



Policy Manual

Official Policies and Procedures

of the

International Society for Pharmacoepidemiology (ISPE)

This document is a working document
that describes ISPE's current policies and procedures.

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1 Mission of ISPE

1.1 Mission Statement

(Adopted October 2002; amended August 2003; alternate version April 2005; amended April 2006; April 2009; April 2017)

The International Society for Pharmacoepidemiology (ISPE) is an international organization dedicated to advancing the health of the public by providing a global forum for the open exchange of scientific information and for the development of policy, education, and advocacy for the field of pharmacoepidemiology, including such areas as pharmacovigilance, drug utilization research, comparative effectiveness research, and therapeutic risk management.

1.2 Objectives

(Amended in accordance with the strategic plan of October 2002; April 2004; April 2017)

The objectives of the Society include:

- Establishment of scientific fora
- Dissemination of scholarly and practical information
- Facilitation of professional communication
- Capacity building
- Provide and facilitate education in pharmacoepidemiology

1.3 Vision Statement

(Adopted April 2017)

ISPE defines and regularly updates its vision of the future for the field of pharmacoepidemiology. The Strategic Plan of the Society is based on the Vision Statement.

1.3.1 Current Vision and Goals

(Adopted April 2017)

The current vision for the Society is that by the year 2022:

1. ISPE drives development of the fields of pharmacoepidemiology to maximize benefits and minimize harm in individuals and populations
2. ISPE is recognized internationally as a leading authority in pharmacoepidemiology by integrating epidemiology and public health perspectives into the way medical interventions are researched, developed and used
3. ISPE advocates for the role of pharmacoepidemiology in health affairs
4. ISPE is the driver of pharmacoepidemiology training and placement
5. ISPE is a broadly dispersed, vibrant, truly global community
6. ISPE seeks to expand membership and build pharmacoepidemiology capacity globally, especially in areas where pharmacoepidemiology is less developed.

Goals:

- Maintain and expand membership
- Build on existing strengths
- Promote education, training and communication
- Increase member involvement worldwide

- Ensure sufficient resources to meet ISPE's goals.

1.4 Roles of the Society.

(Adopted May, 1992; amended April, 2004)

The International Society for Pharmacoepidemiology (ISPE) is a non-profit, international, professional membership organization dedicated to promoting pharmacoepidemiology, the science which applies epidemiological approaches to studying the use, effectiveness, values and safety of pharmaceuticals. ISPE is firmly committed to providing an unbiased scientific forum to the views of all parties with interests in drug, biologics, and devices development, delivery, use, costs and value, adverse and beneficial effects, and therapeutic risk management.

As such, ISPE occupies and embodies many roles and undertakes a wide range of activities. These roles may be conceived broadly as:

- Scientific and professional convener
- Academy
- Advocate
- Certifier
- Arbiter

1.5 Customers of the Society.

(Adopted October, 2002; amended April, 2004)

1. Private Sector: experts in pharmacoepidemiology, pharmacovigilance, risk management, drug safety, marketing, advertising, market research, biostatistics, regulation and outcomes, clinical development, discovery, PR, communications, economics and senior management personnel
2. Government: epidemiologists, evaluators/post market surveillance experts, legislators, economists, advertising personnel, medical surveillance organizations (e.g. CDC), research funders (e.g. NIH), post-licensing evaluators/policymakers, drug plan managers, risk managers, health plan managers (e.g. VA), health plan reimbursement experts
3. Academia: students; researchers; schools of pharmacy, public health, medicine, etc.; economists and statisticians, demographers, guideline writers
4. Other: contract researchers, payers, NHS, practitioner organizations (e.g. in medicine, nursing, etc.), clinical practitioners (physicians, pharmacists, nurses, etc.), legal practitioners (in all sectors)

1.6 Strategic Plan.

(Adopted, August 2004; amended April 2007; August 2019)

1.6.1 Planning:

ISPE is a forward-looking leadership society. To that end, ISPE commits to orderly strategic deployment of the resources and energies of the Society. To guide these efforts, ISPE maintains and regularly updates a formal strategic plan.

A comprehensive review and redesign of the strategic plan should occur at least every five years. For each five year period an implementation program will be adopted and its progress will be monitored by the Board. Both the plan and the implementation program will receive regular review and updating at each strategic planning session of the Board.

A current version of the strategic plan and implementation program will be maintained in the ISPE offices, and these documents will be accessible on the ISPE website for ISPE members only.

1.6.2 Responsibility for strategic planning:

(amended April 2007; August 2019)

- The Board assumes the responsibility for the strategic plan and implementation program.
- The President Elect oversees and facilitates the strategic planning function along with the Strategic Planning Committee.
- Each Board meeting will include a session devoted to review and discussion of the strategic plan and its implementation. In addition, it is desirable that the strategic planning committee has separate face-to-face meetings in conjunction with ISPE conferences.
- The strategic planning session will be open to all ISPE members.

1.6.3 Preferred Future:

(Adopted October, 2002; revised August 2004, amended April 2013; updated August 2013; April 2017; August 2019)

To guide ISPE's strategic planning, whenever necessary, and in the year prior to the beginning of each five-year planning cycle, ISPE examines and revises its vision and goals for the future (1.3.1 – Page 1). The Strategic Planning Committee develops for Board consideration, adjustments to the Board's vision and goals for the future of the field. (11.1.17 – Page 52).

1.7 Public Policies

(Amended April, 1999; Amended February 2021)

ISPE is committed to advancing and promoting the field of pharmacoepidemiology and the profession of its members. This is achieved by ISPE's example of excellence in scientific products and professional conduct of our members.

Compatible with ISPE's status as a not-for-profit professional society, ISPE is also committed to the open debate of matters of scientific and professional controversy, to ensure that ISPE members may be informed and effective agents for positive change. The Board may from time to time commission or receive scholarly, scientific, or professional positions. Upon due consideration, including, as necessary, broad deliberations throughout the membership, such positions may be adopted as official public policy of the Society, and transmitted as the endorsed positions of the Society to external agencies and organizations, keeping the membership apprised.

The Public Policy Committee is responsible for oversight and maintenance of a body of endorsed ISPE Public Policies.

1.7.1 Endorsement of documents as ISPE Public Policy

(Adopted February 2021)

Any documentation, guideline, policy, or commentary on pharmacoepidemiology issues which is developed by a writing group associated with ISPE, has the potential to be viewed by the wider world as being affiliated with ISPE.

Unless such documentation has been specifically endorsed by the process described below, it must contain clarifying language disclosing that the document reflects the authors' personal views and does not necessarily reflect those of ISPE or any group associated with ISPE. This disclaimer is required even if the authors collaborated together as members of a SIG, RIG, Council, Committee,

Task Force, manuscript writing group or other group of ISPE members convened under the auspices of ISPE.

The default expectation is that all ISPE-affiliated writing groups will seek endorsement of any documentation, guidelines, policies, or commentaries on external-facing pharmacoepidemiology issues. Writing groups should inform the Public Policy Committee if endorsement is not going to be sought.

Publications which aspire to be endorsed by ISPE should, after final drafting by the writing group, be submitted for review by the Public Policy Committee. Within a one-week period, the Public Policy Committee will provide feedback on content and suitability of the paper before it moves forward within ISPE's endorsement process.

The (revised) paper will then be posted by the Executive Secretary for review and comment by the General Membership for a period of three weeks. The authors will address all comments and accommodate them if appropriate and provide a rebuttal if not.

A summary of all commentary will be provided to the Public Policy Committee to ensure that comments were adequately addressed in the final, revised version submitted for approval. The final version of the paper should be provided to the Chair(s) of the Public Policy Committee and the Board for review and approval. Following Board approval, the paper will then be designated as an ISPE-endorsed document/public policy with an expiration date of up to three years.

If desired, after the first review by the Public Policy Committee, the writing group may submit the manuscript for target journal review (i.e., simultaneous review by the journal and ISPE membership). The writing group should inform the journal of this ongoing review within ISPE. If the journal or other publishing body requires revisions to the text, the revised text should be submitted to the Public Policy Committee who shall decide whether the revisions are substantial enough to require further consultation with the General Membership and/or the Board. If further consultation is required, the Public Policy Committee shall decide the length of the period of consultation.

Graphic details of the above processes are found at Appendix B (see page 73)

Final versions accepted for publication, whether or not ISPE endorsed, should be provided to the Publications and Communications Committee.

1.7.2 Circumstances of Public Importance and/or Urgency

(Adopted February 2021)

When circumstances of public importance and urgency present, and current ISPE public policies are silent or need further elaboration, any ISPE member or ad hoc group may develop written proposals for official public policy presentation in the form of manuscripts, policy statements, or other written content. This documentation will be submitted to the Executive Secretary and the Public Policy Committee Chair(s) for review of clarity, appropriateness to ISPE's mission, public importance and/or urgency.

Upon review, and with the Public Policy Committee Chair(s) concurrence, the Executive Secretary will inform the Executive Committee and Board that a matter of public importance and/or urgency has been received. Concurrently the Executive Secretary will post the document for review and email a request for urgent review and comment from all ISPE members including Public Policy Committee, Board, and Executive Committee members. No less than 72 hours

will be allowed for responses. All comments received will be addressed and accommodated by the author(s) if appropriate and rebutted if not.

A summary of all commentary will be provided to the Public Policy Committee to ensure that comments were adequately addressed in the final, revised version submitted for approval.

The Executive Secretary will arrange an electronic poll of the Full Board, and upon a simple majority vote, the Board may endorse the documentation as ISPE public policy.

A graphic of this process is found at Technical Appendix B (See page 73)

1.7.3 ISPE-Funded Manuscripts

(Adopted February 2021)

ISPE periodically seeks proposals from the membership for manuscripts that could be used for guideline development or reference documents for a designated set of topics in the field of pharmacoepidemiology. Any ISPE member or ad hoc writing group may develop written proposals for funding to facilitate a manuscript writing process.

After considering the scope and coverage of existing ISPE public policies, the Public Policy Committee initiates the call for manuscripts after soliciting input on suggested topics from the Strategic Planning Committee.

The Public Policy Committee convenes a sub-committee of representatives from the Public Policy and Publications and Communications Committees to review proposals, communicate with writing groups, and recommend the final manuscript proposals to the Executive Committee or Board for funding.

The Executive Secretary facilitates dispersal of funding to manuscript writing groups in accordance with Policy 12.6. The Publications and Communications Committee coordinates with writing groups to track progress of manuscripts and as appropriate, promotes content following publication. Upon completion, ISPE-funded manuscripts will seek ISPE endorsement as per policy 1.7.1.

1.7.4 Public Policy online compendium

(Adopted August 2002; Amended February 2021)

A compendium of all policy statements, endorsed documents and publications, press releases, and other expressions of official ISPE Public Policy will be maintained on the ISPE website.

1.7.5 Public Policy periodic review and maintenance

(Adopted August 2002; Amended February 2021)

All public policies, endorsed documents and publications will bear a specified 'suspense' date, beyond which time it must be reviewed, renewed for a similarly specified time, or automatically superseded/suspended.

The processes for these reviews are found at Appendix B.

1.8 ISPE Advocacy for pharmacoepidemiology

Compatible with all applicable local laws and regulations governing such activities, ISPE commits to transmission of agreed policies and endorsed ISPE positions to external agencies, keeping the membership apprised.

1.8.1 Public Commentary

(Adopted August 2002; Amended April 2003; Amended February 2021)

ISPE commits to providing to the public the expertise of the Society and expert guidance upon matters of pressing public interest in the absence of endorsed public policies on such matters. To that end, ISPE will maintain a roster of self-designated members who profess expertise in the several fields of anticipated need. Such members agree to respond to requests for public comment. They may represent themselves as members of the Reference Panels of ISPE, but representing their own professional positions and opinions.

Any public statement made by ISPE representatives, if it is in writing, must be provided to ISPE for evaluation and endorsement according to Policy 1.7.1

Where there is no ISPE public policy covering matters under discussion, a representative must use a suitable disclaimer: viz. 'ISPE is a multi-national voluntary professional and scientific society. As yet, it has not adopted an official position on these matters.'

ISPE makes no claims regarding the professional expertise of its representatives/panellists or the content of their representations. Rather it makes access to their volunteered services available upon request as a public service.

1.8.2 Designated Spokespersons

ISPE will designate members, generally from among elected leadership of ISPE, to provide expert testimony or other representations of its public policies. Such spokespersons will agree to represent these (and all other appropriate) positions as 'the official position of ISPE', provided, however, that they may, in addition provide their personal professional views, clearly so identified. Spokespersons not in agreement with the relevant official ISPE policy should resign from this role for the specific matter under consideration.

1.9 Policy Regarding Strategic Collaboration.

(Adopted August 2003; amended, April 2006)

1.9.1 General Policy

To advance ISPE's mission and impact, ISPE embraces strategic collaborations with many organizations with related missions, both internationally and within one or more of the countries, in which our leaders live and contribute. Members are encouraged to identify opportunities for such mutual advantage and where appropriate nominate or volunteer themselves as leaders in a partner organization.

1.9.2 Designation of strategic partners:

The Board, upon advice from a leader with the partner, will designate organizations as "strategic partners".

1.9.3 Designation of Strategic Liaisons:

For each strategic partner, ISPE will designate an ISPE leader with leadership role in the Partner organization. The partner organization will be notified and invited, in return, to designate a liaison (preferably the same individual).

1.9.4 Designation of Delegates

(adopted, April 2006)

In the absence of a strategic partner within the partner organization, the Executive Committee may designate an ad hoc delegate to represent ISPE within

that organization. This action must be announced to the Board and, if the delegation exceeds one meeting, be approved by vote of the Board at the next Board meeting.

1.9.5 Responsibilities of liaisons

Keep each organization apprised of major program, project, and policy initiatives of the other. Seek opportunity for collaboration and complementary activities. Participate in ISPE strategic planning. Report (briefly in writing) to the Board annually.

1.10 The Logo of the Society.

(Adopted April 1998; Amended April 2011; August 2019)

The logo of the Society shall be as adopted by the Board on April 6, 2019 (see Technical Appendix A — Page 71).

The ISPE logo may not be altered by ISPE functional groups (SIGs, RIGs, Councils, Committees), nor may these groups introduce their own logo.

ISPE groups such as SIGs, RIGs, Councils or Committees may only use the official full ISPE logo with a line underneath specifying the official name of their functional group as it is named in the Policy Manual (e.g. Student Council) see Technical Appendix A – Page 71

2 Policy on Policies

[Authority: Bylaws, Article III.]

“The Board may adopt such rules and regulations for the conduct of its business as shall be deemed advisable,” and “The Board shall be the policy making body of the Society.”

(Amended April 1999 to add the following)

NOTE 1: “Policy” as used in this section, refers to the operational policies of the Board. In addition, the Board is the public policy agent for the Society as described in Section 1.7 – Page 3.

(Adopted, August 2004 to add the following)

NOTE 2: As a U.S.-incorporated International Professional Society, ISPE adopts the US convention regarding calendar dates for its official statements, publications, and these policies; i.e., month, day (if relevant), year. However, to reflect the international nature of ISPE, the month should be designated in words, not numbers.

2.1 Organizational Structure for Development and Management of Policies:

The Bylaws Policies and Procedures Committee is a standing committee of ISPE.

2.2 Committee Mission

The committee is charged to monitor the bylaws and ensure conformance between the practices of the board and the society’s bylaws; if non-congruence is determined, the committee advises the board and/or develops and recommends changes in the bylaws as appropriate.

To encode those policies adopted by the board recommending general operational principles for these policies, a framework of procedures by which they are implemented, and, if necessary, criteria of eligibility for those to whom the policies apply and to re-direct to the board for adoption.

To monitor Board actions which articulate policies derivative of the bylaws; to flag inconsistencies and ensure reconciliation; to monitor the application of policies of the board.

To monitor the development and regular update of the policy manual of the Board.

2.3 Policies of the Board

The Board is committed to equitable, consistent, and accountable actions. To this end, many aspects of the conduct of regularly recurring official Board business and the principles, which underlie our actions, are debated and agreed by the board. Codification of such actions of the board is maintained for ready reference as the "Official Policies of the Board". This is intended to facilitate and not to impede decision-making. The Board reserves the right to make exceptions to policy in response to specific questions and to change the policies as required in accordance with the following procedure.

2.3.1 Policy Development

Members of the Board and of active Committees are encouraged to develop proposals for the orderly conduct of business outlining criteria and steps for their accomplishment. These may be introduced to the board for discussion. By formulation, second and discussion, the board will vote for possible adoption as "Official Policy". Policies may be adopted by simple majority vote at any meeting if a quorum is present. Formal policies will be recorded in the minutes and added verbatim to the "Official Policies of the Board".

2.4 Administrative Policies and Procedures

The Board steers the offices of the Society. The Executive Secretary carries out the will of the Board, coordinates, and facilitates the activities of the Society. To this end, an office will be maintained which shall be the official residence of the Society. The Executive Secretary is responsible for the administrative coordination of the business office. The Board is committed to refrain from "micro-managing" the Board's office. This is the prerogative of the management company. The office shall comply with all of the rules of good management and be guided by published internal administrative policies and procedures. These will be reviewed as part of the annual performance review of the management company by the Executive Committee. However, such administrative procedures are not themselves part of the policies of the Board.

2.4.1 Preparation of Correspondence from ISPE President

The President must review/revise/approve correspondence that goes out with his/her name. Written approval by the President of the correspondence is preferred whenever possible. When written approval is impractical, verbal approval should be documented by a memo for the file.

2.4.2 Standards of Excellence for All Correspondence & Other Documents Prepared Using the ISPE Logo

All correspondence, reprints of materials, brochures, surveys, which are produced for the ISPE, reflect the professionalism of our Society. ISPE policy is for all materials using the ISPE logo to be produced by the ISPE office or reviewed for consistency by the Executive Secretary before printing and distribution. ISPE stationery may be used by officers, Board members, and committee chairs only while representing their ISPE role, and this role must be clearly identified in the

closing (Chairman, President, etc.) and body of the correspondence (Technical Appendix A – Page 71).

2.4.3 Travel

Specified allowable maximum expenditure amounts will be reviewed annually by the Finance Committee, and the list of allowable expenditure ceilings maintained by the ISPE office.

2.4.4 Travel Expenses

Direct travel expenses for the management company staff will be reimbursed to the staff by the management company by filling out the appropriate management company expense reports. The management company will invoice ISPE for all staff travel directly related to the administration and management of ISPE.

2.4.5 Archive

(Adopted August 2004; Amended April 2017)

ISPE wishes to preserve the history of the Society. To achieve this, relevant documents and other material will be maintained in an official Archive. The Archive shall be held securely in the most relevant format (either physical storage or electronic) for the particular material. This Archive will include a formal record of documents and other material placed on the Society's web-page.

Maintaining and expanding the Archive will be the responsibility of the Archives and History Committee assisted by the ISPE office staff.

2.5 Implementing Procedures

(Adopted August, 2000)

The implementation of the operating policies of the board is a responsibility shared by all members, but particularly borne by those in leadership positions, including committee or project chairs. Consistency and accountability should characterize this implementation effort. Those responsible are encouraged to consider whether their efforts will require replication, e.g. annual processes for awards, or application consideration. If so, committees and groups are encouraged to develop implementing procedures and share these with their colleagues in ISPE's leadership. Such procedures, for single committee use, do NOT require Board Action. However, the board will receive them, recognize them by a motion to 'accept', and attach them to this Policies Manual for future reference and possible application by other committees.

Committees are encouraged to modify and update these procedures regularly. Such updates should be similarly filed with the board and the manual's technical appendix amended accordingly. Superseded procedures will not be maintained in the policy manual.

3 Roles and Responsibilities of Board Members

3.1 General Responsibilities

(Adopted April, 2000; amended April, 2004)

At the time of assuming duties as a member, the new or re-elected member will complete the Board member agreement (Technical Appendix O – Page 99).

A member of the Board of Trustees of the ISPE works to:

- Ensure the mission of the ISPE is carried out and contribute actively to it,

- Maintain fiduciary responsibilities that ensure mutual accountability,
- Maintain board confidentiality and integrity,
- Recognize/prevent/ address conflicts of interest,
- Respect and support staff and maintain appropriate lines of communication,
- Voice opinions and questions and accord respect to others who do the same,
- Enhance the public image of ISPE,
- Recruit others to membership, programs, working committees, and leadership of ISPE
- Use ISPE slides in presentations and distribute ISPE materials to prospective new members, where appropriate

3.2 Responsibilities during the ICPE and other sponsored programs

(Adopted April, 2001)

3.2.1 Membership Recruitment and Retention

- Each attendee is an ISPE member or a potential ISPE member. Board members should:
- Welcome everyone; sell the benefits of membership of the Society.
- Encourage non-members to join the Society, and reaffirm current members' support of the Society.
- Visit the exhibitors and thank them for supporting the ICPE. Encourage them to attend the next ICPE.
- Thank sponsor representatives for their contributions and support of ICPE. Supporters will display a "SPONSOR" ribbon on their badges.
- Recruit members to serve on ISPE committees. The Committee Chairs are responsible for infusing enthusiasm and activity within their committees and councils. ICPE is the best time to prospect for new ideas, new volunteers, etc.

3.2.2 Social/Professional

Board members represent ISPE when attending the ICPE. They should:

- Welcome newcomers. Attend social functions, mingle, seek out people new to the ICPE and engage them in conversation. Do not spend the entire time with your friends, meet new friends.
- Attend Board, Committee and Council meetings. Serve as a conduit of information to and from the Board.

3.2.3 Relationship with Staff

Board members should:

- Alert ISPE staff stationed at the Registration Desk about problems.
- Stay in front of the registration desk and lend a hand if needed, especially welcoming participants to the meeting.
- Allow ISPE staff and the hotel staff to do their jobs.

4 Policies Regarding Nomination, Election and Succession

The fundamental principles for the nominations and subsequent elections are that they should be open, conducted in a fair and transparent manner, and encourage members to seek leadership within the International Society for Pharmacoepidemiology.

4.1 Policy on Nominations (Ref. Bylaws Article III/4 - Page 121)

4.1.1 Principles of Nomination

(Amended, August 2006; August 2010; April 2019)

The nomination process is to seek candidates for leadership within the International Society for Pharmacoepidemiology (ISPE).

The leadership of ISPE consists of the Executive Committee and Members of the Board of Directors, all of whom are elected.

The nomination procedure should aim to create a Board of Directors which represents the distribution of disciplines and geography within the Society. The Board consists of Officers (the Executive Committee) and Members. The total number of Members of the Board (i.e. excluding Officers) shall not exceed 15 as laid out in the ISPE Bylaws (Article III/2 – See Page 120).

For the purposes of board representation, ISPE defines three constituencies by their affiliation and work interest: academic, government, and industry/service provider. For purposes of board representation, ISPE defines three geographic areas: The Americas (NA), Asia-Pacific (AP) and Europe/Africa.

The table below shows the preferred target representation for Members of the Board. However, if a specific sector and/or region slot cannot be filled in any given year (e.g. Government / regulator), then the vacant slot may be filled by the candidate with the highest total vote among those candidates that were not elected in that year.

Constituency	Region			Total
	Americas (NA)	Europe/Africa	Asia-Pacific (AP)	
Academic	2	2	1	
Government	2	2	1	
Industry/Service Provider	2	2	1	
	6	6	3	15

The Nominating Committee will periodically, but at least every 5 years, review the above table in light of the ISPE membership distribution and advise the Board on any suggested changes to the target Board distribution.

4.1.2 Terms of Office

(April 2019)

The Executive Committee consists of the President, the President Elect, the Immediate Past President, the Vice-President/Finance and the Vice-President/Finance Elect.

The President-Elect, President and Immediate Past President serve one-year terms with the President-Elect proceeding to President and the President becoming the Immediate Past President. The Vice President/Finance - Elect serves a one-year term. At the end of one year, the Vice President/Finance-Elect shall become the Vice President/Finance and serve a term of two years.

An ISPE member who has concluded a term as a member of the Executive Committee is not eligible for nomination to the Board or Executive Committee for at least one year.

Other Board Members are elected for three-year terms. Board members may serve a maximum of two consecutive terms. In clarification of Article III/4, (Page 121 last sentence, they are again eligible for election to one or more future terms to begin not sooner than one year after completion of two consecutive terms on the Board.

4.1.3 Criteria for nomination

(Amended August 2002, August 2009, April 2019)

Nominees should be active leaders in the field of pharmacoepidemiology or be distinguished by special contributions to the International Society for Pharmacoepidemiology.

Nominees must be current, dues-paying members of ISPE at the time of the publication of the slate of nominees. A continuous period of prior membership of at least five (5) years is desirable, though not required. In the rare event that a person selected for nomination may have allowed membership to lapse currently or at any time in the most recent five years (e.g. from a change in employ or leave of absence), the Nomination Committee should consider such extenuating circumstances and the implications, if any, of the membership lapse upon the suitability of the candidate. In any such circumstance, the candidate should be expected to have renewed membership in accordance with Paragraph 6.6 – See Page 27.

If possible, Officers and Board members should be nominated so that sector and geographic regions are represented for each office on a rotational basis.

Candidates for Board of Directors:

- should be nominated so that the balance of sector and geographic region is maintained.
- must reside in the geographic region for which they are being nominated.
- should be employed at least 50% in the sector for which they are being nominated. Employed means "being paid by."

4.1.4 Nomination Procedures

(Amended April 2009; April 2010, April 2019)

The Nominating Committee consists of at least four members of the Society and is chaired by the Immediate Past President (Bylaws Article VIII/2 – Page 123).

The nominating Committee is selected by the Immediate Past President and is named on the ISPE website.

Candidates for spaces on the Board and Executive will be nominated and elections held annually.

Officers will be nominated according to the bylaws.

4.1.4.1 Process and timetable for nominations:

(Adopted April 2019)

August:

The outgoing President should publicly solicit interest for the elections and nomination of candidates at the Society's annual meeting (General business meeting held during the scientific conference).

September:

The Immediate Past President selects at least three members of the Society to form the Nominating Committee with him/her as Chair.

The Nominating Committee identifies the Officer and Board positions to be filled on the basis of board members who will complete their term in office at the Annual General Meeting or who have resigned from the Board for other reasons.

These Board members are to be replaced by nominees within the same category or with members within a targeted, unfilled category as described in 4.1.1 – see page 11

October:

Nominations (including self-nominations) from general membership are publicly solicited through a blast email to the membership. The call for nominations is posted on the ISPE website along with policies and procedures for self-nomination and a closing date for nomination which shall be at least 30 days following the call.

The responsibilities of the posts should be displayed on the ISPE website (Policy 3 Roles and Responsibilities of Board Members).

To assess conformity, information on constituency, region, membership status, and history of Board or Executive Committee membership must be provided for each nominee. Nominees should enclose a brief CV including details of any previous service to ISPE.

December/January:

Based on the positions to be filled and the nominations received from the general membership, the Board and the Executive, the Nominating Committee reviews the nominations and produces a list of proposed candidates.

- Every attempt should be made to have at least two candidates nominated for each Board position. However, having a single candidate will be acceptable, as an exception to the norm, for practical reasons.

After the nominating committee has developed a draft slate of nominees, the list is ratified by the Executive Committee and reviewed by the Bylaws and Policies Committee (BLPC) for conformity to policy.

The proposed candidates and the conditions of acceptance are announced to the nominees by letter or electronically. Nominees who are not being proposed as candidates should also be contacted. A nominee who is not proposed as a candidate may ask the Nominating Committee for an explanation as to why he/she was not proposed

Until a candidate is ratified as above, all information should be kept confidential.

4.2 Policy on Elections

(Reference: ISPE Bylaws, Article III.5)

4.2.1 Principles of Elections

(Amended April, 1999, August, 2008; April 2019)

Elections to leadership within ISPE should be held in an open, accessible fashion within an orderly and visible process. Elections must not be held in vacation months or at times when a majority of members will predictably be unable to participate. The voting deadline must be such that the results can be tabulated and accepted and all nominees notified in sufficient time that the newly elected officers and directors can plan to attend the board meeting held just prior to the annual meeting.

4.2.2 Procedures for Elections

(Amended April 1999; April 2004, August 2008, April 2019)

4.2.2.1 Timetable

The following timetables outlining the procedures for election and succession are based on the premise that the Annual General Meeting is held in August of any year.

End January / Early February:

Each nominee is asked to provide a short biography (2-3 paragraphs), a vision statement, and a recent digital photograph suitable for posting on the ISPE website. Any nominee not providing the above within 3 weeks of the request is deemed to have withdrawn themselves from the election unless there are mitigating circumstances which shall be considered by the Nominating Committee.

March:

The background information (i.e. short biography, vision statements, and digital photographs) of the candidates will be posted in the Members Only section of the ISPE website. A blast email will be sent to the membership announcing the election, where to find information about the candidates and the deadline for voting.

A minimum period of two weeks (14 days) is allotted for ballot returns.

March/April:

Election results are evaluated by the Nominating Committee and newly elected officers and Board members are notified, as are nominees who were not elected.

The Chair, Nominating Committee announces the results of the election at the April Board meeting.

May:

Election results are posted on the website.

August:

Newly elected officers and board members join their predecessors at the August Board Meetings.

The second board meeting at the Annual Meeting constitutes the first meeting of the newly formed Board.

4.2.3 Tie-Break

(Amended April, 1999)

In the unlikely event of an exact tie vote, the Executive Committee shall choose between candidates. Criteria guiding the choice will include: length and extent of service to the society and balance of credential and experience with others currently serving on the Board.

4.2.4 Interim Appointments

(Amended April, 1999)

In the event that a member of the Board is unable to complete a full term, the position shall be declared an interim vacancy and filled ad hoc by action of the Board (Bylaws Article III/6 – Page 121). At the next regular election, the position shall be declared vacant. The interim (incumbent) appointee is then eligible for election to the first of two full terms.

4.2.5 Change in status within Pharmacoepidemiology.

(Adopted August, 2003)

While the Board is constituted to assure the best possible balance among the various interests within ISPE, from time to time, individual members may be expected to change nature or location of employ during their tenure in elected office. In the event that such a job change results in a change in nominating category (e.g. from academia to industry or North America to non-North America) the member in office will complete the current term, but be ineligible for re-nomination for the specific prior category. If otherwise eligible for re-nomination, and if there is a vacancy in the new category, an incumbent may be re-nominated for a single term in the new category.

4.2.6 Change in status leaving Pharmacoepidemiology.

(Adopted April, 2004)

If a duly elected Board member leaves pharmacoepidemiology (e.g., by move to another unrelated discipline or full or partial retirement from active practice) but wishes to remain active in ISPE, including payment of dues, the individual may complete the term for which elected. Consideration for re-nomination, if otherwise eligible, will be based upon assessment by the Nominating Committee of the appropriate category in which the incumbent currently serves. If continuing in the same category and otherwise eligible, the individual may be nominated for an additional term. If the suitable category has changed, policy 4.2.4 – Page 15 will apply.

4.3 Procedures for Succession

- The President becomes the Past President at the Annual Meeting.
- The President-Elect becomes the President at the Annual Meeting.
- The Ceremony for Presidential succession takes place during the Annual Meeting.
- The successions of other officers and board members occur at the close of business at the annual general membership meeting.
- The Vice President/Finance retires and is recognized at the Annual Meeting that ends the two-year term.
- The Vice President Finance-Elect becomes Vice President/Finance at the Annual Meeting.

- A Vice President/Finance-Elect serves only for the second year of the two-year term of the Vice President/Finance.

5 Policies on Committees/Councils/Special & Regional Interest Groups

(Amended April, 1999; August 2019)

Authority: Bylaws Article VIII – Page 123, “The Board may establish such committees as may be necessary and appropriate.”

The President-Elect is responsible for overseeing the internal operation of the Society including especially coordination and assuring effective conduct of the affairs of the operating committees. The President-Elect shall serve as an ex officio member of all committees

5.1 Committees

5.1.1 Principles of Committees

The committees constitute the working arm of the Society.

Broad membership participation in committee work is encouraged.

Committees are established by the Board specific to a “necessary and appropriate” purpose (Article VIII/1 – Page 123), and their work is designed to provide a service to the Society in an acceptable fashion and in keeping with the general goals of the Society.

The body or work of the committees is ongoing; their activity does not cease in the interval between annual meetings.

Depending on the purpose for which they were created, committees may be either standing (permanent) or ad hoc (temporary) institutions.

While retaining a degree of autonomy in their actions, committees are directly responsible to the Board and are dependent on Board approval prior to incurring obligations on the part of the Society.

Due to the nature of their task, the on-going work of the Publications and Communications Committee and the ICPE Scientific Program Committee is more independent of Board approval than are all other committees.

5.1.2 Establishment and Mission Statement

Committees are created by the Board by efficient action.

The purpose of Committees must be formally designated by the Board.

Committees must formulate a mission statement in keeping with their designated purpose. This mission statement must be put before the Board for approval.

Upon approval, the mission statement must be included in the policies, section 11

5.1.3 Committee Chairs

(Amended April, 2004; Amended April 2016)

Each committee shall have a chair, who will provide leadership, convene meetings and liaise with the Board. Each committee shall also have a vice chair, preferably from a different continent to that of the chair. The vice chair shall substitute for the chair if the latter is not available. If agreed by the Executive Committee, a co-chair may be appointed instead of a vice chair.

Meeting minutes will be taken by the chair, vice chair, or delegated member and the minutes shall be circulated to the committee members and to the Board of Directors and will be kept by the office.

The Executive Committee invites nominees from the committee and will appoint the chair and vice chair/co-chair. The committee should nominate members for these posts based on a democratic and transparent process that actively invites members to run for chair/vice chair and encourages other members to vote if there is more than one candidate.

With exceptions described elsewhere in these policies, the chair and vice chair normally will have staggered two-year terms to ensure continuity and renewal. Similarly co-chairs will have staggered four year terms. Chairs/vice chairs are responsible for producing meeting summaries and reports to the Board.

If there is a vice chair, usually the vice chair will transition to chair after two years. The retiring chair will remain in a leadership position on the committee as the past chair. However, at the discretion of the Executive Committee a new appointment to chair or vice chair may be made by the Executive Committee.

Should the vice chair not wish to become chair of the committee, members of the committee may nominate an alternative candidate, or an individual selected by the Executive Committee will assume the role.

Committee chairs are invited to, and should attend Board meetings, run annual meetings, and ensure committee objectives are met. All committee activities should be under the auspice of the committee leadership and membership.

5.1.4 Committee Membership

(Amended April, 2001; amended August 2004; amended April 2018)

The number of members within a given committee should be manageable and appropriate to the committee's purpose. Volunteers for committee activity should be regularly solicited electronically and at Scientific meetings. Membership should be by annual appointment or confirmation by the committee chair. Volunteers not appointed should be so notified and their continued interest in and willingness to service solicited and recorded.

5.1.5 Communication with Committees

Chairs and Vice Chairs are held to communicate regularly with the members of their committees. When the committee is in an active phase, communication should be directed at involvement of members. During time of less activity, courtesy communications should be sent out. A minimum of two communications per year is recommended.

5.1.6 Committee Meetings

(Amended August 2021)

Committee Chairs and vice chairs should arrange for at least one annual meeting of the committee. Time and place should be chosen and announced so that the maximum number of committee members can attend. Meetings can be held in person or virtually.

Committee meetings held at ISPE conferences should not conflict with the conference program.

On written request the ISPE office will assist the Committee chairs in making arrangements for committee meetings.

5.1.7 Committee Reports

(Amended April, 2001; April, 2004; April 2018)

All committee chairs are accountable to the President-Elect. Committees must report semi-annually to the Board. This report should include periodic assessment of committee function, a list of annual goals and objectives, a work plan, and the milestones achieved by the committee within the preceding year. It is the responsibility of the Committee chair(s) to submit a written report of Committee activities to the Board prior to the Board meeting and, if necessary, to make an oral presentation of the report at the Board meeting if Board action is required. If the Committee chair(s) is/are unable to attend the Board meeting, prior arrangements with the Committee vice chair or other Committee member should be made by the Committee chair(s) to attend the Board meeting.

The general membership of the International Society for Pharmacoepidemiology (ISPE) should be kept informed of the committee's activities by publication of (at least) an annual report. Reports will be posted on the ISPE website following adoption at the preceding Board meeting.

5.1.8 Committee Budget

(Amended April 2004, amended April 2009)

Each Committee, council and special interest group shall on application receive an annual budget of \$500 for expenses (postage, conference calls, website programming, etc.) from the ISPE office. Any expense over \$100 needs be documented with a receipt.

The request for funds should be on the consensus of the committee and is generally not intended to pay for the travel of committee members. The request for funds must be accompanied by a budget proposal, for consideration by the Vice President Finance and the Executive Committee. If more than \$500 is anticipated for committee, council, or special interest group activities, the Chair must submit a budget request including detailed expenses and a justification to the Executive Secretary with a copy to the Vice President Finance by January 1 for inclusion in the draft budget for the subsequent fiscal year.

Expenses for refreshments or meals during meetings may be appropriate. Committees may not use these funds for non-meeting related social functions or for alcoholic beverages. The ISPE office will pay submitted bills according to the submitted budget. Exceptions require approval of the Executive Committee.

5.1.9 Criteria for committee participation

Active interest in or membership upon one or more of ISPE's committees is strongly encouraged for all members.

Where logically feasible, generally, committee meetings should be open to all ISPE members; however, only official committee members may vote.

Closed sessions of committees are appropriate as provided elsewhere in these policies.

5.1.10 Committee chronology

(Amended April, 2004)

August:

- Chairs confirmed for succeeding year;
- Committees meet at Annual Meeting;

- Review missions and work plans for coming year;
- Review and present accomplishments for past year;
- Committee membership for coming year proposed/accepted

Fall:

New committee structure and committee chairs are posted on the ISPE website.

Spring:

Committees present status reports to Board at Mid-Year Meeting.

August:

Committees present annual reports to Board.

On-going:

- New volunteers kept in touch/know their status;
- Committee work continues; periodic meetings as appropriate.

5.1.11 Subcommittees

(Amended April, 2004)

From time to time based upon volume and complexity of work, committees may elect to organize separate working groups/subcommittees. Such sub-organizations are within the purview of the committee chairs, report to and fulfil the changes of the committees. Their deliberations should be included in the overall reports of the committees; except under unusual circumstances, subcommittee chairs are not expected to attend or present separate reports at the Board meetings.

5.1.12 Policies and Procedures of Committees:

(ref: Policy 2.5; amended April, 2004)

Committees are encouraged to establish and as appropriate codify standard operating procedures, criteria for decision-making, and other unique standing rules for their conduct. These should be presented to the Board for their information and the motion to "accept the report" duly passed. They do not require approval of the Board. For information, they will be appended to the Policy Manual as Technical Appendices when so directed by the Board.

5.2 Councils

(Amended April 1999)

5.2.1 Principles of Councils

(Amended April, 1999; April 2000; April 2004)

The foregoing policies regarding committees notwithstanding, ISPE is also committed to ensuring an effective forum for concerns and issues of major constituents of the field. To that end, councils have been created to deliberate and represent the sector-specific issues; e.g., academia, government, industry, students, and others

5.2.2 Membership.

Membership on a council is open to all members of ISPE with primary occupational affiliation within the sector represented. Thus, unlike other committees, membership is restricted to constituency.

5.2.3 Governance of Councils

(Amended, April 1999; April 2005; April 2011)

Each council will have a chair and vice-chair (the latter from another continent). To ensure an effective constituency voice, and in contrast with other committees, the officers are elected from among the membership of the council, subject to concurrence by the ISPE Executive Committee. Officers of the Student Council will be elected annually. The co-chair shall be chosen from among candidates with at least one further year of study. It is recommended that the chair and vice chair/secretary have staggered three-year terms to ensure continuity.

5.2.4 Conduct of Councils

(Amended, April 1999)

Except as outlined above, the principles and rules of conduct of business of councils are the same as those of committees.

5.3 Ad Hoc Committees, Working Groups and Task Forces

5.3.1 General Principles

(Amended April 1999)

To achieve time limited and purpose specific tasks, the Board creates from time to time ad hoc committees, working groups and task forces. Organizing and governing principles for such ad hoc committees are the same as those for all committees; in addition, however, ad hoc committees will have a specific time limit for conduct of business and specified task(s) and deliverables.

5.4 Special Interest Groups

(Adopted, August 2005; amended, April 2006; August 2007)

5.4.1 Principles of Special (or Specialty) Interest Groups

The foregoing policies regarding committees and Councils notwithstanding, ISPE is also committed to ensuring an effective forum for concerns and issues of major specialty interest groups within the field. To that end, Special Interest Groups are created to facilitate interactions among those with interests in specialized areas of activity within pharmacoepidemiology. An example of such a Special Interest Group is the Drug Utilization Research Special Interest Group. Upon acceptance of a petition for organization by at least 5 ISPE members [including at least one FISPE], the ISPE Board will confirm the organization of a Special Interest Group. A listing of all Special Interest Groups, their missions, and the years of their organization will be maintained in the Policy Manual.

5.4.2 Membership.

Membership on one or more Special Interest Groups is open to all members of ISPE. Members interested in joining any Special Interest Group need to so notify the Special Interest Group Vice-Chair/Secretary.

5.4.3 Governance of Special Interest Groups.

(Amended April 2011)

Each Special Interest Group will have a Chair and a Vice-Chair/Secretary. To ensure an effective constituency voice, similar to councils and in contrast with committees, the officers are elected from among the membership of the Special Interest Group, subject to concurrence by the ISPE Executive Committee. It is recommended that the chair and vice chair/secretary have staggered three-year terms to ensure continuity.

5.4.4 Conduct of Special Interest Groups.

Except as outlined above, the principles and rules of conduct of business of Special Interest Groups are the same as those of committees. In addition, each Special Interest Group, with the concurrence of the ISPE Executive Committee, may request identified meeting time (for discussion of Special Interest Group business and for presentation of scientific papers during the annual and mid-year scientific meetings) from the Scientific Program Committee.

5.4.5 Removal of Special Interest Group status.

(Adopted August 2007)

Special Interest Group (SIG) status may be removed on request of the SIG itself, by Board action, or if no evidence of sustained activity is shown (e.g. by failing to submit reports to the Board at least once a year). In the last case, the SIG will be put on probationary status by the ISPE Board for a period not to exceed twelve months, and given due notice. Failure to show satisfactory activity by the next subsequent full Board meeting will result in removal of recognition as a Special Interest Group.

5.4.6 Reinstatement of Special Interest Groups status.

(Adopted August 2007)

Once removed, a Special Interest Group can be reinstated by petition for organization by at least 5 ISPE members [including at least one FISPE], and confirmation by the ISPE Board.

5.5 Regional Interest Groups

(Adopted August 2019)

5.5.1 Principles of Regional Interest Groups

ISPE Regional Interest Groups are created to provide a vehicle for ISPE members who share an interest in extending the Society's goals and activities in specific regions of the world.

Regional Interest Groups will be established by the Board on the recommendation of the Leadership group of the Global Development Committee.

Proposals for establishment of a Regional Interest Group must be made to the Global Development Committee by at least five ISPE members including at least one FISPE. Proposals must include:

- The region and its geographic and other boundaries (eg. language)
- The mission of the Group

After discussion designed to minimise overlaps between Regional Interest Groups, the Leadership group of the Global Development Committee will provide a recommendation to the Board.

A listing of all Regional Interest Groups, their missions, and the years of their organization will be maintained in the Policy Manual.

5.5.2 Membership

Membership of one or more Regional Interest Groups is open to all members of ISPE. Members interested in joining any Regional Interest Group need to notify the Regional Interest Group Vice-Chair/Secretary of their wish to join.

Membership and/or leadership of Regional Interest Groups will not require residence in the region in question.

5.5.3 Governance of Regional Interest Groups

Each Regional Interest Group will have a Chair and a Vice-Chair/Secretary. To ensure an effective constituency voice, similar to councils and in contrast with committees, the officers are elected from among the membership of the Regional Interest Group, subject to concurrence by the ISPE Executive Committee. It is recommended that the Chair and Vice-Chair/Secretary have staggered three-year terms to ensure continuity.

5.5.4 Conduct of Regional Interest Groups.

Except as outlined above, the principles and rules of conduct of business of Regional Interest Groups are the same as those of committees. In addition, each Regional Interest Group, with the concurrence of the ISPE Executive Committee, may request from the Scientific Program Committee an identified meeting time (for discussion of Regional Interest Group business during the annual and mid-year scientific meetings).

5.5.5 Removal of Regional Interest Group status.

Regional Interest Group (RIG) status may be removed on request of the RIG itself, by Board action, or if no evidence of sustained activity is shown. In the last case, the RIG will be put on probationary status by the ISPE Board for a period not to exceed twelve months, and given due notice. Failure to show satisfactory activity by the next subsequent full Board meeting will result in removal of recognition as a Regional Interest Group.

5.5.6 Reinstatement of Regional Interest Groups status.

Once removed, a Regional Interest Group may be reinstated by the ISPE Board through a petition in the first instance to the Global Development Committee. Such requests for re-instatement or re-organization must be made by at least five ISPE members (including at least one FISPE), before consideration by the ISPE Board.

6 Policy Regarding Conduct of Membership

6.1 Criteria for Membership

6.1.1 General Membership

(Amended April 1999)

ISPE, as a professional membership society in a rapidly evolving arena of science and public policy, seeks the broadest possible participation by and scholarship from those whose professional pursuits or interests enhance and advance the mission of the society. By intent, the Board commits not to exclude and actively to recruit all those with a bona fide professional commitment to the field.

6.1.2 Fellowship

(Adopted August 2002; amended April, 2004, April 2009)

ISPE is committed to recognizing and advancing leadership in Pharmacoepidemiology. To that end it creates a special category of membership for its leadership to be designated: ISPE Fellow (FISPE). Fellow Status is awarded upon recommendation by a committee of peers (see 11.1.7 – Page 47 Fellowship and Awards Committee) and ratification by the Board of Directors, as outlined below.

6.1.2.1 Benefits of Fellowship

Upon achievement of Fellow Status, Fellows may:

- Refer to themselves in public statements, documents, and resumes or curricula vitae as Fellow of the International Society for Pharmacoepidemiology
- Add the letters FISPE to designations following the name;
- Receive appropriate recognition on ISPE correspondence, membership lists, attendance lists;
- Wear identifying ribbons on meeting nametags, and
- From time to time receive other special awards and recognitions
- be referred by ISPE to those seeking recommendations from ISPE for speakers, consultants, and the like.

6.1.2.2 Conditions of Fellowship

- Fellows must sign a pledge to embody the mission, vision, and values of ISPE.
- Fellows must agree to provide service to ISPE including mentoring of new members.

6.1.2.3 Criteria for Fellows

(Amended, April 2005; April 2009; April 2010; August 2021)

The following criteria are guidance for both members who would consider applying for Fellow status and to the committee that reviews applications. The committee shall consider each of these areas in its deliberations.

- **Seniority:** at least five (5) years of non-student membership contiguous with current membership: candidates are permitted to backpay dues to complete missing years.
- **Scholarship:** evidence of substantial scholarship in the field of pharmacoepidemiology as reflected in the quality and impact of his/her publications. Reasons for rare exemptions to this criterion must be presented in writing to the Board of Directors for approval on a case-by-case basis.
- **Service to ISPE:** substantial active and leadership roles in ISPE, such as board member; chair or co-chair of a committee, council, task-force or working group.
- **Leadership:** Evidence of leadership in the discipline of pharmacoepidemiology
- **Member in good standing** of ISPE, including being current in dues payment.
- All past Presidents who are members in good standing automatically qualify.
- The President-Elect automatically qualifies.

6.1.2.4 Procedure for Election of Fellows

(Adopted August 2003; amended April, 2004; April 2005; April 2009)

Applicants will identify two (2) current Fellows to sponsor their application. Applicants will provide a completed application and resume or curriculum vitae to the sponsoring Fellows, who will provide these materials to the ISPE office together with a letter of support for the application.

6.1.2.5 Procedure

(Adopted August, 2003; amended April 2018)

Completed applications should be filed with the ISPE office by December 15 of the year for consideration to Fellow status in the next calendar year. Letters of support should be submitted by their authors directly to the ISPE office. Copies of the applications are provided to members of the Fellowship & Awards Committee (see 11.1.7 - Page 47). The Committee considers all applications and makes it report to the Board for consideration at the Mid-Year Board meeting. The Board takes action on the nominees at its Mid-Year meeting. Notification is sent to the applicants subsequent to the Board meeting. The ISPE office ensures that the new Fellows pay appropriate dues. Board-approved Fellows may consider themselves a FISPE as soon as their current dues are paid. The new Fellows are inducted at the ISPE annual meeting.

6.1.2.6 Revocation or Termination of Fellowship

(Adopted August, 2003; amended April, 2004, April 2009)

Fellowship status requires maintenance of ISPE membership status by payment of applicable dues. Non-payment of applicable dues will result, upon due notice, in revocation of this status.

6.1.2.7 Restoration of Fellowship

(Adopted August, 2003)

A Fellow with revoked status must re-apply for Fellowship in accordance with 6.1.2 above. Such a re-application must include an explanation for the lapse in Fellowship.

6.2 Policy on applying for and being granted Membership

(Adopted August 2002; Amended April 2021)

6.2.1 Membership Year

(Adopted April 2021)

Effective 2022, ISPE's membership year is the calendar year beginning January 1.

6.2.2 Individual Membership

[Authority: Bylaws Article I, VI, VII]

(Amended April 2004; amended April 2006; Amended April 2021)

A person normally gains ISPE membership through one of two methods: by completing the online membership application process and paying applicable dues, or attending the latest ICPE annual meeting.

If attained by completing the online membership application, membership begins immediately upon acceptance and is valid through to the end of the current calendar year. ISPE does not prorate dues for joining after the start of the membership year, however, individuals joining in the fourth quarter (Oct-Nov-

Dec) will have membership extended through to the end of the following calendar year.

Members and non-members who have registered and paid for the full annual meeting in the appropriate category are automatically enrolled as members through to the end of the following calendar year. Persons in receipt of a scholarship to attend the annual meeting are also entitled to membership through to the end of the following calendar year.

Categories of Individual Members

- Individual
- Fellow
- Retired
- Student
- Honorary/Lifetime

All ISPE members and fellows, in any category of membership, will enjoy full privileges of their membership class, without limitation. These include the rights and obligations of members to assure proper and prudent governance of the Society, to vote in elections and on other ISPE matters, and to participate in projects, activities, and leadership.

6.2.3 Organizational Membership

(Adopted April 2004; amended April 2006; amended April 2021)

An organization gains ISPE membership by completing the online organization membership application process and paying applicable dues. Membership begins immediately upon acceptance and is valid through to the end of the current calendar year. ISPE does not prorate dues for joining after the start of the membership year, however, organizations joining in the fourth quarter (Oct-Nov-Dec) will have membership extended through to the end of the following calendar year.

Categories of Organizational Members

- Large Service Providers (total annual revenue >\$5.0 million)
- Small Service Providers (total annual revenue <\$5.0 million)
- Executive Search Firm
- Academic Program/CERT
- Academic Program/Developing Country
- Government Agency
- Consultant
- Pharmaceutical/Corporate Organization

Membership in an organizational category incurs specific financial obligations and entitles these member organizations and their representatives to commensurate benefits. These are established by ISPE and revised from time to time as appropriate. The current outline of fees and benefits is posted on the ISPE website.

6.2.4 Retired Members

(Adopted, April 2012)

ISPE honours and respects the years of contribution of its most senior members and commits to a continued strong relationship with them as they enter the years of retirement.

Members with more than five years of membership and over the age of sixty, who retire from full-time employ without the intent to return (irrespective of whether they continue to consult, teach, or do research part time) may self-designate as "retired". No formal Board or Committee review is needed for this step.

These members may adopt the categorical affiliation most commensurate to their current primary occupation.

Membership and registration fees for retired members will be the same as those for students.

6.2.5 Charter Members

[Article II, Paragraph 2 of the By-Laws] (adopted, April 2011; amended August 2011)

Charter members will have that status recorded in the membership records of the Society. Charter members will receive a certificate declaring their status as Charter Member of ISPE and may be identified as such at the mid-year and annual conferences.

Charter members will be identified by the list of attendees of the 6th, 7th, and 8th ICPEs (1989, 1990, 1991 unless a membership list for the year 1990 can be produced.)

6.3 Agents of the Society

(Amended April, 2000; August 2004)

No one group or committee shall establish an official position or conduct an official transaction in the name of the Society on the letterhead of the International Society for Pharmacoepidemiology (ISPE) without explicit authorization of the Executive Secretary and/or President of the Society. (See also Policy 1.7 – Page 3 Public Policies and Advocacy)

6.4 Conflict of Interest

(Adopted April, 2002; amended August 2005, August 2013 and April 2015)

No Trustee, Officer or Committee Member shall use his or her position, or the knowledge gained there from, in such a manner that a conflict between the interest of ISPE or any of its affiliates and his or her personal interests arises, except as explicitly sanctioned elsewhere in the official policies and procedures of the Society. Examples of acceptable practices are receipt of fees for teaching on ISPE courses, and receipt of an award. No Trustee, Officer, Committee or SIG Member shall use his or her position to endorse specific scientific projects in their capacity as ISPE agents.

Each Trustee, Officer, and Committee Member has a duty to place the interest of ISPE foremost in any dealings with ISPE and has a continuing responsibility to comply with the requirement of this Policy.

The conduct of personal business between any Trustee, Officer, or Committee member and ISPE and any of its affiliates is prohibited.

Trustees, Officers or Committee Members may not obtain for themselves, their relatives or their friends a material interest of any kind from their association with ISPE.

If a Trustee, Officer, or Committee Member has an interest in a proposed transaction with ISPE, either by having a significant personal financial interest in the transaction or having a significant financial interest in an organization involved in the proposed transaction, or holds a position as trustee, or officer in any such

organization, such trustee must make full disclosure of such interest prior to any discussion or negotiation of such transaction.

Any Trustee, Officer, or Committee Member who is aware of a potential conflict of interest with respect to any matter coming before the Board or a Committee shall not be present for any discussion of or vote upon or in connection with the matter.

In circumstances where attestation of an understanding of these conflicts of interest policies (and those found in policy 7.1.7) is required, Technical Appendix G – page 88 provides a suitable template which can be adjusted to suit situations as they arise.

6.5 Whistleblower policy

(Adopted April 2015)

The Society is committed to ensuring openness in responding positively to whistleblowers, and endorses the principles outlined in Technical Appendix S – page 103.

6.6 Payment of Dues

[Authority: Bylaws Article IX]

(Adopted May 1999; amended August 2000, April 2001 and April 2006)

All ISPE members must be current in their dues to participate in ISPE activities and receive membership benefits. All members receive three notices and dues statements before they are dropped from the ISPE membership roster, 30 days before expiration date, 30 days delinquent, and 60 days delinquent]. A letter will accompany each notice from the President or Executive Secretary encouraging timely submission of dues. The last delinquency notice will provide for a single 10-day period for response, after which membership privileges will be revoked. Individuals may apply for reinstatement in ISPE by full payment of dues.

6.7 Policy on Journal

(Adopted August 2000; amended April, 2001; amended April 2006)

As a scientific society, ISPE sponsors a professional journal. It is for the good of the society that Pharmacoepidemiology and Drug Safety (PDS) is ISPE's official journal. The National Library of Medicine indexes PDS. ISPE encourages members to publish in PDS and cite publications in PDS.

6.7.1 Policy on Freedom from Censorship:

ISPE adopts by reference the World Association of Medical Editors Statement on Geopolitical Intrusion on Editorial Decisions as amended by ISPE. (Technical Appendix Q – Page 102).

6.8 Waiver of Dues

(Adopted April, 1999; amended, April 2005)

ISPE is committed to encouraging membership among all those with an interest in the field and support for the mission of ISPE. In the face of documented undue hardship, members and candidates for membership may apply for a partial or complete waiver of dues. Hardship comes in many forms including economic level, country of residence, etc. Hardship also varies with career status, i.e. student, retiree, etc. The Membership Committee will develop and periodically revise the criteria (Technical Appendix C – Page 79) to assess and grant waivers; the Board will approve the criteria; the Executive Director will approve individual requests, which meet the designated criteria.

6.9 Official Lists of Membership

(Amended April, 1999, April 2009; August 2009)

6.9.1 General Policy Regarding Lists/Archives

The Board is committed to ensuring necessary institutional memory for its major transactions. This includes maintenance of records regarding membership and participation. ISPE retains several official lists:

- An "ever member" list, documenting membership and dates
- A meetings participants list for each major event conducted under ISPE auspices.
- A current members roster, with personal identifications, listings of career interests and other relevant information

All lists are the property of ISPE and uses beyond those intended or allowed are restricted to permission of the Board.

6.9.2 Distribution of Lists

ISPE commits to enhancing the effectiveness of its members; professional colleague relationships are an essential membership benefit. Thus, all members are afforded access, without charge, to the membership registry.

Likewise, lists of meeting attendees are available at each meeting for the personal use of all participants.

Access rights to these lists are for the purpose of professional, personal communication only. Each list will so state.

6.9.3 Mailings on Behalf of Third Parties

(Adopted April 2009; Amended August 2009)

In order to promote the dissemination of information to ISPE members from vendors (public or private) that offer educational content (meetings, books, journals, etc.) relating broadly to the topic of pharmacoepidemiology including research on the safety and effectiveness of drugs and medical devices, including research methods and policy issues and issues related to using pharmacoepidemiology to further health care quality, ISPE may assist Third Party vendors in their mailings with appropriate safeguards to identify misuse.

ISPE's Executive Secretary is empowered to make decisions independently about such mailings. The Executive Committee should be consulted when it is not clear to ISPE's Executive Secretary that the proposed mailing meets the purpose described above.

6.9.4 Privacy

Each ISPE member will be notified of the policy regarding data release at each membership renewal. Provision will be made for the member to request to have any or all personal identification removed from the list or from release.

6.10 General Business Meeting

(Adopted August 2000; amended April, 2004)

6.10.1 Time and Announcement of General Business Meeting

The general meeting of ISPE members is held in conjunction with the Annual Meeting. At least 30 days advance notice of the date, time and location will be

provided to all members in good standing electronically and posted on the ISPE website.

6.10.2 Agenda for the General Business Meeting

The agenda for the General Business Meeting will include, but is not limited, to the following agenda items:

- Call to Order
- President's Report
- Executive Secretary's Report
- Treasurer's Report
- Nominations Committee Report
- Installation of New Officers
- New Business
- Awards Ceremony
- Installation of Fellows
- Adjournment

7 Policies on Scientific meetings

(Amended August 2016)

ISPE convenes two global scientific meetings each year, the Annual Scientific Meeting (ICPE) and the Mid-year Meeting, as well as the regionally based Asian Conference on Pharmacoepidemiology (ACPE).

7.1 Annual Scientific Meeting (ICPE)

7.1.1 General Policy

(Amended April, 1999)

The Society declares the annual international conference on pharmacoepidemiology and therapeutic risk management (ICPE) its official annual scientific meeting. In addition, the annual general membership meeting of ISPE (Authority, Bylaws, Article VI) will occur at the ICPE. At the ICPE, scholarly progress in the field and important matters of policy will be rigorously debated; full independence of scientific and policy debate will be assured.

In addition, adequate time and proper facilities will be provided to ensure full airing of matters requiring attention of the general membership; formal meetings of all major committees; annual meetings of councils; and an annual meeting of the Board of Directors.

7.1.2 Policy on Attendance

(Amended April, 1999)

All meetings of ISPE and all events at ICPE are open to all attendees unless otherwise specified in these policies.

7.1.3 Policy on Profitability of the Annual Scientific Meeting (ICPE)

(Adopted August, 2000; amended April, 2004; amended October, 2014; amended August 2016)

The Board affirms that the primary purpose of the annual meeting (ICPE) is scholarly interchange for the membership. A number of fee waivers and travel reimbursements will be awarded annually to facilitate attendance by members who would otherwise find it financially difficult.

7.1.4 Site of the Annual Scientific Meeting (ICPE)

7.1.4.1 Process

(Amended August 2016)

The sites for the annual meetings of the Society/International Conference on Pharmacoepidemiology and Therapeutic Risk Management shall be chosen by a committee designated by the President and chaired by the President. Recommended sites will be accepted, or not by majority board vote. For planning purposes, the site should be selected three years in advance and announced for discussion at the Annual General Meeting.

7.1.4.2 Criteria

The choice of the conference sites will be guided by the following criteria:

- accessible to major international transportation
- affordable, compatible with the budgetary constraints and reasonable attendance fees
- attractive as a site for recreation and culture
- identifiable with pharmacoepidemiology
- facilitated by a local "host" among the ISPE leadership

In general, sites will alternate such that every other year a site outside of North America will be selected. Suggestions from members are always encouraged; however, elaborate proposals from members are discouraged.

7.1.5 Policy on Meeting Content

(Adopted August 2003; amended April 2004; August 2007; August 2015; April 2016)

7.1.5.1 Research Abstracts

Research abstracts are eligible, whether or not their content has been presented at meetings of other scientific societies, as long as they meet the following criteria:

- Relevant to the field of pharmacoepidemiology as broadly defined
- Results may not have not been published (except in abstract form) either on-line or in printed full form before January 1 of the year of the meeting, and
- Results have not been presented at a previous ISPE annual meeting.

7.1.5.2 Workshops

Workshops may be either submitted as abstracts and reviewed by the Scientific Program Committee and their Review Panel, or else are initiated by the Scientific Program Committee itself based on perceived interest.

- A workshop provides an opportunity for a highly interactive engagement among all participants, with a minimum of expository information required to permit full active participation.
- Workshops must be regarded of interest to a sufficiently large part of the ISPE membership to ensure adequate attendance.

- Workshops address a specific current or an ongoing issue of interest in the field of pharmacoepidemiology in a focused, interactive manner, inviting participation of attendees.
- Workshops conceived as a series of presentations on a given topic are discouraged. Such submissions may be considered as a symposium.
- Workshops catering explicitly to a commercial or political interest are discouraged.

7.1.5.3 Symposia or Special Sessions

Symposia (or special sessions) may be either submitted as abstracts and reviewed by the Scientific Program Committee and their Review Panel or initiated by the Scientific Program Committee itself.

- A symposium provides a setting for an exploration of current issues in the field in greater depth and for greater periods of time than can be afforded in a platform session.
- Symposia must be of interest to a sufficiently large part of the ISPE membership to ensure adequate attendance.
- Symposia address a specific current issue of interest in the field of pharmacoepidemiology in a focused manner in a series of presentations by experts on that issue.
- The organization of a symposium is overseen by the Scientific Program Committee who monitor its substance, quality, and composition with advice from the symposium initiators.
- Symposia must show a balance of current views on a given topic and must not cater to a single scientific, commercial, or political view.

7.1.6 Abstract Processing Procedures

(Adopted August, 1999)

To ensure equity and fairness in selection and to promote scientific rigor, ISPE has developed a standard procedure to review and accept abstracts for presentation at its scientific meetings. The procedure applied for ICPE is described in Technical Appendix D – Page 81. Where abstracts are solicited for presentation at Mid-year and regional meetings, the same principles of independent author/institution-anonymous review will be applied using processes parallel to those used for ICPE.

7.1.7 Policy on Financial Disclosure and Conflict of Interest

(Adopted August, 2001; amended April 2003)

7.1.7.1 General policy

All presenters at any ISPE scientific meeting must disclose financial or other interests which could potentially pose a conflict or the appearance of a conflict of interest.

7.1.7.2 Disclosure Statements

(Amended August, 2003)

A disclosure statement must accompany each abstract and each presentation. This statement must list all funding sources for the current project, as well as other potentially conflicting relationships that existed at any time during the conduct of the study, or the 1-year period before

the meeting in question. Non-financial conflicts (e.g., a close relationship with, or a strong antipathy to, a person or organization whose interests may be affected) should also be disclosed. For oral presentation, potential conflicts must be listed on a conflict of interest slide immediately following the title slide. For posters, potential conflicts must be listed on the poster in a type size consistent with the rest of the poster.

7.1.7.3 Exceptions

This policy applies to all presentations, whether submitted or invited.

7.1.7.3.1 Invited Speakers:

This requirement may be waived, at the discretion of the Core Program Committee, for certain invited presentations (e.g. by non scientists such as political dignitaries). Invited speakers will be informed of this policy at the time of the invitation. Session moderators are responsible for reminding speakers about this policy.

7.1.7.3.2 Moderators:

Session moderators themselves are not, ordinarily, required to declare such conflicts. They are, however, encouraged to consider whether their comments or planned participation are substantive in the subject area in which such a conflict may be relevant, in which case they should volunteer to be governed by the same principles.

7.1.8 Policy on Waivers of Registration Fees

(Adopted August, 2000; amended August 2004)

ISPE encourages wide access without undue hardship to its educational programs among its members.

A limited number of registration fee waivers and reimbursements for travel expenses will be made available annually for the ICPE, the Mid-year meeting and ACPE. Estimates of fee waivers and travel reimbursements will be made part of the annual ISPE budget. External funding will be sought to support additional, but limited reimbursement for travel expenses. See Technical Appendix C – Page 79 for procedures.

7.1.9 Policy on Scholarships

(Adopted August 2002, amended, April 2006, amended, August 2021)

A limited number of scholarships (expense reimbursement) may be available to assist with attendance at the ICPE, the Mid-year meeting and ACPE. Scholarships may be used for registration, lodging, and travel to the conference. Students and those in genuine financial need who otherwise would be unable to attend ICPE are invited to apply. Scholarships for non-students from developing and non-developing countries may be available. See Technical Appendix C– Page 79 for procedure details.

The Scholarship Committee Chair is responsible for the review of applications and allocation of funds. These funds are then endorsed or rejected by the committee. The Chair seeks to assist as many students and others in need as possible, but available funds are limited. This means applicants may not receive the full amount requested.

Applications are judged on the following criteria:

1. Student status: (active and registered part- or full-time in a program)

2. Geographic location: priority will be given to participants from developing countries vs. North American and western Europe, depending on need
3. Submission of abstract, acceptance of abstract for presentation, and score.

The applicant will confirm acceptance of the scholarship as soon as possible after notification with the ISPE office. ISPE will reimburse recipients for approved expenses on receipt of appropriate documentation after the meeting in question.

7.1.10 Annual awards and scholarships open to both researchers and students

(Adopted, August 2011; amended August 2015, April 2018)

In order to further recognize and encourage excellence in scholarship, the awards as shown below will normally be awarded annually:

7.1.10.1 ISPE-PDS Ronald D. Mann Best Paper Award

(Adopted April, 2001; Amended April 2018)

A prize to be awarded at each year's ICPE to the "best" paper published in PDS during the prior calendar year. See Technical Appendix E – Page 85 for implementation.

7.1.10.2 'Andrew McAfee Award': Best abstract from a developing country.

The Andrew McAfee Award commemorates a passionate teacher, drug safety researcher and long-time active participant and supporter of ISPE who died in a tragic accident in 2010. It is awarded for the best abstract submitted from a researcher or student living in a developing country (as defined by UN guidelines). The award consists of free admission to the annual ICPE meeting, to any associated educational sessions, a scholarship to attend the meeting, and a plaque.

The recipient will be selected by the Scientific Program Committee, and the Scholarship Committee will administer the award. The amount of the scholarship will be determined by the Scholarship Committee in accordance with principles laid down in the ISPE Policy Manual concerning costs covered by developing world scholarship awards (Technical Appendix C – Page 79). Costs associated with the Andrew McAfee Award would be independent of and in addition to the budgeted funds associated with ICPE Scholarships.

7.1.10.3 'The John Snow Award'

The John Snow Award commemorates a pioneering nineteenth century British epidemiologist. It is awarded for the best abstract submitted by a female researcher/student who is living in a developing country (as defined by UN guidelines). In the case where the Andrew McAfee Award is won by a woman, the John Snow award will be made to the next most highly ranked abstract from any researcher or student living in a developing country irrespective of gender. The award consists of free admission to the annual ICPE meeting, to any associated educational sessions, a scholarship to attend the meeting, and a plaque. The abstracts will be ranked by the Scientific Program Committee, and the Scholarship Committee will administer the award. Costs associated with the John Snow Award will be met independent of, and in addition to, the budgeted funds associated with ICPE Scholarships.

7.1.11 Annual awards and scholarships open only to students

(Adopted August, 2000; amended April, 2002; April 2004, April 2018)

In order to recognize and encourage excellence in the scholarship of students in pharmacoepidemiology, the Board has created the student award categories below. The Scientific Program Committee will oversee the selection and presentation of awards.

7.1.11.1 'Stanley A. Edlavitch' Award: Most Highly Rated Student Abstracts

The 'Stanley A. Edlavitch' award, created by the Board at the time of retirement of the Society's first Executive Director, Dr Stanley Edlavitch, and funded in perpetuity, is presented each year at the annual meeting. The award is given to the student who submits the most highly rated abstract for presentation of the meeting, and consists of a certificate and a financial award to defray the costs of transportation, housing, and food, and a complimentary registration to the annual meeting.

Awards for the Second and Third Most Highly Rated Abstracts submitted by a student also will be presented, and will consist of a certificate and a complimentary registration to the meeting.

7.1.11.2 Most Highly Rated Methods Abstract Submitted by a Student

At each ICPE, an award will be presented for the Most Highly Rated Methods Abstract submitted by a student. The award will consist of a certificate and a complimentary registration to the meeting.

7.1.11.3 Award for the most highly rated abstract submitted by a student in the Drug Utilization Research category

ISPE will award a prize for the best student abstract in the drug utilization research category. This award will consist of a certificate and a complimentary registration to the meeting.

7.1.11.4 Precedence of Awards

A given person will be eligible for only one ICPE student award ever. If, in a given year, the most highly rated student abstract overall is also a Methods or content area of a joint meeting organizer, then the student will be awarded the Stanley A. Edlavitch Award only. If the second or third most highly rated student abstract also is a Methods abstract or is in the content area of a joint meeting organizer, then that student will be awarded only the Most Highly Rated Methods or most highly rated content area-specific award, rather than the Second or Third Most Highly Rated Abstract by a Student award.

7.1.12 Speaker Travel Reimbursement and Honoraria

(Adopted August 2000; amended August 2003; August 2004; April 2005; April 2006; April 2010; August 2016)

Both ISPE members and non-members are expected to pay their own expenses and a suitable registration fee for attendance of any ISPE scientific meeting, even if they are invited speakers. The following exceptions may apply:

- Pending approval of the Executive Committee, the Scientific Program Chair may provide travel expenses (best-price economy) to ISPE members who are invited to speak at a session, workshop, or satellite educational program and who are unable to finance their travel.

- Non-members who are invited as speakers may be provided with round trip economy travel (best price), free ISPE registration, and hotel reimbursement for the night before and after the event subject to funds made available (budgeted to) the Program Chair by the Executive Committee.
- Should the number of non-ISPE invitees to symposia and workshops exceed the available budget or number of waivers, the Program Committee will, in consultation with the Executive Committee, determine their allocation.

ISPE does not award honoraria for its scientific meetings as a matter of policy.

- Non-ISPE keynote and equivalent (e.g., invited plenary, patient representative) speakers are the only exceptions contingent on the approval of the Executive Committee in consultation with the Program Committee Chair. Honoraria and reasonable travel-related expenses may be provided to such speakers. The honorarium should be consistent with usual and customary amounts offered by professional societies for such speakers.

The above applies to all ICPE, Mid-year and regional meetings and their contingent program events.

7.1.13 Policy on International Travel Visas

(Adopted April, 2003, amended April, 2005)

International travellers may require travel Visas to visit countries in which ISPE functions are occurring. ISPE requires that people must have formally registered for an ISPE-sponsored meeting and staff must verify the credit card or check payment before a letter of invitation to support application for a travel visa is issued.

ISPE will respond to inquiries for letters of invitation to attend a meeting with language to the effect of: "Thank you for writing to request a letter of invitation to support application for a travel visa. We will be pleased to send a Visa letter once you have registered and paid to attend the conference and payment has cleared."

The applicant will be advised to allow adequate time for Visa approval.

In the event of the Visa application is not approved after appropriate and timely application to attend the meeting, ISPE will refund the registration fee, compatible with other refund policies of the ICPE.

7.1.14 Promotional Activities at Scientific meetings

(Adopted April, 2003)

7.1.14.1 General Policy:

ISPE encourages broad and active support from and participation by commercial and other proprietary interests in its activities, compatible with the protection of full scientific independence of the activity.

7.1.14.2 Exhibitors fees and other considerations

(Amended April, 2004)

ISPE encourages commercial and proprietary, as well as scholarly and voluntary organizations to participate as exhibitors for all of its major events. Fees for exhibits are based upon class of exhibit, floor space required, and other considerations. Fees for exhibitors are set annually by the Development Committee. Waivers for fees for specific organizations or displays may be granted by the Executive Committee

under special circumstances. In general, recipients of such waivers will be asked to pay the actual costs to ISPE of such an exhibit.

7.1.14.3 Policies regarding display and distribution of other commercial materials at the ICPE and other ISPE meetings

Exhibitors will confine their proprietary activities and materials to the exhibits area/exhibit hall. Members wishing to distribute or display proprietary or other promotional information, e.g., announcements of new or forthcoming publications, upcoming meetings, or other services in which the member may be directly involved, will be encouraged to do so, but only in areas designated for this purpose. Such promotional materials will not be permitted to be displayed or otherwise distributed in the general meeting areas.

7.1.14.4 Occupational recruiting and interviewing

Public meetings of ISPE, including the ICPE, provide useful occasions for job market activities. Postings regarding availabilities and opportunities are encouraged, provided, however, that they will be limited to areas specifically designated for these purposes. At each ICPE a binder of Resumés for those available for recruitment and a separate binder of Postings for those actively offering job placements will be available in the exhibits hall or at the registration desk.

7.1.14.5 Policies regarding distribution of commercial materials and solicitations to members

Distribution of materials by exhibitors or their agents is limited to the area rented by the exhibitors. Flyers or other printed material may not be delivered to hotel rooms of ISPE registrants without advance permission from the Hotel and ISPE. Any costs for such authorized distribution shall be the sole responsibility of the exhibitor. Other than the above, advertising circulars, brochures, etc. may only be distributed from the exhibit booths, and may not be placed in any meeting room or in the registration area.

Pre-meeting mailings to members or registrants may be undertaken only with the explicit permission of the Executive Committee and only upon receipt of specific proposals with rationale for pre-distribution and payment of an additional fee, to be established annually by the Executive Committee.

7.1.14.6 Exhibitor seminars, lectures.

(Adopted August, 2003)

As a condition of receiving exhibit space, the Exhibitor agrees not to conduct, sponsor or promote any general seminars, lectures, or clinics in the same geographic area (within a radius of 50 miles) for a period of 3 days pre- and post- the event.

7.1.15 Policy on Externally-Funded Symposia

(Adopted April 2005; amended April 2006)

From time to time, ISPE receives proposals for externally-funded symposia in association with its meetings (eg. the ICPE, and the Mid-year meeting and Regional meetings). This policy provides a mechanism by which such proposals can be accommodated. Externally-funded symposia are not part of the official ISPE meeting, but may be listed in the meeting program, provided that their

status as externally-funded symposia are clearly indicated in the program. "ISPE" cannot appear in the title of the session without approval of the Board or the Executive Committee, and it must be made clear that such sessions have not necessarily been reviewed by the Scientific Program Committee or its equivalent for other Scientific meetings. Proposals for externally-funded symposia will be evaluated by the Board or the Executive Committee to ensure that they are consistent with ISPE goals and that they do not promote particular products or services. The following principles apply to externally-funded symposia:

1. They must be open to all attendees of the ISPE meeting without additional charge.
2. All participants, including speakers, must be registered for the associated ISPE meeting, at least for one day.
3. They must not be scheduled for times that conflict with official ISPE functions, including podium sessions, workshops, symposia, poster sessions, board meetings, committee meetings, council meetings, and social functions. They may be scheduled for times that conflict with other externally-funded symposia.
4. Sponsors will bear all costs of externally-funded symposia, including room rental, audio-visual costs, refreshments, honoraria, travel costs, administration, etc. In addition, it is expected that such symposia will produce net income to ISPE similar to that gained by sponsorship activities that result in similar visibility. By special request, government and non-profit organizations may be granted exemption from the expectation of income commensurate with sponsorship activities. Such requests will be evaluated by the Board or the Executive Committee. Even in such cases, externally-funded symposia must fully cover their cost to ISPE.
5. Policy 7.1.12 – Page 34 on speaker travel reimbursement and honoraria applies to externally-funded symposia.

7.2 Policy on the ISPE mid-year meeting

(Adopted August 2007; Amended April 2017)

The ISPE mid-year meeting is the mid-year meeting of ISPE Board and its various committees, notably the Scientific Program Committee which shapes the program for the forthcoming annual meeting based on the rated abstract submissions and on a review of current topics in the field of pharmacoepidemiology.

The extended program of the ISPE mid-year meeting consists of:

- A topical, one-day session organised by the Local Organisation Committee and the Scientific Program Committee according to the prevailing standards of independence and quality and according to the ISPE policies. The one-day session may be split into two half-day sessions.
- One or two half day session(s) of oral presentations by ISPE students. The presentations shall be chosen following submission of abstracts by interested students.
- Introductory and advanced educational sessions organized by the Education Committee.

For the ISPE Mid-year meeting, the policies of the annual meeting (ICPE) apply except:

- that there is no provision for a meeting of the general membership,
- that not all committees are expected to meet at the mid-year meeting, and
- that there is no general call for abstracts.

7.3 Regional scientific meetings

(Adopted August 2016)

7.3.1 ISPE Asian Conference on Pharmacoepidemiology (ACPE)

(Adopted August 2016)

7.3.1.1 General

ACPE Scientific meetings typically are three-day conferences convened in the final quarter of each calendar year, including both pre-conference educational sessions followed by several days of plenary sessions, contributed symposia and podium and poster presentations.

These meetings are held in the Asian region focussing on topics of interest to ISPE members and workers in the host country.

ISPE Scientific meeting standards and conventions outlined at Policy 7.1 apply to ACPEs.

An objective of ACPE meetings is to foster partnerships and co-sponsorships with relevant local professional bodies.

Registration fees to attend ACPEs are kept at levels affordable for developing world constituencies in Asia.

7.3.1.2 Administration and Finance

The Global Development Committee maintains an ACPE International Steering Committee which oversees planning and organization of the structure and scientific program for each ACPE. (See para 11.1.9 – Page 48) For each ACPE, a Local Host and Local Host Committee work together with the ISPE Office to manage the meeting. (See Technical Appendix U – Page 109).

After appointment of an ACPE Local host, in the calendar year prior to the ACPE, in consultation with the ACPE Steering committee Chair and Local host, the ISPE office will develop an ACPE budget. This budget process will be overseen by the Vice-President Finance and Finance Committee and the agreed budget will be integrated within the ISPE Annual budget presented to the Mid-year Board meeting.

Principles guiding this budget development include:

- Specific designation of conference operation/management functions for each ACPE.
- Registration fees at levels affordable in Asian developing world constituencies
- Target incomes from both local and global sources will be set in consultation with ISPE's Development Committee
- Costs of local organizational infrastructure will be estimated, including amongst other elements, a local conference manager, the costs of website development, creditcard receipt management, professional abstract and scholarship management

- Over the long term, the objective of achieving eventual budget neutrality with respect to ISPE's finances

8 Society Special Awards and Recognition

(Adopted August, 2000; amended August 2004, August 2007, April 2018)

The Board is committed to recognition of excellence for long-term service, both to the field of pharmacoepidemiology and public health, and to the Society. To that end, it creates and may confer Society Special Awards and other recognitions. (See also: Fellowship - 6.1.2 – page 22).

The Board will consider each individual award in these categories on its merits. Normally, waiver of the annual meeting registration fee and/or reasonable travel and lodging costs will only be awarded if specifically mentioned under the individual award. Exceptionally, the Board may agree to waive the registration fee, and may also exceptionally grant reimbursement for reasonable travel and lodging costs, to the annual meeting where the award will be made, for other Special Society Awards and Honorary Lifetime Fellowship/Membership.

Unless specified elsewhere, consideration of nominations for these awards, and subsequent recommendations to the Board, will normally be under the remit of the Fellowship and Awards Committee. Each of the designated responsible committees creates implementation procedures for the awards under their jurisdiction. These are appended to the Technical Appendices of these Policies, at Appendix E – Page 85.

These awards reflect long-term excellence and so it is unlikely (with the exception of the Sustained Services to ISPE recognition) that each award will be awarded each year.

8.1 ISPE Sustained Scientific Excellence Award and Lecture

(Adopted April 2005)

The "International Society for Pharmacoepidemiology Scientific Excellence Award and Lecture" award is presented from time to time to recognize an active investigator for sustained scientific excellence in the field of pharmacoepidemiology.

The candidate must be an investigator who is actively engaged in state-of-the-art research in pharmacoepidemiology, as defined broadly, who has exhibited sustained scientific excellence in the field. Although it is encouraged, a nominee need not be a member of the Society.

The award consists of a plaque, waiver of the meeting registration fee, and reimbursement for reasonable travel and lodging costs to the annual meeting. The awardee must ordinarily be present at the annual meeting to receive the award. In addition, ISPE will invite the recipient to deliver an address on a topic of the awardee's choosing at the time of the presentation of the Award, for which the awardee will receive a \$1000 honorarium.

Nominations must consist of a letter of nomination from an ISPE member stating the reasons supporting the nomination, and a copy of the candidate's curriculum vitae and bibliography. Nominators should obtain permission from an individual before nominating her or him.

Upon recommendation by the Fellowship & Awards Committee, the Board will select the awardee. Previous recipients are ineligible.

A list of all prior award winners shall be posted on ISPE's website.

8.2 Honorary/Lifetime Memberships and Fellowships

(Adopted August, 1999; amended August, 2003; August, 2004, April 2018)

From time to time, ISPE may choose to honour an individual to celebrate special accomplishments or a special occasion. Under such circumstances, ISPE may choose to present such an honouree with Honorary Membership. Such a status is commensurate with that of any regular member, except that payment of annual membership dues is waived. From time to time, ISPE may choose to publish special listings or convene select panels of such honoured members of the specialty.

All ISPE members are encouraged to identify and nominate persons meriting such honours. Nominations should be provided to the Chair of the Fellowship and Awards Committee with a brief description of the rationale for the recognition.

In the event that the individual so nominated is already an ISPE Fellow, or is also nominated for elevation to the status of Fellow at the time of the honorific, the title will be Honorary Lifetime Fellow.

8.3 Distinguished/Outstanding Service Award

(Adopted April 2018)

This award is for a Fellow who has provided significant leadership, dedication and contribution to the Society over a period of time.

8.4 Sustained Service to ISPE recognition

(Adopted April 2018, Amended August 2018)

This is granted to individuals who have given significant and sustained service to ISPE and who fulfil the following criteria:

- FISPEs who have been members of the Society for at least 12 years, altogether. These 12 years of membership need not be consecutive.
- Indicate to the Fellowship and Awards Committee that they are retired, or about to retire professionally, (irrespective of whether they continue to consult, teach, or do research part time).
- Indicate to the Fellowship and Awards Committee that they are unlikely to attend any more ICPEs.
- Have continued their service to ISPE post FISPE. This would include:
 - Regular attendance at ICPE
 - Provision of advice to ISPE through regular participation in activities of ISPE including the Board, Committees, Council, SIGs or task forces. It may also include representing ISPE at other fora
 - Guidance and/or mentorship to younger ISPE members.

Recipients of the Sustained Service to ISPE are encouraged to continue their engagement with ISPE and are eligible for "retired member" status. The Sustained Service Recognition can only be awarded once to an individual.

The Fellowship and Awards Committee will issue a call for nominees for sustained service recognition to all Fellows. Candidates for sustained service recognition may be self-nominated or nominated by a Fellow.

The Fellowship and Awards Committee considers all nominees for this recognition and makes it report to the Board for consideration at the Mid-Year Board meeting.

The Board takes action on the nominees at its Mid-Year meeting. Notification is sent to those selected subsequent to the Board meeting.

Recipients may apply for free registration at the ICPE at which the Recognition is being conferred.

8.5 ISPE Emerging Leader Award

(Adopted August 2019)

The ISPE Emerging Leader Award recognizes ISPE members who have shown, early in their careers, the potential for leadership and have already made significant contributions to the Society. Only one award can be granted in each year and it may not necessarily be granted every year.

Selection process

- A call for nomination is announced together with the calls for FISPEs.
- Nominees must be ISPE members in good standing and have between two years and seven years of membership in the Society, consecutive or non-consecutive.
- Nominees must have demonstrated entrepreneurship and leadership within the Society. Specific examples must be provided.
- The following examples are provided for guidance and might include:
 - Spearheading development of an important concerted ISPE document
 - Establishing or further developing an important new initiative within ISPE, such as students' night out, new member luncheon, mentor program, or newcomer submission track.
 - Establishing or further developing a major new SIG, committee or Regional Interest Group.

Involvement will normally have been over several years and demonstrate continuing leadership and service in furthering ISPE's aims.

- Upon recommendation by the Fellowship and Awards Committee, the Board will select the awardee.
- Previous recipients are ineligible, as are FISPEs.

Nominations

- Can be made by another ISPE member or by self-nomination.
- All nominations must include: a letter indicating the reason for nomination, i.e., the nominee's leadership contribution to the Society and its mission; and the nominee's curriculum vitae.

The award

- The award consists of a plaque and waiver of the annual meeting registration fee when the award is to be conferred. The awardee must normally be present at the annual meeting to receive the award.
- Names of award winners will be posted on the ISPE website.

8.6 Judith K. Jones Award for Impact on Public Health through Pharmacoepidemiology

(Adopted August 2021)

The Judith K Jones Award recognizes an individual making a demonstrable impact on public health through work in the area of pharmacoepidemiology. The individual must reside and work in a country ranked lower than 'Very High Human Development' by the UN Human Development Index (<http://hdr.undp.org/en/composite/HDI>). Up to two awards may be granted in each year but the award may not necessarily be granted every year.

Selection process

- A call for nomination is announced during ICPE and immediately afterward on the ISPE website. This call will encourage ISPE members to nominate colleagues including those who may not have established connections to ISPE. The nomination process may rely on active ISPE members to propose deserving candidates.
- Nominees do not have to be active ISPE members, but their work must focus on an area consistent with pharmacoepidemiology.
- Nominees must have demonstrated public health impact in a country ranked lower than "very high human development" through their work in pharmacoepidemiology. Such impact could be achieved through:
 - Consistent contributions of evidence that guides public health interventions,
 - Training and mentorship to build capacity in pharmacoepidemiology or,
 - other leadership positions that have impacted public health through the application of pharmacoepidemiology.
- Females are preferred for this award, however, a well-deserving male nominee will not be excluded from consideration.

The nominee's track record will normally show a sustained public health impact through work in the area of pharmacoepidemiology over several years and demonstrate the potential to foster relationships with ISPE on a broader level (eg. by connecting others in the nominee's institution to ISPE).

Following recommendation by the Fellowship and Awards Committee, the Board will select the awardee. Previous recipients are ineligible, as are individuals who work and reside in countries considered 'Very High Human Development' by the UN Human Development Index.

Nominations

- Can be made by any ISPE member.
- All nominations must include: the nominee's curriculum vitae, a letter justifying the nomination, including the nominee's contribution to public health, potential to foster relationships with ISPE and relevance to pharmacoepidemiology, and two letters of recommendation recognizing the nominee's impactful work from individuals of the nominee's country.

The award

- The award consists of a plaque, a waiver of the annual meeting registration fee, and travel support to attend the ICPE when the award is to be

conferred. The awardee must normally be present at the annual meeting to receive the award.

- Names of award winners will be posted on the ISPE website.

9 Policy Regarding Special Projects and Educational Offerings

(Adopted August 2000; amended April 2005; amended August 2006)

The membership from time to time may generate proposals for projects, grants or other funding. Each project must have a single, responsible lead person (e.g., project chair), and generally, a small steering committee as needed. Such proposals must be accompanied by a budget and full fiscal impact analysis, and approved by the Board.

The membership also from time to time may generate proposals for special educational offerings, short courses, and symposia. Such proposals must be accompanied by a budget and full fiscal impact analysis, and approved by the Executive Committee (or Board): all such documentation will be available for information at the next subsequent Board meeting. Each educational program must have a single, responsible lead person (e.g., program chair), and generally, a small steering committee as needed. These programs may provide reimbursement and honoraria for invited speakers at the discretion of the program chair subject to available funds. Such financial arrangements may be expected to be program specific and differ from program to program.

An educational offering or symposium approved by the Executive Committee and/or Board is considered an ISPE co-sponsored function and the Executive Committee (or Board) may grant the right to use membership lists for a reasonable fee and the ISPE letterhead or logo for advertisement.

See also Technical Appendix F – Page 86: Financial Guidelines for Invited Speakers at ISPE-Sponsored Educational Programs.

9.1 Webinars

(Adopted August 2016; Amended April 2017)

The Society wishes to share its educational content with the research community at large to encourage growth of the discipline worldwide. However, the Society has an obligation to maintain the value of membership of the Society and provide certain benefits to members to help them develop professionally.

The following principles guide direction of this program:

- Appropriate ISPE educational content that is available usually without additional cost to members shall be available on the website to both members and the public. This material shall include (but is not limited to) the history of pharmacoepidemiology videos, webinars and annual recordings of any “no-additional cost” ICPE pre-conference courses, provided permission is given by the Presenters.
- ISPE members do not receive remuneration to develop and/or present educational material
- Educational material should not include content of a commercial nature, or be used, for marketing or third party commercial purposes.

10 Management Company Oversight

10.1 Management Oversight Committee

(Amended April 2001; amended April, 2004; amended August 2006)

The Immediate Past President chairs the Management Oversight Committee. The committee is independent of the Executive Committee and the office. All performance appraisals shall be based upon the agreed-upon objectives and activities in the contract consonant with the duties of the management company.

There will be an annual performance review of the management company, which will review performance against agreed objectives and set an agreed-upon body of work for the next year which will include determining staffing levels and contractual responsibilities. The Management Oversight Committee shall also review and propose modifications and extensions to the contractual relationship between the Board and management company.

10.2 Contract Renewal or Termination

(Amended August, 2006)

Six calendar months prior to the expiration of the contract, the management company will notify the Executive Committee of the expiration deadline. Negotiations on a new contract must be concluded within 45 days of notification. If not concluded within this time frame, the Executive Committee has the option to declare that the contract will not be extended. Additionally, if either party wishes to increase or eliminate certain services called for in the contract, they may do so, but only upon mutual written consent of both parties.

10.2.1 Contract Renewal

The initial conditions of the contract required a twelve month operational year. Now, and hereafter, the contract does not require re-negotiation, i.e. it is considered "evergreen" unless an explicit act of termination is undertaken by either party (see 10.3 below). The management Company's fee and other services to be included in this continuing agreement are negotiated annually as part of the budget process. The performance of the executive director is also assessed every year, and salary and bonuses considered as a formal component of the budget process.

10.3 Cancellation

If, during the performance review deficiencies are noted, ISPE will give the management company the opportunity to correct said deficiencies and improve performance. If, in a reasonable amount of time defined by the Executive Committee, the deficiencies have not been corrected to ISPE's satisfaction, ISPE will give no less than a three months written notice to the management company.

Note: The management company has the option of cancelling the contract with no less than six months written notice to ISPE, after a reasonable opportunity given for ISPE to correct any deficiencies.

10.4 Terms of Succession

10.4.1 General Terms

(Amended April, 1999)

If the board terminates or does not renew the contract of the management company, the Board (Management Oversight Committee) must designate and begin negotiations with (an) appropriate successor(s) immediately.

10.4.2 Orderly Transition

Compatible with mutual contractual obligations, in the event of transition, the Board shall promptly develop an interim strategy to ensure continuation of the vital functions of the Society. This strategy may include ad hoc service-specific contracts with the prior or other management organizations or third party.

10.4.3 Criteria for Executive Secretary and Management Company Appraisal

The Executive Secretary/management company's duties are outlined in ISPE Bylaws Article V/6 & 9, (Administrative – Page 122). These should provide the objective criteria by which the Executive Secretary/management Company's performance is measured. The individual points noted in the by-laws are as follows:

1. proper and legal mailing of meeting notices to members
2. proper recording of proceedings of meetings of the Society, Board, and Executive Committee
3. ensure accurate records of all members are kept
4. keep the seal of the Society
5. in charge of society's funds
6. collect all member dues and assessments
7. establish proper accounting procedures for the handling of the Society's funds
8. supply a report of the financial condition of the Society at annual Board and general meetings.
9. prepare annual report at the end of fiscal year reflecting an audit by a certified public account
10. make available, in a reasonable time following each fiscal year, an annual budget covering all activities of the society.

10.4.4 Appraisal of the Executive Secretary

(Adopted August 2001)

An appraisal of the Executive Secretary must therefore include:

1. handling of membership communications, records and dues
2. handling of Society communications and proceeding,
3. handling of Society finances.
4. consistency with Executive Secretary job description as described in Technical Appendix H – Page 89.

All the above must be deemed formally correct and appropriate to the goals of the Society by the evaluators.

In addition, the position of the Executive Secretary requires functions beyond the strictly administrative ones mentioned in the by-laws, including implementation of Board initiatives and directives.

1. Representative of the Society in public
2. Activities in advocacy of the discipline
3. Committee activities on behalf of the Society

4. The conduct of conferences, educational efforts, and organization activities.

In these activities, the evaluation must consider the extent to which these conform to the directives and policies of the Board.

11 Committees, Councils, Special & Regional Interest Groups (SIGs & RIGs)

11.1 Committees

The Board has established the following committees and adopted these related mission statements and operational guidelines:

11.1.1 Archives and History Committee

(Adopted April 2017)

The mission of the Archives and History Committee is to preserve the history of ISPE in an official Archive and to select and prepare suitable content for the Society's website relating to that history and that of the field of Pharmacoepidemiology. As such the Committee will:

- Identify, codify and preserve to archival standard, materials and artefacts of historical importance for ISPE, and
- Compile, document and advance understanding and appreciation of materials which portray the history of ISPE and the field of Pharmacoepidemiology.

This Committee will be chaired by a current Fellow of the Society, who is appointed annually by the President. The Committee chair shall be known as the ISPE Archivist. The appointment may be renewed

11.1.2 Audit Committee

(Adopted August, 2004; Amended October, 2015; See Finance Committee)

The mission of this committee is to be responsible for the hiring of the auditor, meeting with the auditors to review the scope of the work, and reviewing the end results (i.e., oversight). Roughly once every ten years the contracted audit firm will be changed. Additionally, the committee will establish procedures for the 'receipt, retention, and treatment of complaints' received by the Society from members or the general public regarding accounting, internal controls and auditing, and have the authority to engage independent counsel or other financial advisors as it determines necessary to carry out its duties. At least one member must be knowledgeable about accounting and finance. The Audit Committee is a sub-committee of the Finance Committee.

11.1.3 Bylaws, Policies and Procedures Committee

(Amended April 1999)

The mission of the Bylaws, Policies and Procedures Committee is to monitor the implementation of existing bylaws and policies; to make changes to the bylaws and the policy handbook as instructed by the Board; to flag areas where changes to the bylaws and policies are needed; to make bylaws and policies available to Board, committees and membership. Membership of the Committee is by Board appointment only. See also 2.1 – Page 7: Organizational Structure for Development and Management of Policies.

11.1.4 Development Committee

(Adopted April, 2000; amended August 2003, amended August 2006)

The mission of the Development Committee is to develop, propose and, under direction from the Board implement, along with others in ISPE leadership, strategies and tactics to ensure the long-range fiscal integrity of ISPE.

The ISPE Development Committee leadership consists of a chair and two (co-/vice) chairs representing the three different geographic regions (The Americas, Europe, Asia-Pacific and Africa). In any year, the chairperson will be from the region where the annual ICPE is held that year. The chair will lead the Development Committee and present the annual Development Committee report to the ISPE Board of Directors; the presentation of the mid-year ISPE meeting may be delegated to the co-/vice chair of the region where the mid-year meeting is held. A co-/(vice) chair serves a 4-year term, with as many as 2 years as chair of the Development Committee. Every 4 years a new co-/vice chair should be nominated from the region where the annual ICPE is held that year (replacing the outgoing chair of this region). After election, (s)he serves as co-chair for the 1st year on the Committee, transitioning into the chairpersonship the next year. A new co-chair from Asia Pacific region is also nominated/elected every 4 years.

11.1.5 Education Committee

(Amended August 1999; Amended August 2016; April 2017)

The mission of the Education Committee is to provide leadership in pharmacoepidemiology education at all levels of training and expertise. Areas of endeavour include the planning, organization, and evaluation of educational events including the Introductory Course offered at the annual ICPE; review of ongoing training programs; evaluation of educational needs of ISPE members.

The Education Committee oversees operation of ISPE's Webinars and other educational programs. (See policy 9.1 – page 43). In particular the Education Committee shall decide, in agreement with the providers of the material, which material shall be made public and which should be available solely for members of the Society.

The Committee will regularly review the educational material made available on the ISPE website for relevance and currency and shall, in agreement with the Publication and Communications Committee, add, remove or revise as required.

The Education Committee is tasked with developing and maintaining the required forms and permissions, necessary for developing and making available education content.

11.1.6 Executive Committee

Between meetings of the Board, the Executive Committee may, in place of the Board, take action on all matters not inconsistent with the goals of the Society.

11.1.7 Fellowship And Awards Committee

(Adopted August 2002; amended April 2004; August 2004; 2005, April 2009, April 2018)

The Fellowship committee is chaired by the immediate Past President and shall include the President and 6 members drawn from the FISPE list, with 2 members rotating off the committee each year. The immediate Past President appoints two new members for three year terms to replace the outgoing members.

In the event of a member being unable to complete their term of office, the immediate Past President shall appoint a new member for the remainder of the departing member's term.

The Committee's tasks are:

- To review nominations and make recommendations to the Board for Fellowship of the Society, in accordance with the formally agreed criteria and procedures of the Board.
- To review, and propose nominations and make recommendation to the Board of the Society for Society Special Awards and Recognition, (see Section 8 – page 39), in accordance with the formally agreed criteria and procedures of the Board.
- From time to time, to review new opportunities and propose designation of specific awards and other recognitions to the Board.

11.1.8 Finance Committee

(Adopted August 1999)

The mission of the Finance Committee is to support the Vice President/Finance in being the fiscal conscience of the society. The committee ensures short and long-term financial planning and develops financial policies for the board's approval: See Page 64 – Para 12 Financial Policies. The committee oversees development and implementation of the budget, monitors all financial transactions including investments and reserve funds and provides accountability to the board and the society according to the bylaws and policies and according to accepted business practices.

11.1.9 Global Development Committee

(Adopted August 2002; Amended August 2016; August 2019)

11.1.9.1 Mission

The mission of the Global Development Committee includes the delivery of developmental support for internationally applicable education and research programs, and the provision of assistance in such endeavours in those areas of the world where Pharmacoepidemiology expertise is yet to be fully established.

11.1.9.2 Governance

At the annual ICPE meeting, the Global Development Committee elects a Chair and Vice-Chair who hold office for staggered terms in accordance with policy 5.1. The Chair and Vice-Chairperson together with the Regional Interest Group Liaison Officers (see 11.1.9.4) constitute the Leadership Group for the Global Development Committee.

The Chairperson of the Global Development Committee is responsible for reporting to the Board semi-annually. At the Annual ICPE, reports from the Regional Interest Group Liaison Officers concerning operations of their respective Regional Interest Groups will be presented as an addendum to the Global Development Committee Report.

11.1.9.3 Global Regions

ISPE currently recognises four loosely defined regions of the world where the Global Development Committee works to support development of the field of Pharmacoepidemiology: Africa, Central/Southern America, Asia and the Middle East.

11.1.9.4 Regional Interest Group Liaison Officers

When Regional Interest Groups have been approved in or near ISPE's defined global regions, the Global Development Committee will submit to the Board names of suitable ISPE members for a three year (renewable) appointment to the position of Regional Interest Group Liaison Officer. Roles and responsibilities of Regional Interest Group Liaison Officers are found in Appendix V: see page 114.

11.1.9.5 Asian Conferences on Pharmacoepidemiology (ACPE)

Asian Conferences on Pharmacoepidemiology (ACPE) are regional scientific meetings overseen by the Global Development Committee. An ACPE International Steering Committee (ACPE-ISC) is established by the Global Development Committee for this purpose.

The mission of the ACPE-ISC is to oversee planning and organization of the structure and scientific program for each ACPE in conjunction with the ISPE Office and the Vice President Finance. (See policy 7.3.1 – Page 38, and Technical Appendix U – Page 109)

On the recommendation of the Global Development Committee, the ACPE-ISC Chair is appointed by the Board for a three year term, additionally assuming the responsibilities of a Regional Interest Group Liaison Officer for Asian affairs.

The Global Development Committee appoints members of the ACPE-ISC for three year terms. Members are drawn from at least five Asian countries as well as including at least one member representing the Americas and Europe/Africa. *Ex officio* members include the ISPE Executive Secretary as well as Local Hosts of each successive ACPE who serve at least for the duration of their ACPE.

11.1.10 ICPE Scientific Program Committee

(Adopted August 1999; amended August 2000, August 2015)

The mission of the Scientific Program Committee is to organize the scientific program for the annual International Conference on Pharmacoepidemiology (ICPE). The committee is responsible for determining the overall structure, content, and daily schedule for the conference. The committee chair serves as the chair for the conference, and the committee is responsible for selecting the plenary speakers for the meeting. A major responsibility of the committee involves managing soliciting, reviewing, and selecting scientific abstracts for presentation at the ICPE, appointing one or more panels at the ICPE to judge and recommend the awards listed in Policy 7.1.11 – Page 34, and presenting awards for the best oral and poster presentations, and the Edlavitch Award. The committee is responsible for overseeing the conference expenditures in accordance with budget and granting waivers of registration fees.

11.1.11 Local Host Committee

(Adopted August 2001)

The Committee may appoint a 'Local Host' and 'Local Host Committee' particularly under circumstances when the program chair does not reside in the conference city. The Local Host will report to the Program Chair, and the Program Chair will oversee the activities of the Local Host and Host Committee. However, the Local Host may be invited to be a member of the Core Committee for purposes of local arrangement and assuring the local responsiveness and

appropriateness. Suggested activities for the Local Host Committee include, but are not limited to soliciting local exhibitors, identifying local supporters (any solicitation of funds should be coordinated with the Development Committee), working with staff to identify/coordinate social events, promoting the ICPE, inviting public officials to give welcoming comments at the ICPE, developing list of attractions, restaurants, etc. for dissemination at the ICPE, on the website, etc.

11.1.12 Management Oversight Committee

(Amended April 2001)

The Management Oversight Committee provides broad oversight of the ongoing operation of the ISPE offices and the Executive Director, and the execution of the management contract. The committee is independent of the Executive Committee and the office. The Immediate Past President chairs the committee; the composition includes at least two committee chairs. Preference will be given to chairs that are Fellows. (See Policy 10.1 – Page 44).

11.1.13 Membership Committee

(Amended August, 2000; August 2003, August 2008, April 2018, August 2021)

The mission of the Membership Committee is to promote ISPE globally in order to increase membership among scientists and others active in pharmacoepidemiology and related fields and work toward increasing awareness of the aims and activities of the organization.

The Membership Committee is responsible for building membership and increasing member involvement through a number of activities, including:

- Organizing, throughout the year, membership engagement activities at the Annual Conference, Mid-Year Meeting and other events
- Growing and improving dissemination of volunteer positions for member engagement
- Periodically obtaining member feedback on ISPE priorities
- Enhancing membership database maintenance and analysis to inform recruitment and deliver audience-relevant messages.

The total commitment to Membership Committee leadership is three years. At any given time, the leadership of the Membership Committee consists of a Chair, Vice Chair, and Past Chair. Each year at the Annual Conference, the Membership Committee holds an election for a new Vice Chair, and promotes the current Vice Chair to Chair.

11.1.14 Nominating Committee

(Amended April 2004; April 2009, April 2018)

The fundamental principle for the Nominating Committee is to develop and advance candidates for election to the positions of leadership for ISPE. The Nominating Committee will be chaired by the Immediate Past President.

The Nominating Committee ensures that the Board distribution approximates the membership's distribution in terms of constituency and geographic region and informs and advises the Board on the current and target Board distributions by periodically reviewing Paragraph 4.1.1– Page 11.

11.1.15 Publications and Communications Committee

(Amended August, 2000, August 2001, August 2003, April 2004, April 2010, April 2014, April 2015, September 2020)

The mission of the Publications and Communications Committee is to advise the ISPE Board on activities regarding publications and communications in service to ISPE's membership and the wider pharmacoepidemiology community. The Publications and Communications Committee will also offer guidance about content designed to increase awareness of the organization and its membership via official ISPE-communication channels.

Specifically,

Regarding the Society's journal *Pharmacoepidemiology and Drug Safety* (PDS):

- represent the Board in dealings with the editor(s) and the editorial board of PDS;
- annually review the ISPE representation on the PDS Editorial Board and submit replacement nominations to the Board when required. Appointment process description - see Technical Appendix I – Page 91;
- assist the Board, as requested, in negotiations with the journal publisher;
- and engage with the Editorial Board of PDS to set policy for the content of ISPE pages in the journal;

Regarding the ISPE website:

- periodically review the quality and relevance of the website and offer suggestions for content and structure;
- monitor member engagement. Operating principles for the ISPE website see Appendix J – Page 93;

Regarding ISPE-funded manuscript initiatives:

- in accordance with policy 1.7.1 on eEndorsement of documents as ISPE public policy, support the Public Policy Committee's review process;
- assist ISPE administrative staff members in facilitating general membership consultation and Board acceptance of such manuscripts as ISPE sponsored publications, ensuring inclusion of appropriate statements acknowledging ISPE's financial support and endorsement in any final publications;

Regarding social media and digital channels beyond the website, maintain a Social Media Subcommittee which will:

- monitor, review, and facilitate where appropriate ISPE's social media presence to further distribute content and encourage engagement in service to the society's mission. – See Technical Appendix T – Page 105.

11.1.16 Public Policy Committee

(Amended April 2004; Amended February 2021)

The mission of the Public Policy Committee is to identify and evaluate external public policies which impact the conduct of pharmacoepidemiology research; and, to develop and maintain a body of public policy documentation which promotes sound pharmacoepidemiologic research for improving the health of the public.

Specifically, as laid out in Technical Appendix B (See page 73):

- To manage review of documents, guidelines, policy or commentary on pharmacoepidemiology, as well as other publications prepared by ISPE members or groups, and as necessary, recommend to the Board endorsement as ISPE public policy in accordance with Policy 1.7.1 and 1.7.2: – See page 3;
- To manage ISPE’s funded manuscripts program in accordance with Policy 1.7.3;
- To receive public policy statements of kindred organisations, to review them for clarity, urgency, and appropriateness to ISPE’s mission, and to arrange for their review and presentation to the Executive Committee or Board in accordance with Policies 1.7.1 or 1.7.2;
- In accordance with Policy 1.7.5, to review prior to their suspense date, existing Public Policies maintained in the ISPE Public Policy Compendium to determine whether revision, renewal or retirement is necessary; and to submit periodic reports to the Executive Committee or Board with recommendations on Public Policies for renewal or retirement, as well as where new Public Policies may be commissioned.

11.1.17 Scholarship Committee

(Adopted August 2000. Amended August 2008, Amended August 2021)

The mission of the Scholarship Committee is to review and award scholarships and waiver of fees for qualifying individuals based upon agreed criteria and subject to available funds. The Board will appoint/re-appoint a Scholarships Committee Chairperson who will serve a three-year term. Under the leadership of the Scholarships Committee Chair, The President, the Vice-President-Finance, the Chair of the Membership Committee, the Chair of the Global Development Committee, and the Executive Secretary shall comprise the Committee.

11.1.18 Strategic Planning Committee

(Adopted April, 2013; Amended August 2019)

The Strategic Planning Committee is chaired by the President-Elect.

Every five years, the Committee prepares for Board consideration:

- a review and suggestions for update of the vision and goals of the Society (1.3.1 – Page 1)
- A strategic plan and an implementation program for the ensuing five year period based on the updated vision and goals of the Society. (1.6.1– Page 2)

The Committee will meet at least twice each year to review the plan and progress of the implementation program so that each Board meetings’ strategic planning session is adequately informed. In the year prior to commencement of a new five-year planning period the Committee will meet more frequently.

Mission:

The mission of the Strategic Planning Committee is to oversee development and implementation of the Society’s strategic plan and its five-yearly review. In addition, the Board’s approved plan and implementation program will be continually monitored by the Strategic Planning Committee and, where necessary, recommended adjustments will be brought to a Board strategic planning session.

Members:

- The President Elect (one-year term)
- The Vice-President (Finance) (two-year term)
- The Executive Secretary
- Regular members serve staggered three-year terms to ensure that during each fifth planning-revision year a sufficient proportion of members have had experience in reviewing the plan and monitoring its implementation.

Regular members are appointed by the Board:

- One representative of the Global Development committee selected by the Global Development committee.
- One representative of the Public Policy committee selected by the Public Policy committee.
- One representative of the Publication and Communication Committee selected by Publication and Communication Committee.
- Up to two Board members selected by the President-Elect
- At least one member who was part of the committee that prepared the previous five-year plan selected by the President-Elect. This member may represent one of the other committee member categories above.

Board members, once appointed to the Committee by the Board will continue their three-year membership of the Committee irrespective of changes in their status within the Board. Strategic planning committee members representing another committee are expected to be actively involved in that committee for the entirety of their three-year term.

Regular members may be nominated by their respective Committee/the Board for a second three year term.

- Additional ad-hoc members may be co-opted as necessary during the period of the plan. These ad-hoc members are not full members of the Strategic Planning Committee.
- When discretion is possible for appointment/co-option of Committee members, attention will be paid to ensure that a balance of the Society's occupational and regional constituencies is maintained in the Committee's membership.
- The Committee may consult with outside experts.

Roles & Responsibilities:

- At least once each five years, review the Society's mission, vision and goals, its strategic plan and the associated implementation programs. Major programs and services will be kept under review, and recommended changes will be brought to the Board for consideration during strategic planning sessions.

Throughout the currency of each strategic plan the Committee will:

- Along with management, with input of the Board as necessary, identify critical strategic issues facing the organization
- Analyse alternative strategic options

- Develop recommendations for further actions to meet the Society's goals and vision.
- Review and evaluate the strategic plan and implementation program to determine that goals and priorities remain applicable and are being met.
- Maintain a timeline and action plan in the implementation program in line with the annual budgeting process.
- Determine areas of weakness in the implementation program and take remedial action.

11.2 Councils

The Board has established the following councils and adopted these related mission statements:

11.2.1 Academic Council

(Amended April 2003)

The mission of the Academic Council is to represent the academic members of the pharmacoepidemiology community and their interests within ISPE in order to serve as a forum for their concerns; to consider how ISPE can assist the growth of academic programs; to consider how academic members can help pharmacoepidemiology and ISPE grow; to provide a liaison for and advance the interests of the Student Council and students attending the annual meeting, and to monitor the intellectual quality of the annual conference as well as ISPE's other scientific activities.

11.2.2 Government Council

(Approved April 2000)

The mission of the Government Council is to represent the government members of the ISPE community and serve as a forum for the expression of government members' concerns within ISPE; to consider ISPE's role in encouraging government programs; to consider government members' role in facilitating the function of pharmacoepidemiology and ISPE within their organizations and elsewhere.

11.2.3 Industry and Service Providers Council

(Industry Council Renamed August, 2009)

The mission of the Industry/Service Provider Council is to represent the industry members of the ISPE community and serve as a forum for the expression of industry members' concerns within ISPE; to consider ISPE's role in encouraging industry programs; to consider industry members' role in facilitating the function of pharmacoepidemiology and ISPE within their companies and elsewhere, and to consider how industry members can help pharmacoepidemiology and ISPE within their companies and elsewhere, and to consider how industry members can help pharmacoepidemiology and ISPE grow.

11.2.4 Student Council

(Approved April 2000; amended April 2003; amended April 2005)

The mission of the Student Council is to represent the student members and the broader interests of students attending the ICPE and to serve as a forum for the expression of student concerns within ISPE; to consider ISPE's role in encouraging the development of training opportunities and scholarship-fellowship funding; to monitor and report to the Board regarding activities of Student Chapters; and to advocate for student participation in the ICPE and

other activities of ISPE. (Technical Appendix K – Page 71 outlines criteria and steps to establish student chapters) To assure liaison, the Student Council will name an official liaison delegate to the Academic Council.

11.3 *Ad hoc* Committees/Task forces

(Amended April 1999; amended April 2001; amended April 2016)

The Board establishes *ad hoc* Committees with designated deliverables and completion dates. Each *ad hoc* Committee chair must ensure a current functional statement to be added to this section.

11.3.1 Real World Evidence Task Force

(Adopted August 2021)

Functional Statement:

The Real World Evidence Task Force will:

- Coordinate and consolidate ISPE efforts to promote expertise in the science of pharmacoepidemiology research as fundamental to RWE across academia, government, service providers, pharmaceutical and biotech industry; and
- Foster collaborations with other societies, agencies, academic institutions, and patient advocacy groups with the goal to establish ISPE as leader in RWE.

11.4 Special Interest Groups

(Adopted August 2005; amended October 2014)

Special Interest Groups (SIGs) address specific specialty interests within pharmacoepidemiology. For their function, SIGs may cover a broad range of disciplines. Unlike the membership in Councils and committee membership, SIG membership is therefore not restricted to ISPE members. The Board has established the following Special Interest Groups and adopted these related mission statements:

11.4.1 Special Interest Group in Drug Utilization Research

(Adopted April 2006)

Mission:

To create a global forum for discussion and cooperation between drug utilization researchers

Initial Objectives:

- An ISPE website with a collection of national drug dictionaries, linked to the Anatomical Therapeutic Chemical classification system (ATC) and the Defined Daily Dose unit of measurement system (DDD)
- Development of an ISPE policy statement (through regular ISPE policy statement processes) on Prescribing Quality Indicators
- Playing a participatory and official representative role in the current initiative of the European Science Foundation for development of a range of prescribing quality indicators: (eg. antibiotic prescribing quality indicators)
- Formal cooperation with large cross national comparative drug utilization studies (eg the European Surveillance of Antibiotic consumption (ESAC), and the European Society of Cardiology's EUROASPIRE group - European Action on Secondary Prevention through Intervention to Reduce Events)

- Enhanced participation in ISPE in communication with health insurer's organisations (both public and private) in Europe and US.

11.4.2 Special Interest Group in Medications in Pregnancy & Lactation

(Adopted August 2006, renamed April 2020)

Mission:

The Medications in Pregnancy & Lactation Special Interest Group seeks to enhance communication, improve the quality of science, and expand knowledge related to the use and safety of the wide range of medications taken by pregnant women.

11.4.3 Special Interest Group in Genomics & Precision Medicine

(Adopted August 2006, Renamed August 2009, Renamed April 2020)

Mission:

To create a global forum for discussion and cooperation between pharmacoepidemiologic researchers interested in genetic, genomic and biomarker research (i.e., molecular epidemiology, genetic epidemiology, pharmacogenetics, and genomic and protein-based biomarkers, and imaging biomarkers). Specifically, this special interest group is interested in research involving the intersection of genetics, genomics, and biomarkers with pharmacovigilance, drug utilization research, comparative effectiveness research, therapeutic risk management, risk communication, health economics and health policy, where the intersection issues relate to drug development, drug delivery, drug use, drug costs, and drug effects.

Objectives:

- Education of general pharmacoepidemiologists to the terminology, methodologic approaches, and epidemiologic applications used in genetic, genomic and biomarker research.
- Identification and promotion of discussion of key genetic, genomic and biomarker-based research and policy issues that affect or are likely to affect the research of ISPE members, or that intersect with the field of pharmacoepidemiology. Examples include the role of observational studies, use of high dimensionality data analysis, biomarker-environmental and gene-environmental relationships in drug effectiveness or pharmacovigilance, and molecular predictive and prognostic factors.
- Increased participation, communication and cooperation between ISPE members and other groups in academia, industry, and regulatory agencies that are focused on genetic, genomic, and biomarker research as they relate to therapeutics. Examples include National Institutes of Health (NIH), Food and Drug Administration (FDA), Agency for Health Care Research and Quality (AHRQ), the NIH-sponsored Pharmacogenetics Research Network (PGRN), the Trans-NCI Pharmacogenomics and Pharmacoepidemiology Working Group (PPWG), the European Task Force on Pharmacogenetics/ Pharmacogenomics, and the International Serious Adverse Events Consortium (iSAEC).

11.4.4 Special Interest Group in Health Services Research and Education on Therapeutics

(Adopted August 2007)

Mission:

To advance the safety and practice of health services research and education on therapeutics

Objectives:

11.4.5 Special Interest Group in Databases for pharmacoepidemiological research

(Adopted August 2007, Amended August 2021)

Mission:

To provide the Pharmacoepidemiology community a forum to share expertise on the use and applications of Real World electronic healthcare databases (eg. medical claims, electronic health records, registries, surveys and other cross-sectional and longitudinal linked databases).

Objectives:

- To discuss, develop and improve methods and approaches in the science of pharmacoepidemiology database research, and disseminate the results
- To create and encourage the use of guidelines for database studies to increase transparency and quality
- To educate ISPE members and stakeholders on the strengths and limitations of database research and the availability of resources.

11.4.6 Special Interest Group on Biologics and Biosimilars

(Established October 2007; Name amended April 2016)

Mission:

The ISPE Biologics and Biosimilars Special Interest Group provides a forum to discuss, develop, and improve the use of pharmacoepidemiologic techniques for biologic agents.

Objectives:

11.4.7 Special Interest Group on Comparative effectiveness Research (CER)

(Established April, 2010; mission statement updated Jan 2014)

Mission:

To provide a forum for the development, application, and dissemination of comparative effectiveness research activities, education, and methods.

Objectives:

- To develop, implement, and disseminate appropriate and advanced approaches to study design and analytic methods in comparative effectiveness research.
- To review and communicate current activities in comparative effectiveness research.
- To support comparative effectiveness research education and training.
- To establish and revise good comparative effectiveness research practices.

11.4.8 Special Interest Group on Medical Devices

(Established April, 2011; Amended April 2019)

Advances in epidemiologic methods and information technology now permit access to evidence available from clinical trials, real-world observational studies,

domestic and international registries, medical claims data, electronic health records and published literature.

Mission:

To determine the evidence gaps and questions, datasets and approaches for conducting robust analytic studies and improve understanding of the performance of medical devices. Methodological discussions and real world comparative effectiveness and safety studies will be the main areas of concentration.

Objectives:

- Increase high quality research in the field of medical device epidemiology through instruction, course development, webinars and publications including active contribution to ISPE meetings
- Design and apply innovative methodological solutions to bridge RCTs and real-world studies in medical devices by articulating strong methods and approaches using real-world evidence
- Develop and drive adoption of proper epidemiologic methods through collaboration with key stakeholders

11.4.9 Asian Pharmacoepidemiology Network (AsPEN) Special Interest Group

(Established August, 2012)

The Asian Pharmacoepidemiology Network (AsPEN) is a multinational research network among researchers in the Asia/Pacific and other regions. The vision of AsPEN is: "Safe and effective use of medications and devices in the Asia/Pacific region through high-quality, timely, and collaborative pharmacoepidemiology research".

Mission:

To develop and advance multi-national database research in Pharmacoepidemiology in the Asia-Pacific region.

AsPEN members will work together to carry out the AsPEN mission adhering to the following core values:

- To facilitate cross- and within-country collaboration.
- To practice the highest standards of pharmacoepidemiologic research.
- To respect cultural differences and values.
- To provide members and sites with equal opportunities.

Goals and Objectives:

- To conduct pharmacoepidemiologic research using databases from AsPEN sites.
- To provide educational opportunities for local and international researchers, policy makers, and healthcare practitioners.
- To facilitate collaborations and communications across countries, regions, and research groups

11.4.10 Benefit Risk Assessment, Communication and Evaluation (BRACE)

SIG

(Established August, 2012)

Mission:

To provide an interactive and collaborative forum for education, training and development among ISPE members with an interest in BRACE.

Goals and Objectives:

- To promote awareness, through education and collaboration, of the intersection of pharmacoepidemiology and BRACE.
- To define the role, application and best practices of pharmacoepidemiology to BRACE.
- To develop and advance BRACE via:
 - development, review and implementation of new tools/methods,
 - the development and sharing of applied examples,
 - providing a forum for sharing findings and soliciting constructive input from peers,
 - sharing information on best practices and promoting harmonization.

11.4.11 Adherence to Pharmacotherapy SIG

(Established November, 2012)

Adherence to pharmacotherapy is central to the effectiveness of self-administered medication regimens. Yet, non-adherence is exceedingly common, with upward of 50% of patients not taking their medications as prescribed. There are a number of challenges unique to adherence research that require specialized skills which will benefit from innovative collaborative approaches to solutions. Historically, adherence research has been siloed into the disease content such that methodologic work has been carried out in parallel, limiting synergy.

Mission:

To create a collaborative intellectual home for ISPE members interested in and/or engaged in adherence to pharmacotherapy. The focus of the activities will be discussion of various measurement methods, including cutting edge approaches and novel use of existing data sources, sharing information about availability of data sources, and sharing novel approaches to post-measurement (analysis) challenges.

Goals and Objectives:

The SIG will hold meetings at ICPE and will hold a poster walk to highlight key abstracts at ICPE and further educate ISPE members about the key developments in the field.

11.4.12 Vaccines (VAX) SIG

Vaccines are key tools for global public health. Increasingly, pharmacoepidemiologic studies are providing critical evidence needed for risk-benefit decision making, especially in maturing immunization programs with successful control/elimination of the target vaccine-preventable diseases.

Goals:

- Foster development and adoption of methods to improve the accurate and efficient collection of vaccine exposure information (e.g., 2D barcodes, vaccine generic names, vaccine doses and dates of delivery) for each vaccinee. Lot identifiers, in particular, would allow verification of the exact vaccine product (type and manufacturer) as well as linkage to details of vaccine antigens, preservatives, and excipients).
- Foster development and sharing of new/existing methods for vaccine safety, effectiveness, usage, cost-benefit, risk-management/mitigation across the life cycle of vaccines from pre- to post-licensure, and from signal detection to hypothesis testing.
- Provide a forum for interaction with regulatory authorities and public health agencies to raise awareness and stimulate incorporation of vaccine specific and relevant aspects into regulations and regulatory templates.
- Assist low and middle-income countries with development of their data collection and technical expertise in vaccine pharmacoepidemiology.

The VAX SIG strives to achieve these goals by offering a platform for interested ISPE members to plan educational activities for the ICPE pre-conference courses together with the education committee, shared national and international projects and grant proposals, and joined presentation in form of workshops, symposia or poster walks at annual ICPE meetings. Whenever possible, the VAX SIG will seek to maximize synergy with existing vaccine institutions and stakeholders.

11.4.13 Pediatrics Special Interest Group

(Adopted August 2016; Amended April 2018)

Mission:

Advance research and share knowledge for safe and effective use of medicines in pediatric populations to inform policies and clinical practice, to promote safe use, and to improve child health outcomes.

Objectives:

- To maintain a current reference of existing pediatric data sources and networks for observational research in pediatric pharmacoepidemiology
- To identify important needs and directions for future critical activities in the area of pediatric pharmacoepidemiology
- To adapt and develop standards relevant to the advancement of pediatric pharmacoepidemiology research
- To promote collaborations within the Pediatric SIG and across ISPE SIGs to address issues relevant to pediatric pharmacoepidemiology
- To serve as a resource to the ISPE membership by providing expertise and educational content in the field of pediatric pharmacoepidemiology.

11.4.14 Cancer Special Interest Group

(Adopted August 2016, Renamed April 2020, Amended August 2021)

Mission Statement:

- To identify cancer-related data sources and research networks that may be considered in use of observational studies for clinical, research and regulatory purposes;

- To identify relevant issues unique to cancer pharmacoepidemiology, and to explore methodological approaches to address concerns especially in the context of advancing use of RWD;
- To serve as a resource to the ISPE membership and professional community by providing expertise in cancer pharmacoepidemiology and educational content in the area as well as in scientific review; and
- To encourage the development and representation of cancer pharmacoepidemiology research at ISPE meetings and conferences, provide meeting resources for those interested in cancer pharmacoepidemiology, and facilitate collaboration among colleagues.

Objective:

To create, facilitate and promote a collaborative, multidisciplinary platform for sharing relevant genomic, pharmacological, clinical, and methodological knowledge to advance research in cancer pharmacoepidemiology.

11.4.15 Rare Disease Special Interest Group

(Adopted April 2017)

Mission Statement

To provide an interactive and collaborative forum to discuss, develop and improve the use of epidemiological approaches for rare disease research.

Objectives

- To create a central data repository for definitions and regulatory environments for rare disease therapeutic products
- To identify epidemiological approaches for natural history of rare diseases and safety and long-term outcomes of therapeutic products that treat rare diseases
- To identify existing data sources and professional and research networks that may be considered for rare disease research
- To identify issues unique to rare disease pharmacoepidemiology, and to explore methodological approaches to address these issues
- To serve as a resource to the ISPE membership by providing expertise in rare disease pharmacoepidemiology and educational content in the area

Meeting Schedule

Monthly teleconferences and face-to-face meetings during ISPE mid-year and annual meetings.

11.4.16 Digital Epidemiology Special Interest Group

(Adopted August 2017)

Digitalization across all industries will impact and change the field of pharmacoepidemiology. Contemporary digitalization developments include:

- new data, eg. lifestyle, environmental
- collection tools, eg. apps, Internet of Things (IoT), wearables, social media
- analytical methods, eg. Natural Language Processing (NLP), Artificial Intelligence (AI).

Mission Statement

The Digital Epidemiology Special Interest Group provides an interdisciplinary forum for discussion of challenges and opportunities from digitalization developments.

It also develops, and aims to ensure that sound scientific pharmacoepidemiological methods and techniques become available in this evolving digital space.

Electronic Medical Records (EMR) and claims data are the backbone of our research, however the role and integration of patient generated data, methods for its collection, transmission, analysis and optimization are also a priority. This work will enhance the value of patient-generated data for patients, providers and healthcare systems.

11.4.17 Geriatric Pharmacoepidemiology Special Interest Group

(Adopted April 2018)

Older adults are the main consumers of drugs but are rarely included in pivotal RCTs. Hence, pharmacoepidemiology is central to understanding drug safety in elderly patients.

Mission statement:

The mission of the Geriatric pharmacoepidemiology Special Interest Group is to provide a collaborative forum to discuss, develop, and improve the methods, applications, and dissemination of geriatric pharmacoepidemiology.

Objectives:

- To create a forum for discussing the challenges and endeavours of geriatric pharmacoepidemiology
- To discuss, develop and propose high-quality standards for geriatric pharmacoepidemiology research
- To develop, test, and validate best methods for drug safety research in geriatric populations
- To promote the geriatric perspective by outreach, collaboration and educational activities.

11.4.18 Drug-drug Interaction (DDI) Special Interest Group

(Adopted April 2020)

Mission statement:

Pharmacoepidemiologic studies are essential to confirm (or refute) and elucidate the health effects of potential drug-drug interactions (DDIs). In addition to applying principles for good pharmacoepidemiology practice, researchers conducting DDI studies must consider nuances in design and interpretation that follow from a focus on the health effects of combinations of multiple exposures rather than single medical products. The DDI Special Interest Group (SIG) will serve as a collaborative community of ISPE members with an interest in the design, analysis, interpretation, and translation of pharmacoepidemiologic studies of drug interactions.

Objectives:

- To provide a diverse collaborative forum for persons around the world interested in real-world DDI research

- To improve the quality of real-world DDI research that informs the clinical evidence base
- To foster the development of new pharmacoepidemiologic methods to study DDIs
- To educate the general ISPE membership and external stakeholders on the role of pharmacoepidemiology in studying DDIs
- To promote the professional development of junior ISPE members interested in DDI research
- To facilitate the translation of high-quality real-world DDI studies into clinical practice.

11.4.19 Diversity, Equity, and Inclusion (DEI) Special Interest Group

(Adopted August 2021)

Mission

The DEI Special Interest Group will serve as a collaborative community of ISPE members with an interest in health equity research, disease disparities, clinical trial diversity, social determinants of health, and the translation of this research into public health programs.

Objectives

- To provide a diverse collaborative forum for persons around the world interested in health equity research.
- Share knowledge between members and across the field of health equity research.
- Further the development of epidemiologic methods for real-world health equity research.
- Educate the general ISPE membership and external stakeholders on the role of pharmacoepidemiology in health equity research.
- Promote the professional development of junior ISPE members interested in health equity research,
- Facilitate the translation of high-quality real-world studies into public health interventions.

11.5 ISPE Regional Interest Groups

(Adopted August 2019)

Regional Interest Groups (RIGs) provide a vehicle for ISPE members who share an interest in extending the Society's goals and activities in specific regions of the world. Unlike membership of Councils and Committees, RIG membership is not restricted to ISPE members. The Board has established the following Regional Interest Groups and adopted these related mission statements:

11.5.1 African Regional Interest Group

[Mission statement to be added after Board Approval]

11.5.2 Brazil International Regional Interest Group

Mission Statement:

(Adopted August 2021)

To build technical capacity, provide a forum to exchange scientific information and foster advances in Pharmacoepidemiology including drug utilization research (DUR) and pharmacovigilance among researchers interested in collaborating with other researchers, from Brazil and from other parts of the world.

11.5.3 Latin American Regional Interest Group

[Mission statement to be added after Board Approval]

11.5.4 Gulf Region Interest Group

[Mission statement to be added after Board Approval]

12 Financial Policies

(Adopted August 2000; amended August 2002; August 2003; September 2020)

12.1 General Policies

(Amended April 2021)

12.1.1 Fiscal year

The fiscal year of the Society extends from July 1st until June 30th in the next subsequent calendar year.

12.1.2 Financial Principles

In the interests of its members, ISPE develops and maintains financial resources sufficient to sustain and extend the work of the Society. The primary aim of finance policies is to maintain principal, as well as to resource Society initiatives while obtaining a rate of return afforded by generally conservative financial management: speculation to achieve high rates of return is not acceptable.

12.1.3 Investment Policies

Assets are to be managed in a single brokerage account.

The account will maintain 50 to 60% of the Society's average annual operating expenses, based on the prior three financial years, in a stable major money market fund, to cover operating deficits under worst-case scenarios.

The remainder of the Society's assets will be invested with a 30% allocation to equities and a 70% allocation to fixed income investments.¹

The equity allocation will be held in index funds, socially responsible if available, including both US and international funds. The fixed income funds will be divided among money market funds and other conservative and liquid debt securities, e.g., short-term and intermediate-term bond index funds.

The equity and fixed income funds should have expense ratios of approximately 0.1% or less and gold or silver ratings by an independent rating entity.

The asset allocations will be reviewed quarterly and rebalanced when the allocations are $\pm 5\%$ from the target allocations.

In addition, asset allocations will be rebalanced within 10 business days after any redemption of 20% or more of the account's assets if the remaining assets deviate more than $\pm 5\%$ from the target allocations.

¹ Market research [dating back to 1928] shows that such an asset allocation has produced an average annual return of approximately 7% with a positive annual return 84% of the time. The associated range of annual performances is -14% to +28%.

12.1.4 Investment management transparency

The Finance Committee will produce quarterly reports for the Board of Directors to provide transparency about balances and asset allocations of the Society's investments.

12.2 Policies Regarding Financial Support for Activities of the Society

(amended April, 1999, August 2000)

ISPE is committed to assure independence of its scientific activities from vested or limited proprietary interests. Thus all sponsored activities, including named sponsorship of activities, services, or products, will be reviewed by the Executive Committee for possible conflicts or appearance of conflicts of interest. Where conflict of interest may result, in general restricted funding will not be accepted. The principles of full scientific balance and full disclosure of possible or actual conflicts will always apply.

12.3 Naming Opportunities

[Under Development]

12.4 Budget Development Timetable

(Adopted August 2000, amended April 2005)

February:

Executive Secretary prepares initial draft annual budget for review and approval of the Finance Committee.

March:

Finance Committee reviews Annual Budget.

April:

Finance Committee submits Annual Budget to Executive Committee for review.

12.5 Dinner Policies

(Adopted August 2003)

The Society will invite the Officers, members of the Board, and chairs of committees and councils to dinner on the night of a scheduled Board meeting. Any other guests for whom ISPE will be responsible will be at the discretion and approval of the President. The price per person will be a reasonable amount.

The Society will invite the members of the Scientific Program Committee who attend the committee meeting held in conjunction with the Mid-Year Meeting to dinner the night of the committee meeting. Any others guest, such as invited speakers for the Mid-Year Symposium, will be at the discretion and approval of the President. The price per person will be a reasonable amount.

12.6 Payments to members for work commissioned by ISPE

(Adopted August 2016)

As a general rule, ISPE does not make payments to members for their work for the Society.

Exceptions to this rule include activities commissioned by the Board or Executive Committee. In general when commissioned activities are to be undertaken, expenditure and income budgets must be approved by the Executive Committee. Reimbursements for reasonable expenses will only be made on production of

receipts and attested statements of time taken, as well as evidence of work completed.

Payments of expenses associated with Annual ICPE Scientific meetings are outlined at policy 7.1.12 – page 34.

13 Co-Sponsorship Policy

(Adopted August 2000; amended August 2002)

13.1 Collaboration

Collaboration with other organizations and groups with similar, related or complementary missions is often of strategic advantage to all involved parties. The Board encourages such collaboration including strategic alliances and co-sponsorships, compatible with other competing ISPE priorities.

13.2 Approval

The Board/Executive Committee must approve agreements to co-sponsor events or other activities with other organizations. Any such agreement requires assurance of quality and accountability.

13.3 Non Risk-Sharing Opportunities

(Amended April 2018)

Non-revenue/non-risk sharing co-sponsorship can include:

- exchange of mailing labels (one-time use)
- exchange of membership list
- announcement of event on the ISPE website
- mailing an event brochure to ISPE members at the prevailing mailing list rate and postage cost
- in-kind contributions
- exchange of complimentary registration to attend event
- use of ISPE name and logo

13.4 Risk-Sharing

(Adopted August 2002)

Under certain circumstances, it may be appropriate that collaboration involve sharing of risk (e.g., financial loss for a venture) as well as benefits (e.g., resource generation). Clear provisions for accountability and management of such agreements, including specification of level of risk, must be agreed in accordance with guidelines, Technical Appendix M – Page 97.

13.5 Branding of ISPE-supported meetings

(Adopted April 2015)

The following policies shall apply to the use of the term “ISPE” in the names of conferences:

The term “ISPE” shall be used in the names of sole sponsored and co-sponsored conferences where ISPE is at least a 50% financial sponsor.

Examples:

- ISPE’s International Conference on Pharmacoepidemiology & Therapeutic Risk Management (ICPE) or simply ICPE

- ISPE's 20xx Mid-Year Meeting
- ISPE's Xth Asian Conference on Pharmacoepidemiology

The use of the term "ISPE" in the names of co-sponsored conferences in which ISPE is less than a 50% but at least a 25% financial sponsor is recommended but not required.

Examples:

- The ISPE–EuroDURG 2014 Meeting on Drug Utilization Research
- ISPE's xth Asian Conference on Pharmacoepidemiology & the 20xx Meeting of the Pharmacoepidemiology Committee of the Chinese Pharmaceutical Society

The term "ISPE" shall not be used in the names of co-sponsored conferences in which ISPE is less than a 25% financial sponsor.

Exceptions to the above can only be granted by approval of the ISPE Board.

14 Legacy Provisions

(Adopted August, 2001)

In 1997, the ISPE Board of Directors agreed to long-term relationships with Stanley Edlavitch, Executive Director of ISPE, and certain ISPE staff. The provisions of this agreement are attached as Technical Appendix N – Page 98.

15 Roles and Responsibilities of Officers

Compatible with and in addition to the functions specified in ISPE Bylaws, Article V – Page 122, the officers will generally assume the following roles:

15.1 President

(Amended April 2006)

The "Face of the Society"; chairs the major plenary meetings of the Society, the Board, and the Executive Committee, generally represents the Society to the outside world and is the principal liaison with the Executive Secretary.

15.2 Immediate Past President

(Amended April, 2004)

The "Mentor of the Society"; chairs the Nominating Committee, Management Oversight Committee and Fellowship Committee; represents the Society externally in the President's place, especially on the other continent; serves as vice chair of the Finance Committee; generally available to the President and Executive Secretary for tasks and duties as needed.

15.3 President-Elect

(Amended April 2004; amended April 2007)

The "Engine of the Society"; substitutes for the President in his/her absence or inability to serve; responsible for overseeing the internal operation of the Society including especially coordination and assuring effective conduct of the affairs of the operating committees and for overseeing and facilitating the strategic planning function.

15.4 Vice-President/Finance

The "Fiscal Conscience of the Society"; chairs the finance committee; ensures short and long range financial planning. Oversees development and implementation of the

budget; consults with the Executive Secretary on expenditures and authorized expenditure deviations from the approved budget not to exceed an amount specified by the Executive Committee. Responsible for assuring preparation of the Vice President/Finance-Elect to assume these responsibilities.

15.5 Vice-President/Finance-Elect [Not an officer]

(Adopted August 2000; amended August 2003)

The ISPE membership elects the Vice-President/Finance-Elect every two years to serve during the second year of the term of the Vice-President of Finance. The incumbent spends the year learning about ISPE's financial situation and other financial matters affecting the Society. The incumbent transitions to the Vice-President/Finance for a full two-year term at the conclusion of the year. The Vice President Finance-Elect is an ex officio member of the Executive Committee.

15.6 Executive Secretary [Not an officer]

The Agent of the Society" and "Right Hand of the Board". Manages the day-to-day functioning of the Society and its offices; assures the implementation of the policies of the Board, identifies and proposes new initiatives and solicits new direction from the Executive committee, operation committees, and the Board; serves as the principal contact for all members; generally advances the cause of the Society; organizes the implementation and operation of the Annual Meeting, and all other official meetings and activities of the Society, in accordance with the directives of the Board and in accordance with an agreed plan of work and annual budget; and may authorize deviations from the approved budget as specified by the Vice President/Finance. [See Technical Appendix H – Page 89, Executive Secretary Job Description, accepted April, 2001]

15.6.1 Deputy Executive Secretary

(Adopted August 2021)

ISPE's management company may designate a senior member of staff to serve as Deputy Executive secretary. This person will work closely with the Executive Secretary to fulfil the duties outlined in 15.6, and may stand in for the Executive Secretary when s/he is unavailable to attend meetings.

16 Policy on Meetings of the Board and Other Bodies of the Society

(Adopted April 2007)

16.1 Meeting frequency

There will be at least one meeting of the full ISPE Board (Article III/10 of the Bylaws – Page 121) and of the other bodies of the Society (e.g. ISPE Committees and ISPE Councils) per year. These meetings will be held at the annual ISPE meeting. Further meetings may be additionally convened at the ISPE mid-year meeting.

16.2 Meeting conduct

The meetings of bodies of the Society shall be regulated and controlled according to ROBERT'S RULES OF ORDER¹ (revised) for parliamentary procedure (Article X of the ISPE bylaws – Page 124).

16.2.1 Consent Agenda

(Adopted August 2018)

A consent agenda may be presented by the President at the beginning of a Board meeting.

Items may be removed from the consent agenda at the request of any one Board member. Items not removed may be adopted by general consent without debate.

Removed items will be considered individually under the Board's New Business.

Financial motions, bylaws and policy amendments may not be placed on the consent agenda.

Board members proposing a motion for Board consideration may ask that their motion be added to, or excluded from the consent agenda prior to the posting of the meeting agenda, although the President retains the ability to set the final agenda.

16.3 Principle of open meetings

Members of ISPE may attend all meetings of the Board, Councils, and Committees and other bodies of the Society with the following understanding.

- In the spirit of active involvement in their Society, ISPE members may attend these meetings as observers when space is available.
- Meetings of ISPE bodies are announced to members of these bodies and in the ISPE meeting programs; the general membership will receive no separate notification.
- The chairperson of the Board or other body has full control of any such meeting and may recognize calls from the floor at her or his discretion, or call closed sessions when necessary.

TECHNICAL APPENDICIES

Technical Appendix A

ISPE Logo and Corporate seal of ISPE

(Amended August 2019)

1. ISPE Logo

The logo of the Society was adopted by the Board on April 6, 2019 (see 1.10)

ISPE's branding features two versions of the logo: one with and one without the name of the Society written out in full.

For legal reasons, the logo of the acronym only may only be used for internal-facing communications and environments controlled by ISPE and limited to an ISPE target audience, such as at meetings and the signage featured at it, member sections of the website (e.g. ISPE Exchange, member database profile pages, etc.), and promotional materials where the full name is impractical and the target audience is known and typically representative of ISPE. The use of the acronym-only logo is reserved solely to use by the executive office.

The logo of the acronym only:



The full logo is used for all external-facing communications, such as official letterhead, business cards, envelopes, brochures, print ads, meeting programs, promotional materials etc.

The full logo:



1.1 Policies for use of the ISPE Logo

(1.10) The ISPE logo may not be altered by ISPE functional groups (SIGs, RIGs, Councils, Committees), nor may these groups introduce their own logo.

ISPE groups such as SIGs, RIGs, Councils or Committees may only use the official full ISPE logo with a line underneath specifying the official name of their functional group as it is named in the Policy Manual (e.g. Student Council).

(2.4.2) All correspondence, reprints of materials, brochures, surveys, which are produced for ISPE, reflect the professionalism of our Society. ISPE policy is for all materials using the ISPE logo to be produced by the ISPE office or reviewed for consistency by the Executive Secretary before printing and distribution. ISPE stationery may be used by officers, Board members, and committee chairs only while representing their ISPE role, and this role must be clearly identified in the closing (Chairman, President, etc.) and body of the correspondence.

(9) An educational offering or symposium approved by the Executive Committee and/or Board is considered an ISPE co-sponsored function and the Executive Committee (or Board) may grant the right to use membership lists for a reasonable fee and the ISPE letterhead or logo for advertisement.

(13.3) non-risk sharing opportunities.

2. ISPE Corporate Seal

The seal of the society was adopted in August, 2006, and is shown below.

2.1 Policies for use of the ISPE Corporate Seal

It shall be kept by the Executive Secretary/Treasurer (15.6) and used by her or him officially under the direction of the President of the Society (ISPE By-laws, Article XI).



Technical Appendix B

Public Policies of ISPE

(Adopted February 2021)

- Contents:**
- 1. Endorsement of Documents as ISPE Public Policy**
 - 2. Endorsement of documents in circumstances of public importance and/or urgency**
 - 3. ISPE Funded Manuscripts – Process and Timelines**
 - 4. Periodic Review of Public Policies**

1. Endorsement of Documents as ISPE Public Policy

Any documentation, guideline, policy, commentary on pharmacoepidemiology issues which is developed by a writing group associated with ISPE has the potential to be viewed by the wider world as being affiliated with ISPE.

Unless such documentation has been specifically endorsed by the process described below, it must contain clarifying language disclosing that the document reflects the author's personal views and does not necessarily reflect those of ISPE or any group associated with ISPE.

In accordance with Policy 1.7.1 (see page 3), the ISPE endorsement process is outlined below:

Roles and Responsibilities

Public Policy Committee (PPC) – Coordinates endorsement process, reviews manuscript for policy considerations, informs the Manuscript-authorship Team of endorsement decisions and next steps, reviews all revisions to manuscripts

Executive Secretary – Coordinates expedited endorsement, distributes manuscripts for ISPE member review, consolidates and provides member comments to Manuscript-authorship Team, informs Manuscript Team of expedited endorsement decisions

Publications and Communications Committee (P&CC) – Post published manuscript on ISPE website

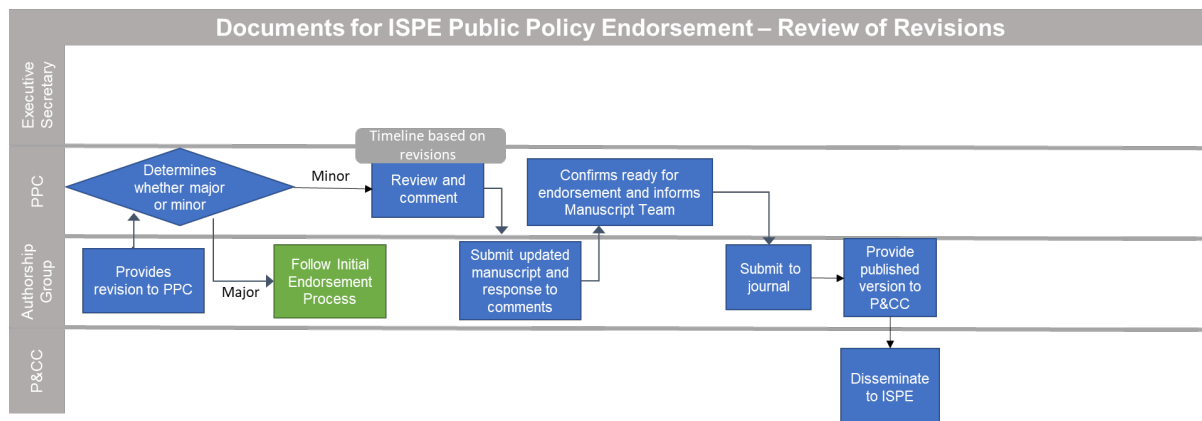
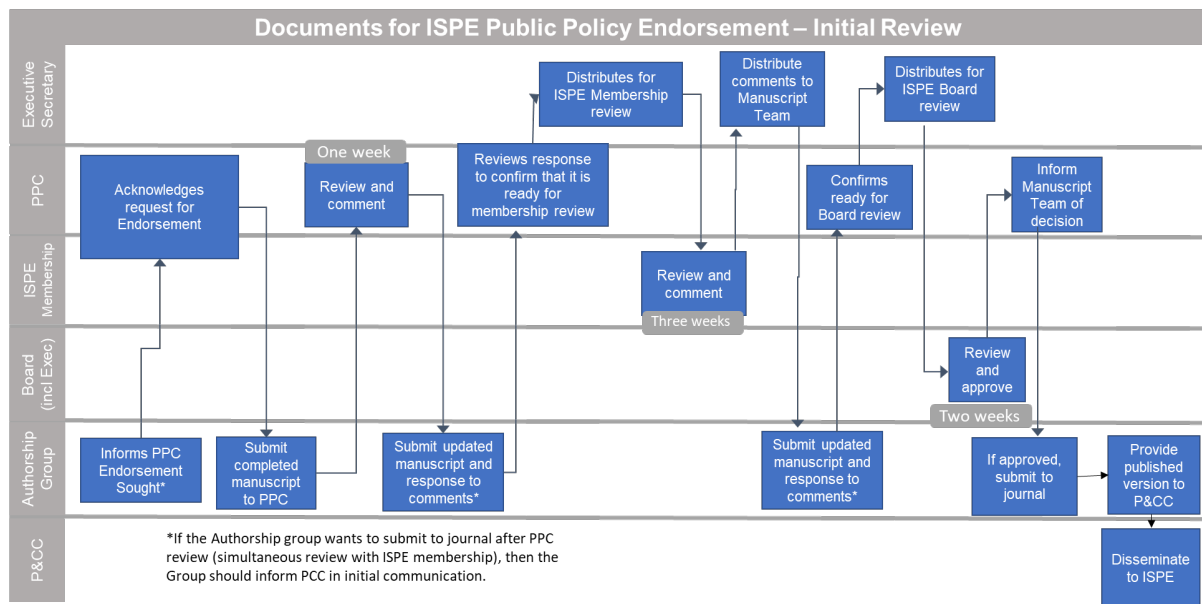
Authorship Groups – inform the PPC that endorsement is to be sought and provide initial and revised manuscript for review, address comments, and provide published version

ISPE Membership – review and comment on manuscripts

ISPE Board (including Executive Committee) – review and approve manuscripts

Workflow

Workflows for the initial review and review of revisions are provided below.



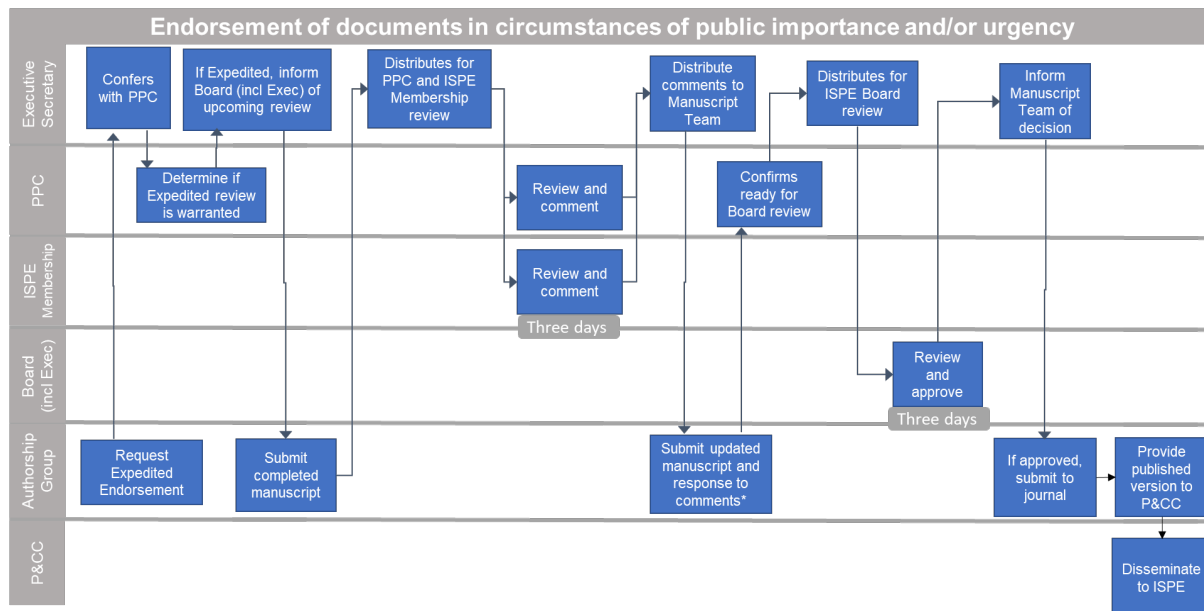
Other Notes

- Authorship groups include all SIG, RIG, Committee, Council, Task Force, manuscript writing groups or other groups of ISPE members convened under the auspices of ISPE.
- The default expectation is that all ISPE authorship groups will seek endorsement of manuscripts.
- Writing groups should inform the Public Policy Committee (PPC) if endorsement is not requested.
- If a document has been endorsed, it should contain an explicit statement that it has been endorsed by ISPE.
- If a document has not been endorsed, it should contain an explicit statement that it has not been endorsed by ISPE.
- ISPE is supportive of simultaneous review of manuscripts by ISPE membership and journal editors/peer review. If this is required, the authorship group should inform PPC during their initial contact about the manuscript.

2. Endorsement of documents in circumstances of public importance and/or urgency

Workflow

In circumstances of public importance and/or urgency, workflows for the initial review of documentation, and endorsement as public policy in accordance with policy 1.7.2 (See page 4) are provided below:



3. ISPE Funded Manuscripts – Process and Timelines

ISPE periodically solicits proposals from the general membership for manuscripts that could be used for guideline development or reference documents for a designated set of topics in the field of pharmacoepidemiology. Topics may include pharmacovigilance, drug utilization research, outcomes research, comparative effectiveness research, and therapeutic risk management.

Any ISPE member or ad hoc writing group may develop written proposals for funding to facilitate the manuscript writing process and subsequent ISPE public policy formation in accordance with Policies 12.6 and 1.7.1.

The annual cycle for a call for proposals, review and recommendation of selected proposals, funding, and tracking of selected proposals is outlined below:

General Timeline of Annual Cycle

- End April – Finalize list of suggested topics
- Mid-May – Initial call for manuscript proposals
- End September – Manuscript proposal submission deadline
- End October – Completion of first review and comments sent to Writing Teams
- End November – Writing Teams’ responses to reviewer comments due
- End December – Notification of selected manuscript proposals
- Each subsequent March & July until completion – Writing Team provides update on progress to P&CC for inclusion in Board reports

Roles and Responsibilities

Executive Secretary – coordinates process, distributes call for manuscripts and rubric for proposal review, informs Writing Teams of selection, disperses funds.

Public Policy Committee (PPC) – solicits input from the Strategic Planning Committee, initiates call for manuscripts, convenes Subcommittee for review of proposals, and after receiving recommendations from the lead author, determines a Suspense date for each finalised endorsed manuscript in accordance with Policy 1.7.5

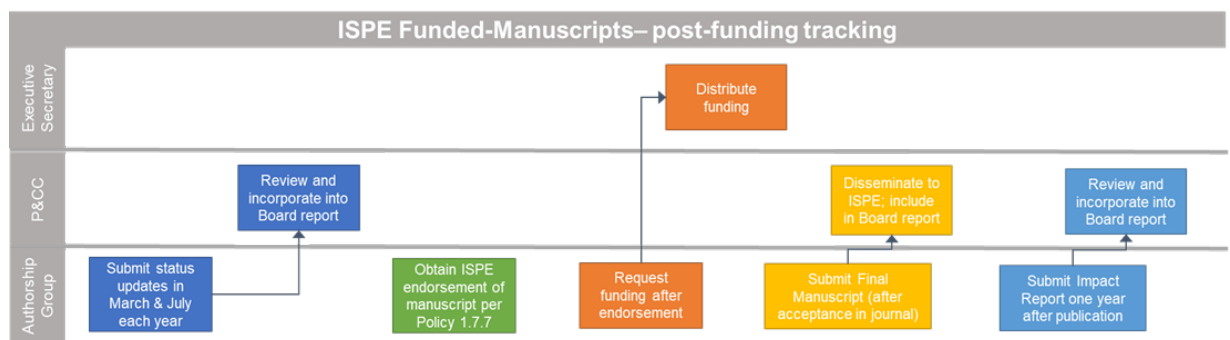
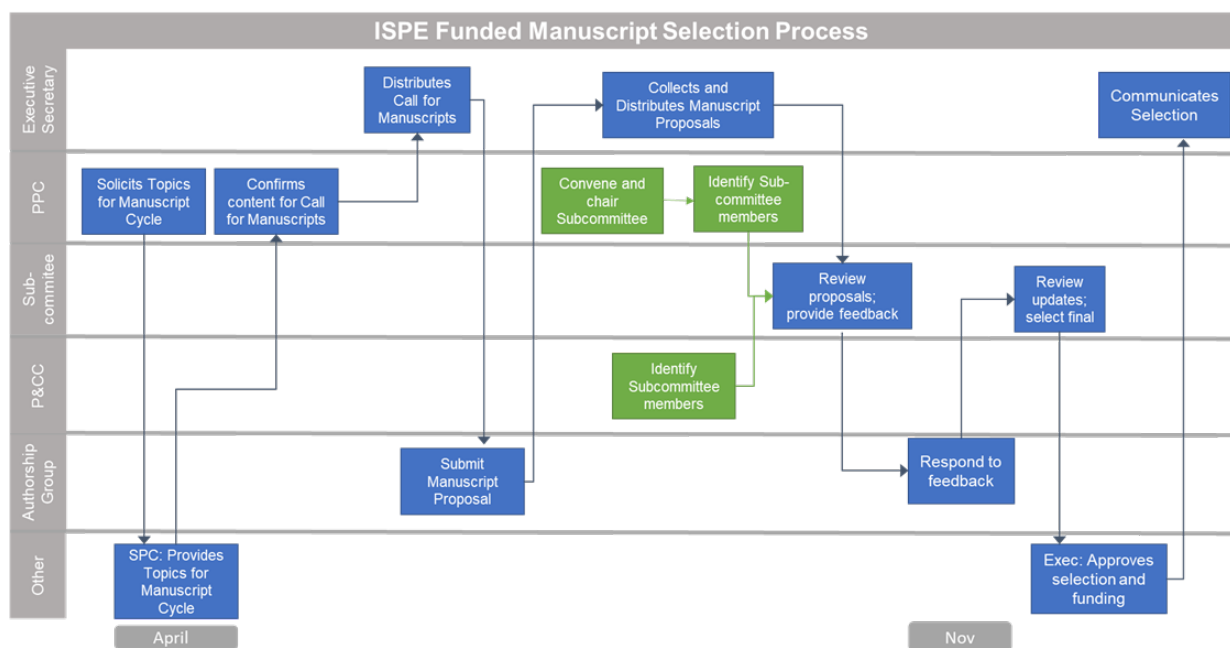
Joint Manuscript Proposal Review Subcommittee – consists of members from PPC and P&CC (chaired by PPC; ~5-7 people) – reviews proposals, communicates with Writing Teams, provides recommendation to the Board or Executive Committee

Publications and Communications Committee (P&CC) – participates in Subcommittee, tracks progress of manuscripts, disseminates and promotes published manuscripts to ISPE membership (e.g., post on ISPE website and social media channels)

Writing Teams – submit manuscript proposals and proposed expenditure/income budgets; (if requested) respond to comments; (if selected) provide updates on writing progress to P&CC; provide Impact Report to P&CC one year after publication; submit receipts and attested statements of time taken for cost reimbursements in accordance with policy 12.6.

Board and/or Executive Committee – approves selection and funding.

Workflow



Content of Manuscript Proposal Submissions

Maximum of two (2) pages, excluding CVs, biosketches, references and any supplemental information. Two pages include the following:

- Title
- Background
- Objective
- Rationale/Priority (consistent with ISPE mission, strategic plan, and topics)
- Issues to be addressed
- Content of Proposal
- Composition of Working Group (Members) and Anticipated Contributions
- Conflict of interest
- Expenditure/Income Budget (with justification)
- Target journal(s) for submission
- Bibliography
- Timeline

Considerations in Review of Manuscript Proposals

Proposals are assessed against the following criteria:

- Appropriateness of issue to the general ISPE membership
- General interest of topic to ISPE membership
- Feasibility to accomplish the stated objectives
- Importance (or significance) of proposal to the field of pharmacoepidemiology
- Visibility (the extent to which the proposed manuscript will be used and, if so, raise the visibility of pharmacoepidemiology)
- Collaboration among multiple organizations, work sectors, and geographic regions,
- Consistency with ISPE strategic goals, objectives and priorities.

Other Notes

- For one year following publication, working groups are required to complete an annual Impact Report to help ISPE monitor the success of the manuscript initiative. Work group chairs will be contacted by the Executive Secretary to complete this report in the period immediately preceding ISPE's annual meeting.
- Funds disbursement. In accordance with the agreed budget and Policy 12.6, funds are usually paid out upon endorsement of the final public policy by ISPE, not at the time of submission of a draft to the P&CC. Open access costs may follow later. Occasionally, if key milestones involve significant costs, on presentation of receipts and suitable attestations, ISPE will consider an interim invoice. Invoices, receipts and suitable attestations (as well as where applicable, United States IRS form W-9's) are required to substantiate disbursements.

4. Periodic Review of Public Policies

In accordance with Policy 1.7.5 (See page 5), at the time of approval, endorsed policy statements, documentation etc. will be required to:

- Include an expiration date: - it is the responsibility of the lead author(s) to provide such a date
- The expiration date is not to exceed 3 years from date of approval

Once annually (no later than 2 months prior to end of calendar year), a subcommittee of the Public Policy Committee will convene to review any policies contained in the online Compendium that are scheduled to expire within that calendar year, to determine whether they should be revised, renewed or retired.

Review criteria to be used in this determination are:

- Ongoing consistency with ISPE mission, strategic goals, objectives and priorities
- Importance (or significance) of the policy to the field of pharmacoepidemiology
- Whether the policy content is no longer accurate or is otherwise outdated
- Timeliness and/or continued relevance of the policy to the field of pharmacoepidemiology

Upon completion of this annual review, the subcommittee will prepare a report for submission to the Executive Committee. The report will contain the following:

- A list of policies that are recommended to be renewed along with a brief explanatory rationale, and the recommended term of the renewal (1 – 3 years)
- A list of policies recommended to be retired at year's end along with a brief explanatory rationale;
- A list of recommended topics of policies to be commissioned by ISPE to address existing gaps in its set of public policies. Gaps are to be determined based on absence of an existing ISPE Public Policy on a topic that is deemed relevant to the conduct of pharmacoepidemiologic research and the application of such research to public policy.

Technical Appendix C

Technical Considerations for Waivers and Scholarships

(Adopted August 2004; amended April 2005, April 2007; August 2010; August 2019)

Technical Considerations for Waivers of Membership Dues

Anyone who requests reduced membership fees and who is a resident of a country in which the UN Human Development Index (<http://hdr.undp.org/en/composite/HDI>) is considered less than 'Very High Human Development' should be granted an ISPE membership at an appropriately discounted rate for the class of membership, the specific discounts to be determined annually by the Membership Committee and administered by the Executive Secretary. This membership would include access to materials electronically only (that is, only communication via email and electronic access to PDS).

Technical Considerations for Waivers of Registration Fees

(Amended April 2007)

The availability of waivers of registration fees shall be determined by the Scholarship Committee at least two months in advance of the meeting to enable recipients to plan appropriately. The Scholarship Committee shall consider all applications received by the due date, and shall disburse the available monies and waivers as they see fit, taking into account applicants' stated reasons for wishing to attend, countries of residence, financial situations, and any statements in support. In general, priority will be given to attendees with accepted abstracts [refers to ICPE] – irrespective of ranking, and to the presenting author. Successful applicants will be informed in advance of the conference, but monies, if any, will only be paid by the Society on receipt of appropriate documentation. Additional or excess claims not previously agreed by the Scholarship Committee will not be met

Waiver of registration fees will be offered to any member of the news or professional media attending the annual meeting. Media representative attendee badges will designate their media status.

Technical Considerations for Scholarships

(Amended April 2007; October 2014; August 2019)

The general principles for disbursement of Scholarship funds listed below prevail:

1. A self-explanatory scholarship application form is available from the ISPE Office by the time of the call for abstracts for the meeting.
2. The closure date for receipt of scholarship applications is approximately one month after the closure date for receipt of abstracts for the meeting.
3. All scholarships awarded include the cost of a concessional/student registration fee.
4. Once mean scoring for scholarship-applicant abstracts is finalized, the following principles are followed for disbursement of budgeted Scholarships funds:
 - a. An offer to cover their registration fee only is made to applicants supported in the previous three years.
 - b. An offer to cover their registration fee only is made to applicants who did not submit an abstract.
 - c. If the elected Student Council leader applies for a scholarship, the figure of US\$ 1,000 (inclusive of concessional registration fee) is offered if the individual concerned does not qualify for an award under para 4E.

- d. Applicants who submit an abstract which is ranked with a score >3.5 receive the award of the lower of their request or US \$750*
- e. Applicants who submit an abstract which is ranked with a score <3.5 receive the award of the lower of their request or US\$ 1,500*
- f. Applicants who submit an accepted abstract who are resident in countries falling below the 'Very High Human Development' category in the UN Human Development Index <http://hdr.undp.org/en/composite/HDI>) are awarded the amount they request (inclusive of registration fee)
- g. Applicants having received Scholarships within the previous three years, and whose abstracts score sufficiently highly to warrant awards under sections (d), (e), or (f) will be considered for scholarships if they have taken active leadership roles in Society Committees, Councils, Chapters, or Special Interest Groups.

* Cut-off scores and cash awards in elements 4d and 4e (i.e. 3.5) will be adjusted suitably so that budgeted funds are fully expended.

Once all scholarship applications have been received, and all abstract scores have been assigned, a financial model will be created for consideration by the Scholarship Committee to confirm the continuing reasonableness of the assigned concessional component.

Technical Considerations for recent graduates.

(August 2010)

Within a three-year period following immediately after graduation, graduates from an approved degree-awarding training program are eligible for reduced registration rates at the ICPE. The rate will be the same as for current students. This may be claimed for a maximum of two occasions which do not need to be consecutive. Any graduate claiming this reduced rate must submit proof of recent graduation at the time of conference registration.

Technical Appendix D

Abstract Processing Procedures

(Adopted April 2000; amended August 2001; August 2003; August 2015; April 2018)

1. By the Midyear meeting (if not before) the Board of Directors should make final decisions about the meeting site, the Scientific Program Chair for the meeting, and any additional required chair of a local host committee for the annual meeting two years hence.
2. By September of the year before the meeting, the Scientific Program Chair should recruit a committee of ISPE members including a representative mix of the Society's membership who will serve as the ICPE Scientific Program Committee for the ICPE in question. This committee should communicate by conference call and email as needed.
3. By October, the Scientific Program Committee should review (and refine if needed) research abstract categories so that reviewers can indicate which categories they wish to review.
4. In order to create a Reviewer Panel, by January an invitation to review abstracts (and indicate specific areas of expertise) should be sent to all ISPE members, with a response deadline in February.
5. Between the previous annual meeting and the abstract submission deadline, specific proposals for workshops and symposia are solicited in accordance with Policy 7.1.5. In particular, SIG's are invited to submit such proposals. This solicitation occurs with the explicit understanding that all proposals will be evaluated by the Reviewer Panel and selected by the Scientific Program Committee, and that acceptance of any proposal is uncertain. The following procedure for the development of such SIG-endorsed proposals is provided for guidance:
 - a. Potential topics of interest to the SIG are discussed at the in-person SIG meeting during ICPE. Initial ideas are drafted based on comments from attendees and concepts are distributed as part of Minutes. Potential leader (author) and speakers are discussed.
 - b. All SIG members are emailed after the meeting and asked to contact the chair if they are interested in submitting any other SIG endorsed abstract proposal. Internal deadline for submissions to the SIG is specified.
 - c. Chair serves an organizing role and encourages others to lead the abstract. He/she is the leading author only if nobody else volunteers.
 - d. Topic is listed in the agenda of the next SIG teleconference/meeting, scheduled before November. Refined concepts following feedback from members are distributed ahead of time (preferably before end of December), presented and discussed for final endorsement of one abstract. If more than one competitive abstract is under consideration, SIG members vote.
 - e. The final chosen drafted abstract is provided to SIG members in January. Members have 5 business days to review and add suggestions for authors to consider before submission.
 - f. Comments are consolidated by the abstract authors before the final version is submitted to ICPE.
6. By January 1, the Call for Abstracts should be made, with the submission deadline in February.

- a. The submission instructions should define the formats and, where appropriate, the length of presentations: oral (10 minutes plus 5 minutes discussion – 15 minutes total), workshop (90 minutes), symposium (90 minutes), and poster presentations.
 - b. The instructions should define the word limit or character limit, and specify the headings for structured abstracts. These headings may be different for research abstracts vs. proposals for workshops and symposia.
 - c. The instructions should state that research abstracts are eligible (whether or not their content has been presented at meetings of other scientific societies) as long as they are relevant to pharmacoepidemiology as broadly defined. Results that have been published (except in abstract form) either on-line ahead of print, or in printed version before January 1st of the meeting year are not eligible for submission.
 - d. The instructions should state ISPE's policy on Disclosure of Potential Conflicts of Interest, and ask submitters to disclose all authors' potential conflicts of interest relevant to the current work.
 - e. The instructions should allow first-time submitters to indicate they would like their abstract to be subject to special review in a 'newcomer's' track. The purpose of this track is to allow coaching and collaborative abstract revision (prior to the abstract closure deadline) from experienced volunteer members of the Society.
 - f. The submission process should enable submitters to indicate eligibility for the student scholarships described in the policy manual.
7. By March 1, Reviewer Panel members should be sent scientific abstracts to grade, with a deadline of 2 weeks. Reviewer Panel members should not receive scientific abstracts from their own institute or group.
- a. Reviewers should be blinded to the identity and institution of authors, and to the authors' conflict of interest information.
 - b. Reviewers should be asked to abstain from reviewing abstracts for which they know or believe that they have a potential conflict of interest.
 - c. Each abstract should be sent to at least 7 reviewers. The goal is to assign no more than 60 abstracts to an individual reviewer.
 - d. Grading should be on a scale of 1 to 10, with 1 being 'best' and 10 being 'worst'.
 - e. Proposals for symposia and workshops will be graded by members of the Scientific Program Committee and the Reviewer Panel.
 - f. Abstracts received after the deadline should be considered only if they contain new and very important results. This is at the discretion of the Scientific Program Committee chair.
8. Shortly after the grading deadline, an adjusted average score should be calculated for each abstract using a formula that improves calibration among reviewers.
9. The Scientific Program chair should be provided with reports and databases of the submissions and scores, as desired.
10. The Scientific Program Committee should select symposia and workshops based on score, topic, and time constraints of the program.
11. The Scientific Program Committee should meet at the Midyear meeting together with Reviewer Panel members to select oral presentations and assign them to podium sessions. This process should be facilitated by the Chair and the Executive Secretary.

- a. Prior to the Mid-year meeting, the Chair should develop a preliminary list of sessions based on submitted abstracts and scores. This list can be amended as appropriate during the midyear meeting.
 - b. Participants in the Midyear meeting should be blinded to the identity and institution of the abstract submitters. This information should be revealed once the sessions have been finalized in order to prevent scheduling conflicts for presenters. Participants should also be blinded to conflict of interest information until the sessions have been finalized.
 - c. A threshold score should be established such that abstracts with that score or better are guaranteed oral presentation if that is the stated preference. Similarly, a score should be established such that abstracts scoring worse than that score will generally not be selected for oral presentation unless there is a special need, such as to fill a gap.
 - d. Participants in the Midyear meeting should refrain from re-grading abstracts during the meeting.
 - e. Despite the best efforts of the members at the Midyear meeting, it is likely that not all highly rated abstracts will fit neatly into a topic-based session. A small number of mixed topic ("potpourri") sessions of highly rated research abstracts is therefore perfectly acceptable.
 - f. Abstracts with poor scores should be reviewed individually and a determination made as to the acceptability for presentation even as a poster. Examples of unacceptable abstracts might include those that do not describe pharmacoepidemiologic research and those that lack results.
 - g. The Scientific Program Committee meeting participants should identify potential moderators for each podium session at the Midyear meeting. A list of abstract reviewers may be valuable in this process. Members at the Midyear meeting may also indicate their interest in moderating sessions.
 - h. The final list of moderators should be selected by representatives of the Core Scientific Program Committee based on a combination of the suggestions made at the Midyear meeting, and Midyear meeting participants who indicated an interest in moderating. Scheduling conflicts for presenters and moderators should be avoided.
12. Shortly after the Midyear meeting, without specifying details of allocated session dates and times, notification of oral-presentation/poster-presentation acceptances and rejections should be sent to submitters of abstracts, as well as to submitters of proposals for workshops and symposia. A further communication with full details will be sent during June. Invitations to serve as session moderators should also be sent by June.
 13. Presenters should be required to register by the early-bird deadline and provide the abstract numbers of the abstracts that they will be presenting.
 14. In addition to the conflict of interest disclosures required in the policy manual, the Executive Secretary will maintain a list of the conflict of interest disclosures submitted by presenters and this listing will be available for inspection by members.
 15. Upon special request and subject to the approval of the program chair, ISPE may waive a 1-day registration fee for a non-member who has agreed to speak at an accepted workshop or symposium or to moderate a podium session or a poster walk/spotlight session.
 16. About a month before the annual ICPE meeting, the Scientific Program Committee chair should recruit from among poster presenters a handful of presenters who will come

to the annual meeting prepared to give an oral presentation of their research in addition to the poster. These oral presentations can then be inserted into the program to substitute for oral presenters who do not show up to the meeting.

Technical Appendix E

Award Implementation Procedures

The ISPE Pharmacoepidemiology and Drug Safety (PDS) Best Prize Paper

(Accepted April, 2001, amended March 2013)

1. Description

The “Ronald D. Mann Best Paper Prize” is to be awarded at each year’s ICPE to the “best” paper published in PDS during the prior calendar year. The prize will consist of a monetary award and a certificate. If the recipient is not an ISPE member, Wiley will provide a one-year membership and subscription to PDS.

2. Amount

\$1,000.00 (US dollars).

3. Jury

The editors of Pharmacoepidemiology and Drug Safety and one person chosen by the ISPE President, from the pool of ISPE past Presidents. The ISPE Publications and Communications Committee will recommend a nominee to the Executive Committee. Typically the immediate Past-President who stepped off the Board in August is invited to be a judge.

4. Eligibility

Any paper authored (author responsible for correspondence) at the time of publication of the paper and published during the calendar year preceding the annual meeting in which the prize will be awarded, who has not receive the award in the past.

5. Mechanism and Criteria

All papers published in the prior calendar year will automatically be considered as candidates for the prize. Specific criteria for selection among the paper are to be established by the first selection committee, and revisited each year thereafter, as a weighted average of originality, methodological soundness, and public health importance.

6. Prize will be awarded to the first author.

Technical Appendix F

Financial Guidelines for Invited Speakers at ISPE-Sponsored Educational Programs

(Adopted April 2004, amended April 2005; amended August 2007)

Background

These guidelines have been developed for use with ISPE-sponsored educational programs.

ICPE and ISPE Mid-Year Symposium satellite educational programs

(Adopted August 2004; amended April 2005, amended August 2007)

When satellite educational programs are offered to ICPE- and ISPE Mid-Year symposium attendees, remuneration will be made available to invited speakers for these educational programs as follows:

ICPE Satellite educational programs

Faculty for these programs will generally be ISPE members: the provisions of Policy 7.1.12 will apply to speakers in such satellite educational programs. However where an additional night's accommodation is required for participation in the program, one-night's accommodation (room and tax only) will be provided on request. For those ISPE members who have difficulty financing their travel, the Chair of the Education Committee has the flexibility to provide travel expenses pending approval of the Executive Committee. The suggested budget for this is \$ 6,000 for the annual and \$ 3,000 for the mid-year meeting.

Where it is impractical to recruit suitable ISPE members as faculty for certain required topics, reimbursements may be provided as follows:

Non-Member

- Travel:** round trip coach airfare, ground transportation, parking
Accommodation: one night (room & tax only).
Incidentals: \$50 US per diem. ISPE will not pay for a meal, which is offered as part of the meeting.
Honorarium: \$1000 - plenary speaker
\$200 - panellist
Other Benefits: Complimentary registration to ICPE.

ISPE Member

Complimentary registration to ICPE.

ISPE Mid-Year Symposia satellite educational programs

(Adopted August, 2004)

ISPE will reimburse speakers for:

Non-Member

- Travel:** round trip coach airfare, ground transportation, parking
Accommodation: one night (room & tax only).
Incidentals: \$50 US per diem. ISPE will not pay for a meal, which is offered as part of the meeting.
Honorarium: \$1000 - plenary speaker
\$200 - panellist
Other Benefits: Complimentary registration to the Mid-Year Symposium.

ISPE Member

Complimentary registration to Mid-Year Symposium.

The Chair of the Education Committee will have discretion in approving amounts up to the stated limits for each participant. The agreed upon financial arrangement will be communicated to the Executive Secretary who will send a confirming letter to the speaker. Expenses will be reimbursed after the meeting upon receipt of original receipts within 30 days of meeting.

Educational programs not associated with ICPE or the ISPE Mid-Year Symposium

Establishment of educational programs away from the time of regular ISPE scientific meetings and symposia is encouraged in accordance with ISPE's strategic plan. Such initiatives are developed to be both ISPE profile- and revenue-raising ventures.

It is expected that teaching faculty for such educational programs will generally comprise ISPE members.

It is acknowledged that both honoraria and expense-reimbursement will be needed to allow faculty members to participate in such ISPE-initiated programs.

In preparation of the budgets and fiscal analyses for these programs, (required by Policy X. Regarding Special Projects and Educational Offerings) recipient names and amounts of all such honoraria and expense re-imbusement limits are to be documented.

Projected remuneration levels in all such proposals are to be commensurate with those conventionally provided for casual teaching faculty in the health sciences field.

Technical Appendix G

Conflicts of Interest

(Adopted April 2015)

The International Society for Pharmacoepidemiology and its Officers and Committee members are dedicated to serving the interests of the Society's constituency in the most honourable and ethical manner possible; the Society's Officers and Committee members are committed to fulfilling their fiduciary duties to the Society, including the avoidance of conflicts of interest or the appearance of conflicts.

Detailed Policies adopted by the Society in this regard are found in the Policy Manual (Section 6.4 for fiduciary duties and potential conflicts, and 7.1.7 for scientific and financial potential conflicts). By signing this Acknowledgement statement, I confirm that I have read, understood, and will abide by these policies and their underlying principles.

[For Officers and Committee members]

The Society requires all those acting on its behalf to avoid conflicts of interest between their duties to the Society and their duties to other organizations or entities, and to disclose to the Society any actual or potential conflicts of interest.

A conflict of interest exists when an individual participates in the deliberation and resolution of an issue important to the Society while, at the same time, the individual has other professional, business, or volunteer responsibilities outside the Society that could predispose or bias the individual to a particular view or goal.

The Society will generally address conflicts of interest in one of three ways in order to avoid potential legal liability. For serious and actual conflicts, the individual must voluntarily withdraw – or be withdrawn involuntarily if necessary – from the Society position. For less serious conflicts, there must be disclosure to the Society and avoidance of participating in all or part of the debate and voting on the issue for which there is a conflict. Finally, for minor or potential conflicts, there simply must be full disclosure to relevant parties. The Society has the authority to make determinations on how to proceed in all such cases.

Therefore, as an Officer or Committee member of the Society, I recognize that I owe fiduciary duties of care and loyalty to the Society and that one aspect of fulfilling those duties is to avoid conflicts of interest and the appearance of conflicts. Therefore, I am disclosing below all relevant and material facts and situations or areas in which it might appear that I have conflicting duties to other entities. I invite any further review by the Society of any aspects of these situations or areas that might be considered appropriate. I agree to disclose to the Society any facts or situations that may occur during my term in office subsequent to my submission of this statement. Also, if it is deemed appropriate, I will take other steps, such as avoiding deliberation and involvement in certain issues, if it is determined that those steps are necessary to protect against legal liability to the Society or to me arising from conflicts of interest.

Professional, business, or volunteer positions or responsibilities that might give rise to conflicts: _____

I know of no professional, business or volunteer position or responsibilities, including vendor situations, that might give rise to conflicts (check here): _____

Signature

Name (print)

Date

Technical Appendix H

Executive Secretary Job Description

(Adopted April 2001)

The Executive Secretary is the Chief Executive Officer (CEO) of the Society. The Executive Secretary reports to the Board of Directors and is responsible for the organization's consistent achievement of its mission and financial objectives.

Program Development The Executive Secretary will:

1. Assure that the organization has a long-range strategy which achieves its mission, and toward which it makes consistent and timely progress.
2. Provide leadership in developing programs, organizational and financial plans with the Board of Directors and staff, and carry out plans and policies authorized by the Board,
3. Promote active and broad participation by volunteers in all areas of the Society's work,
4. Maintain official records and documents, and ensure compliance with federal, state, and local regulations,
5. Maintain a working knowledge of significant developments and trends in the field

Communication - The Executive Secretary will:

1. See that the Board is kept fully informed on the condition of the organization and all-important factors influencing it,
2. Publicize the activities of the Society, its programs and goals,
3. Establish sound working relationships and cooperative arrangements with organizations and agencies,
4. Represent the programs and point of view of the Society to agencies, organizations and the general public.

Budget and Finance - The Executive Secretary will:

1. Be responsible for developing and maintaining sound financial position.
2. Work with staff, Finance Committee, VP-Finance and the Board in preparing a budget, see the organization operations within budget guidelines
3. Ensure adequate funds are available to permit the organization to carry out its work
4. Jointly, with the President, conduct official correspondence of the Society, and jointly, with designated officers, execute legal documents

Staff The Executive Secretary will:

1. Be responsible for the recruitment, employment and release of all personnel, both paid staff and volunteers
2. Ensure that job descriptions are developed, that regular performance evaluations are held, and that sound human resource practices are in place
3. See that an effective management team, with appropriate provision for succession, is in place
4. Encourage staff and d volunteer development and education, and assist program staff in relation to their specialized work to the total program of the organization

5. Maintain a climate, which attracts, keeps, and motivates a diverse staff of top quality people.

Technical Appendix I

PDS Editorial Board Appointments

(Accepted April 2004; amended April 2010, April 2018, September 2020)

Background:

Ten (10) seats on the Editorial Board of Pharmacoepidemiology & Drug Safety (PDS) are assigned by ISPE. This guidance describes the process for selecting people to be appointed to those seats and the duration of those appointments.

Selection:

Notice that seats are available will be given to ISPE members via e-mail and the website. Full members or fellows of ISPE may become candidates for assignment to ISPE's seats on the editorial board of PDS by indicating their interest by a letter or e-mail to the Chair of the ISPE Publications and Communications Committee. This letter or e-mail should be accompanied by a *curriculum vita*.

When seats become available, the Chair of the Publications and Communications Committee will forward information on each member who has indicated interest to the Vice-Chair of the Publications and Communications Committee (and/or one/two designated Publications and Communications Committee members). The Chair and the Vice-Chair of the Publications and Communications Committee (and/or one/two designated Publications and Communications Committee members) will meet (in person or virtually) to select at most one candidate for each available seat. The Chair of the Publications and Communications Committee may solicit the advice of one further reviewer, who will attend the meeting. Overall, three persons will constitute a quorum. Selection will be based on scientific qualifications, relevant publications, and service to ISPE. In the event of disagreement, the selection will be based on the opinion of the majority of the people participating in the meeting.

Appointment:

The Chair of the Publications and Communications Committee will forward the names of the members selected, along with supporting information on each selected candidate, to the ISPE Board as recommendations for appointment. The ISPE Board will accept or reject each selection by majority vote. The names of the accepted candidates will be forwarded to the editor of PDS for inclusion on the editorial board of PDS; they will be identified as ISPE representatives. If a candidate is rejected by the ISPE board, an alternative candidate will be recommended by the same group as before, i.e. by the Chair of the Publications and Communications Committee, the Vice-Chair of the Publications and Communications Committee (and/or one/two designated Publications and Communications Committee members). Though this would not normally occur, the alternative candidate can be the same person as the previously rejected candidate.

Duration of service, renewal of appointments:

Members appointed as above to serve in ISPE's seats on the editorial board of PDS will serve for the first of: Three (3) years from the date of appointment, cessation of ISPE membership, or resignation by a letter or e-mail to the Chair of the Publications and Communications Committee with a copy to the Executive Secretary of ISPE.

Appointments are renewable once by the same process as above. Six months before an appointment expires, the appointee and the Chair of the Publications and Communications Committee will be notified by the Executive Secretary of ISPE that the term is ending and the appointee will be asked whether a renewal is desired. After one renewal a member cannot be appointed as above until at least four years have passed from the start of the second appointment. At that point, i.e. after break of at least one year, the member can be

reappointed anew. That appointment will be treated as a new appointment, i.e. it can be renewed once.

Timing:

Appointments are on a calendar year basis. Names of interested members will be accepted with supporting information through January 15 of the year preceding appointment. The committee will consider the applicants and submit its report to the Board for consideration at the August Board of Directors meeting. ISPE will send names and contact information of its representatives to the PDS Editor-in-Chief with a copy to the Regional Editor for the Americas after the Board of Directors meeting.

Technical Appendix J

Operating Principles for Distribution of Content

(Adopted August 2000; amended September 2020)

1. General Policy

ISPE seeks to take advantage of emerging technology to disseminate content effectively and efficiently and to promote communication among its members and interested parties. ISPE is committed to developing, maintaining and enhancing a financially viable, globally linked network to facilitate ISPE's commitment to its members to be an accessible, international, effective membership organization. To achieve this goal, ISPE will facilitate electronic communication among and between members and among and between members and the international office. ISPE will create electronic forums for rapid communication and digitally-assisted discussions among committees and members utilizing current and emergent channels and social platforms (e.g. website, LinkedIn, Twitter, etc).

2. Access to ISPE on-line communities (Exchange)

Access to ISPE on-line communities will be open to ISPE members or potentially interested non-members by request to the Exchange Administrator. If there are matters of privileged communication, committee/council chairs will communicate off-line.

3. Reciprocal content linkages

Consistent with ISPE's mission, ISPE seeks to inform and disseminate information about ISPE activities and pharmacoepidemiology-related content. The practice of having reciprocity between organizations with shared goals is to be encouraged as appropriate.

Technical Appendix K

Technical Considerations for Student Chapters

(Accepted August 2004; amended August 2005)

1. Formation of an ISPE Student Chapter

- a. Complete the ISPE Student Chapter Application
- b. Send a letter to the ISPE Executive Secretary. With the letter, include the following information:
 - ISPE Student Chapter permanent address, phone number, and email contact address
 - ISPE Student Chapter faculty advisor, including an explanation of why this person is capable of serving as a faculty advisor for this organization (the faculty advisor must be a member of ISPE)
 - ISPE Student Chapter Officers, including contact information for each. At least half of the Student Chapter officers must be members of ISPE
 - A letter indicating that the ISPE Student Chapter has approval from the University
 - A detailed description of the student interest and capacity in forming an ISPE Student Chapter (i.e. Why do the students at your university want to form an ISPE Student Chapter?)
 - An outline of how often the Student Chapter will meet and types of pharmacoepidemiologic activities it plans to participate in

2. Requirements:

- a. The President of the ISPE Student Chapter, in cooperation with the Faculty Advisor, is required to submit an annual report to the ISPE Board of Directors by July 1 of each year highlighting the activities of the Student Chapter over the previous year, demonstrating the benefits to students from being involved in the ISPE Student Chapter, and identifying potential activities in the next year.

b. Criteria

(Amended August 2005; amended April, 2014)

Membership Numbers: there is NO minimum number of students required to form a chapter, as long as the condition is met that at least 25% of those student members must be current ISPE members.

ISPE Student Chapter Application Form

University Name: _____

Faculty Advisor

Name: _____

Position: _____

Address: _____

City: _____ State/Province _____ Zip/Postal _____ Code: _____

Email: _____ Phone: _____

Chapter President

Name: _____

Position: _____

Address: _____

City: _____ State/Province _____ Zip/Postal _____ Code: _____

Email: _____ Phone: _____

Officers

Vice President: _____ Email: _____

Secretary: _____ Email: _____

Treasurer: _____ Email: _____

Please submit this application to:
ISPE
5272 River Road, Suite 63-
Bethesda, MD USA 20816

Technical Appendix M

Risk-Sharing

(Adopted August, 2002)

Under circumstances in which risk sharing is proposed, in addition to the considerations for non-risk sharing agreements (policy 13.1-13.3), the following requirements apply:

- Clear contractual language in writing, agreed by all responsible agents/Boards in advance of major "go-no-go" decisions.
- Conflicts of interests (e.g., fiduciary relationship with both parties) are clearly defined and appropriately addressed
- Authority and accountability assigned for budget, program/scope, recognition or credit, and logistic/program management (e.g., funding program management/overhead)
- Clear formulas to assure limitation to risk and potential loss must be agreed.

Technical Appendix N

Legacy Provisions

(Adopted August 2001)

RE: Stanley Edlavitch:

1. Lifetime complimentary registration to the ICPEs
2. Lifetime complimentary registration to the ICPEs for one accompanying person
3. Named Emeritus Chair of the ICPEs; to be reflected in final ICPE program
4. Established Stanley Edlavitch Award; a scholarship awarded to the best student abstract submitted for the ICPE. Scholarship will include travel, hotel and registration for the ICPE.
5. Given lifetime emeritus, nonvoting status on ISPE Board of Directors
6. Lifetime complimentary Individual Membership in ISPE

RE: Dale Kennedy, and Marilyn Sponsor

Lifetime complimentary Individual Membership in ISPE.

Technical Appendix O

Board Member Agreement

(Adopted August 2000; amended April 2004)

To be completed, signed and filed at the ISPE Office by each member of the ISPE Board of Directors.

I, _____, understand that as a member of the Board of Directors of the International Society of Pharmacoepidemiology (hereafter referred to as the society), I have a legal and moral responsibility to ensure that the society does the best work possible in pursuit of its goals. I believe in the purpose and the mission of the society, and I will act responsibly and prudently as its steward.

As part of my responsibilities as a board member:

1. I will interpret the society's work and values to the public, represent the society, and act as a spokesman.
2. I will attend at least 75% of board meetings, committee meetings, and special events (such as the mid-year meeting and annual meeting).
3. I will act in the best interest of the organization, and excuse myself from discussions and votes where I have a conflict of interest.
4. I will stay informed about ISPE initiatives and activities. I will ask questions and request information. I will participate in and take responsibility for making decisions on issues, policies and other board matters.
5. I will work in good faith with staff and other board members as partners towards achievement of our goals.
6. If I do not fulfil these commitments to the society, I will expect the Board President to call me and discuss my responsibilities.

In turn, the society will be responsible to me in several ways:

1. I will be sent, without request, an annual audited financial report, and updates of society activities.
2. Opportunities will be offered to me to discuss with the executive secretary and the Board President the society's programs, goals, activities and status; additionally, I can request such opportunities.
3. The society will help me perform my duties by keeping me informed about issues in the industry and pharmacoepidemiology generally, and by offering me opportunities for professional development as a board member.
4. Board members and staff will respond in straightforward fashion to questions I believe are necessary to carry out my fiscal, legal, and moral responsibilities to the society. Board members and staff will work in good faith with me towards achievement of our goals.
5. If this society does not fulfil its commitments to me, I can call on the Board President and Executive Secretary to discuss these responsibilities.

Signed:

Member, ISPE Board of Directors

Date

President, ISPE Board of Directors

Date

Original Filed at ISPE Office

Technical Appendix P

Guidelines for Journal – part I

(Adopted August 2001)

Guidelines for Protecting the Responsibility and Authority of Editors-in-Chief and Owners

Editors-in-chief and the owners of their journals both want the journals to succeed but they have different roles. The primary responsibilities of editors-in-chief are to inform and educate readers, with attention to the accuracy and importance of journal articles, and to protect and strengthen the integrity and quality of the journal and its processes. Owners are ultimately responsible for all aspects of publishing the journal, including its staff, budget, and business policies. The relationship between owners and editors-in-chief should be based on mutual respect and trust, and recognition of each other's authority and responsibilities, because conflicts can damage the intellectual integrity and reputation of the journal and its financial success.

ISPE subscribes to the following principles for Pharmacoepidemiology and Drug Safety

- The conditions of employment for editors-in-chief, including authority, responsibilities, term of appointment, and mechanisms for resolving conflict, should be explicitly stated and approved by both editor and owners before the editor is appointed.
- Editors-in-chief should have full authority over the editorial content of the journal, generally referred to as "editorial independence." Owners should not interfere in the evaluation, selection and editing of individual articles, either directly or by creating an environment in which editorial decisions are strongly influenced.
- Editorial decisions should be based mainly on the validity of the work and its importance to readers, not the commercial success of the journal. Editors should be free to express critical but responsible views about all aspects of medicine without fear of retribution, even if these views might conflict with the commercial goals of the publisher. To maintain this position, editors should seek input from a broad array of advisors such as reviewers, editorial staff, an editorial board, and readers.
- Editors-in-chief should establish procedures that guard against the influence of commercial and personal self-interest on editorial decisions.
- Owners have the right to hire and fire editors-in-chief but they should dismiss them only for substantial reasons such as a pattern of bad editorial decisions, disagreement with the long-term editorial direction of the journal, or personal behaviour (such as criminal acts) that are incompatible with a position of trust.
- Editors-in-chief should report to the highest governing body of the owning organization, not its administrative officers. Major decisions regarding the editor's employment should be made by this body with open discussion and time to hear from all interested parties. Some owners have found it useful to appoint an independent board to advise them on major decisions regarding their editor and journal.
- Editors should resist any actions that might compromise these principles in their journals, even if it places their own position at stake. If major transgressions do occur, editors should participate in drawing them to the attention of the international medical community.

Source: The Relationship Between Journal Editors-in-Chief and Owners, Statement of the World Association of Medical Editors (WAME), March 2000

Technical Appendix Q

Guidelines for Journal - Part II

(Adopted April 2004)

World Association of Medical Editors Statement on Geopolitical Intrusion on Editorial Decisions as amended by ISPE

ISPE subscribes to the following principles for Pharmacoepidemiology and Drug Safety

Decisions to edit and publish manuscripts submitted to biomedical journals should be based on characteristics of the manuscripts themselves and how they relate to the journal's purposes and readers. Among these characteristics are importance of the topic, originality, scientific strength, clarity and completeness of written expression, and potential interest to readers. Editors should also take into account whether studies are ethical and whether their publication might cause harm to readers or to the public interest.

Editorial decisions should not be affected by the origins or the manuscript, including the nationality, ethnicity, political beliefs, race, or religion of the authors. Editors should defend this principle, as they do other principles of sound editorial practice, and enlist their colleagues' support in this effort if necessary.

Technical Appendix S

Whistleblower Principles

(Adopted April 2015)

General

The whistleblower Principles of the International Society for Pharmacoepidemiology:

- (1) encourage Staff, Officers, Committee members, or other volunteers to come forward with credible information about potentially illegal practices or serious violations of adopted policies of the Society, including but not limited to financial, accounting, or auditing issues;
- (2) specify that the Society will protect the person from retaliation; and
- (3) identify where such information can be reported.

The Society requires Staff, Officers, Committee members, and volunteers to observe high standards of business and personal ethics in the conduct of their duties and responsibilities. Staff and representatives of the Society must practice honesty and integrity in fulfilling their fiduciary duties and organizational responsibilities, and also comply with all applicable laws and regulations.

No retaliation

No Staff member, Officer, Committee member, or other volunteer who in good faith reports serious conduct committed by another Staff member, Officer, Committee member, or volunteer shall suffer harassment, retaliation, or adverse employment or other consequence. An individual who retaliates against someone who has reported such a matter in good faith is subject to discipline up to and including termination of employment or position. These whistleblower Principles are intended to encourage and enable Staff, Officers, Committee members and volunteers to raise serious concerns within the Society without retaliation prior to seeking resolution outside the organization.

Reporting violations

Staff, Officers, Committee members, or other volunteers should share serious questions, concerns, suggestions or complaints of potentially illegal or unethical conduct with someone who can address them properly. All reports will be promptly investigated and appropriate corrective action will be taken if warranted by the investigation.

For Staff, in most cases, the immediate supervisor is in the best position to address an area of concern. If the Staff member is not comfortable with approaching his or her direct supervisor regarding a serious matter as covered by these Principles, the Staff member may contact the Executive Secretary. If the direct supervisor is the Executive Secretary or the Executive Secretary is the subject of the complaint, then any serious concerns under this Policy should be directed to the Society's President.

Officers, Committee members, or other volunteers should report any questions, concerns, suggestions, or complaints to the President or, if the President is the subject of the complaint, the President-Elect.

The President is required to report to the Board at least annually on any matters brought forward under these Principles to the extent they are not considered confidential.

Confidentiality

Serious issues under these Policies may be submitted on a confidential basis or may be submitted anonymously (though anonymous complaints may be more difficult to investigate

and resolve). Such matters will be kept confidential to the extent possible, consistent with the need to conduct an adequate investigation.

Acting in good faith

Anyone filing a complaint under these Principles must be acting in good faith and have reasonable grounds for believing the information disclosed indicates a violation. Any allegations that prove not to be substantiated or made maliciously or knowingly to be false will be viewed as a serious disciplinary offense and may result in termination of employment or removal from office.

Technical Appendix T

Social Media and Digital channels

(Adopted April 2015, Amended April 2017, September 2020)

The ISPE social media goals are:

- To establish mechanisms for pharmacoepidemiologists to engage on important developments in the field
- To further the distribution and impact of content relevant for pharmacoepidemiologists and the stakeholders of pharmacoepidemiology evidence beyond the website
- To connect ISPE members on important society news

The Publications and Communications Committee has established a Social Media Subcommittee to pursue ISPE's goals for social media and digital channel use.

Social Media Subcommittee – Guidelines

Members

The Social Media (SoMe) subcommittee consists of 6-8 members. One Publications and Communications Committee (P&CC) chair representative (either current, past or chair-elect) must always be part of the Subcommittee as well as The Chair, (or designate) of the Public Policy Committee.

Purpose

This document describes the guidelines and procedures for maintenance, review, and oversight of the SoMe accounts affiliated with ISPE as well as content generation and dissemination through these SoMe accounts.

The overall aim is to support the objectives of the Society to establish scientific fora, disseminate scholarly and practical information, and facilitate professional communication as well as to support ISPE goals of being recognized internationally as a leading authority in pharmacoepidemiology. Expansion to new constituencies by promoting ISPE's expertise in designing, conducting and interpreting

Real World Evidence and making available to key stakeholders relevant ongoing ISPE activities is a further objective. Key stakeholders comprise of, but are not limited to, health authorities, clinicians, researchers (interdisciplinary), academics, industry, payors, and patients.

ISPE SoMe Channels

Currently ISPE is active on Twitter and LinkedIn. The SoMe subcommittee recommends later expansion to Facebook and later Youtube as other primary outlets. Websites are not included in the scope of this SoMe plan.

Policy for account administrators

Account passwords will be shared between ISPE's administrative staff and members of the SoMe subcommittee. A document with relevant passwords will be created and stored at the ISPE Exchange.

Creation/resharing of content

The SoMe subcommittee will be responsible for the creation and posting of content.

All actions, including e.g. posting or resharing content or liking or following, will be defined as belonging to one of the five following levels specifying what level of consensus is necessary for that action, to ensure the quality of content and adherence to the policies described in this document.

Level	Description
1	Action can be performed by any member of the SoMe subcommittee
2	Action requires review and approval by at least one additional member of the SoMe subcommittee to be carried out
3	Action requires review and approval by at least one additional member of the SoMe subcommittee AND a written statement has to be available for review and comment for at least 24-hours before action to ensure all SoMe subcommittee members have had the opportunity to review
4	Action requires review and approval by at least one additional member of the SoMe subcommittee AND requires review and approval by the P&CC chair representative in the SoMe subcommittee AND a written statement has to be available for at least 24-hours before action to ensure all SoMe subcommittee members have had the opportunity to review
5	For any 'level 4 content' where the P&CC chair representative feels that it is necessary to obtain additional awareness and agreement, the action can only be carried out after both fulfilling level 4 requirements and obtaining agreement from the additional group (e.g. from the full P&CC committee or the ISPE Executive Committee)

Content to promote

The SoMe subcommittee should aim to produce at least one post per week in the social media channels throughout the year. Exceptions to this cadence may be expected during July/early August and between December 15-31 each year.

In line with the Society's goals and mission, we recommend the following content should be promoted on social media accounts. The number in [parentheses] refers to the levels outlined above.

- [1] Administrative content from PAI
- [2] Announcements and promotion of ISPE conferences (Mid-Year, ICPE, ACPE)
- [2] Announcements and promotion of ISPE awards (e.g., new Fellows)
- [2] Content related to ISPE conferences created during conferences
- [2] ISPE Endorsed content (e.g. manuscripts and guidelines)
- [2] Webinars offered by the ISPE Education Committee and other ISPE-associated groups
- [3] Educational programs (internal & external endorsed by ISPE)
- [3] Official ISPE symposia or workshops held at other conferences

Other content, i.e. falling outside the categories above, will initially be classified as level 4 content. The list will be expanded as experience is accrued on types of content.

Policy for liking and promoting other non-ISPE content

The SoMe accounts WILL follow:

- Accounts for ISPE-affiliated groups (e.g. ISPE SIGS/RIGS)
- Accounts representing organizations sponsoring ISPE meetings

- Non-profit professional organizations related to ISPE's areas of research or with overlapping membership and interests (e.g. University pharmacoepidemiology departments and teams)
- Competitors and peers from professional societies
- Government agencies/regulators and HTA bodies related to ISPE's areas of research
- Health-related accounts from news organizations
- ISPE Fellows, Board members, SIG/RIG/Council/Committee Chairs

The SoMe accounts MIGHT "like" posts that positively mention or follow:

- ISPE sponsored events, announcements, or publications/documents
- ISPE-sponsored events
- Members attending ISPE events
- Mentions of ISPE
- Members following the ISPE account

The SoMe accounts WILL NOT follow accounts and WILL NOT like content for:

- Pharmaceutical companies or individuals working for these companies with content not directly related to ISPE events
- Academic or government institutions or individuals working for these institutions, other than those outlined above
- Patient advocacy groups of any kind
- Individuals holding political appointments from any country
- Individuals or companies not affiliated with an institution that reflects ISPE goals (e.g. public figures, pundits, troll accounts, etc)

In case of ambiguity on whether to like or follow a certain account or post, the SoMe subcommittee process will be that of a level 3 action. As it currently is detailed the accounts will not engage in dialogue or reply to mentions/comments. Unique situations where clarity is needed will be handled as a level 4 action.

Plan for direct messages (DMs) to SoMe Accounts

SoMe account administrators will not engage with followers and the public through direct messages, except when requesting other accounts to promote content already published (which is in itself considered a level 3 action). Any direct messages received will receive the following auto-generated message: *"Thank you for contacting ISPE. The account administrators do not monitor direct messages on (social media platform) and request that you direct your question or comment directly to info@pharmacoepi.org. Many thanks!"*

Considerations for increasing outreach

Several actions will be taken to increase the value-gain from posting on social media.

- Accounts should share content across platforms when possible (i.e. content that is created in LinkedIn also shared on the Twitter account etc.).
- ISPE conferences should have a single hashtag that gets used for promotion of the meeting. These hashtags should contain conference abbreviation and year, e.g. "#ICPE21", "#ACPE21", and "#ICPEMY21".

- The account handles and logos for the Society should be included in promotional materials and should be prominent in the main ISPE website.

Plan for rapid response

Members of SoMe subcommittee will monitor content posted for unanticipated outcomes. Problematic content may be removed at the discretion of the SoMe subcommittee (Level 2 action). If other ISPE stakeholders (e.g., Executive Committee) have concerns, these can be raised with the P&CC chair representative and will be treated as a Level 5 action (timeline waived).

Plan for ISPE-affiliated group SoMe

ISPE-affiliated groups (e.g., SIG, RIG) will submit an official proposal to the P&CC before creating new SoMe accounts and will share access with an ISPE-administrative staff member. Active existing accounts (actions at least once per month in the past three months) will be grandfathered but will need to share their guidelines and procedures for use of SoMe. This will include, but is not limited to, adherence to branding and messaging standards (see Policy Manual); rules regarding content generation, following, "liking", and amplifying accounts and posts; and hashtag creation and utilization. These ISPE-affiliated groups are invited to utilize the guidelines and procedures outlined within this document.

Technical Appendix U

Asian Conference on Pharmacoepidemiology (ACPE)

(Adopted August 2016)

1. Site selection for the ACPE

Process

The ISPE office with advice from the ACPE Steering committee will periodically call for expressions of interest from ISPE members wishing to become an ACPE Local host for an ACPE within a particular country or region.

The ACPE Steering committee, after evaluation of expressions of interest will make recommendations to the Board, and recommended sites will be accepted, or not, by majority Board vote. For planning purposes, sites should be selected three years in advance.

Criteria for site selection

In evaluation of expressions of interest for hosting an ACPE, the ACPE Steering Committee will take account of the following factors:

- The Local host's willingness, experience and ability to successfully undertake management of an ACPE
- The levels and nature of institutional support for an ACPE which are available to the Local host
- The strength of the proposed Local host committee,
- The country having an established or developing pharmacoepidemiology base
- The commitment of the country to pharmacoepidemiology; the need for scientific development
- Local organizations agreeing to collaborate and/or sponsor the ACPE
- The potential for local fund raising in support of the meeting
- The site being within a major Asian city
- Easy accessibility for participants from both within and outside of the host country (ie. air, train, car/bus, parking, etc.)
- The attractiveness, reputation and international marketability and accessibility of the proposed city
- Convenience of access to area attractions and dining
- Proposed dates which dovetail appropriately with locally proclaimed holidays, kindred Society scientific meetings and other major religious observances and holidays (eg. US Thanksgiving)
- Any additional factors that may be deemed important during the review of proposals.

2. Meeting operations

ISPE ACPE International Steering Committee (See policy 11.1.9 – Page 48)

The mission of the ACPE Steering Committee is to oversee the planning and organization of the scientific program for the ISPE Asian Conference on Pharmacoepidemiology (ACPE).

For each successive ACPE, the ACPE Steering committee is responsible for determining the overall structure, content, and daily schedule for the conference in consultation with the ACPE Local host and Local host committee.

The Steering committee chair serves as the co-chair for the conference with the Local host convenor of the Local host committee. The Steering committee is responsible for selecting the speakers for the meeting and supervising the solicitation, review, and selection of scientific abstracts for presentation at ACPE using principles outlined in Technical Appendix D.

The ACPE Steering committee is responsible for oversight of scholarship awards and waivers of registration fees in accordance with ISPE policies.

All ACPE Steering committee responsibilities are carried out in consultation with each successive Local host convenor and Local host committee so that the relevance of ACPE scientific programs is maximized for the local constituency.

ISPE ACPE Local host and Local host committee

For each successive ACPE, the ACPE Steering committee will confirm appointment of a Local host and Local host committee members. The Local host and several committee members will be invited to serve as members of the ACPE Steering committee during the year prior to each ACPE. Local hosts will be invited to continue membership of the ACPE Steering committee in subsequent years.

The ACPE Local host committee will provide guidance and assistance to the ISPE office in matters of local arrangement ensuring local responsiveness and appropriateness, as well as promoting the meeting among colleagues, potential participants and organizations.

Throughout preparation for, and operations of each ACPE, the ACPE Local host will liaise closely with the ISPE office and the ACPE Steering committee Chair. Once a Local host and an ACPE location has been confirmed, the Local host will:

- Assist in budget preparation through:
 - Evaluation of suitable locations, facilities and possible local organizing associates for ACPE as well as provision of estimates of costs involved,
 - Providing estimates of numbers of registrants from the host country.
 - Providing estimates of the amounts of locally sourced financial support/sponsorships which can be achieved in accordance with ISPE's policies on sponsorship,
- With direction from the ISPE office, and recognizing local institutional and legal requirements, oversee establishment of acceptable procedures for receipting, expending and accounting for ACPE funds. This will generally require conclusion of formal contractual arrangements between the ISPE office and a responsible local institution.
- Designate roles of Local host committee members
- Convene the ACPE Local host committee and oversee its harmonious operation.
- Suggest suitable conference themes, symposia topics and desirable speakers for consideration by the ACPE Steering committee

Activities of the ACPE Local host committee include, but are not limited to:

- Cooperating with the ISPE office and any local organizing company who may be engaged to facilitate smooth logistic arrangements for the ACPE
- Inviting speakers and attending to local hospitality
- Inviting public officials to give welcoming comments at ACPE

- Identifying and assisting engagement of local supporters and potential co-sponsors of ACPE
- Soliciting local exhibitors
- Implementing tactics to meet budget targets for local financial support for ACPE
- Assuming responsibility for marketing ACPE within the host country
- Working with ISPE staff to identify/coordinate social events
- Developing lists of accommodation, attractions, restaurants, etc. for dissemination through the ISPE/ACPE website, and onsite at the conference
- Providing local volunteer support

3. Conference operation/management functions

A. Financial & accounting:

- prepare draft meeting budgets for the Vice President Finance and ISPE Board
- provide periodic reports, actual vs. budget, to the ISPE Board
- prepare and distribute a post-meeting financial report to the ISPE Board within 60 days of meeting;

B. Hotel negotiation & site selection:

- assist in selecting meeting hotel;
- select and coordinate with various subcontractors required, e.g., audio-visual, decoration, security, etc.;
- negotiate hotel contracts to assure compliance with ISPE's needs and competitive pricing;
- develop a detailed agenda book providing the hotels and contractors with all meeting details, functions schedules, room set-ups, etc.

C. Promotion, marketing, & public relations:

- develop a marketing strategy to meet the program objectives for attendance and content;
- develop a conference identity with graphics and fonts appropriate for the association and conference location;
- create promotion materials (brochures, posters, postcards, broadcast email address, website postings, news releases, advertising in specific publications) matching identity according to budget;
- obtain appropriate mailing lists for direct mail marketing;
- supervise printing and mailing of promotion materials according to agreed strategy.

D. Program support:

- coordinate agenda development with Program Committee chair and provide administrative support to Committee;
- manage CE accreditation, when required, including developing key vendor relationships, required filings, recordkeeping, attendee documentation, etc.;
- develop procedures/policies to guide the Program Committee, staff, invited speakers, etc.;

- provide staff support for solicitation of education grants and corporate sponsorships;
- assist in securing accredited continuing education provider, if needed;
- assist speakers, including writing confirmation letters;
- manage an electronic, Web based, abstract submission and evaluation process.

E. Pre-conference registration:

- receive pre-conference registrations and record in the membership database;
- acknowledge receipt of registrations;
- generate registration packets (including ribbons, tickets and badges) for attendees to pick up on-site;
- ship all registration materials to conference site.

F. Social events

- work with Local Host Committee as needed;
- work with professional conference organizer/destination management company as needed;
- coordinate on-site with the professional conference organizer/destination management company.

G. On-site management:

- schedule pre-conference briefing prior to start with meeting venue (e.g., hotel) and outside vendors;
- manage the registration desk on-site (with temporary staff, or volunteer help if needed);
- account for on-site registrations and entering into main association database after meeting;
- manage conference logistics and hotel personnel on-site;
- supervise room set-ups, food functions, hospitality amenities, and audio visual equipment;
- interact with hotel convention services and catering personnel to assure smooth service;
- arrange VIP reservations; solve guest room problems;
- obtain conference signage as needed;
- act as overall on-site conference coordinator.

H. Post-meeting & general activities:

- handle post-meeting follow-up;
- provide financial and attendance reports within two months of meeting;
- provide summary report on attendee satisfaction, geographic attendance, and recommendations for future meetings within two months of meeting;
- make recommendations for improvement, including researching and recommending new meeting services and program concepts in response to committee ideas, suggestions, and goals.

I. Other services

- Abstract management (e.g., submission, grading, correspondence)
- Scholarship Management

Technical Appendix V

Regional Interest Group Liaison Officers

(Adopted August 2019)

Nominees for appointment by the Board to these Global Development Committee posts will have experience of, and broad connections with ISPE Committee and Council structures.

They will also preferably have interest and achievement in successfully establishing/managing current Regional Interest Groups or their predecessor 'Chapters - Regional National Affiliates'.

The responsibilities of these Officers of the Global Development Committee include:

- To work at all times with the leadership of each Regional Interest Group located in their region to assist in achieving the stated goals of each Group. In particular assisting in ensuring the full scope of support and relationships with ISPE Committees and Councils is brought to bear.
- To become an ex officio member of all Regional Interest Groups situated within their particular area of the globe.
- To ensure compliance of Regional Interest Groups with Policies of the Society.
- To prepare an annual report on the activities of Regional Interest Groups in their region for presentation at the Board meeting held at the commencement of each ICPE.
- When a proposal to establish a Regional Interest Group is received by the Global Development Committee:
 - If there are already existing Regional Interest Groups operating in the same region, the Regional Group Liaison Officer will endeavour to negotiate an amalgamation of existing group(s) with the proposed new group.
 - When the requirement for establishment of a new Regional Interest Group has been met, the Global Development Committee Leadership group will recommend to the Board the establishment of the new Regional Interest Group.
 - Where there is some ambiguity over which ISPE region encompasses the notional new geographic area: Africa, Middle East, Latin America or Asia; the Leadership Group of the Global Development Committee will decide which Regional Liaison Officer will carry responsibility for support of the proposed new Regional Interest Group.

Technical Appendix X

Superseded policies

1. ISPE/ISPOR Relations AD HOC Committee

Established April 1998

End Date: April 2000 [Committee sunset 4/12/00.]

Purpose: To review policies, practices and issues of each organization, ensure coordination between the two, explore and propose to each opportunity for collaboration and coordination of mutual activities.

Membership: Three members, all drawn from the general membership of both ISPE and ISPOR; one each appointed by ISPE and ISPOR; a chair appointed by both.

Accountability: Each Board will receive an update on the other organization and other issues of mutual interest at each meeting. (Amended 4/21/99)

2. AD HOC Committee on Data Quality for Risk Assessment

Established: Fall 1998; End Date: August 23, 2000

3. AD HOC Committee for Global Capacity

Established: Fall 1999; End Date: Fall 2001

Board disbanded committee April 18, 2001.

Board reconstituted for two years, August 22, 2001.

Board converted to full committee status, August 2002.

4. Procedures for Elections of Fellows

Initial Cohort of Fellows: All members who feel they meet the above criteria are encouraged to self-nominate. The Fellowship Committee will screen applications and duly nominate for appointment to the Board, which will officially appoint the Initial Fellows to be announced and honoured at the 2003 ICPE. All past Presidents meet the criteria and are Fellows.

5. Technical Appendix "O" and "D"

(Complete texts on file at ISPE office), currently reflected in Technical Appendix "D" (Amended and expanded 17 April 04; 22 August 15)

6. Technical Appendix S

("Think Bold Team" complete text on file at ISPE office). The recommendation of categories and benefits of organizational membership is retained in Appendix R.

7. Long Range Planning Committee:

Superseded by the Strategic Planning Committee, 2003.

Strategic Planning became a Board function in August 2006, and the Strategic Planning Committee was retired.

8. Technical Appendix F.

Never formally adopted, this appendix was removed April 2005 and replaced with the Appendix F governing financial guidelines for invited speakers.

9. Ken Rothman Epidemiology Prize (formerly ISPE-Roche Epidemiology Prize)

Adopted 4/18/01; amended 8/22/01

Funds for this prize were withdrawn effective August 2007. The prize was presented to the first author of the most deserving manuscript published each year in the journal "Epidemiology" and included a cash award, a commemorative plaque, and the cost of travel to the New England Epidemiology Summer Program.

10. Website Task Force AD HOC Committee

(Established August 2003, End date August 2007)

The Website Task Force was formed to assess ways the ISPE site may be made more useful to the membership. The Task Force reported its suggestions with estimates of implementation and maintenance expenses to the Publications and Communications Committee and to the Board and was disbanded in August 2007.

11. Council of Service Providers

Due to the large numbers of members with a service provider background in the Industry councils, a council of service providers was established in August 2008. The decision was reversed in April 2009 and the Industry Council was renamed Industry/Service Provider Council.

12. External Communications Committee

(Amended August 2003, August 2008; discontinued August 2010)

The mission of the External Communications Committee (formerly named Public Relations Committee) was to design, implement and revise as needed a communications plan for the release of information related to drug issues and Society matters. The committee was disbanded given its success in reaching out to FDA and EMA.

13. Ad Hoc Task Force on first Asian ICPE meeting

(Established August 2009; discontinued August 2010)

The committee successfully explored the feasibility and practicality of holding a future International Conference of Pharmacoepidemiology & Therapeutic Risk Management (ICPE) in a location the East Asian-Pacific Rim region and was disbanded.

14. Ad Hoc Task Force on Information Technology (IT) exploration

(Established August 2009; discontinued August 2010)

The ad hoc task force on Information Technology was formed to explore the use of modern information technology (IT) at ISPE's annual conferences (ICPE), regional ISPE conferences, and for other ISPE activities, such as marketing and membership. The committee provided a report to the Board and was disbanded.

15. Technical Appendix "R"

(Deleted October 2014)

Excerpted Report of the Bold Ideas Committee, November 1, 2001

1. Create new types of membership

At present the Society's efforts at raising organizational support have all been aimed at large pharmaceutical corporations. However it is recognized that the membership includes a significant number of individuals who work in other types of organizations, many of which are not presently affiliated in any way with ISPE. These include organizations both in academia and the private sector which provide pharmacoepidemiology related services to the pharmaceutical industry. In addition, there are a number of individuals who work as consultants in the field.

We propose that several new types of individual and organizational membership be created to reflect these two groups, and that these be complemented by the development of new member benefits tailored to these groups. Specifically, we propose broadening membership categories from 4 (individual, student, with and without journal, and corporate) to 7 categories by adding: CONSULTANT, ACADEMIC, SMALL and LARGE SERVICE PROVIDERS and changing corporate to include MEMBER and BENEFACTOR.

One of the benefits of these new "CONSULTANT" and "SERVICE PROVIDER" levels of membership would be inclusion in a Service Provider Directory on the Society's website

(See below). Introduction of this level of membership could also be used as a springboard to the growth of Exhibitor participation at ISPE Conferences. It was envisaged that different levels of membership reflecting the wide range of size of organizations in this sector (i.e., individual consultant through large public company CRO's) should be available.

Significant proportions of ISPE members are on the staff or are students at academic institutions. It is therefore proposed that the Society offers a new "ACADEMIC" level of institutional membership. The main goal of such membership would be to attract students from those institutions into the society in the hope that they will become long-term full members following completion of their studies. Reflecting this, one of the major benefits of such membership would be reduced membership and meeting registration fees for all students enrolled in qualifying programs run by an ACADEMIC Institutional Member. Listing all Academic Institutional Members on its web site should also help bolster the Society's image/standing. Academic Institutional Membership will also provide member organizations with seats on the proposed new ACADEMIC COUNCIL (See below). It is recognized that some academic groups both run academic programs in pharmacoepidemiology and provide pharmacoepidemiological services to the pharmaceutical industry. In recognition of this, a combo Academic/Service Provider membership is also proposed.

(Subsequent action: Board considered this issue, accepted in principle, referred to Executive Committee for action April 2003. Executive Committee accepted new organizational categories in May 2003.)

16. Membership Revenue Target

(Deleted October 2014)

The Board should set a target that at least 30 percent of total annual expenses should come from membership dues.

17. Committee and Council Liaisons

(Amended April, 2004; amended April, 2005; Deleted April 2016)

In the event that the Chair is not a Board member, a liaison will be assigned from among the members of the Board. These liaisons will attend committee or council meetings and assure full bi-directional communications with the Board. Committee and Council Liaisons will be named annually by the Board Chair. The Council liaison will be designated among those elected to represent their respective constituencies, i.e. industry, academia and government.

18. Ad hoc Task force on common data models

(established April, 2010, Deleted April 2016)

The purpose of the Task Force is to explore the establishment of a "consensus conference" to clarify a possible approach to "common data models" by various consensus gathering methods.

Charge:

- To evaluate the type, characteristics, strengths, weaknesses and purposes of common data models that are currently being used
- To assess the commonalities and differences between them with the potential implications
- To report to the Board and ISPE membership on the status and provide recommendations

19. Ad hoc Task force on post marketing safety findings

(established August, 2010; amended August 2011, Deleted April 2016)

The International Society for Pharmacoepidemiology establishes a task force to explore options for a timely presentation, discussion, and dissemination of results of post-marketing safety findings. This approach will build on and enhance the current communications vehicles including the annual conference, the midyear and the ISPE publications, including Scribe and PDS, but shall emphasize the internet as an important alternative for the posting and discussion of time sensitive safety findings.

THE INTERNATIONAL SOCIETY FOR PHARMACOEPIDEMIOLOGY

BY-LAWS

These by-laws were formally adopted by the First Board of the Society on November 9, 1989.

Amended May 14, 1993
Amended March 16, 1995
Amended August 23, 1997
Amended August, 2006
Amended April 2021

Reference:

Robert HM, Evans JW, Cleary JW (eds). Robert's rules of order newly revised. 9th Edition. Scott, Foresman (HarperCollins Publishers), 1990. ISBN 0-673-38734-8 (pbk).

BY-LAWS OF THE INTERNATIONAL SOCIETY FOR PHARMACOEPIDEMOLOGY

These by-laws were formally adopted by the First Board of the Society - November 9, 1989.

Amended May 14, 1993

Amended March 16, 1995

Amended August 23, 1997

Amended August, 2006

Amended April 2021

Article I: Purpose of the Society

In addition to the general purpose described in the Certificate of Incorporation, the purpose of this society is the promotion of the science of pharmacoepidemiology by assisting its members and providing such services as may be appropriate to conduct their research and educational activities, by facilitating and encouraging communication among its members and with other research and educational groups, the communications media and the general public, by educating public and private agencies on the need for research in pharmacoepidemiology, by seeking out important issues concerning drug safety and efficacy and contributing to the development of scientific public policy dealing with these issues and by advocating the views of our society and its constituent scientific organizations to international scientific organizations.

(AMENDMENT 1. [MAY 14.1993])

Article II: Membership

1. Membership in the Society is open to any individual dedicated to pharmacoepidemiology research, education, and practice and its related disciplines, and demonstrates an interest in promoting the growth of this field.
2. Charter members of the Society are those individuals and organizations that have joined the Society prior to August 14, 1990.

Article III: Board of the Society

1. The general business of this Society shall be transacted by the Board of the Society in the interim between General Meetings. The Board of the Society shall have supervision, control and direction of the affairs of the Society, its committees and publications, if any; shall determine its policies or changes therein; shall approve the budget and shall actively pursue its objectives and approve the disbursement of funds. The Board may adopt such rules and regulations for the conduct of its business as shall be deemed advisable, and may, in the execution of the powers granted, delegate authority and responsibility to the Executive Committee, the Executive Secretary, or other specified groups or individuals. The Board shall be the policy making body of the Society and shall establish general guidelines for action by the Executive Committee and Executive Secretary.
2. The Board shall consist of 15 members elected for three years on a staggered basis, plus all of the officers of the Society for the duration of their terms.
3. The seven members of the Board ("initial board"), consisting of six Board Members and Executive Secretary/Treasurer, as designated in the Society's Articles of Incorporation shall, by majority vote, select the remaining nine members of the First Board. All First Board members shall serve until the 2nd General Meeting, which will be held at the 7th

International Conference on Pharmacoepidemiology in the fall of 1991, provided, however, that the Executive Secretary/Treasurer shall initially serve three (3) years and thereafter shall serve as provided herein in Article III, Section 3. The First Board shall elect a President and Vice President from the membership to serve until the expiration of the terms of the members of the First Board.

4. Upon the expiration of the terms of the members of the First Board, the membership of the Society shall elect all future Board members to serve for staggered three-year terms. The Nominating Committee shall put forth to the membership a list of candidates for election to the Board. The ISPE Nominating Committee shall also nominate a President, President-Elect, and Vice President of the Society. Any member not selected by the Nominating Committee as a Board Member or an officer can add his/her name to the ballot by submitting to the Nominating Committee a petition signed by at least 14 Society members. The terms of members elected to the Second Board will be randomly allocated to one, two, or three years. In future terms, only one-third of Board members will be elected each year for three-year terms. With the exception of First Board members, an elected Board member may not serve for more than two consecutive terms.
5. Elections shall be conducted by mail ballot of all members not delinquent in dues. Ballots shall be mailed to all members eligible to vote at least thirty (30) days prior to the election.
6. Vacancies on the Board resulting from death, disability or resignation will be filled by a majority vote of the remaining members of the Board. Successor Board members will serve until the expiration of the term of their predecessors.
7. Elected officers and elected members of the Board shall not be compensated for their services.
8. At any meeting of the Board, a majority of the members of the Board shall constitute a quorum for the transaction of business of the Society. Any business transacted at a meeting at which a quorum is present shall be valid if affirmatively passed upon by a majority of the Board members present or as otherwise required by these By-Laws.
9. The President shall serve as the Chairman of the Board. The First Board will elect a Chairman and Vice Chairman to serve until elections of the general membership are held.
10. A regular meeting of the Board shall be held at least once during each year at such time and at such place as the Board may prescribe. Notice of regular meetings shall be given to members not less than thirty (30) days before the meeting is to be held. Special meetings of the Board may be called by the Chairman of the Board or at the request of a majority of Board members by notice mailed, delivered, telephoned, telegraphed, or faxed to each member not less than three (3) weeks before the meeting is held.
11. Action taken by mail ballot or telephone conference call of the members of the Board in which a majority of the Board, in writing, indicate themselves in agreement, shall constitute a valid action of the Board if reported at the next regular meeting of the Board.
12. The Board of Directors shall break any tie votes in elections to the Board of Directors.
13. The Executive Secretary of the Administrative Office shall serve ex officio as Secretary/Treasurer, as a non-voting member of the Board and its committees. The Executive Secretary may not serve as a voting member of the Board of Directors, the Executive Committee, or as a Committee Chair.
14. The founding Executive Director maintains lifetime Society membership and lifetime non-voting emeritus membership on the Board of the Society. The founding Executive

Director shall be standing Emeritus Chair of the annual International Conferences on Pharmacoepidemiology (ICPE).

Article IV: Executive Committee

1. Between meetings of the Board, the Executive Committee may, in place of and instead of the Board, take action on all matters not inconsistent with the goals of the Society.
2. The Executive Committee shall consist of the Past President, the President, the President-Elect, the Vice President/Finance and the Executive Secretary/Treasurer of the Society ex officio. The President shall be Chair of the Executive Committee, and the Executive Secretary/Treasurer shall serve as its secretary.
3. A majority of the voting members of the Executive Committee shall constitute a quorum at any duly called meeting of the Committee. The Executive Committee shall meet or confer at least three times a year, at places and times to be established by the Committee. A meeting of the Executive Committee may be called by the President as the business of the Society may require, or at the request of two members of the Executive Committee.

Article V: Officers

1. The officers of the Society shall be its Past President, President, a President-Elect, a Vice President/Finance and an Executive Secretary/Treasurer. The President-Elect shall assume all the duties and functions of the President whenever the President is unable to perform these duties and functions, and the President-Elect shall be Acting President until the President resumes his or her duties or until the Board or Executive Committee appoints a successor to the President.
2. The President shall serve for a one-year term and shall become Past-President upon expiration of his/her term.
3. The President-Elect shall become President upon expiration of the President's term.
4. The Vice President/Finance-Elect shall be elected every other year and serve for a one-year term. At the end of one year, the Vice President/Finance-Elect shall become the Vice President/Finance, who shall serve a term of two years.
5. The President-Elect shall be elected annually and serve for a one-year term, or until a successor is elected and assumes office. No individual may serve more than one term as President, President-Elect, or Vice President of the Society.
6. The Executive Secretary/Treasurer of the Society shall be appointed by the Board of the Society and shall serve as the Society's Chief Administrative officer. The term of appointment shall be clearly specified and may be renewed annually indefinitely.
7. The Executive Secretary/Treasurer shall be in charge of the Society's records; shall be responsible for the proper and legal mailings of meeting notices to its members, shall see to the proper recording of proceedings of meetings of the Society, Board, and Executive Committee. He or she will ensure that accurate records of all members are kept and shall keep the seal of the Society. He or she shall be in charge of the Society's funds and shall collect all member dues and assessments, shall cause to have established proper accounting procedures for the handling of the Society's funds. He or she shall report on the financial conditions of the Society at annual Board meetings and at the annual General Meeting. At the end of the fiscal year, he or she shall prepare an annual report which shall reflect an audit by a certified public accountant.

8. Any officer may be recalled by a two-thirds (2/3) vote of all eligible members of the Society.
9. All Board positions except for the Executive Secretary/Treasurer shall be unpaid positions. The salary of the Executive Secretary/Treasurer shall be reviewed annually by the Board and cost-of living and merit increases approved by the Board.
10. The Executive Secretary/Treasurer shall employ such members of the staffs as may be necessary to carry out the work of the Society and fix the compensation of the Staff members within the approved budget. The Executive Secretary/Treasurer shall define the duties of the staff, supervise their performance, establish their titles, and delegate responsibilities of management as shall in his or her judgement be in the best interest of the Society.

Article VI: General Meetings

1. The Board shall convene minimally one General meeting of the Society each year. Notice of the date, time, and location of the General Meeting shall be mailed to all members in good standing at least thirty days prior to the meeting.
2. Any member of the Society who is not in arrears of dues may submit a motion for consideration by the members as a whole or the Board of the Society. All such motions must be submitted in writing to the Executive Secretary/Treasurer at least 48 hours prior to the General Meeting or Board Meeting, unless notice is waived by the President.
3. A quorum at the General Meeting shall be thirty percent of all members eligible to vote.
4. Motions receiving a majority vote at a General Meeting where a quorum is voting shall be binding on the Board, unless a mail ballot is requested. A motion to refer business to mail ballot of the general membership requires a majority vote of those attending the General Meeting.
5. The general membership may amend or repeal these By-Laws upon affirmative vote of a majority of all the members of the Society eligible to vote as indicated by mail ballot.

Article VII: Amendments

1. These By-Laws may be amended or repealed by action of the Board or by action of the General members, as specified in Article VI, Section 5.
2. The Board may amend or repeal these By-Laws upon the affirmative vote to two-thirds (2/3) of all votes represented on the Board.

Article VIII: Committees

1. The Board may establish such committees as may be necessary and appropriate.
2. The Board shall establish a nominating committee consisting of at least four members of the Society. The nominating committee shall be chaired by the immediate Past President.
3. The Executive Committee, on its own initiative, may establish ad hoc task forces, subcommittees and working groups to assist in conducting the affairs of the Society.

Article IX: Dues

[AMENDED, APRIL, 2021]

1. Dues and admission fees for all classes of membership shall be established by the Board.

2. Dues are not refundable for any reason.

Article X: Rules of Order

1. The meetings and proceedings of this Society shall be regulated and controlled according to ROBERT'S RULES OF ORDER (revised) for parliamentary procedure, except as otherwise specified in these By-Laws.

Article XI: Corporate Seal

1. There shall be a seal of the society which shall be kept by the Executive Secretary/Treasurer and used by her or him officially under the direction of the President of the Society.
2. The corporate seal of the Society shall be the letters ISPE bordered by seven lines each on top and bottom, encircled by the words "International Society for Pharmacoepidemiology".

[AMENDED, AUGUST, 2006 (the seal was created)]

Article XII: Finance

[AMENDED, APRIL, 2021]

1. The fiscal period of the Society shall be prescribed by the Board.
2. The Board shall make available, in a reasonable time prior to each fiscal year, an annual budget covering all activities of the Society.
3. The accounts of the Society shall be audited annually by an independent certified public accountant appointed by the Board.

Article XIII: Dissolution

1. The Society shall use its funds to accomplish the objectives and purposes specified in these By-Laws and no part of such funds shall inure, or be distributed to the members of the Society. Upon the dissolution of the Society, any funds remaining or other assets shall be distributed to one or more charitable, educational, or scientific organizations, as specified by the Board.