by (full name of organization)". Endorsing organizations will be listed in alphabetical order.

As soon as possible, staff will provide a link to the published S&G Document to all endorsing organizations.

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## ISHLT ENDORSEMENT OF OTHER ORGANIZATIONS' S&G DOCUMENTS

When warranted due to the relevance of the topic to ISHLT members' interest or due to the need for common patient care approaches among the memberships of related organizations, ISHLT will consider endorsing S&G Documents developed by other organizations. **Such organizations are limited to not-for-profit organizations and governmental agencies with similar and/or complementary interests in advanced heart failure and transplantation, advanced lung failure and transplantation, mechanical circulatory support, and/or pulmonary vascular disease.**

A. Endorsement requests will be considered when the following conditions are met:

- The request is made in writing to ISHLT by the authoring organization
- The topic of the document is of relevance to at least one ISHLT Professional Community (preferably more than one) and one Interdisciplinary Network and is, ideally, of international relevance
- The final document in its entirety as approved by the drafting organization's leadership body and including COI information, references, appendices, and publication plans, is provided to ISHLT (ISHLT will not consider documents submitted as separate manuscripts or submitted incrementally).
- ISHLT has not already developed, or is not in the process of developing, its own S&G Document to address the topic
- ISHLT has not already endorsed a similar document by a different organization
- ISHLT has been advised of any other organizations that have been invited / have agreed to endorse the document
- ISHLT will be acknowledged in the published document as having endorsed the document
- ISHLT will have the right (but not the obligation) to publish a link to the endorsed document on the ISHLT website
- There has been no commercial support associated with the document
- ISHLT will be provided with a minimum of 3 weeks to review the document and make a decision regarding endorsement

B. ISHLT will not appoint writing committee members for any project for which endorsement is sought, even if invited to do so by the authoring organization.

C. Staff will present the S&G Committee's recommendation to the POC to consider the document for endorsement. If the POC agrees with the recommendation, staff will then coordinate Expert Review of the document by representatives of the relevant Professional Communities and/or Interdisciplinary Network Steering Committees as determined by the S&G Committee. Such review is limited solely to a

recommendation to endorse or not endorse the document as written. No recommendations for revisions will be accepted. The S&G Committee will evaluate the recommendations of the Expert Reviewers and will make a recommendation to the POC to endorse or not endorse the document. The POC will make the final decision regarding endorsement and will advise the Board regarding that decision.

- D. Staff will notify the authoring organization in writing regarding ISHLT's endorsement decision.
- E. Staff will follow-up with the authoring organization to obtain a link to the published document as soon as it is available and to add it to the ISHLT website.

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# **SPECIAL POLICIES AND PROCEDURES FOR COLLABORATIVE ISHLT S&G DOCUMENTS**

## **DOCUMENTS PROMULGATED BY ISHLT AND DEVELOPED IN COLLABORATION WITH OTHER ORGANIZATION(S)**

The following special policies and procedures apply when the Publications Oversight Committee (POC) and Standards and Guidelines (S&G) Committee determine via the above Identification of Need process that an S&G Document should ideally be developed in collaboration with one or more other organizations.

When warranted due to the need for common patient care approaches among the memberships of related organizations, ISHLT may desire to develop an S&G Document in collaboration with another organization(s). **Such organizations are limited to not-for-profit organizations and governmental agencies with similar and/or complementary interests in advanced heart failure and transplantation, advanced lung failure and transplantation, mechanical circulatory support, and/or pulmonary vascular disease.**

A decision to develop an ISHLT S&G Document in collaboration with another organization must be made prior to the submission of the Final Application.

## **APPLICATIONS**

### **A. Invitation to Collaborate**

1. Following approval by the Board of the POC's recommendations regarding S&G Documents to be developed collaboratively, staff will extend an invitation to the Executive Director of the proposed partnering organization(s) inviting their collaboration and outlining the general terms for such a collaboration and the responsibilities of each organization.
2. Once the invitation has been accepted, ISHLT will send the collaborating organization a Memorandum of Understanding (MOU) to sign, such MOU to address all relevant policies, procedures, responsibilities, and rights of each organization and to identify a Project Leader to represent their organization.
3. Once the MOU has been signed by all parties staff will communicate to the relevant Interdisciplinary Network (IDN) Steering Committee regarding the decision of the S&G Committee and the agreed upon collaboration, and request that they consult with members of the IDN and relevant Professional Communities as needed to identify a Project Leader for the S&G Document.

4. Once the ISHLT Project Leader has been identified, staff will then issue formal invitations to the ISHLT Project Leader and the Project Leader of the collaborating organization, provide details of the proposed project, collect Conflict of Interest Disclosure information, and request that they:
  - Identify Section Leaders representing each of the organizations
  - Complete the Initial Application, taking care to ensure that the document will be maximally relevant to the various ISHLT Professional Communities and collaborating organizations
  - Submit the Initial Application to ISHLT staff for review and approval by the S&G Committee
5. Project Leaders and Section Leaders serving on behalf of ISHLT 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 collaborating organization(s), the ISHLT Board of Directors, POC, IDN Steering Committees, or the S&G Committee.
6. The S&G Committee will review the Initial Application and vote to approve it, return it for revisions, or not approve it.
7. Two (2) weeks should be allowed for the Initial Application review and decision process.
8. Staff will communicate the S&G Committee decision to the IDN Steering Committee and the collaborating organization.
9. Staff will then issue formal invitations to the Section Leaders, provide details of the proposed project, and collect Conflict of Interest Disclosure information.
10. Once the Project Leaders and Section Leaders have accepted their invitations, staff will request that the Project Leaders and Section Leaders complete and submit the Follow-up Application within six (6) weeks. Copies of this and all other communications will be provided to the collaborating organization's staff.

## **B. Follow-up Application**

1. The ISHLT Project Leaders and Section Leaders are responsible for working with the leaders of the relevant ISHLT Professional Communities and the Project and Section Leaders of the collaborating organization 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. Six (6) weeks should be allowed for the development of the Follow-up Application and its submission to ISHLT staff.

3. Writing Committees must be composed to ensure that the interests of the relevant ISHLT Professional Communities and the collaborating organization are adequately represented, that a broad geographic perspective will be achieved, and that genders and generations are adequately represented. The Society strongly encourages the inclusion of Early Career Professionals (<6 years out of formal training) in the S&G Document writing process, especially if they are paired with senior or mid-career mentors.
4. The proportion of writing committee members should be comparable among the collaborating organizations. ISHLT representatives to the Writing Committee and Expert Reviewers must be ISHLT members at the time of appointment and throughout the duration of the project. They may be member of the collaborating organization, but it is strongly recommended that there be minimal to no overlap among participants from the collaborating organizations. The Project and Section Leaders of the collaborating organization are responsible for ensuring that their identified writing committee members have been approved by the appropriate leadership within their organization.
5. The S&G Committee will review the Follow-up Application to ensure that the table of contents and the content contributors are reflective of the identified relevant ISHLT Professional Communities and provide geographic, gender, and generational diversity.
6. Once these conditions are met, the S&G Committee will vote to approve the Follow-up Application and will submit it to the Publications Oversight Committee (POC) for final approval.
7. Two (2) weeks shall be allowed for review and approval of the Follow-up Application by the S&G Committee.
8. The POC will review the S&G Committee's decision regarding the Follow-up Application and will provide final instructions regarding publication plans (including those in the collaborating organization's journal or website or other vehicle) and endorsement (if any).
9. One (1) week shall be allowed for POC review and approval of the Follow-up Application.
10. Staff will communicate the decision of the POC to the S&G Committee, to the Project Leaders and Section Leaders, and to the collaborating organization, and will provide instructions regarding next steps and publication / endorsement plans.

## **WRITING COMMITTEE INVITATIONS / CONFLICT OF INTEREST MANAGEMENT**

- A.** Following approval of the Follow-up Application by the Publications Oversight Committee (POC), staff will issue invitations to the Sub-Section Leaders and Writing Committee members, and Expert Reviewers of both organizations, including details of the proposed project, writing assignments, the approved timeline, and publication / endorsement plans, and will collect Conflict of Interest Disclosure information.
- B.** All individuals involved in the development of the S&G document are required to adhere to ISHLT's conflict of interest policies.
- C.** Staff will work with the POC to ensure that no more than 49% of all individuals involved in the development of the S&G Document (including those from the collaborating organization) have current conflicts of interest relevant to the subject matter of the S&G Document. If more than 49% have relevant COI, the Project Leaders will identify alternate Writing Committee members/Expert Reviewers to be invited.
- D.** Once all Sub-Section Leaders, Writing Committee members, and Expert Reviewers have accepted, staff will notify the Project Leaders and Section Leaders.
- E.** In collaboration with staff, Project Leaders and Section Leaders will then communicate detailed instructions, including Policies for the writing of S&G Documents and the deadlines for document development, to the Writing Committee members and the writing process will begin. Staff will also distribute the master COI spreadsheet and COI policies to all individuals.

## **DOCUMENT WRITING POLICIES**

- A.** S&G Documents should be created as a single manuscript rather than multiple papers.
- B.** If multiple papers are strongly preferred by the Project Leads, the rationale for such must be outlined in writing and in detail to the JHLT Editor and must be agreed to by the JHLT Editor at the time the Follow-up Application is approved.
- C.** The typical length of a full S&G Document should not exceed 25,000 words, and an Executive Summary should not exceed 5,000 words.
- D.** Approval for documents exceeding the above limits must be obtained from the JHLT Editor in advance.
- G.** The structure of full S&G Documents must adhere to the ISHLT S&G Document Writing Policies. These policies are under development.

- H. The structure of the Executive Summary must adhere to the ISHLT S&G Document Writing Policies. These policies are under development.

## **DOCUMENT WRITING PROCESS**

- A. **IMPORTANT NOTE:** If the publication decision made at the time of approval of the Follow-up Application is for an Executive Summary to be published in JHLT, the Executive Summary **MUST** be submitted for review and approval at the same time that the full document is submitted for such.
- B. The Project Leaders and Section Leaders are responsible for overseeing and managing the engagement of the Sub-Section Leaders and Writing Committee members and monitoring their adherence to the policies and procedures and to the established deadlines and timetable.
- C. All work on the development of S&G Documents shall take place via telephone, email, and online ISHLTconnect discussion forums. ISHLT staff will arrange for conference calls and ISHLTconnect discussion forums for the Writing Committees.
- D. A face to face meeting of the Writing Committee members or Project Leaders/Section Leaders/Sub-Section Leaders at the ISHLT Annual Meeting will be arranged upon request. Meeting space will be provided, 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.
- E. Staff will check in with the Project Leaders once a month to ensure that work is progressing in accordance with the approved timetable. If the project is falling behind, 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 Publications Oversight Committee (POC). 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 POC for review and, if necessary, intervention and course correction.

## **DOCUMENT REVIEW AND APPROVAL**

- A. Staff will monitor and track the flow of documents through the review and editing process and will notify responsible parties when deadlines have not been met.
- B. The review and comment period for each step shall not exceed Two (2) weeks except under unusual circumstances.
- C. Initial drafts will be submitted by the Writing Committee members for review and comment by the Section/Sub-Section Leaders.

- D.** Revised drafts incorporating comments/revisions from Section/Sub-Section Leaders will be developed by the Writing Committee members and will be submitted for review/editing by the Section/Sub-Section Leaders. At this time, staff will also notify the Expert Reviewers to be prepared for the forthcoming document.
- E.** 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 and for the development of the Executive Summary, if relevant.
- F.** Staff will coordinate the review of the draft document (and Executive Summary) by the assigned Expert Reviewers from both organizations and the members of the appropriate Interdisciplinary Network (IDN) Steering Committee.
- G.** Staff will collate the comments from the Expert Reviewers and the IDN Steering Committee members and provide them to the Project Leaders.
- H.** The Project Leaders, with assistance from the Section Leaders if desired, will create a Revised Final Draft of the document (and the Executive Summary), incorporating comments from Expert Reviewers and IDN Steering Committee members.
- I.** Staff will then submit the Revised Final Draft (and Executive Summary) to the members of the relevant Interdisciplinary Networks and to the collaborating organization for peer review.
- J.** Staff will collate the comments from the peer review process and submit them to the Project Leaders for consideration and, if warranted, incorporation into a FINAL Final Draft of the document (and Executive Summary). The FINAL Final Draft of the document must have been approved by all members of the Writing Committee prior to submission to the Standards and Guidelines (S&G) Committee and Publications Oversight Committee (POC) for review and approval.
- K.** Staff will submit the FINAL Final Draft (and Executive Summary) to the S&G Committee and the POC and the collaborating organization simultaneously for review and approval.
- L.** Staff will submit the POC-approved document (and Executive Summary) to the Board of Directors for approval.
- M.** Once approved by the ISHLT Board and the collaborating organization's leadership, staff will notify the Project Leaders and the JHLT Editor of the Board's decision and direct the Project Leaders to submit the manuscript (and the Executive Summary, as appropriate) to the JHLT for publication. The JHLT Editor

will be directed to work with the Editor of the collaborating organization's publication regarding simultaneous publication, if any.

## **PUBLICATION**

- A.** Publication options for S&G Documents promulgated by ISHLT and developed in collaboration with other organization(s) are as follows:
1. Publication of the full S&G Document in the print and digital JHLT
  2. Publication of an Executive Summary only in the print and digital JHLT with the full S&G Document published as supplementary e-only files (requires Board approval of a budget for professional medical editing of the supplementary e-files). Supplementary e-only files must include a table of contents and must be tagged to the main components of the Executive Summary. If the supplementary e-only files contain separate "task force" documents authored by a distinct set of authors, these will not be credited separately as de novo papers and those authors will not receive publishable credit.
- B.** The JHLT has the right of first refusal for publication of the full S&G Document and/or the Executive Summary.
- C.** Board-approved S&G Documents will not undergo peer / editorial review by the JHLT Editorial team (copy editing and medical editing will be provided by the publisher), however, the following specifications must be adhered to for all documents published in the JHLT:
- S&G Documents should be created as a single manuscript rather than multiple papers.
  - If multiple papers are strongly preferred by the Project Leads, the rationale for such must be outlined in writing and in detail to the JHLT Editor and must be agreed to by the JHLT Editor at the time the Follow-up Application is approved.
  - The typical length of a full S&G Document should not exceed 25,000 words, and an Executive Summary should not exceed 5,000 words.
  - If a longer document is deemed necessary by the Project Leads, it will likely be necessary to pursue publication option #2 above. Approval for documents exceeding the above limits must be obtained from the JHLT Editor in advance.

- Staff will provide a list of the Writing Committee members and Expert Reviewers and their Conflict of Interest Disclosures to the Project Lead for submission with the final, approved manuscript to the JHLT.

**D.** The structure of full S&G Documents structure of full S&G Documents must adhere to the ISHLT S&G Document Writing Policies/ These policies are under development.

**E.** The structure of Executive Summary must adhere to the ISHLT S&G Document Writing Policies. These policies are under development.

**F.** The Project Leader is responsible for submitting the final approved document (and Executive Summary) to the JHLT in accordance with the process and standards established by the publisher. Such document must have been approved by all members of the Writing Committee prior to submission.

**G.** All ISHLT S&G Documents published in the JHLT will be made available for free access to the general public on the JHLT website, with links to them created by staff on the S&G pages of the ISHLT website.

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

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## **SPECIAL POLICIES AND PROCEDURES FOR COLLABORATIVE ISHLT S&G DOCUMENTS**

### **DOCUMENTS PROMULGATED BY OTHER ORGANIZATIONS AND DEVELOPED IN COLLABORATION WITH ISHLT**

The following special policies and procedures apply when ISHLT is invited to collaborate with another organization(s) on an S&G Document they are initiating and leading.

When warranted, due to the relevance of the topic to ISHLT members' interest or due to the need for common patient care approaches among the memberships of related organizations, ISHLT will consider collaborating on the development of S&G Documents initiated and led by other organizations. **Such organizations are limited to not-for-profit organizations and governmental agencies with similar and/or complementary interests in advanced heart failure and transplantation, advanced lung failure and transplantation, mechanical circulatory support, and/or pulmonary vascular disease.**

In general, the following policies apply to such collaborative documents:

- ISHLT will appoint representatives in the same proportion as other participants.
- ISHLT's name will be included in the title of the S&G Document and it will be titled as a "joint" document.
- ISHLT will have full joint publication rights and, ideally, simultaneous publication rights.
- No costs will be incurred by ISHLT in the development of the document.
- No commercial support will be received by any parties involved in the development of the development.
- The initiating organization will collect and resolve all COI disclosures in accordance with its policies.
- The initiating organization will coordinate all efforts of the writing committees and will provide ISHLT with the document once it is ready for expert review.
- The document will be created as a single manuscript rather than multiple papers.
- The full document length will not exceed 25,000 words, and any Executive Summary will not exceed 5,000 words.

### **COLLABORATION INVITATION AND APPROVAL**

- A. Invitations to ISHLT to collaborate on an S&G Document must be submitted in writing by the appropriate staff member / elected leader of the initiating organization to ISHLT staff for processing.

B. Before presenting the request to the Standards and Guidelines (S&G) Committee for consideration, staff is responsible for obtaining the following information regarding the project:

- Names of other collaborating organizations
- Working title of document
- Approximate start date and completion date
- Whether one or more face-to-face meetings be required
- Any costs ISHLT will be expected to pay
- Number and percentage of project leaders, section chairs, writing committee members, and expert reviewers ISHLT will be permitted to appoint
- Publication plans (including Executive Summary and/or e-only files) and ISHLT's publications rights (including free access to the document via the JHLT website)
- The names of any commercial supporters associated with the document and the nature of such support
- Confirmation that ISHLT will be provided with a minimum of one (1) week to conduct expert review, two (2) weeks to conduct peer review, and two (2) weeks to secure Board approval
- A copy of the initiating organization's COI policy regarding S&D Documents

C. Staff shall present the invitation and the above information to the S&G Committee for consideration. The S&G Committee will assess the presented information and ensure the following:

- The topic of the document is of relevance to at least one ISHLT Professional Community (preferably more than one) and one Interdisciplinary Network, and is, ideally, of international relevance
- ISHLT has not already developed / is not in the process of developing, its own S&G Document to address the topic
- ISHLT has not already / is not already collaborating on a similar S&G document with a different organization
- ISHLT has not already / is not in the process of endorsing a similar S&G document with a different organization

Based on the above assessment, the S&G Committee will make a recommendation to the Publications Oversight Committee (POC) regarding whether or not to accept the invitation to collaborate.

D. Once the invitation to collaborate is approved by the POC, ISHLT staff will contact the staff of the initiating organization and request an MOU outlining the terms of participation and collaboration, including the above policies.

## **WRITING COMMITTEE MEMBERS AND DOCUMENT DEVELOPMENT**

Once the MOU has been signed by both parties, the appointment of ISHLT representatives to the project may begin. ISHLT staff will work with the appropriate Interdisciplinary Network (IDN) Steering Committees and Professional Communities to identify the needed Project Leader(s), Writing Committee members, and Expert Reviewers. The Project Leader(s), if any, will participate in the selection of Writing Committee members.

All ISHLT representatives on the project 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 collaborating organization(s), the ISHLT Board of Directors, Publications Oversight Committee (POC), IDN Steering Committees, or the Standards and Guidelines (S&G) Committee.

ISHLT staff will coordinate all communications with the appropriate staff member of the initiating organization.

The initiating organization may choose to disseminate invitations to the ISHLT writing committee members or may request that this be done by ISHLT staff. Once all writing committee members have been confirmed, a complete list of participants will be provided by the initiating organization to ISHLT Staff, along with the final timeline for the project. Development of the document will proceed in accordance with the policies and procedures of the initiating organization.

ISHLT staff will communicate with the staff representative of the initiating organization every three months to obtain a status update on the project and timeline. If delays of more than 3 months are anticipated or experienced, ISHLT staff will work with the staff of the initiating organization to get the project back on track. If necessary, the Chair of the S&G Committee will communicate with his/her counterpart at the initiating organization to get the project back on track and resolve any problems causing the delay.

## **DOCUMENT REVIEW AND APPROVAL**

All versions / drafts Joint S&G Documents must be submitted by the staff representative of the initiating organization to ISHLT staff. Drafts submitted by members of the Project Leaders or members of the writing committee will not be accepted for review.

Once writing has concluded, ISHLT staff will coordinate the review of the First Draft (and Executive Summary, if applicable) by the invited ISHLT Expert Reviewers.

Comments from the Expert Reviewers will be collated by ISHLT staff and provided to the ISHLT Project Leaders and the staff representative of the initiating organization.

ISHLT staff will submit the Revised Draft (and Revised Executive Summary, if applicable) to the members of the relevant Interdisciplinary Networks and Professional Communities for peer review.

Comments collected from the peer review process will be collated by ISHLT staff and submitted to the ISHLT Project Leaders and the staff representative of the initiating organization.

ISHLT staff will submit the Final Draft of the document (and Final Executive Summary, if applicable) to the Standards and Guidelines (S&G) Committee and Publications Oversight Committee (POC) simultaneously for review and approval.

Staff will submit the POC-approved document (and approved Executive Summary, if applicable) to the Board of Directors for final approval.

Any revisions made to the document by either ISHLT or the initiating organization after POC or ISHLT Board approval will require review and approval by the POC and the ISHLT Board.

## **PUBLICATION**

Once approved by the ISHLT Board of Directors and the initiating organization's leadership, ISHLT staff will notify the Project Leaders and the JHLT Editor of the Board's decision.

The JHLT Editor will work with the appropriate staff member or journal editor of the partnering organization to coordinate the publication of the final document in the JHLT.

The JHLT Editor reserves the right to make the final decision regarding publication and associated specifics of all S&G Documents. In the event of a disagreement, the Editor will discuss his/her thoughts with the Publications Oversight Committee (POC) and the ISHLT Executive Committee prior to reaching a decision.

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## CONSENSUS CONFERENCES

From time to time, ISHLT may initiate or be invited to participate in Consensus Conferences. Such conferences consist of multidisciplinary experts, reflecting broad geographic representation, and are designed to review information related to a specific area of patient care and come to consensus on recommendations regarding the area and/or gaps in information that require further study.

ISHLT's participation in Consensus Conferences is limited to conferences of **not-for-profit organizations and governmental agencies with similar and/or complementary interests in advanced heart failure and transplantation, advanced lung failure and transplantation, mechanical circulatory support, and/or pulmonary vascular disease.**

A Consensus Conference should begin with a presentation of the current scope of knowledge and practice regarding the topic, based upon a literature review, and should include group discussion of background information and recommendations.

A Consensus Document should result from most Consensus Conferences; however, a Consensus Conference is not a required precursor to the development of a Consensus Document.

The Board of Directors will make the decision to initiate or participate in a Consensus Conference based upon the recommendation of the Publications Oversight Committee (POC). The policies governing such Consensus Conferences will be specified by the POC, in conjunction with ISHLT staff leadership.