

**ISPE Real World Evidence Collaborative SIG: Publications & Education Working Group Guidance on Coordination, Outreach, and Co-author Identification**

**Version 2, August 8, 2023**

The key objectives of the ISPE RWE Collaborative SIG **Publications & Education Working Group** are to help advance the field of RWE research and methods through collaborative efforts and to increase awareness of the strengths and limitations of such research by encouraging and coordinating publications and educational activities related to RWD and RWE. As there may be overlap in manuscript topics proposed by other ISPE groups **the following guidance is proposed to**:

* Facilitate collaboration on manuscripts and to enable broad representation from various ISPE sectors and geographic regions to promote diversity when identifying co-authors.
* Communicate and coordinate with other ISPE groups to avoid duplicative efforts

1. **Communication within the ISPE RWE SIG**

The Publications & Education Working Group co-leads will first share manuscript ideas with RWE Collaborative Leadership or ISPE members using the standard manuscript proposal template (**non-funded manuscript pathway via RWE SIG**) for review and comment. As needed, the topics can also be presented via virtual presentation to the RWE Collaborative SIG leadership team and/or at SIG meetings. Publication and Education WG co-leads will communicate suggested changes to the proposal authors and once revised, will send revised proposals to RWE SIG leadership.

If authors of the proposed manuscript(s) are seeking additional co-authors, depending on the topic, collaborative pathways within ISPE will be discussed within the RWE SIG leadership team (e.g., vaccine SIG if it’s a vaccine-related topic). In addition, RWE SIG members will be informed of manuscript proposal ideas and asked about interest in co-authoring. Any administrative support from the Internal Collaborations working group will be sought, as needed.

1. **Communication/outreach with other SIGs or ISPE groups**

After circulating to the RWE SIG, the Internal Collaborations (including Publications & Education Working Group)work group co-leads will share manuscript ideas with:

* + (Depending on the topic) Leadership of other SIGs for comments and interest in collaboration through a “live tracker” document. Administrative support may be sought from ISPE.
  + (Depending on the topic) Other groups such as RIG, committees, councils, and task forces

The Publications & Education Working Group will also coordinate with other ISPE groups (SIG/RIG/Initiatives/ Council/Committees) to identify and track **other initiated manuscripts related to RWE** to avoid duplication and identify collaboration. Ideally, this should be available in a “live tracker” document available to co-leads of each SIG workgroup. The Publications & Education Working Group co-leads will be the contacts for any proposed manuscript along with authors.

1. **Determination of authorship**

Final decisions on authorship are evaluated by the lead(s) of each manuscript workstream.

* + For each proposed manuscript, the Publications & Education Working Group co-leads will circulate the list of interested contributors to manuscript lead(s) and have them follow-up and make the final determination on authorship.
  + If the RWE SIGand another SIG or group independently propose to lead a manuscript on a similar topic, an ideal outcome would be for both groups to co-lead the development of the manuscript. Alternatively, they can work together on the content of each manuscript to avoid overlap/duplication and create separate independent manuscripts with unique perspective/content.
  + The lead(s) of each manuscript can invite additional ISPE and non-ISPE members (e.g., collaboration with other organizations/clinical societies) to be co-authors, as appropriate.
  + All authors need to fulfill ICMJE authorship criteria. The total N of co-authors (as decided by manuscript proposal leads) may be limited (e.g., <10-15) to establish efficient process.

1. **ISPE endorsement**

It is encouraged that each manuscript will be endorsed by ISPE, as applicable. The ISPE endorsement process is described in section 1.7.1. of the [ISPE Policy Manual](chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https:/www.pharmacoepi.org/pub/?id=FF2E0B27-E5F2-877C-B787-3E95D07D0611). In brief, to initiate the ISPE endorsement process for a manuscript, the co-leads of the Publications & Education Working Group will inform the Public Policy committee chair via email with an attachment of the completed manuscript. The Public Policy committee will have 1-2 weeks to review and approve before sending it for ISPE membership review. After ISPE membership review, the authors will receive a document specifying line by line suggestions for further revisions. Once the revisions are complete, the Public Policy committee will escalate the final version of the manuscript to ISPE board review for full approval. Once it is approved by the Board, the ISPE office will inform co-authors and the co-leads of Publications & Education Working Group on the decision of ISPE endorsement.

1. **Other groups**

Given the ISPE Policy Committee and ISPE Publications Committee are both involved in the ISPE manuscript endorsement and tracking process, the Publications & Education Working Group will provide regular updates to these committees on RWE SIG manuscript proposals

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| Version | Date | Changes made | Approved by and Date |
| 1.0 | DDMMYYYY | Initial draft guidance | XXXX on DDMMYYY |