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Upcoming 2019 ISMPP Conferences

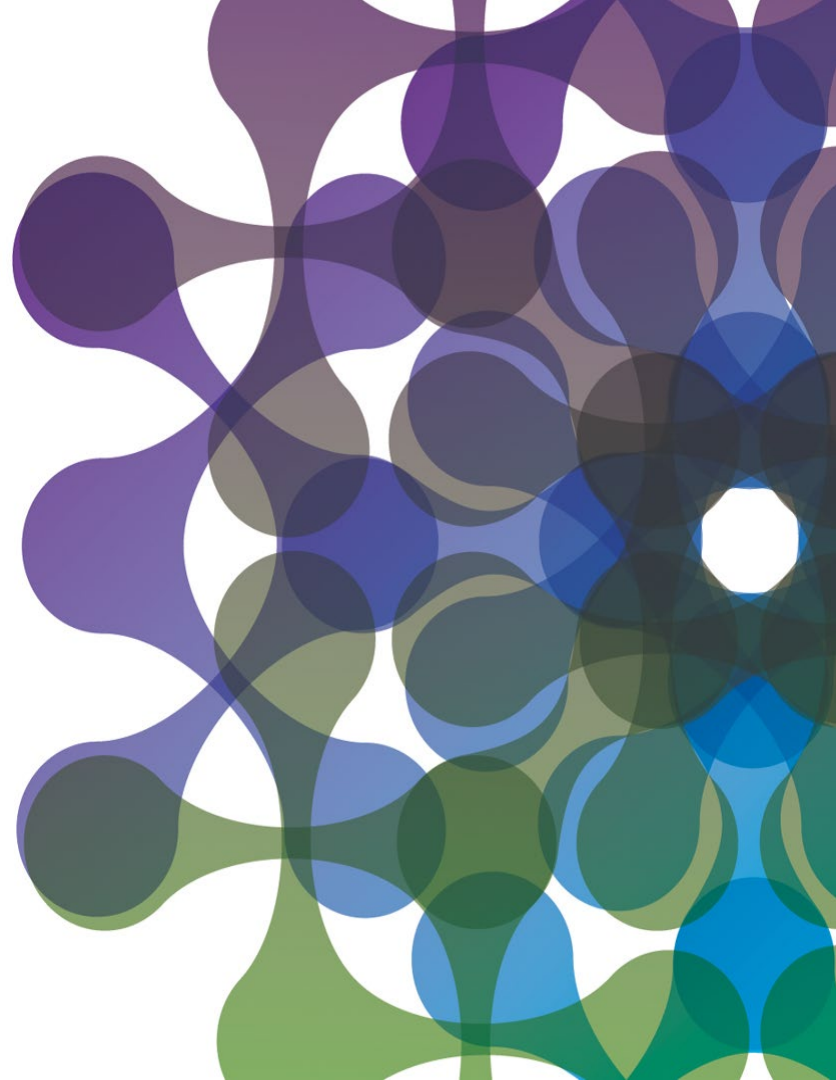


Mark your diaries!

2020 European Meeting of ISMPP



**January 21-22, 2020
etcVenues - Bishopsgate
London, United Kingdom**

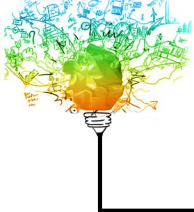




Become an ISMPP CMPP™!

- Next exam will take place in September 1 – 30th
- Are you a 2014 ISMPP CMPP™? CMPP Recertification Application deadline for 2019 is September 30
 - This is **YOUR** year to recertify
 - Earn 50 CE credits by September 30 OR
 - Recertify by exam in September (LAST chance!)
- Questions? Contact cmpp@ismpp.org
- This ISMPP U qualifies for 1 CMPP recertification credit





For Your Best ISMPP U Experience...

To optimize your webinar experience today:

- Use a hardwired connection if available
- Use the fastest internet connection available to you
- If you are accessing the presentation over your computer, please be sure to increase the volume of your computer speakers



Questions

- To ask a question, please type your query into the Q&A box
- To ensure anonymity and that all presenters receive your question, please choose the drop down box option:

"Host & Presenters"

Otherwise, all audience members will be able to see your submitted question

- We will make every effort to respond to all questions

1. Click on the question mark icon to view the Q&A box

2. Type your question into the Q&A box and SEND

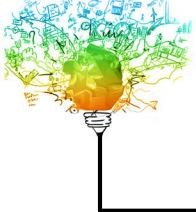
NOTE: Make sure you send your question to: "Host & Presenters"

The screenshot shows the Zoom interface with the 'Participants' panel at the top. A red arrow points to the question mark icon in the top right corner of the Zoom window. Below it, a green box contains the instruction '1. Click on the question mark icon to view the Q&A box'. The 'Chat' panel is open, showing a text input field and a 'Send' button. A red arrow points to the 'Send to' dropdown menu, which is currently set to 'All Participants'. A green box contains the instruction '2. Type your question into the Q&A box and SEND'. Below the 'Send to' dropdown, a note in a blue box says 'NOTE: Make sure you send your question to: "Host & Presenters"'. The 'Send to' dropdown is open, showing options: 'All (1)', 'My Q&A (1)', 'Lisa Klos', 'Host', 'Presenter', and 'Host & Presenter'. A red arrow points to the 'Host & Presenter' option.



Disclaimer

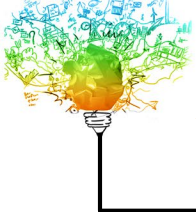
Information presented reflects the personal knowledge and opinion of the presenters and does not necessarily represent the position of their current or past employers or the position of ISMPP



Objectives for this ISMPP U

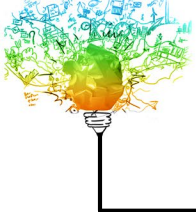
At the end of this session, participants should be able to:

- Understand the rationale for relevant disclosures in biomedical publications
- Apply techniques to inform authors of appropriate disclosures and facilitate the complete and accurate disclosure of potential conflicts of interest
- Provide support and guidance to authors to help them submit accurate and comprehensive disclosure statements



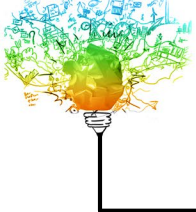
Yvonne Yarker

- Yvonne has over 25 years of experience in medical communications and publication planning. She is a coauthor of Good Publication Practice for Communicating Company-Sponsored Medical Research (GPP2 and GPP3), and has published and presented on medical communications, authorship, compliance, and ethical best practices. She is a past Chair of the ISMPP Board of Trustees, past Chair of the ISMPP Ethics Committee, and is an Overseas Fellow of the Royal Society of Medicine, UK and a member of ISMPP, the American Society of Clinical Oncology (ASCO) and the American Medical Writers Association (AMWA). Yvonne has a Bachelor's degree in Pharmacology and a PhD in Medical Biophysics.



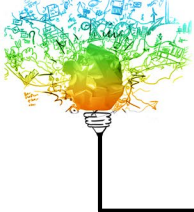
Tanya Stezhka

Tanya is the Senior Editor for Current Medical Research & Opinion at Taylor & Francis, and is an active member of the ISMPP Ethics & Standards Committee. Tanya has been with T&F for six years and works closely with the Ethics & Integrity team to ensure good publication practices across the medical portfolio.



Steve Rizk

- Steve has over 18 years of experience in the biopharmaceutical industry and is a Global Group Director of Medical Communications, most recently with Genentech, A Member of the Roche Group. He has served as the Global Process Owner for two corporate policies, the Publication Policy and the Scientific Credibility Policy, and has been a core member of the Roche Data Sharing Leadership Committee. In his role, he recently oversaw the development of a lean global process to support author financial disclosures. Steve has been an active member of ISMPP serving as faculty at Meetings, as member and chair of Industry Executive Forums and has recently served on the ISMPP Board of Trustees. He has a Bachelor's and Doctorate degree in Pharmacy and a Juris Doctor degree.



Moderator: Neil Adams

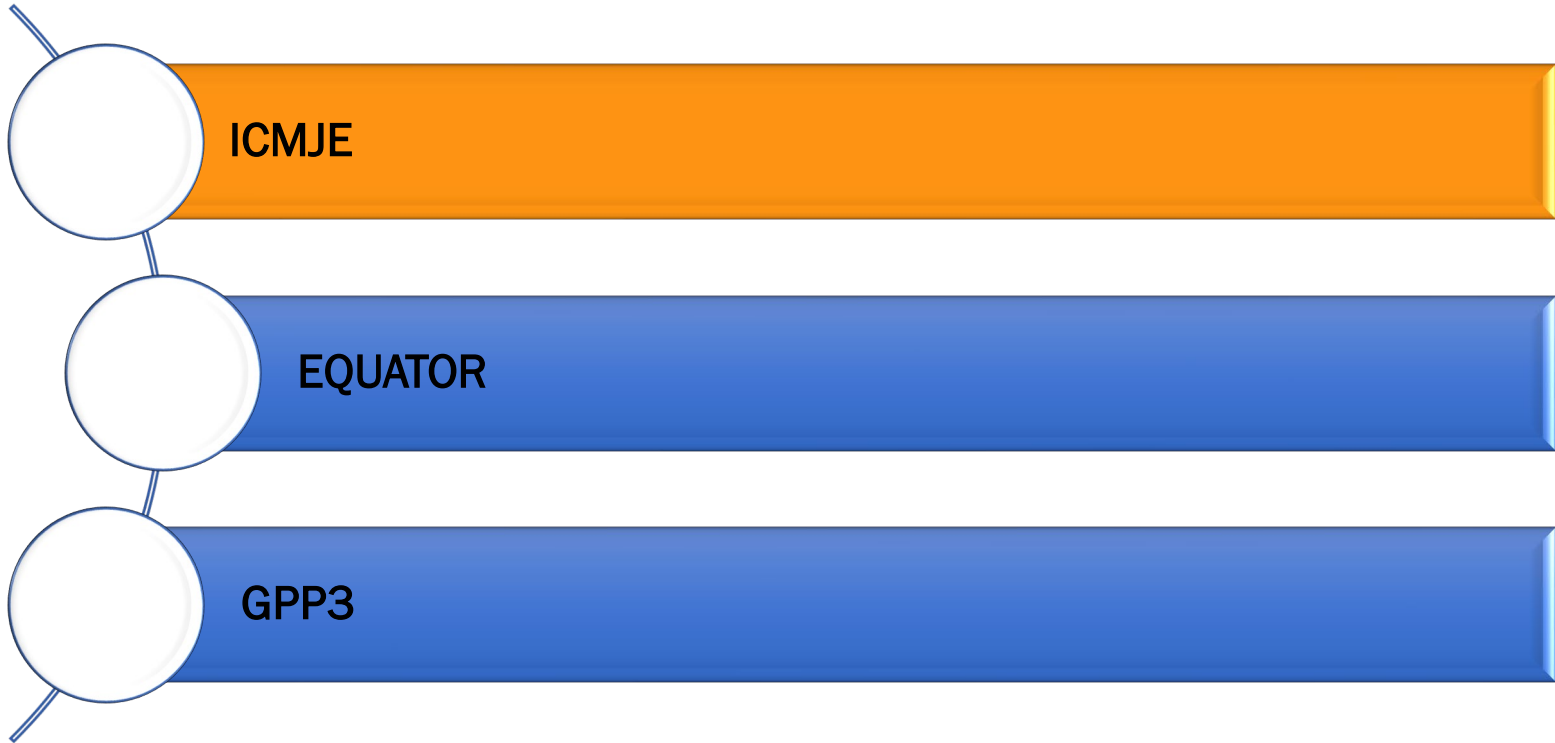
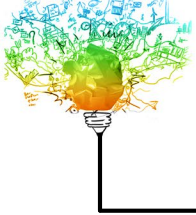
Neil has worked in medical publishing for the past 20 years at companies such as Informa Healthcare, Pharmaceutical Press and Springer Nature. He is currently sales director for Health Sciences at John Wiley & Sons, Inc., where he works with pharmaceutical, biotech and medical device companies to deliver online and print educational resources for healthcare professionals. A current member of the ISMPP U committee, Neil served as committee chair from 2016-2017 and he has also been a workshop faculty member at ISMPP's European and Annual meetings. Neil received his B.A. from Bates College and is an ISMPP Certified Medical Publication Professional™

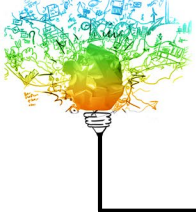


What current guidance is there for authors on disclosures and COI?

Yvonne Yarker







ICMJE

- “A conflict of interest exists when professional judgment concerning a primary interest (such as patients’ welfare or the validity of research) may be influenced by a secondary interest (such as financial gain). *Perceptions* of conflict of interest are as important as *actual* conflicts of interest.”¹
- 2009 (updated 2010): ICMJE published a standardized and interactive form for authors to disclose potential COIs²

1. <http://www.icmje.org/recommendations/browse/roles-and-responsibilities/author-responsibilities--conflicts-of-interest.html>.
2. <http://www.icmje.org/conflicts-of-interest/>.



ICMJE Form for Disclosure of Potential Conflicts of Interest



SAVE

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) 2. Surname (Last Name) 3. Date

4. Are you the corresponding author? ☐ Yes ☐ No

5. Manuscript Title

6. Manuscript Identifying Number (if you know it)

Section 2. The Work Under Consideration for Publication

Did you or your institution at any time receive payment or services from a third party (government, commercial, private foundation, etc.) for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.)?

Are there any relevant conflicts of interest? ☐ Yes ☐ No

ADD

Section 3. Relevant financial activities outside the submitted work.

Place a check in the appropriate boxes in the table to indicate whether you have financial relationships (regardless of amount of compensation) with entities as described in the instructions. Use one line for each entity; add as many lines as you need by clicking the "Add +" box. You should report relationships that were **present during the 36 months prior to publication**.

Are there any relevant conflicts of interest? ☐ Yes ☐ No

ADD

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? ☐ Yes ☐ No



SAVE

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 5. Relationships not covered above

Are there other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work?

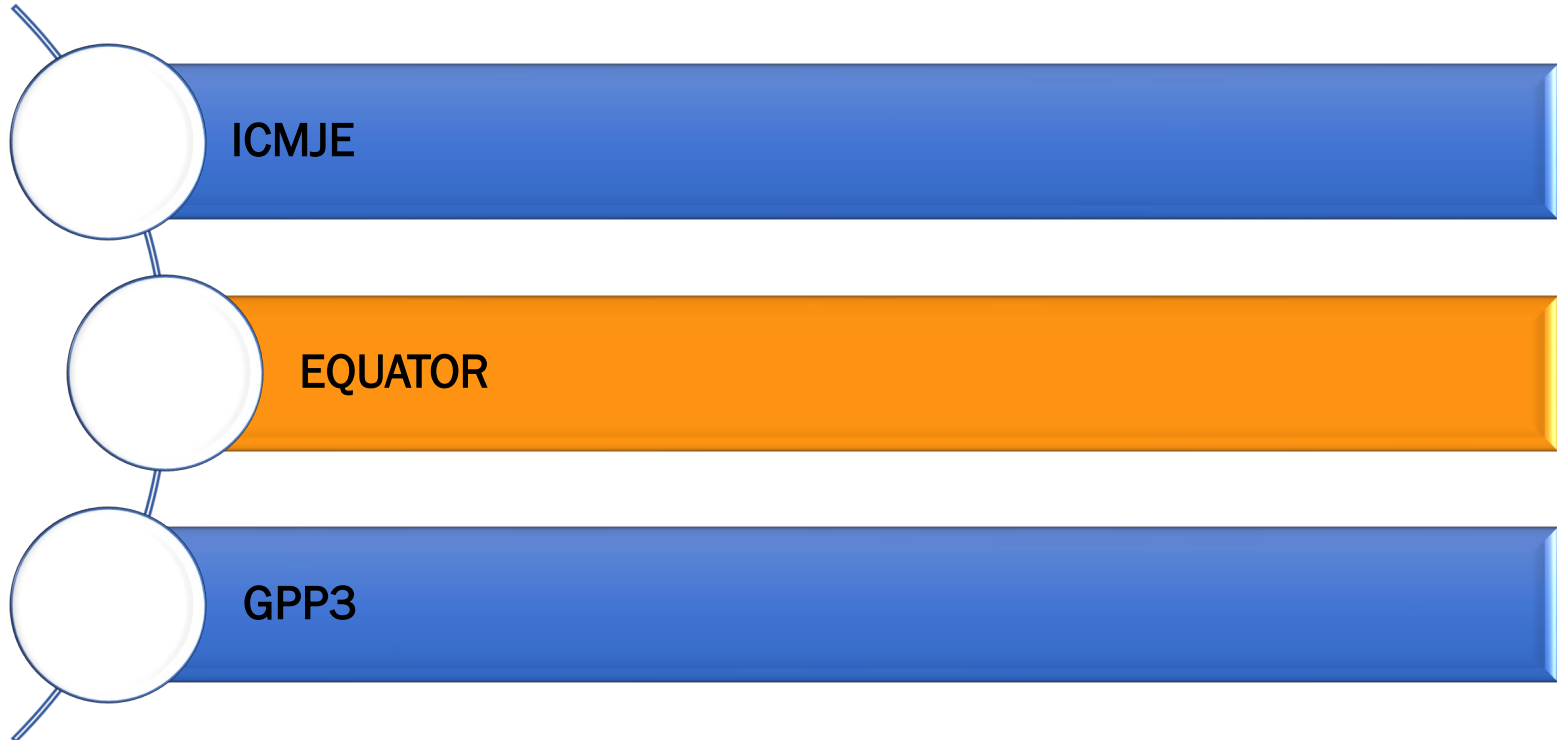
- ☐ Yes, the following relationships/conditions/circumstances are present (explain below):
- ☐ No other relationships/conditions/circumstances that present a potential conflict of interest

At the time of manuscript acceptance, journals will ask authors to confirm and, if necessary, update their disclosure statements. On occasion, journals may ask authors to disclose further information about reported relationships.

Section 6. Disclosure Statement

Based on the above disclosures, this form will automatically generate a disclosure statement, which will appear in the box below.

Generate Disclosure Statement





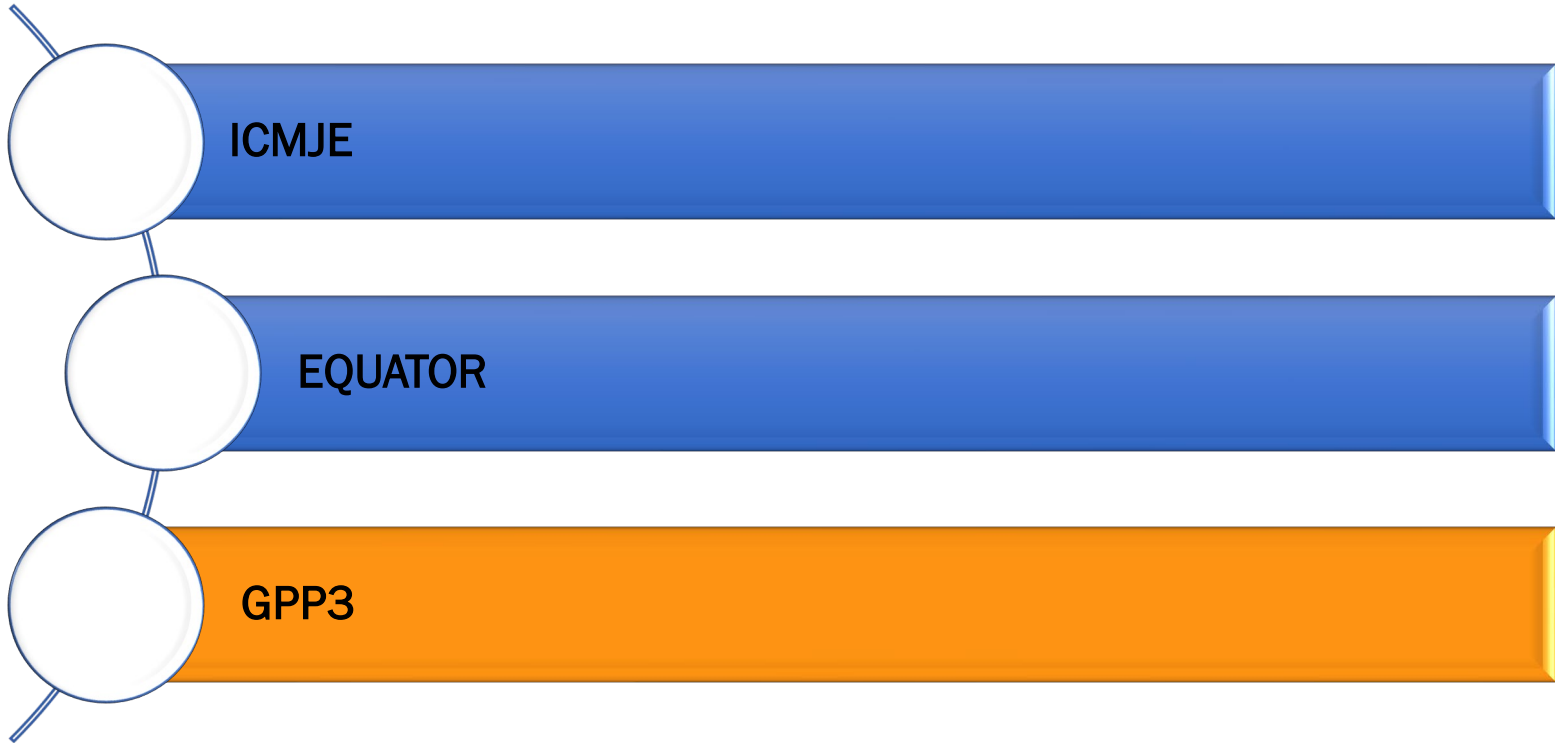
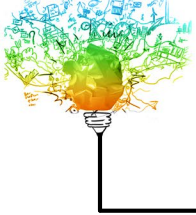
- A repository of reporting guidelines relevant to biomedical literature
- Lists 6 reporting guidelines relating to COI¹
- Only 2 provide practical checklists or forms:
 - ICMJE COI form
 - A financial COI checklist²

1. <http://www.equator-network.org/>. 2. Rochon PA, et al. Open Medicine 2010;4:e69-91.



Financial COI Checklist 2010 for Clinical Research Studies

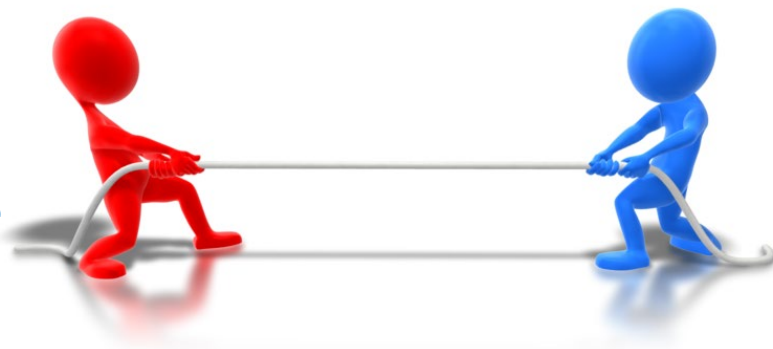
- 4 sections covering administrative, study, personal financial, and authorship information
 - Administrative Information
 - Study Information
 - Personal Financial Information
 - Authorship Information
- 6 modules
- 15 items and related sub-items; total of >70 questions
- Includes a glossary of term





GPP3: 2.6 Disclosures

- Generally propose using the ICMJE form and reporting relevant relationships over a 3-year time period
- *When discussing relevant relationships authors may have with commercial (or noncommercial) entities, the term “disclosures” may be preferable to “conflicts of interest” or “competing interests” because these latter terms may imply actual (rather than perceived or potential) conflicts and may inadvertently prevent full disclosure if the authors interpret them narrowly or fail to consider other relationships that may affect the manuscript.*

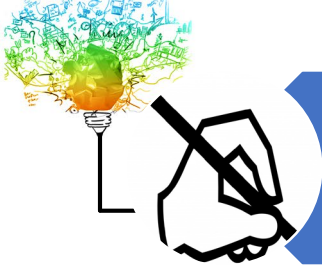


Conflict or Disclosure?



What is the role of the medical publication professional?





Often required to collect disclosures from authors during the development and submission of presentations to congresses and manuscripts to journals



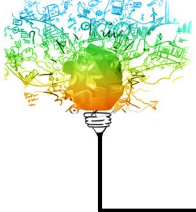
Likely to receive questions from authors about what to disclose and need to encourage authors to provide their information in a timely manner



NOT responsible for the accuracy or completeness of author disclosure statements



CAN assist authors in providing appropriate disclosures and in streamlining a sometimes onerous process



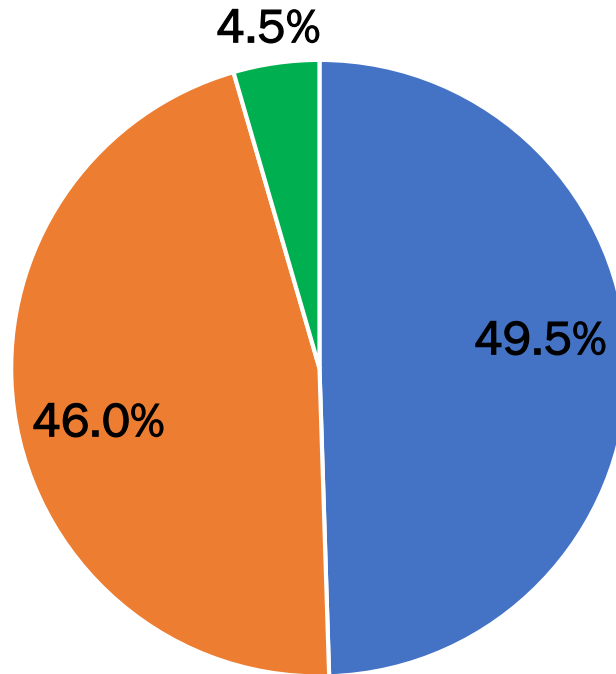
ISMPP Poll, The MAP Newsletter, July 2019

- You are a publication professional. A non-industry author states on his/her conflict of interest (COI) form that he/she has “no COI”, despite your knowledge that he/she is engaged by several companies for consultancy and speakers engagements.
- **What would you do?**



ISMPP Poll Results: What would you do?

N = 109



- Explain to the author the importance of accurate disclosure of COI, asking him/her to think about any potentially overlooked COI without pointing it out specifically, with the author ultimately deciding what to disclose
- Point out specific overlooked COI to the author as a courtesy, update the COI accordingly, and ask him/her to confirm the updated COI
- Do nothing; you are not responsible for the accuracy of the author's COI



This is how it feels to collect author disclosures...





How can medical publication professionals help make disclosure guidance less confusing, ambiguous, and inconsistent?





Upfront preparation is essential

Upfront Preparation

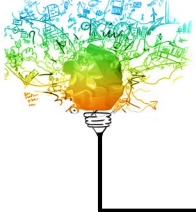
- Start collecting disclosures early – often they are the last thing that authors are concerned about, yet missing disclosures may delay a submission
- Review the congress or journal disclosure or COI policy and summarize key requirements for authors so they know what they are expected to provide
- Download the relevant journal disclosure form and send it to the author to complete, providing further explanation if needed; if the journal does not have a specific disclosure form, use the ICMJE COI form or provide it as an example of the types of information needed
- For certain society congresses and journals (eg, ASCO), disclosure statements are part of the member profile, so may be automatically populated in submissions – try to access these statements early, then ask authors to update as needed
- Check in advance if the journal uses a central repository to obtain disclosures (eg, CONVEY), then ask the author to update as needed
- Keep a spreadsheet or database of author disclosure statements and update as needed



Provide support to the authors

Author Disclosure Support

- Provide authors with sample disclosure statements or sample completed COI forms for guidance on developing their own disclosure statements
- If acceptable, complete general sections of a disclosure form before sending it to the author (eg, author name, title of work, journal, study name/number)
- If you have worked with an author before, send the author his or her previous disclosure statement and ask for updates
- Author disclosure statements from recent publications may be a starting point to draft a disclosure statement for the author to review and update, **although these statements may be specific to the content of the published paper and not the manuscript currently being developed**



In Summary

- Disclosure guidance for authors is confusing, ambiguous, and inconsistent
- Until requirements are clearly defined, authors will continue to be at risk for exposure and sanction over incomplete disclosures, whether because of carelessness, lack of understanding of what constitutes appropriate disclosure, or intentional omission
- **Medical publication professionals can provide valuable support and guidance to authors to help them submit accurate and comprehensive disclosure statements**

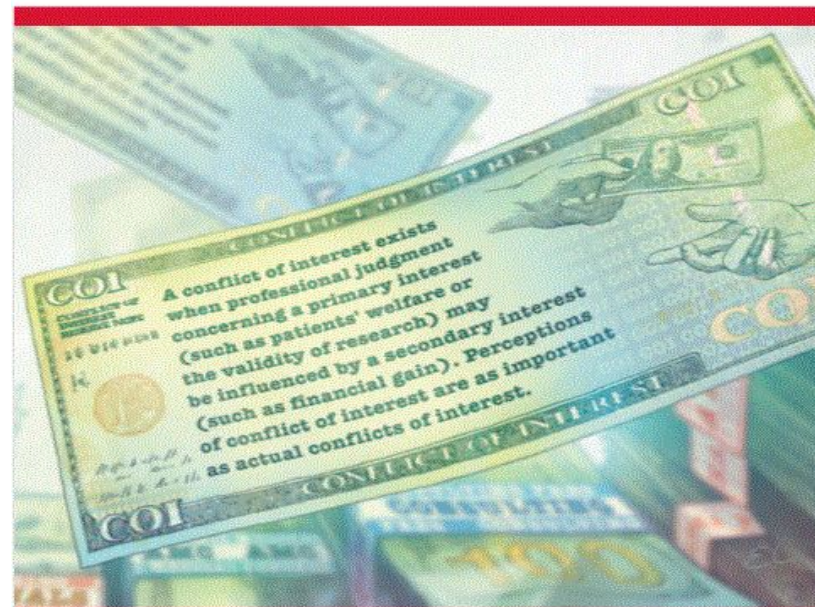




Final Thought

- “COIs are likely to become more challenging in the years to come. As more investigators and their institutions have and enter into financial relationships from which they benefit, it is critical that authors report COI information **accurately, completely, and transparently** so readers can evaluate whether the information in the article could be biased because of authors’ potential COIs.”

In This Issue of JAMA



Conflict of Interest

Edited by Howard Bauchner, MD, and Phil B. Fontanarosa, MD, MBA



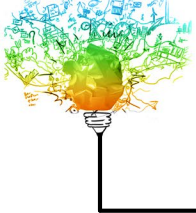
Publisher Perspective

Tanya Stezhka

Tanya.Stezhka@informa.com



Taylor & Francis
Taylor & Francis Group



Publisher perspective:



- What T&F medical journals are doing
- Sources of confusion
- What journals can be doing better



What T&F medical journals request



- Over 400 journals in medicine and health
- Subscription, hybrid and OA models
- International readership and authorship
- Streamlined submission system modelled on *ICMJE* disclosure form [1]
- Mandatory declaration policies
- Peer/review model adaptations
- Reviewer disclosures
- Editorial board disclosures



[1] <http://www.icmje.org/conflicts-of-interest/>



- Over 400 journals in medicine and health
- Subscription, hybrid and OA models
- International readership and authorship
- Streamlined submission system modelled on *ICMJE* disclosure form [1]
- Mandatory declaration policies
- Peer/review model adaptations
- Reviewer disclosures included in published paper
- Editorial board disclosures online



Did you know that conflict of interest declarations, acknowledgments and notes on contributors are all openly available to view on all articles on Taylor & Francis Online? This ensures transparency of key information and helps potential readers to evaluate articles more easily.





Transparency statement

Declaration of funding

- If no sponsor, include confirmation
- Study sponsor
- The role of the sponsors
- NIH/Wellcome grant number(s)



Transparency statement

Declaration of funding

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- NIH/Wellcome grant number(s)

*Declaration of financial/
other relationships*

- All relationships (financial, employment, other relevant relationships)
- Confirm if no relationships to be declared
- Reviewer disclosures added by Editor



Transparency statement

Declaration of funding

- If no sponsor, include confirmation
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- All relationships (financial, employment, other relevant relationships)
- Confirm if no relationships to be declared
- Reviewer disclosures added by Editor

Author contributions

- Conception, design, analysis, interpretation of the data
- Drafting of the paper or revising it critically for intellectual content
- Final approval of the version to be published
- All authors agree to be accountable for all aspects



Transparency statement

Declaration of funding

- If no sponsor, include confirmation
- Mention the sponsors for the study
- NIH/Wellcome grant number(s)
- The role of the sponsors in the preparation of this article

Declaration of financial/ other relationships

- All relationships (financial, employment, other relevant relationships) for each author
- Confirm if no relationships to be declared
- Reviewer disclosures added by Editor

Author contributions

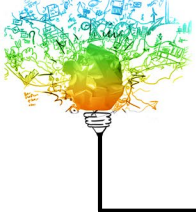
- Conception, design, analysis, interpretation of the data
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- Final approval of the version to be published
- All authors agree to be accountable for all aspects

Acknowledgements

- Non-author assistance (e.g., medical writer(s), statistician...)
- Their sources of funding
- Gratitude - e.g., other investigators, other study centres, data management
- None reported
- Previous presentations

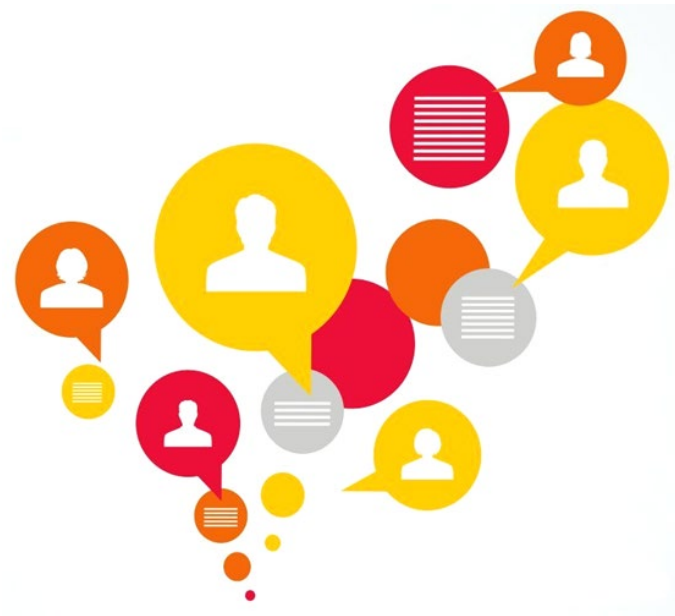


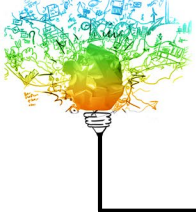
Sources of confusion



Sources of confusion

- Terminology (e.g. “conflict of interest” vs “competing interests”)
- Non-financial/personal/institutional competing interests
- Who’s responsibility is it? Author/Submitting agent/Editor





Could we be doing better?

- Clean up terminology
- State editorial declarations
- Refine messaging for authors, keep definitions consistent with ICMJE
- Ask all authors at point of submission and confirm at revision/acceptance
- Have processes in place to proactively address issues
- Engagement with Editors-in-Chief, editorial board members to ensure the policies are clear and easy to access
- Research integrity and ethics team to help address issues, and is responsible for refining editorial policies



How can sponsors help support transparency?

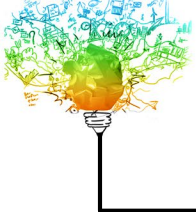
Steve Rizk





First thing to keep in mind...

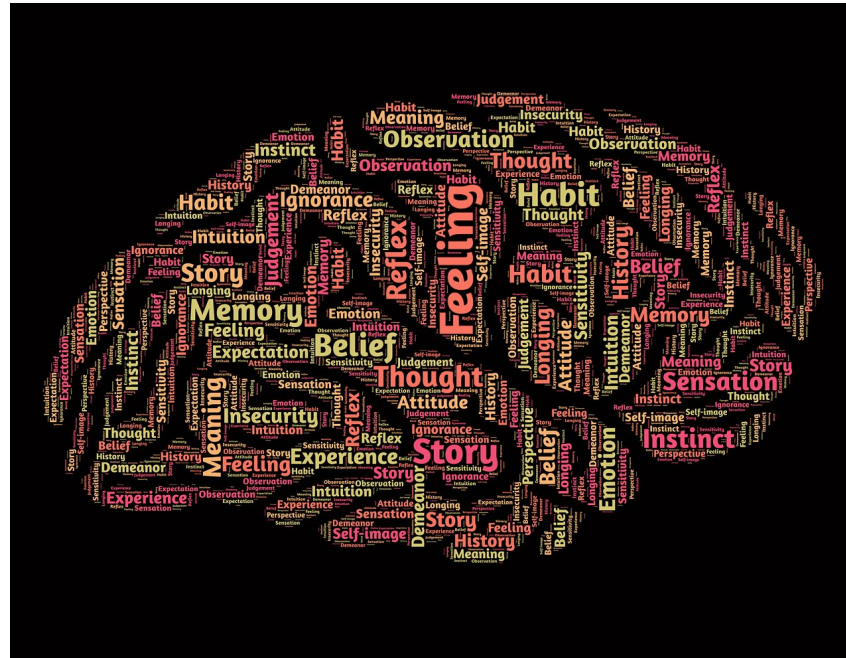
It is **highly unlikely** that an author on a **sponsored** publication **does not** have a **potential** conflict of interest to disclose...



How can I be so confident?

- Investigators: “The requested information is about resources that you received, **either directly or indirectly** (via your institution), to enable you to complete the work. Checking "No" means that you did the work without receiving any financial support from any third party...”
- KOLs: “If your article is about...EGFR antagonist in lung cancer, **you should report all associations** with entities pursuing diagnostic or therapeutic strategies in **cancer in general**, not just in the area of EGFR or lung cancer”
- Previous Authors: Non-Financial Support: Examples include drugs/equipment supplied by the entity, **travel paid** by the entity, **writing assistance**, administrative support, etc.

Authors understandably may believe they are not conflicted

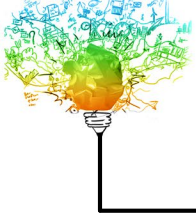




Steps sponsors should take...

- **Explain** requirements **early** in publication development
 - Author invitation/agreements
 - Kick-off calls
- Ensure medical writers **review** author financial disclosure forms to flag any '**no conflict**' declarations
 - For US HCPs, consider reviewing Sunshine Act Open Payments Site*
- **Address/Escalate** any 'no conflict' declarations
 - Discuss directly with author; encourage author update disclosures appropriately
 - Document and notify compliance if author refuses to update disclosure despite sponsor knowledge of a potential conflict

*<https://openpaymentsdata.cms.gov/>



Final points...

- **Authors** have direct responsibility for the completeness and accuracy of reporting
- However, **sponsors** can help ensure authors do not declare 'no conflict' when they have direct knowledge of some potential conflict of interest (not necessarily complete and accurate)

15TH ANNUAL MEETING OF ISMPP

THANK YOU!





Questions

- To ask a question, please type your query into the Q&A box
- To ensure anonymity, before sending please choose the drop-down box option, "Hosts and Presenters." Otherwise, **ALL** audience members will be able to see your submitted question



Upcoming ISMPP Us

DATE	TOPIC	FACULTY
September 18, 2019	<i>Medical Publications and Competitive Intelligence</i>	<ul style="list-style-type: none">Shula Pollard
October 2019	<i>Good Practice for Conference Abstracts and Presentations (GP-CAP)</i>	<ul style="list-style-type: none">To be announced



Thank You for Attending!

- We hope you enjoyed today's presentation.
- **Please check your email for a link** to a survey that should take only a few minutes to complete.
- We depend on your feedback and take your comments into account as we develop future educational offerings. Thank you in advance for your participation!