

**INTERNATIONAL SOCIETY FOR HEART AND LUNG TRANSPLANTATION  
PROTOCOL AND POLICIES FOR DEVELOPING  
STANDARDS STATEMENTS, GUIDELINES, AND CONSENSUS DOCUMENTS  
AND FOR  
CONDUCTING CONSENSUS CONFERENCES**

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# ISHLT STANDARDS AND GUIDELINES DOCUMENT AND CONSENSUS CONFERENCE DEVELOPMENT PROTOCOL AND POLICIES

## ***Preamble***

Subjects chosen for ISHLT Standards Statements, Guidelines, Consensus Documents, and Consensus Conferences are usually broad medical and clinical issues within our discipline and our core competencies, related to the topics 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, etc.

The ISHLT Standards and Guidelines (S&G) Committee will seek the advice of the appropriate Committees and Councils of the ISHLT for the choice of new Standards Statements, Guidelines, Consensus Documents, and Consensus Conference topics. Importantly, ideas and proposals for Standards Statements, Guidelines, Consensus Documents, and Consensus Conferences may be initiated from within one of the ISHLT Councils and submitted to the S&G Committee. The S&G Committee may also ask for advice and input from other bodies within ISHLT or consult experts who are not members of ISHLT. Suggested topics will be reviewed and prioritized by internal decision within the S&G Committee.

Duplication of good quality, previously existing guidelines issued by other societies is discouraged unless new data exists which make previous guidelines out of date.

Updates of previously published guidelines have high priority when new data have emerged in the relevant field.

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## **I. Activities and Documents under S&G Committee Purview**

- A. ISHLT Guidelines
- B. ISHLT Consensus Documents
- C. ISHLT Standards Statements
- D. ISHLT Policy Statements
- E. Guidelines, Consensus Documents, and Standards Statements developed jointly with other organizations
- F. Consensus Conferences (including joint consensus conferences with other organizations)
- G. ISHLT Endorsement of Guidelines/Consensus Statements developed by Other Organizations
- H. Endorsement by Other Organizations of ISHLT Guidelines/Consensus Statements

## II. Definitions

- A. **Guidelines:** documents that include strategies, information, and specific **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:
1. A development process that includes multi-disciplinary and broad geographic representation within ISHLT
  2. A comprehensive literature search and expert opinion which provide the evidence for recommendations
  3. Specific recommendations which include a formal grading based on the quality of available evidence
  4. Each recommendation formally graded by an evaluation of benefits, harms, burdens, and costs
- B. **Consensus Documents:** documents which summarize available information, supply general recommendations on complex or controversial areas of patient care, and include the following components:
1. A development process that includes multi-disciplinary and broad geographic representation within ISHLT
  2. A comprehensive literature search and expert opinion which provide the evidence for recommendations
  3. Consensus documents do **NOT** include individual recommendations that are quantified by level of evidence and strength of recommendation
- C. **Standards Statements:** documents which describe standards for training, competency, or nomenclature and incorporate a development process that includes multi-disciplinary and broad geographic representation within ISHLT.
- D. **ISHLT Policy Statements:** documents which present ISHLT positions on ethics and public health policy issues
- E. **Consensus Conferences:** A conference of experts designed to review information related to a specific area and come to consensus on recommendations regarding the area and/or gaps in information that require further study. The conference should be multidisciplinary, begin with a presentation of the state of the art concerning the topic based upon a literature review, and include group discussion of background information and recommendations. A Consensus Document or Guideline should result from most Consensus Conferences. A Consensus Conference is not a necessary precursor to the development of a Consensus Document. 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.

### III. Process for Development of Policy Statements

- A. Policy Statements are generated/revised at the request of the Board of Directors.
- B. The final document requires approval by the S&G Committee and the Board of Directors.

### IV. Process for Development of Standards Statements/Guidelines/Consensus Documents (see also Appendices A, B, C, and D)

- A. The S&G Committee will formally review existing ISHLT documents each year and will request new or updated Standards Statements/Guidelines/Consensus Documents from the relevant Council Operating Boards as deemed appropriate.
- B. Suggestions for Standards Statements/Guidelines/Consensus Documents may arise from the individual Councils, the S&G Committee or the Board of Directors.
- C. A concept for a Standards Statement/Guideline/Consensus Document must first be brought before the relevant Council Operating Board for consideration. If the Operating Board approves the concept, an Initial Application [http://ishlt.org/ContentDocuments/INITIAL\\_APPLICATION-STANDARDS\\_AND\\_GUIDELINES.docx](http://ishlt.org/ContentDocuments/INITIAL_APPLICATION-STANDARDS_AND_GUIDELINES.docx) must be completed in collaboration with the Council's S&G Workforce Leader. The completed application must be submitted to the Council's S&G Workforce Leader who will then submit it to the S&G Committee.
- D. The S&G Committee will approve or disapprove the Initial Application **(2 weeks)**.
- E. Applicants whose Initial Application is approved are required to submit a completed Follow-up Application [http://ishlt.org/ContentDocuments/FOLLOW-UP\\_APPLICATION-STANDARDS\\_AND\\_GUIDELINES.docx](http://ishlt.org/ContentDocuments/FOLLOW-UP_APPLICATION-STANDARDS_AND_GUIDELINES.docx) via the relevant S&G Workforce Leader **(within 3 months of initial application acceptance)**.
- F. The S&G Committee will approve or disapprove the follow-up application **(2 weeks)**.
- G. Once the Follow-up Application is approved, ISHLT staff will work with the Project Lead to issue invitations to the writing committee members and expert reviewers and collect their COI disclosure information **(6 weeks)**.
- H. ISHLT staff will also coordinate the review process with the S&G Committee and the Board, can assist with setting up conference calls and online community discussions, will coordinate the review of documents by the S&G Committee and Board of Directors, and, if a face to face meeting is requested, with the arrangement of space and AV equipment. The S&G Workforce Leader and the Leadership of the sponsoring Council must be copied on all relevant communication throughout the development of the document.
- I. Once the final document draft is complete **(10 months)**, it must be submitted to ISHLT Staff to be distributed for expert review to the reviewers identified in the follow-up application and approved by the S&G Committee **(3 weeks)**.
- J. Following revision based upon the expert review, ISHLT staff will distribute the document to the relevant Council membership for peer review. Council Chairs are encouraged to request invited peer reviews from specific Council members (3-4) to ensure that adequate and careful review is obtained **(2 weeks)**.
- K. Following revision based upon peer review, the final document must be submitted to the S&G Committee for review **(2 weeks)**.

- L. Following S&G Committee approval, the final document will be submitted to the Board of Directors for review **(2 weeks)**.

**V. Process for Publication of Standards Statements/Guidelines/Consensus Documents**

- A. Once the initial application is approved, the project Lead will initiate discussions with the JHLT Editor and the Monograph Editor regarding publication of the Executive Summary and/or the full guidelines. The publication plans must be included in the follow-up application. Publication options are as follows:
  - 1. Publication of the full guidelines in the printed JHLT
  - 2. Publication of only the Executive Summary in the printed JHLT
  - 3. Publication of the Executive Summary in the printed JHLT with full guidelines published as supplementary e-files on the JHLT website (requires Board approval of a budget for professional medical editing).
  - 4. Publication of the Executive Summary in the printed JHLT with full guidelines published in the printed Monograph
  - 5. Publication of the Executive Summary in the printed JHLT with full guidelines published as an e-only Monograph (requires Board approval of a budget for professional medical editing).
- C. If warranted, the S&G Committee Chair will discuss funding for a medical editor with the Finance Committee. The Board will make a final decision regarding publication **(4 months)**.
- D. The S&G Committee Chair will notify the JHLT Editor or the Monograph Editor regarding the publication decision and anticipated time frame for delivery of final documents.
- E. If funds for medical editing are approved, staff will contract with a medical editor **(2 months)**.
- F. Once the final document is approved by the Board of Directors, the S&G Committee Chair will notify the JHLT Editor or the Monograph Editor that the document has received Board approval.
- G. Once the final document is approved by the Board of Directors, the Project Lead will write the Executive Summary (if planned) for publication in the JHLT **(1 month)**.
- H. The Executive Summary will be reviewed by the S&G Committee **(2 weeks)**.
- I. The S&G Committee will discuss and decide whether the Executive Summary will be published in additional languages. If warranted, it will be the responsibility of the S&G Committee to determine into which languages the document be translated. The Committee will then make a request to the Board to fund the translation.
- J. After approval by the S&G Committee and any required revisions, the Executive Summary will be submitted to the Board of Directors for review **(2 weeks)**.
- K. After Board approval, the S&G Committee Chair will notify the JHLT Editor that the document has received Board approval.
- L. If budgeted, the medical editing of the full guidelines will begin once Board approval of the document has been obtained.
- M. Editing of the Executive Summary to be published in the JHLT will be done by Elsevier.
- N. If budgeted, Elsevier will translate the final Executive Summary into language designated by S&G Committee.

- O. Once Elsevier has translated the Executive Summary it will be returned to the S&G Committee. Staff will coordinate peer review for translational accuracy. Each Summary must be reviewed by two members of the appropriate Council who are native speakers of the language of translation.
- P. The Project Lead is responsible for working with the Medical Editor or the Monograph Editor to prepare the document for publication **(4 months)**.
- Q. Following Board approval, the Project Lead is responsible for submitting the Executive Summary to the JHLT for publication.
- R. Following Board approval, the Project Lead is responsible for submitting the final edited full guidelines to the JHLT Editor or the Monograph Editor for publication.

**VI. Policies for Development of Standards Statements/Guidelines/Consensus Documents Jointly with Other Organizations** (see also Appendices A, B, C, and D)

**A. Joint S&G Projects Initiated by ISHLT**

- 1. ISHLT will serve as the lead organization for joint standards and guidelines projects initiated by ISHLT.
- 2. Such projects will follow the established ISHLT development policies, protocols, and processes.
- 3. ISHLT will issue invitations to partner organizations to contribute members to the writing committee and the expert review committee.
- 4. ISHLT will manage all communications with writing committee members and expert reviewers.
- 5. Partner organization writing committee and expert review committee appointees will be required to adhere to ISHLT's conflict of interest policies.
- 6. ISHLT will collect conflict of interest disclosure from all writing committee members and expert reviewers.
- 7. Partner organizations will be invited to participate in the peer review/public comment process
- 8. The partner organization's Board of Directors will be offered the opportunity to approve the final document and have their organization's name listed as a partnering organization.
- 9. Any costs incurred by or on behalf of writing committee members or expert reviewers in conjunction with face to face meetings will be borne by that writing committee member's/expert reviewer's appointing organization in accordance with that organization's policies and procedures.
- 10. Partner organizations must be not-for-profit organizations or governmental agencies with similar and/or complementary interests in end stage heart and/or lung disease.
- 11. Commercial support for such projects may not be solicited or accepted by the partner organization(s).
- 12. The Executive Summary will be published in the JHLT.
- 13. Partner organizations will be offered the opportunity to publish the Executive Summary in their organization's journal and/or on their website.

14. Publication of the full guidelines in a publication other than JHLT by a partner organization is subject to the approval of ISHLT. Requests for such approval will be considered on a case by case basis in consultation with the JHLT Editor.
15. A written agreement regarding publication of the executive summary and/or full guidelines and regarding publication rights and copyrights must be in place prior to the project being initiated.

## **B. Joint S&G Projects Initiated by Other Organizations**

1. The initiating organization will serve as the lead organization for joint standards and guidelines projects on which ISHLT is invited to participate.
2. Such projects will follow the lead organization's established development process, protocols, and processes, a copy of which shall be provided to ISHLT at the time of invitation to participate.
3. ISHLT will be permitted to appoint members of its choosing to both the writing committee and the expert review committee.
4. The lead organization will manage all communications with writing committee members and expert reviewers.
5. ISHLT's writing committee appointees and expert reviewers will be required to adhere to ISHLT's conflict of interest policies and the conflict of interest policies of the lead organization.
6. The lead organization will collect conflict of interest disclosure from all writing committee members and expert reviewers.
7. ISHLT will be invited to participate in the peer review/public comment process
8. The ISHLT S&G Committee will be offered the opportunity to review the final document and make a formal recommendation to the Board regarding approval and, if Board approved, have ISHLT's name listed as a partnering Society.
9. Any costs incurred by or on behalf of ISHLT's writing committee members or expert reviewers in conjunction with face to face meetings will be borne by ISHLT in accordance with ISHLT's policies and procedures.
10. Partner organizations must be not-for-profit organizations or governmental agencies with similar and/or complementary interests in end stage heart and/or lung disease.
11. Commercial support for such projects may not be solicited or accepted by the lead organization or any of the other partner organization(s).
12. ISHLT will be offered the opportunity to simultaneously publish the Executive Summary in the JHLT and/or on our website.
13. An agreement must be in place for publication of the executive summary and the full guidelines by each participating organization and an understanding must occur about publication rights and copyrights prior to the project being initiated.

## **VII. Policies for Oversight and Monitoring of Standards Statements/Guidelines/Consensus Documents**

- A. Monitoring of writing committee performance and adherence to ISHLT policies, protocols, and timelines is the responsibility of the Project Lead(s). If additional or replacement writers are needed to meet quality and/or timeline goals, such changes must be communicated by the Project Lead(s) to, and approved by, the S&G Committee Chair.
- B. Performance surveillance and mentorship of the Project Lead(s) is the responsibility of the relevant Council S&G Workforce Leader(s) with assistance from the S&G Committee Chair, if needed.

**VIII. Process and Policies for ISHLT Endorsement of Guidelines/Consensus Statements Developed by Other Organizations**

- A. Organizations from whom endorsement requests will be considered should reflect the core missions of the ISHLT. Such organizations must be not-for-profit organizations or governmental agencies with similar and/or complementary interests in end stage heart and/or lung disease
- B. All potential endorsements must be approved in advance by the Board of Directors.
- C. Any desires regarding simultaneous or subsequent publication in the JHLT must be expressed by the Board at the time of approval and communicated to the other organization at the time the endorsement invitation is accepted.
- D. A 2-week review period by 2 ISHLT reviewers appointed by the S&G Committee is required prior to S&G Committee approval (2 weeks) and subsequent referral to the Board of Directors for approval (2 weeks).

**IX. Process and Policies for Endorsement by Other Organizations of ISHLT Standards Statements/Guidelines/Consensus Documents**

- A. Potential organizations to endorse ISHLT Standards Statements/Guidelines/Consensus Documents must be identified on the initial and follow-up applications. Additional requests for endorsement may be initiated by the Board of Directors or the S&G Committee.
- B. Organizations from whom endorsement is requested should reflect the core missions of the ISHLT. Such organizations must be not-for-profit organizations or governmental agencies with similar and/or complementary interests in end stage heart and/or lung disease
- C. All such potential endorsements must be approved by the Board of Directors prior to the other organizations being contacted.
- D. Any desires regarding simultaneous or subsequent publication by the endorsing organization must be negotiated prior to the final endorsement.

**X. Process and Policies for ISHLT Consensus Conferences**

- A. Suggestions for Consensus Conferences may arise from the Councils, the S&G Committee, or the Board of Directors.
- B. A concept for a Consensus Conference must first be brought before the relevant Council Operating Board for consideration. If the Operating Board approves the concept, an Initial Application [http://ishlt.org/ContentDocuments/INITIAL\\_APPLICATION-ISHLT\\_CONSENSUS\\_CONFERENCE.docx](http://ishlt.org/ContentDocuments/INITIAL_APPLICATION-ISHLT_CONSENSUS_CONFERENCE.docx) must be completed in collaboration with the Council's S&G Workforce Leader. The completed application must be submitted to the S&G Committee by the relevant Council's S&G Workforce Leader. The Initial Application must be submitted no less than **15 months prior to the planned conference.**
- C. The S&G Committee will approve or disapprove the Initial Application (**2 weeks**).

- D. Applicants whose Initial Application is approved are required to submit a completed Follow-up Application [http://ishlt.org/ContentDocuments/FOLLOW-UP\\_APPLICATION-ISHLT\\_CONSENSUS\\_CONFERENCE.docx](http://ishlt.org/ContentDocuments/FOLLOW-UP_APPLICATION-ISHLT_CONSENSUS_CONFERENCE.docx) via the relevant S&G Workforce Leader(s) **within 3 months** of Initial Application acceptance. The program agenda, participant list, speaker list, and letter from the Council Chair(s) indicating that the Council Operating Board(s) have reviewed and approved the program agenda, must be submitted as part of the Follow-up Application.
- E. The S&G Committee will approve or disapprove the Follow-up Application (**2 weeks**).
- F. If there are budgetary implications, the Follow-up Application must then be reviewed by the Finance Committee and approved by the Executive Committee and/or the Board of Directors before proceeding further (6-8 weeks).
- G. Once the Follow-up Application and funding (if applicable) are approved, ISHLT staff will work with the Project Lead(s) to issue invitations to conference speakers and participants and collect COI (6-8 weeks).
- H. Staff will coordinate the logistics regarding the Consensus Conference. The Project Lead will coordinate the content of the Consensus Conference.
- I. Once the Consensus Conference has concluded, the development and publication of a Consensus Document or similar output must adhere to the policies and processes outlined in Sections IV and V.

**XI. Policies for Consensus Conferences Planned and Conducted Jointly with Other Organizations**

- A. Joint Consensus Conferences Initiated by ISHLT (TBD)**
- B. Joint Consensus Conferences Initiated by Other Organizations (TBD)**

## APPENDIX A

### Rules for Writing Guidelines and Consensus Documents

#### 1. Introduction

Guidelines aim to present all the relevant evidence on a particular clinical issue in order to help clinicians weigh the benefits and risks of a particular diagnostic or therapeutic procedure. They should be helpful in everyday clinical decision-making.

A great number of guidelines have been issued in recent years by different national and international organizations, and other related societies. Several hundred guidelines are now available; however, this profusion of documents can endanger the authority and validity of all guidelines, which can only be guaranteed if they have been developed by an unquestionable decision-making process. This is one of the reasons why the ISHLT and others have issued recommendations for formulating and issuing guidelines.

Guidelines and Consensus Documents originating with the ISHLT should reflect the core missions of ISHLT.

In spite of the fact that standards for issuing good quality guidelines are well defined, recent surveys of guidelines published in peer-reviewed journals between 1985 and 1998 indicate that methodological standards were not complied with in large numbers. It is therefore of great importance that guidelines and recommendations are presented in formats that are easily interpreted. The ISHLT feels strongly that our guidelines should be succinct compilations of evidence-based recommendations. Gaps in evidence should be so stated, ideally in a table, and not simply detailed in long paragraphs with numerous examples of what has been tried but not proven. Adherence to the ISHLT's guideline development guide, contained herein, will help to ensure useful documents that will aid in clinical decision-making.

#### 2. Suggested Document Length

**Guidelines:** Guidelines will result in two different documents: a full version of the guidelines which may be quite extensive (see below) and an executive summary of the guidelines. The executive summary should be no more than 4500 words/15 double spaced typed pages including references.

**Consensus Documents:** 4500 words/15 double spaced typed pages including references

**Standard Statements:** 4500 words/15 double spaced typed pages including references

**Policy Statement:** 3000 words/10 double spaced typed pages including references

**Note:** If it is anticipated that the proposed document will exceed these prescribed lengths, this can be discussed with the S&G Chair and the JHLT Editor prior to document writing to define if a longer document might be considered appropriate. However, it is to be remembered that succinctness is to be valued.

### 3. Writing Group Organization

The Chair(s) of the Writing Group(s) are to be selected by the Project Leader and identified in the follow-up application, as are the proposed Writing Group members. A maximum of 10 to 30 total Writing Group Members is recommended.

There are several considerations in the choice of members for a specific Writing Group:

- . The Project Leader and Writing Group members must be renowned for their scientific expertise in the field. **They must be members of ISHLT.**
- . Efforts must be made to ensure wide geographical representation among the Writing Group members.
- . The Writing Group members are also chosen according to their willingness and availability to participate actively, respond promptly, and meet the established deadlines.
- . Appropriate representation from the various ISHLT Councils should be sought. Especially important to represent in many of the guidelines will be allied health professionals, infectious disease professionals, pharmacy professionals, and pediatric clinicians.
- . In cases where the subject area is felt to require the expertise of other disciplines, a representative of the relevant related society(ies) can be invited to participate. This should be a rare occurrence, as the guidelines emanating from the ISHLT should be representative of the ISHLT's expertise. Representatives from related societies may be invited to participate as full members or can be invited at a later stage to review the Writing Group document.
- . Writing Group members must be willing to disclose all relationships with industry that might represent a potential conflict of interest. (see below)
- . Writing Group members are expected to participate in all of the Writing Group conference calls/meetings and adhere to the time schedule of the document production. If a member does not meet these obligations, he or she may be asked to step down from the Writing Group at the discretion of the Chair(s).

### 4. Rules for Guidelines and Consensus Document Writing

#### ***Evidence Gathering and Review***

The prerequisite for data to be considered for inclusion and integration into Guidelines and Consensus Documents is their credibility. An important undertaking of the Writing Group should be to gather and weigh the available evidence. To this end, new tools are now available for literature searching which can make this process much easier, i.e. advanced PubMed, Medline, etc. A formal literature review must be performed. If deemed necessary and appropriate, the Writing Group can undertake a formal meta-analysis.

With regard to evidence gathering, the following rules apply:

- . Only English language peer reviewed published literature will be considered.
- . **The use of abstracts should be avoided except in very rare instances.** Abstracts older than 2 years will not be accepted as reference and quotation of any abstract must clearly indicate that it is an abstract and not a full paper.
- . **Unpublished clinical trials cannot be quoted unless they have been formally presented at a major international meeting and on condition that the authors of the trial have provided the Writing Group with a draft of the final document to be submitted for publication.** Quotation of such trials must indicate at which international meeting it has been presented.

***Classes of Recommendations and Levels of Evidence***

The Class of Recommendation relates to the strength of the recommendation based on available evidence (see table below)

The Levels of Evidence in favor of or against a particular treatment or diagnostic procedure must be cited. The levels of evidence must be ranked in three levels according to the type of available data (see table below).

Recommendations must be linked to their level of evidence or highlighted by comment stating for example: "...this recommendation is based on level of evidence A".

The classes of recommendations and the levels of evidence are graded as follows:

<b>Class I</b>	Evidence and/or general agreement that a given treatment or procedure is beneficial, useful and effective
<b>Class II</b>	Conflicting evidence and/or divergence of opinion about the usefulness/efficacy of the treatment or procedure;
<b>Class IIa</b>	Weight of evidence/opinion is in favor of usefulness/efficacy;
<b>Class IIb</b>	Usefulness/efficacy is less well established by evidence/opinion;
<b>Class III</b>	Evidence or general agreement that the treatment or procedure is not useful or effective and in some cases may be harmful.

<b>Level of Evidence A</b>	Data derived from multiple randomized clinical trials or meta-analyses
<b>Level of Evidence B</b>	Data derived from a single randomized clinical trial or large non-randomized studies
<b>Level of Evidence C</b>	Consensus of opinion of the experts and/or small studies, retrospective studies, registries

### ***Consensus Achievement***

Consensus can be achieved for recommendations without much discussion when strong evidence exists. However, the Writing Group must also critically consider the applicability of the recommendations to a specific field or area. For example, recommendations on particular treatments based on trials carried out in patients aged 70 years or younger cannot be extended to patients older than 70 years.

In controversial areas, or in issues without evidence other than usual clinical practice, different processes can achieve consensus:

- . Expert panel discussion and common sense.
- . Quantification of expert opinions. These are interesting but time-consuming methods.

It should be emphasized that ISHLT guidelines should be succinct summaries of evidence based recommendations. There should not be long paragraphs about controversies or various schema that institutions have used (dealing with pre-sensitized patients prior to transplant, as an example) where no definitive evidence exists. The Writing Group may present, instead, a table of “Gaps in Evidence” summarizing areas that are not clarified by trials. As a rough guide, no more than half of the recommendations should be at a Level of Evidence C.

### ***Format of Documents***

In general, each Writing Group will produce two different documents:

1. Full version of the guidelines: The full version of the guidelines should be a maximum of 50,000 words, including references. This corresponds to 50 ISHLT formatted pages (1000 words per page, 40 references per page).
2. Executive summary of the guidelines: The executive summary of the guidelines should be no more than 4500 words/15 double spaced typed pages including references.

The document must be written in English. The document may later be translated into additional languages, pending approval from the S&G Committee. Simple and clear wording is essential to aid comprehension and avoid ambiguity. The use of tables, drawings, figures, decision-

making algorithms and other illustrations is encouraged. **In particular, tables summarizing “Gaps in Evidence” are strongly encouraged.**

The body of the guidelines should typically contain the following items:

- . Background and aim of the document.
- . Scope of the problem with relevant epidemiological information.
- . Grading of recommendations (Class I, IIa, IIb, or III) and levels of evidence (A, B or C) for all recommendations. The use of summary tables is recommended.
- . Treatment goals and/or other indicators of “best practice”.
- . Reference to relevant changes or discrepancies with older versions of the guidelines.
- . The use of tables illustrating the differences with older versions of the guidelines is encouraged, if applicable.
- . Suggestions for implementing the recommendations of the guidelines in clinical practice.
- . Identification of ongoing research that may change some of the recommendations.
- . In addition to the body of the report described above, the final guidelines document should include the names of the Writing Group members (plus affiliations in case of members from related societies), and names of the expert reviewers on the first page

### ***Abbreviations, Units and Standards***

The Writing Group Leader must employ ISHLT’s standardized abbreviations, units, and standards for the document. These are available at **Appendix D**.

## **5. Conflict of Interests**

The Writing Group(s) must make every effort to avoid any actual or potential conflicts of interest that might arise as a result of an outside relationship or personal interest. Specifically, before being appointed by the Committee, all the proposed members of Writing Group must disclose all relationships that might be perceived as real or potential conflicts of interest. The disclosure must be updated if any changes occur during the development of the document.

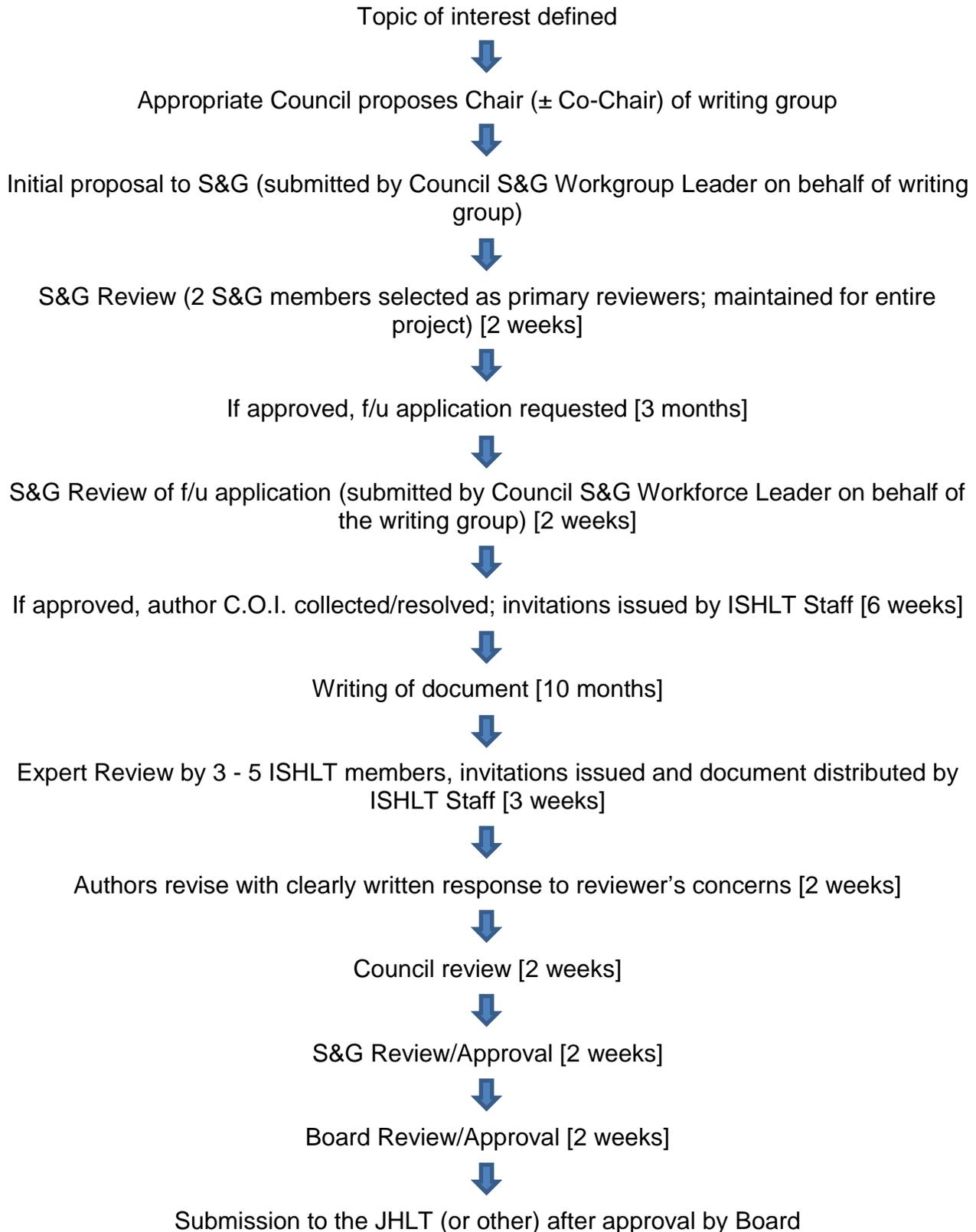
The final published Standards, Guidelines, and Consensus Documents must contain a statement of relationship with industry and conflicts of interest for each writing group member and each reviewer whose name will appear on the document. Format consistent with the Journal of Heart and Lung Transplant should be followed.

## **6. Acknowledgement**

The ISHLT Standards and Guidelines Committee acknowledges that many portions of this guideline are patterned closely after the European Society of Cardiology’s and the American Society of Transplantation’s documents of a similar name. We are indebted to the wisdom of these Societies in formulating their documents, available on their web sites.

## APPENDIX B

### FLOW CHART RE: DEVELOPMENT OF OFFICIAL ISHLT DOCUMENTS



## APPENDIX C

### **Initial Application for Standards Statements/Guidelines/Consensus Documents**

[http://ishlt.org/ContentDocuments/INITIAL\\_APPLICATION-STANDARDS\\_AND\\_GUIDELINES.docx](http://ishlt.org/ContentDocuments/INITIAL_APPLICATION-STANDARDS_AND_GUIDELINES.docx)

### **Follow-up Application for Standards Statements/Guidelines/Consensus Documents**

[http://ishlt.org/ContentDocuments/FOLLOW-UP\\_APPLICATION-STANDARDS\\_AND\\_GUIDELINES.docx](http://ishlt.org/ContentDocuments/FOLLOW-UP_APPLICATION-STANDARDS_AND_GUIDELINES.docx)

### **Initial Application for ISHLT Consensus Conference**

[http://ishlt.org/ContentDocuments/INITIAL\\_APPLICATION-ISHLT\\_CONSENSUS\\_CONFERENCE.docx](http://ishlt.org/ContentDocuments/INITIAL_APPLICATION-ISHLT_CONSENSUS_CONFERENCE.docx)

### **Follow-up Application for ISHLT Consensus Conference**

[http://ishlt.org/ContentDocuments/FOLLOW-UP\\_APPLICATION-ISHLT\\_CONSENSUS\\_CONFERENCE.docx](http://ishlt.org/ContentDocuments/FOLLOW-UP_APPLICATION-ISHLT_CONSENSUS_CONFERENCE.docx)

## APPENDIX D

### ISHLT Approved Abbreviations, Units and Standards (from International Committee of Medical Journal Editors)

#### Style and Format

References should follow the standards summarized in the NLM's International Committee of Medical Journal Editors (ICMJE) Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals: Sample References ([www.nlm.nih.gov/bsd/uniform\\_requirements.html](http://www.nlm.nih.gov/bsd/uniform_requirements.html)) webpage and detailed in the NLM's Citing Medicine, 2nd edition ([www.ncbi.nlm.nih.gov/books/NBK7256/](http://www.ncbi.nlm.nih.gov/books/NBK7256/)).

#### Tables

Titles in tables should be short but self-explanatory, containing information that allows readers to understand the table's content without having to go back to the text. Be sure that each table is cited in the text.

Give each column a short or an abbreviated heading.

Authors should place explanatory matter in footnotes, not in the heading. Explain all nonstandard abbreviations in footnotes, and use symbols to explain information if needed.

Identify statistical measures of variations, such as standard deviation and standard error of the mean.

Additional tables containing backup data too extensive to publish in print may be appropriate for publication in the electronic version of the document. An appropriate statement should be added to the text to inform readers that this additional information is available and where it is located. Submit such tables for consideration with the document so that they will be available to the peer reviewers.

#### Illustrations (Figures)

Letters, numbers, and symbols on figures should be clear and consistent throughout, and large enough to remain legible when the figure is reduced for publication. Figures should be made as self-explanatory as possible, since many will be used directly in slide presentations. Titles and detailed explanations belong in the legends— not on the illustrations themselves. Figures should be numbered consecutively according to the order in which they have been cited in the text. In the manuscript, legends for illustrations should be on a separate page, with Arabic numerals corresponding to the illustrations. When symbols, arrows, numbers, or letters are used to identify parts of the illustrations, identify and explain each one clearly in the legend.

#### Units of Measurement

Measurements of length, height, weight, and volume should be reported in metric units (meter, kilogram, or liter) or their decimal multiples. Temperatures should be in degrees Celsius. Blood pressures should be in millimeters of mercury. Authors should report laboratory information in International System of Units (SI). Drug concentrations may be reported in either SI or mass units, but the alternative should be provided in parentheses where appropriate.

#### Abbreviations and Symbols

Use only standard abbreviations; use of nonstandard abbreviations can be confusing to readers. Avoid abbreviations in the title of the manuscript. The spelled-out abbreviation followed by the abbreviation in parenthesis should be used on first mention unless the abbreviation is a standard unit of measurement