ISoP Guidelines for Drug Safety Manuscript Submissions and Editorial Workflow for *Drug Safety* Journal

Version 1 dated July 2026	Responsible: Felipe Villalobos (ISoP Secretary General - 2025-2028) Executive Committee 2025 – 2028 Nitin Joshi – Editor (*Drug Safety Journal*)
Approval date: July 2026	Advisory Board 2025 - 2028

This guide provides ISoP members with a clear and transparent roadmap for proposing, developing, internally reviewing, and submitting manuscripts intended as ISoP-sponsored content to *Drug Safety* . Its purpose is to ensure scientific quality, procedural consistency, and appropriate coordination.

1. Phase 1. Scope and submission pathways

Before preparing any submission, authors should determine whether their manuscript is intended to be submitted as **ISoP-sponsored content** or as a **standard journal article**. This distinction is essential because the review pathway, level of institutional endorsement, and submission route differ between the two categories

Track	Content Type	Peer-Review Process
ISoP-Sponsored Content	Organizational statements, society-led commentaries, consensus papers, policy or position documents, and other manuscripts formally endorsed by ISoP.	Internal review and approval by ISoP bodies before journal submission; final editorial consideration by *Drug Safety* remains independent.
Standard Articles*	Original research, systematic reviews, and other manuscripts submitted by authors without formal ISoP sponsorship	Submitted directly through the journal's standard external peer-review process in accordance with the journal requirements.

This article types are excluded from this document.

Note: ISoP-sponsored manuscripts must fall within the aims and scope of *Drug Safety* and should also fit the Society's publication priorities and available publication planning. Where relevant, authors should be reminded that internal ISoP endorsement does not guarantee acceptance by the journal. These must align with the journal's Aims and Scope.

2. Phase 2: The Preliminary Proposal (Pre-Submission)

Authors wishing to develop an ISoP-sponsored manuscript should first submit a preliminary proposal to the ISoP Secretariat before drafting the full paper.

Action: Send an email to the **ISoP Executive Secretary** (secretary@isoponline.org, administration@isoponline.org)**,** including the following documentation (*see the Annex 1: ISoP Template: Manuscript Submission to Drug Safety Journal*):

- A **structured proposal** of up to 300 words, covering background, objectives, methods or approach, expected or key messages, and conclusions
- A short **impact statement** of 5 to 10 lines explaining the relevance of the topic for pharmacovigilance, patient safety, public health, or society more broadly.
- When appropriate, basic information on the proposed authorship group and any relevant ISoP working group, special interest group, or committee involved

3. Phase 3: Initial internal assessment

Once the proposal is received, the ISoP Secretariat should first verify that the required documents are complete and that the proposal fits the intended ISoP-sponsored track . If key information is missing, the authors should be asked to complete the file before scientific assessment begins .

After this administrative screening, the proposal should be shared for content review with appropriate representatives from the **Scientific Board** and the **Advisory Board**, selected according to the subject matter . Their feedback should then be considered by the **Executive Committee**, which makes the formal decision on whether the proposal is accepted for development, returned for revision, or declined .

To improve transparency, the decision categories should be standardized as:

- **Accepted for full manuscript development**
- **Revision requested before full manuscript development**
- **Declined**

The communication to authors should briefly summarize the rationale for the decision and, where relevant, identify the points that must be addressed before moving forward.

4. Phase 4: Full manuscript development and final ISoP reviewoval

If the proposal is accepted, authors may prepare the full manuscript in accordance with the current *Drug Safety* instructions for authors and any additional journal formatting requirements. At this stage, the manuscript should remain consistent with the approved proposal in scope, purpose, and authorship rationale, unless substantial changes are justified and communicated.

The authorship list must comply with the **to ICMJE authorship criteria** and should reflect genuine and substantial intellectual contribution to the work. Individuals who do not meet authorship criteria should not be included as authors based on seniority, courtesy, institutional role, or other

forms of captatio benevolentiae; where appropriate, their contribution may instead be recognized in the acknowledgements section.

Once the draft is completed, it should be resubmitted to the ISoP Secretariat for a second internal review. This review should focus on scientific quality, consistency with the approved concept, clarity of messaging, appropriateness for ISoP endorsement, readiness for submission to the journal, and compliance of the proposed authorship list with accepted authorship standards.

The Scientific Board and Advisory Board should provide final comments, after which the Executive Committee issues the final ISoP decision on whether the manuscript is approved for submission as ISoP-sponsored content. The wording should make clear that this is an **internal endorsement decision** and not a journal acceptance decision.

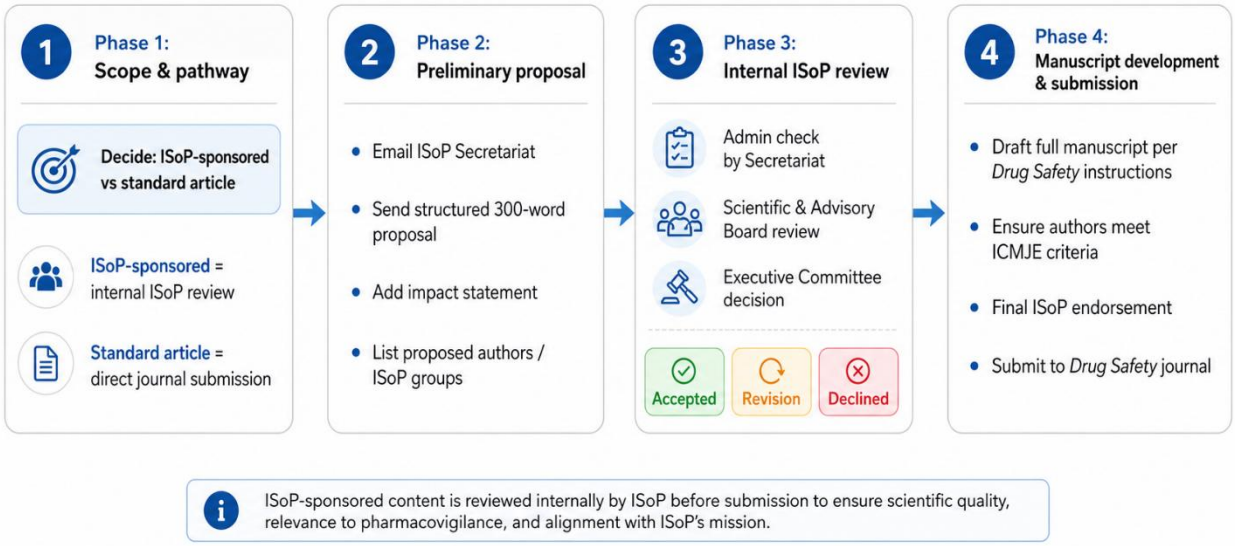

Figure1. Workflow for ISoP-sponsored submissions to *Drug Safety*

5. Phase V: Submission to *Drug Safety*

If the manuscript is considered suitable for formal consideration, authors should then submit it through the journal's submission system following the instructions provided by the *Drug Safety Journal (see the Annex 2: Drug Safety Journal Requirements for 'From the ISoP' Submissions).*

For further questions, please contact the ISoP Secretariat (secretary@isoponline.org, administration@isoponline.org)

This process is designed to ensure that all ISoP members have equal opportunities to contribute to our official journal while maintaining a rigorous and documented selection process.