Benefit Risk Assessment, Communication, and Evaluation (BRACE) SIG LEADERSHIP/GOVERNANCE STRUCTURE

Approved by BRACE SIG, 22 Apr2018

Philosophy: transparency, strong organizational structure and operations, continued growth of the SIG and discipline, continuity through smooth leadership transitions & knowledge transfer

Leadership should ideally represent the diversity in the geography, scientific disciplines and affiliations of the SIG membership. Ideally the chair and co-chairs would come from different regions, scientific backgrounds, and sectors, representing academia, government and industry/service providers.

1. **PROPOSED NEW (as of 2018) LEADERSHIP STRUCTURE**

- **Chair + 2 co-chairs** (Benefit:Risk Assessment (B:R A) Co-Chair, and Risk Communication Co-Chair) serve 2 year terms starting/ending in August, with the transition occurring immediately following the ICPE annual meeting
- During leadership transition years, Chair serves as ***immediate past chair*** for one additional year, participating in leadership calls and consulting on leadership and organizational decisions. Immediate past Co-chairs can be consulted/included on an as-needed basis.
- **Secretary/Scribe position** (new as of 2018) as officer of the SIG, serving 1-2 yr terms

Chair responsibilities: serve as primary point of contact with ISPE related to the SIG; represent the SIG on the ISPE board; Lead monthly calls and meetings; solicit topics and set agenda in consultation with co-chairs and other SIG members; ensure adequate notes and documentation for key discussions and decisions in meeting minutes that are distributed in a timely manner; complete board report 3x/yr; maintain SIG membership list; lead setting the general direction and strategy of the SIG; share informational updates ad hoc if needed; other functions as needed. Can delegate responsibilities to co-chairs and administrative tasks to Secretary/Scribe or other SIG members as needed.

Co-Chair responsibilities: serve as primary subject matter experts in a) B:RA and b) Risk Communication; serve as additional leadership of the SIG; solicit and suggest agenda topics for SIG meetings; lead scientific agenda for the respective workstream remits (including drive abstract, manuscript, and SIG-sponsored pre-conference course development in collaboration with workstream members); represent the SIG on the ISPE board and serve as additional points of contact; contribute to/review board reports; contribute to general direction and strategy of the SIG; other functions as needed.

Secretary/Scribe responsibilities: organize SIG meetings; draft agendas in consultation with the chairs/co-chairs; noting, writing minutes. Individual is not part of the official SIG leadership, but would be eligible to run for any vacancies like any other member.

2. General Election Process:

- In April of the 2nd year, a call for nominations for those interested in running for one of the leadership positions would be emailed to entire SIG at least 2x; **also** announced at the March and April monthly calls

- Chair (or delegate) would collect self-nominations over a reasonable time period, and obtain a brief biosketch of the individuals; geographic, professional discipline and sector diversity in candidates should be encouraged
- Election should ideally occur electronically and anonymously (e.g., survey monkey) and contain the relevant biosketches with reasonable time to cast votes (10-14 days)
- Winners should be announced in May or early June the latest to allow for adequate travel preparations to ICPE, if applicable
- If a chair or co-chair needs to step down early, mid-cycle elections for the vacated position(s) should be held as soon as practicable, following the principles of the general election process above
- If the SIG leadership structure needs to evolve, all efforts should be made to ensure a transparent process that ideally involves the entirety of the SIG membership in at least reviewing and commenting and/or formally approving the new governance structure via a voting process.

3. Other General SIG Governance Items:

- Leadership will provide opportunities for input from all SIG members in SIG decisions. At a minimum, an email describing the issue and proposed decision will be sent to the entire SIG allowing at least a one week period for response.
- No decisions will be made until the one week response period has passed. It is preferable that larger decisions are discussed at more than one SIG-wide telecon **and** by email to allow participation from all members and account for different time zones and schedules. Larger decisions include the formation of sub-groups, working groups, new initiatives, requests for funds, and expenditure of funds, if applicable.

4. Authorship guidelines and BRACE SIG review policies

4.1. Background

The BRACE SIG[1] is an active SIG of the International Society of Pharmacoepidemiology (ISPE) and since its inception has produced a number of different publications ranging from educational webinars to peer-reviewed publications. It is important to have clear guidance on publication review, endorsement, and authorship in order to ensure a consistent and efficient publication process. As such, a small BRACE SIG sub-team was formed to examine this issue and make recommendations with the following specific objectives:

- Review existing ISPE policy regarding SIG-sponsored and BRACE-endorsed manuscript authorship and review policies
- Identify gaps in the current process
- Make recommendations for review and authorship policies for each BRACE SIG output type (e.g., webinars, white papers, manuscripts, etc). These recommendations may be shared with other ISPE SIGs; however, adoption by other ISPE SIGs is outside the scope of this sub-teams remit.

Supporting materials have been added as citations in the Annex.

4.2. SIG Output Types

There are two different scientific output types that are in scope for these recommendations. They are as follows:

4.2.1 Publications (as per the Good Publication Practice (GPP) definition of publications[2])

Includes: the full range of formats published in peer-reviewed journals, for example, original research articles, short reports, reviews, or letters to the editor, white papers*
*White papers are not explicitly included in 'publications' as per GPP but have been included in this category.

4.2.2 Presentations

Includes: abstracts, posters, and slides for oral presentations at scientific congresses (including webinars)

4.3 Recommendations:

Recommendations have been made for the Review requirements and Authorship criteria by Output Type (i.e., publications or presentations). In making these recommendations, the required level of ratification has been considered based on the output type and in line with the ISPE Policy Manual and in consultation with the leadership of the ISPE Policy and Procedures Committee. The two levels of ratification are as follows:

4.3.1 BRACE SIG Sponsored: The output planned, developed, and executed by a group of BRACE members as part of a BRACE SIG initiative. This does not include any output developed by members of BRACE but independent of a BRACE SIG initiative. Because SIGs are part of ISPE, the phrases "SIG Endorsed" or "SIG Sponsored" **cannot** be used without following the ISPE Public Policy Process. However, statements such as "The authors collaborated as ISPE BRACE SIG members, however, the views expressed are the authors' personal views and not necessarily those of ISPE of any of its SIGs" can be included.

4.3.2 ISPE Endorsed: The output has received ISPE endorsement as per the process described in section 1.6.4 of the ISPE Public Policy Process[3]. The output will carry the following wording: *"Endorsed by the ISPE Board of Directors Month-Day-Year"*. For publications, the endorsement will be included similar to how it was included in this: https://pharmacoepi.org/pub/1c2a306e-2354-d714-5127-9fd12e69fa66 (the endorsement is found in 3 places: as a footnote to the manuscript title, briefly in the methods, and more detailed in the end 'conflict of interest section').

		SIG Sponsored		ISPE Endorsed
PUBLICATIONS	**Review Requirements**	Authors review & provide comments	•	Follows ISPE public policy process[3]
	Authorship Criteria	• Follow International Committee of Medical Journal Editors (ICMJE) Guidelines[4] for authorship • Follow GPP3[2] Appendix 1 Publication Process for *a priori* publication planning		
PRESENTATIONS	**Review Requirements**	Authors review & provide comments		Not needed

	Authorship Criteria	At the minimum follow ICMJE[4] Criteria #1 & #2		N/A

5. ISPE Symposia Proposals:

Adapted from Policy Manual, Technical Appendix D, Page 65

Individual SIG members submit potential topics of interest to the SIG, ideally before December 1. Initial ideas are presented and discussed at the SIG meeting, and comments from attendees and concepts are distributed as part of Minutes. Person who proposes idea indicates whether he/she is willing to be potential leader (author).

All SIG members are emailed with the minutes after the meeting and asked to contact the chair if they are interested in submitting any other SIG endorsed abstract/symposium proposals. Internal deadline for submissions to the SIG is specified, but not later than December 1.

Symposium Lead organizes a telecon ideally before December 15 to discuss the submitted proposals, and circulates materials in writing to allow comments from SIG members unable to attend the telecon.

Refined concepts following feedback from members are distributed ahead of time (before December 15), presented and discussed for final endorsement of one proposal (before December 15). If more than one competitive proposal is under consideration, SIG members vote.

A working group is formed before Jan 1 to take the final selected topic and develop a proposal for submission. The final proposal is provided to SIG members in January. Members have not less than 5 business days to review and add suggestions for authors to consider before February 1. One of the SIG leadership team will be a member of the working group, and functions to maintain communications between the working group and the SIG. The SIG leadership team is not guaranteed a role as symposium speaker.

Comments are consolidated by the proposal authors before the final version is submitted to ICPE, typically mid-Feb.

General SIG Calendar

Month	Activities
August	ICPE • Attend Board meeting, present report to Board • SIG meeting – Current chair/co-chairs plan agenda and lead meeting, which includes the presentation of symposia ideas for following ICPE, induction of leadership in new roles if applicable • Spotlight session (poster walk) SIG volunteer leads Spotlight session, current leadership work with individual to trouble shoot difficulties, select poster for award
September	• Update membership list • Solicit, review and discuss symposia proposals
October	• Solicit, review and discuss symposia proposals
November	• Solicit, review and discuss symposia proposals

December	• December 1 deadline for submission of symposia ideas. • Review and discussion of symposia proposals, discussion at telecom (held before Dec 15) • A working group is formed to take the final chosen proposal idea and develop a proposal for submission. At least one of the SIG leadership team will be a member of the working group, and functions to maintain communications between the working group and the SIG. The SIG leadership team are not guaranteed roles as symposium speaker.
January	The final proposal is provided to SIG members in January. Members have not less than 5 business days to review and add suggestions for authors to consider before submission.
February	Abstract deadline
March	Prepare board report for mid-year meeting
April	Mid-year ICPE • Attend Board meeting, present report to Board • Review abstracts for annual ICPE • Select abstracts for Spotlight session • Outreach for new leadership volunteers, discussion and selection of incoming leadership, election (if required)
May	• Alternative election (if required) • Notification of incoming leadership (if required) • Solicit volunteers to lead Spotlight Session
June	• Notification of incoming leadership (if required) • Planning for ICPE, discussions with new leaders if applicable
July	• Prepare annual Board Report • Plan ICPE SIG meeting

6. Annex

[1]Benefit Risk Assessment, Communication, and Evaluation (BRACE) SIG

Mission

To provide an interactive and collaborative forum for education, training and development among ISPE members with an interest in Benefit-Risk Assessment, Communication, and Evaluation [BRACE].

Objectives

1) To promote awareness, through education and collaboration, of the intersection of pharmacoepidemiology and BRACE.
2) To define the role, application and best practices of pharmacoepidemiology to BRACE.
3) 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

[2]Good Publication Practice (GPP3) guidelines - Link to GPP3

Battisti WP, Wager E, Baltzer L, Bridges D, Cairns A, Carswell CI, et al. Good Publication Practice for Communicating Company-Sponsored Medical Research: GPP3. Ann Intern Med. 2015;163:461-464. doi: 10.7326/M15-0288.

Excerpt comparing ICMJE and GPP3, see citation for full text

Appendix Table 1. Authorship Criteria

ICMJE 2013 Criteria	GPP3 Guidance
Substantial contributions to the conception or design of the work or the acquisition, analysis, or interpretation of data for the work	"A substantial contribution is an important intellectual contribution, rather than technical assistance, without which the work, or an important part of the work, could not have been completed or the manuscript could not have been written and submitted for publication" (19). Simply collecting data (e.g., enrolling many patients) would not necessarily be considered a qualifying criterion for authorship. Some examples of what might represent a substantial intellectual contribution include actively guiding the scientific or medical content of the publication or presentation, statistical analysis and interpretation, crafting of the discussion, and developing the protocol.
Drafting the article or revising it critically for important intellectual content	This criterion refers to revisions beyond minor corrections for grammar, language, formatting, or layout. The key is sustained intellectual contribution, the provision of substantial comments, and approval of the final version. Although preferred, it is not always feasible or necessary for authors to comment on every stage of manuscript development.
Final approval of the version to be published	To give final approval, it is necessary to have carefully read the entire manuscript from start to finish.
Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved	Each author is accountable for the work and should have confidence in the integrity of the other authors' contributions. Each author should be able to identify who wrote each section.

GPP3 = Good Publication Practice 3 guideline; ICMJE = International Committee of Medical Journal Editors.

[3] Public Policy Process (section 1.6.4): Policy Manual, Official Policies and Procedures of International Society of Pharmacoepidemiology (ISPE)

- Link to ISPE Public Policy Process

This process describes the general review process by which the ISPE board reviews and endorses proposals including request for comments and review and vote for adoption.

[4]Defining the Role of Authors and Contributors – International Committee of Medical Journal Editors (ICMJE)Guidelines -Link to ICMJE Guidelines

Excerpt from Section 2. Who is An Author (see citation for full text)

"The ICMJE recommend that authorship be based on the following criteria:

1. *Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND*
2. *Drafting the work or revising it critically for important intellectual content; AND*
3. *Final approval of the version to be published; AND*
4. *Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.*

An author should be able to identify which co-authors are responsible for specific other parts of the work. In addition, authors should have confidence in the integrity of the contributions of their co-authors. Those who do not meet all four criteria should be acknowledged. The criteria are not intended for use as a means to disqualify colleagues from authorship who otherwise meet authorship criteria, therefore, all

individuals who meet the first criterion should have the opportunity to participate in the review, drafting, and final approval of the manuscript."