

CONTENTS

SUBMISSION DEADLINE	1
INTRODUCTION	1
OVERVIEW	1
GENERAL TIMELINE	2
FUNDED MANUSCRIPT PROGRAM INSTRUCTIONS.....	2
REQUIRED CONTENT IN THE 3-PAGE SUBMISSION	2
REVIEW CRITERIA	4
OTHER NOTES	4

SUBMISSION DEADLINE

October 1, 2024

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.

This year, **highest consideration** will be given toward the following **new topics**:

- A. Pharmacoepidemiology and critical global issues
- B. Transitioning science to policy development
- C. Measuring the impact of pharmacoepidemiology on patients and stakeholders

ISPE is also interested in emerging issues, best practices & guidance for methods in pharmacoepidemiology covering the following topics:

- A. Data quality, transparency, and methodological standards
- B. Real-world evidence for regulatory decision-making
- C. Multi-database pharmacoepidemiologic studies
- D. Drug utilization research
- E. Diagnostic, AI and software-driven drug-delivery and monitoring, and other novel devices
- F. Precision medicine and pharmacogenomics
- G. Risk minimization evaluation
- H. Generative AI, machine learning methods, and new methods for causal inference

OVERVIEW

Proposals are reviewed by a Joint Manuscript Proposal Review Subcommittee led by the chair of the Public Policy Committee. The final slate of papers recommended for funding is ratified by the Executive Committee. Once funding is approved, manuscript writing teams can begin work. When a draft is ready, papers are submitted via the Executive Office for Public Policy Committee evaluation for suitability for ISPE member review. Periodically, writing teams are required to submit progress reports for Board evaluation.

Submissions for 2024, which may only be submitted online, are now being accepted at <https://survey.alchemer.com/s3/7873304/ISPE-Manuscript-Proposal-2024> with a deadline of 11:59 PM US Eastern Time on **Tuesday, October 1, 2024**. Proposals must conform to the proposal format described in this document. *Proposals that do not conform to the format will not be considered for funding.* The deadline will not be extended, and proposals submitted via other means will not be accepted.

GENERAL TIMELINE

- October 1: Submission deadline
- October 31: Joint Manuscript Proposal Review Subcommittee completes first review; if applicable, feedback is provided to writing teams and revised proposals requested
- November 22: If applicable, author responses to feedback due back to ISPE
- December 16: Joint Manuscript Proposal Review Subcommittee makes final selections and notifications are issued to the writing team lead contact

FUNDED MANUSCRIPT PROGRAM INSTRUCTIONS

Proposals are limited to a maximum of three (3) pages and **must be** completed using the Manuscript Program Submission Template later in this document. The following instructions describe the content included in the three pages along with material that is acceptable for the supplement. Supplemental material may not exceed three (3) pages. Proposals exceeding the format page limit and supplemental material page limit **will not** be reviewed or considered for funding.

REQUIRED CONTENT IN THE 3-PAGE SUBMISSION

1. **Title:** Provide a concise and descriptive title.
2. **Background and Issues Addressed:** Summarize the proposed topic; describe the issues concerning the need for guidelines, or a good practice document or a reference manuscript. Identify the issues the manuscript will address.
3. **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.
4. **Objective(s):** Identify the purpose/goal(s) of the manuscript writing team.
5. **Content:** Describe clearly and concisely (i) the work the writing team will conduct and (ii) the outcome or product (i.e., recommendations, guidelines, methodological standards, state of the science, etc.) of the manuscript.
6. **Composition of manuscript writing team:** Identify the team chair. List the name, title, affiliation, area of expertise for all members of the writing team. Manuscript writing team 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 manuscript writing teams exclusively from one organization/institution will not be considered responsive to the Call for Manuscripts.
7. **Budget:** Estimate expenses.¹ ISPE does not pay overhead. Appropriate expenses need to be built in a single-year budget (no multi-year budgets) and may include:

¹ As a general rule, ISPE does not make payments to members for their work for the Society.

- a. Administrative/logistical expenses such as librarian assistance with literature searches and drafting the manuscript. If your project requires a research assistant, they cannot be a current ISPE member (see footnote). Please list the tasks the RA will perform.
 - b. Expenses for one face-to-face meeting (e.g., food and beverages, AV, room rental costs, etc.). Manuscript writing teams 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 access publication of ISPE-endorsed manuscripts. Please include funding in your budget for open access publishing.
8. **Target journal(s) for publication:** *Pharmacoepidemiology and Drug Safety* (PDS) is the preferred journal for publication of all manuscripts funded under the ISPE Funded Manuscripts Program. Please note: ISPE funded manuscripts are required to undergo the usual PDS journal peer review processes. If you wish to publish in a journal other than PDS, please provide the name of your preferred journal and your rationale and justification for doing so.

Final manuscripts will be made available to the ISPE membership through the Society's public policy review process, revised appropriately, then the revised draft will be submitted to the Board for ISPE endorsement. This review is separate and distinct from any journal peer review process. Manuscript writing teams are encouraged to submit ISPE-endorsed manuscripts to PDS or another professional 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.

9. **Timeline:** Define specific work activities from the outline beginning in January following the submission deadline. Your timeline should extend to the delivery of a draft manuscript to ISPE's Public Policy Committee.

SUPPLEMENTAL INFORMATION

1. **Conflict of interest:** Each manuscript writing team 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

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)

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".

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

REVIEW CRITERIA

Proposals are assessed against the following criteria:

- 1) Clarity of the topic & objective(s)
- 2) Importance to the field of pharmacoepidemiology
- 3) Consistent with ISPE strategic goals
- 4) General interest to ISPE membership
- 5) Potential to raise the visibility of pharmacoepidemiology
- 6) Feasibility to accomplish the stated objective
- 7) Collaborations among organizations, sectors, and regions
- 8) Innovative within scope of ISPE's mission
- 9) Appropriateness of the budget request
- 10) Meets submission requirements

OTHER NOTES

- For one year following publication, manuscript writing teams are required to complete an annual Impact Report to help ISPE monitor the success of the manuscript initiative. Manuscript writing team leaders 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 Public Policy 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.

FORMAT PAGE 1

Title

Background & Issues Addressed

Rationale/Priority *(include specific rationale for how an ISPE Strategic Plan 2024-2029 Objective is Advanced through this Manuscript)*

Manuscript Objective(s)

FORMAT PAGE 2

Content

FORMAT PAGE 3

Target Journal

Timeline

Composition of manuscript writing team

Add rows as needed, not to exceed the page limit.

Name	Title & Affiliation	Area of Expertise

Budget

Add rows as needed, not to exceed the page limit.

Item	Description	Cost
Total Cost		