

ISHLT COLLABORATIVE DOCUMENT POLICIES

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

The following special policies and procedures apply when the Statements & Publications Oversight Committee (SPOC) and Standards and Guidelines (S&G) Committee determine via its Identification of Need process that an ISHLT 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 ISHLT 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 ISHLT 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 SPOC's recommendations regarding ISHLT Documents to be developed collaboratively, staff will extend an invitation to the Staff 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 ISHLT 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, SPOC, 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 ISHLT

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 Statements & Publications Oversight Committee (SPOC) 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 SPOC 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 SPOC review and approval of the Follow-up Application.
10. Staff will communicate the decision of the SPOC 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 Statements & Publications Oversight Committee (SPOC), 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 ISHLT Document are required to adhere to ISHLT's conflict of interest policies.
- C. Staff will work with the SPOC to ensure that no more than 49% of all individuals involved in the development of the ISHLT Document (including those from the collaborating organization) have current conflicts of interest relevant to the subject matter of the ISHLT 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 ISHLT 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. ISHLT 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 ISHLT Document should not exceed 25,000 words.
- D. Approval for documents exceeding the above limits must be obtained from the *JHLT* Editor in advance.
- E. The structure of full ISHLT Documents must adhere to the ISHLT Document Writing Policies.

DOCUMENT WRITING POLICIES

- 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 ISHLT 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 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.

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.
- F. Staff will coordinate the review of the draft document 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, incorporating comments from Expert Reviewers and IDN Steering Committee members.
- I. Staff will then submit the Revised Final Draft 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. 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 Statements & Publications Oversight Committee (SPOC) for review and approval.
- K. Staff will submit the FINAL Final Draft to the S&G Committee and the SPOC and the collaborating organization simultaneously for review and approval.
- L. Staff will submit the SPOC-approved document 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 to the *JHLT* for publication. The *JHLT* Editor will be directed to work with the Editor of the collaborating organization's publication regarding simultaneously publication, if any.

DOCUMENT REVIEW AND APPROVAL

- A. Publication options for ISHLT Documents promulgated by ISHLT and developed in collaboration with other organization(s) are as follows:
 - Publication of the full ISHLT Document in the digital *JHLT* only with the associated Perspectives Piece published in print only.
- B. The *JHLT* has the right of first refusal for publication of the full ISHLT Document.
- C. Board-approved ISHLT 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*:
 - ISHLT 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 ISHLT Document should not exceed 25,000 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 ISHLT Documents must adhere to the ISHLT Document Writing Policies.
- E. The Project Leader is responsible for submitting the final approved document 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.
- F. All ISHLT 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.
- G. The *JHLT* Editor 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 will discuss his/her thoughts with the Statements & Publications Oversight Committee (SPOC) and the ISHLT Executive Committee prior to reaching a decision.
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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 ISHLT 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.

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:
 - a. Names of other collaborating organizations
 - b. Working title of document
 - c. Approximate start date and completion date
 - d. Whether one or more face-to-face meetings be required
 - e. Any costs ISHLT will be expected to pay
 - f. Number and percentage of project leaders, section chairs, writing committee members, and expert reviewers ISHLT will be permitted to appoint
 - g. 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)
 - h. The names of any commercial supporters associated with the document and the nature of such support
 - i. 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
 - j. 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:

- a. 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
 - b. ISHLT has not already developed / is not in the process of developing, its own S&G Document to address the topic
 - c. ISHLT has not already / is not already collaborating on a similar S&G document with a different organization
 - d. ISHLT has not already / is not in the process of endorsing a similar S&G document with a different organization
- D. Based on the above assessment, the S&G Committee will make a recommendation to the Publications Oversight Committee (SPOC) regarding whether or not to accept the invitation to collaborate.
- E. Once the invitation to collaborate is approved by the SPOC, 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 (SPOC), 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 ISHLT 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 (SPOC) simultaneously for review and approval.

Staff will submit the SPOC-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 SPOC or ISHLT Board approval will require review and approval by the SPOC 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 ISHLT Documents. In the event of a disagreement, the Editor will discuss his/her thoughts with the Statements & Publications Oversight Committee (SPOC) and the ISHLT Executive Committee prior to reaching a decision.