INTERNATIONAL SOCIETY FOR PHARMACOEPIDEMIOLOGY
CALL FOR MANUSCRIPT PROPOSALS

DEADLINE: September 28, 2020

CONTENTS

INTRODUCTION

The International Society for Pharmacoepidemiology (ISPE) seeks proposals for manuscripts that could be used for guideline development or reference documents for pharmacoepidemiology, including pharmacovigilance, drug utilization research, outcomes research, comparative effectiveness research, and therapeutic risk management.

Suggested topics of interest to the Society include:

- COVID-19
- Real-world evidence
- Precision medicine
- Patient-generated health data
- Signal detection in emerging large data sets such as EHR or social media
- Use of pharmacological / mechanistic data in pharmacoepidemiologic studies
- AI and machine learning approaches vs classical PE to examine causal hypotheses
- New methods in pharmacoepidemiology
- Best practices related to specific approaches in pharmacoepidemiology
- Formal evaluation of risk mitigation approaches
- Measuring impact of pharmacovigilance activities
- Guidance/methods (design/analysis) of multi-database studies
- Any topic contributing to ISPE's strategic mission

OVERVIEW

Proposals are reviewed by ISPE's Strategic Planning Committee; during the review process, the committee may submit questions or request changes to proposals. The SPC submits a slate of papers to fund to the Executive Committee for funding. Once approved, manuscript working groups engage with the Publications & Communications Committee on submission and review process of manuscript drafts according to ISPE policy and procedures.

Manuscript funding averaged USD 7800.00 for the seven accepted in 2019. As the total number of manuscripts funded is governed by the budget allocated by the Board, actual funding changes each year.

Proposals must conform to the proposal format described in this document. Submissions for 2020, which may only be submitted online, are now being accepted online at https://www.surveygizmo.com/s3/5512724/ISPE-Manuscript-Proposal with a deadline of 11:59 PM US Eastern Time on **Monday, September 28, 2020**. The deadline will not be extended, and proposals submitted via other means will not be accepted.

GENERAL TIMELINE
Sep 28 – submission deadline
Oct 31 – Strategic Planning Committee completes first review
Nov 30 – author responses to SPC feedback due
Dec 31 – SPC makes final selections; notifications to lead contacts

FORMAT OF PROPOSAL
Maximum of two (2) pages, excluding CVs, biosketches, references and any supplemental information. Your two pages must include the headings that follow:

1. **Title**.

2. **Background**: Summarize the proposed topic; describe the issues concerning the need for guidelines, or a good practice document or a reference manuscript.

3. **Objective**: Identify the purpose/goal of the working group.

4. **Rationale/Priority**: Include a statement on how the manuscript/topic is consistent with ISPE's strategic plan, mission statement and why it should be a priority for the Society.

5. **Issues to be addressed**: What issues will the manuscript address?

6. **Content**: Specific recommendations or guidelines, or practices and supporting information.

7. **Composition of Working Group**: Name, title, affiliation, a brief description of expertise; identify a group chair. Work group members must be current ISPE members; no exceptions. Composition should address, to the extent possible, membership diversity by geographic region, work sector and organization. Proposals of working group members exclusively from one organization/institution will not be considered responsive to the call for manuscripts.

8. **Conflict of interest**: Each working group member must prepare a conflict of interest statement, which must accompany the manuscript proposal.

   The statement should list all funding sources related to the development of the manuscript. For a manuscript developed purely within a university or governmental institution, with no external funding, the university or governmental institution should be named as the funding source.

   Thereafter, list all other potentially conflicting relationships that exist at the time of submitting the manuscript proposal, or had existed in the one (1) year leading up to the time of submitting the proposal. Nonfinancial 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.

List relationships using the following categories:

- Employment by commercial entity
- Consultancies or advisory Board memberships
- Lecture fees paid by a commercial entity (honoraria)
- Expert witness for a commercial entity
- Industry-sponsored grants (received or pending) including contracted research
- Patents received or pending
- Royalties from a commercial entity
- Stock ownership or options
- Other

Only include categories for which conflict of interest might be involved. If there are no disclosures to make, state "No relationships to disclose".

9. **Budget**: Estimate expenses.[1] ISPE does not pay overhead. Appropriate expenses may include:
   a. Administrative/logistical expenses such as conference calls, meeting notes, library research and drafting manuscript. If a research assistant is budgeted for your project, please indicate if the individual is currently, or likely to be an ISPE member (this is not a disqualifying factor).
   b. Expenses for one face-to-face meeting (e.g., food and beverages, AV, room rental costs, etc.). Work groups are responsible for logistics and arrangements. Funding does not cover travel to an ISPE-scheduled meeting; i.e. Mid-Year Meeting, ICPE, however, funds can be used to cover an extra hotel night, if needed, to ensure attendance for a manuscript team meeting.
   c. ISPE funds open accessing publication of ISPE-endorsed manuscripts. Please include funding in your budget for open access publishing.

10. **Target journal(s) for publication**: Rationale for selection.
    NOTE: The Strategic Planning Committee expects that the final manuscript will be made available to the ISPE membership through the Society's public policy process, revised appropriately, then the revised draft will be submitted to the Board for endorsement. This review is separate and distinct from any journal peer review process. SPC encourages work groups to submit ISPE-endorsed manuscripts to PDS or another professsional journal for publication. The authors should state clearly that the manuscript has been endorsed by ISPE in both the cover letter and manuscript. "Endorsement" by the ISPE Board does not mean that PDS (or another journal) will automatically accept the manuscript; PDS (and other journals) has an independent review process.

11. **Bibliography**: Provide recent relevant articles on the topic.

12. **Timeline**: Define specific work activites from the outline. Your timeline should extend to the delivery of a draft manuscript to ISPE's Publications & Communications Committee.

[1] As a 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. (SOURCE: ISPE Policy Manual)

REVIEW CRITERIA

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, and
- 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 office to complete this report in the period immediately preceding ISPE's annual meeting.
- Funds disbursement. Funds are usually paid out upon endorsement by ISPE, not at the time of submission of a draft to the Publications & Communications Committee. Open access costs may follow later. Occasionally, if key milestones involve significant costs, ISPE will consider an interim invoice. Invoices and, where applicable, United States IRS form W-9 are required to substantiate any disbursements.

MANUSCRIPT PROPOSALS PREVIOUSLY ACCEPTED

2019

- Formal evaluation of risk mitigation/minimization measures for regulatory assessment: Recommendations for future approaches using the RIsk Minimization Evaluation Checklist (RIMEC)
- Guidance on the Use of Narrative Prescribing Instructions in Pharmacoepidemiology and Drug Utilization Research: A Scoping Review
- Guidelines and Best Practices for Evaluating the Causal Effects of Medications on Motor Vehicle Crashes and Driving Outcomes using Observational Data
- Handling bias and confounding: High-dimensional propensity score (HDPS) for empirical covariate selection in secondary database studies
- Pharmacoepidemiology: Core Competencies and Curricula for Academia, Government and Industry
- Visualization in pharmacoepidemiology to design and communicate secondary database studies
- Machine learning for improving high-dimensional proxy confounder adjustment in healthcare database studies: a review of the current literature

2018

- Propensity Scores in Real World Evidence.
- Guidelines for Best Practices in Validation Studies in Pharmacoepidemiologic Studies that Use Routinely Collected Data.
- Guidance for the Application of Longitudinal Methods for Exposure Profiling in Pharmacoepidemiologic Studies in Pregnancy.

- Developing a Framework for Combining Randomized Controlled Trial and Non-Randomized Data in Evidence Synthesis for Informed Health Care Decision Making.
- Observational External Comparator Cohorts as Controls for Long-Term Uncontrolled Extensions to Randomized Clinical Trial.

2017

- Quantifying the impact of outcome misclassification on the results of pharmacoepidemiology database studies (Database SIG)
- Digital Patient Generated Data (Digital Epi SIG)
- Developing a set of best-practice standards for the communication of risk in pharmacoepidemiological research
- Publicly Available Data Sources for Drug Utilization Research in Latin American (LatAm) countries (LA-DURG).
- Requirements for Conducting Multi-Country Safety Surveillance of Vaccines in the Asia-Pacific region (AsPEN SIG)
- Guidance for the Application of Pharmacoepidemiological Research and Methods to Best Inform Therapeutic Decision Making for Off-Label Medicines Use

2016

- Importance of Pharmacoepidemiology for Advancing Precision Medicine
- Guidance for the Application and Reporting of Self-Controlled Study Designs in Pharmacoepidemiology
- Reporting of Pharmacoepidemiology Research Using Routinely-Collected Real World Evidence
- Good Practices of Drug Utilization Studies in Countries from Latin America and African Regions
- Linking Electronic Health Data in Pharmacoepidemiology.

2015

- ISPE Best Practices on the Conduct of Active Surveillance in Resource-Limited Countries
- Good Practice Guidelines for Conducting and Reviewing Cross-National Drug Utilization Studies
- Patient Engagement in Observational Pharmacoepidemiology Research and Registries: Where Are We, Where Do We Need to Be, And What Are the Steps for Getting There?

2014

- Managing Change for Good Pharmacoepidemiology Practice in Healthcare Databases and Related Tools (**Published** Bourke A, Bate A, Sauer B C, Brown J S, & Hall G C, Evidence generation from healthcare databases: recommendations for managing change. Pharmacoepidemiol Drug Saf, 25: 749–754. doi: 10.1002/pds.4004. 2016)
- Importance of Feasibility Assessments Before Implementing Non-Interventional Pharmacoepidemiologic Studies of Vaccines: Lessons Learned And Recommendations For Future Studies (**Published** Pharmacoepidemiol Drug Saf. 2016 Dec;25(12):1397-1406. doi: 10.1002/pds.4081. Epub 2016 Sep 7.)