

Managing COI Compliance: The Importance of Disclosures in Publications & Presentations

2022 HCCA Research Compliance Conference (06.10.22)

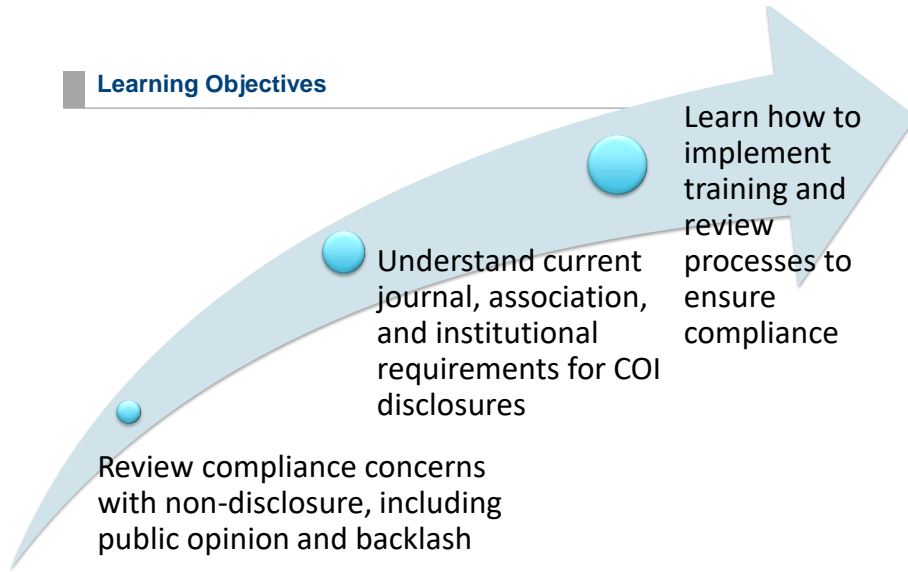
Stacy Pritt, DVM, MS, MBA, CPIA, CHRC, DACAW
Associate Vice President, Research Support & Regulatory Management

Meredith Noto, MBA, MA, CHRC, EXCS
Associate Director, Conflict of Interest & Export Control

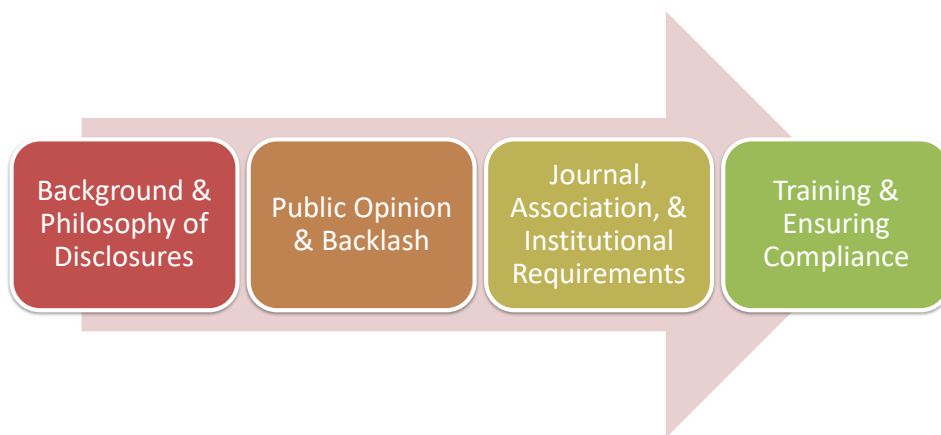
General Disclaimers

- Stacy and Meredith do not have any relevant financial interests with regards to the material being presented here today
- There is a lot of research and commentary on how disclosures are interpreted by researchers, medical professionals, and the public
 - Approaching the topic today from the perspective of compliance professionals, specific to disclosures publications and presentations
 - Not discussing any journal disclosure harmonization efforts

Learning Objectives

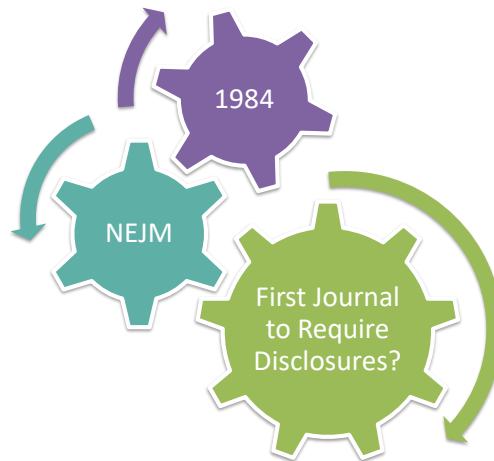


Agenda



Background & Philosophy of Disclosures

A Bit of Trivia



Philosophical Underpinnings of Disclosures

Relationships with industry are “bad”

COIs lead to a suspicion around veracity of study findings and skepticism of clinical recommendations

Current COI systems and processes do not determine ethics of the relationship; but focus on transparency

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The What, Why, & How of Disclosures

What

Acknowledgement of a known conflict or financial interest

Usually found in publications, presentations and other venues

Why

Does not manage the conflict

Meant to inform the recipient

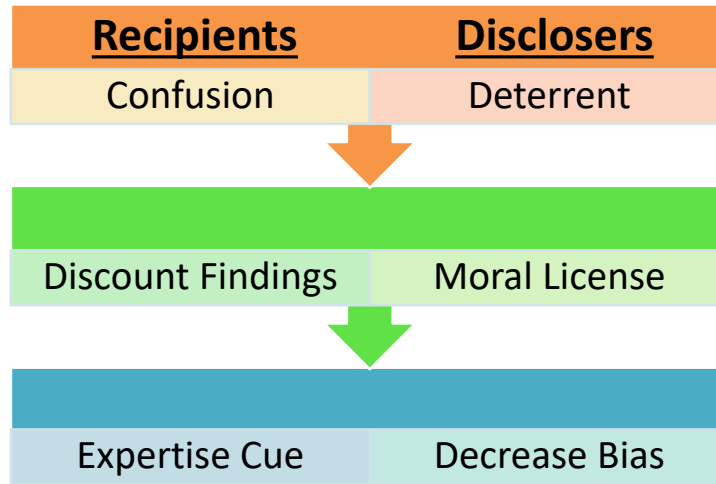
How

Included in the publication, or reference to supplement

Verbal announcement

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Unintended Consequence of Disclosures



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Public Opinion & Backlash

Press Releases

How Coca-Cola Disguised Its Influence on Science about Sugar and Health

Published Oct 11, 2017

Coca-Cola quietly funded a research insti University of Colorado designed to persu on exercise, not calorie intake, for weight

PHARMA
Purdue funneled money to nonprofits, WHO employees to sway opioid guidance: report

By Kyle Blankenship · May 24, 2019 10:13am

The New York Times

Scientist Who Discredited Meat Guidelines Didn't Report Past Food Industry Ties

The lead researcher, Bradley C. Johnston, said he was not required to report his past relationship with a powerful industry trade group.

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Public Perception

When big companies fund academic research, the truth often comes last

Published: October 2, 2019 4:04pm EDT

SCIENCE/BIOSCIENCE SCIENCE AND POLICY
Three percent of NIH grants involved a direct financial conflict of interest, watchdog report finds

Some experts question low figure found by first comprehensive look at National Institutes of Health reports

30 SEP 2019 · BY JOCELYN KAISER

DOLLARS FOR PROFS

Federally Funded Health Researchers Disclose at Least \$188 Million in Conflicts of Interest. Can You Trust Their Findings?

A National Institutes of Health database, which we're making public for the first time, shows that researchers have reported more than 8,000 "significant" financial conflicts, potentially influencing their work.

by David Armstrong and Annie Waldman, Dec. 6, 2019, 8:35 a.m. EST

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Backlash

Targeted and on-going negative press suggesting wrong-doing by institutions and individuals.

SLOAN KETTERING'S CRISIS

Memorial Sloan Kettering Gave Top Doctor \$1.5 Million After He Was Forced to Resign Over Conflicts of Interest

PRACTICES

Prominent doctors aren't disclosing their industry ties in medical journal studies. And journals are doing little to enforce their rules

By Charles Ornstein, ProPublica, Katie Thomas • Dec 11, 2018 11:23am

[Ethics](#) [Physician Practice](#) [Research](#) [American Society of Clinical Oncology](#)

Chief medical officer after payments he received from for-profit... light in 2018. Then, Memorial Sloan Kettering quietly gave... package, according to IRS documents.

and Charles Ornstein, ProPublica, Dec. 22, 2020, 2:04 p.m. EST

Decreased trust in research and medical establishment

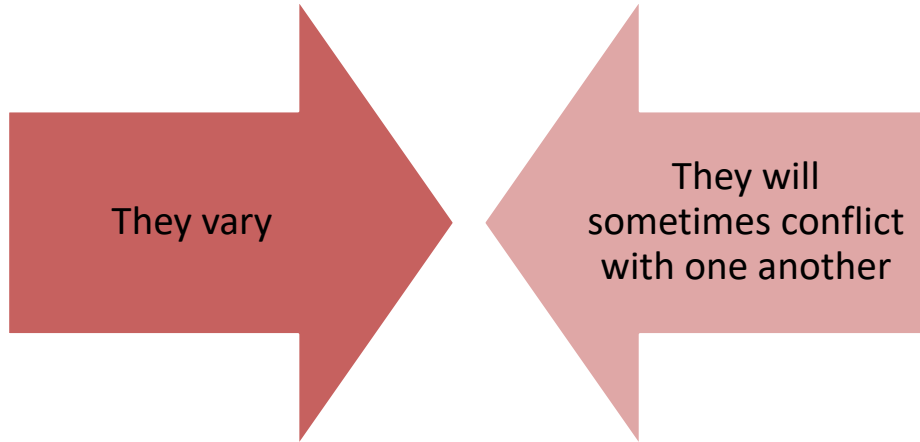
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Journal, Meeting & Institutional Disclosure Requirements

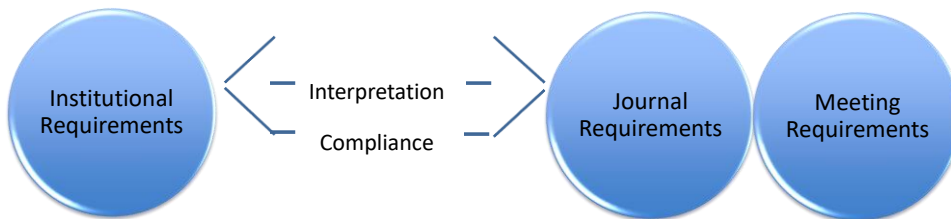
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Journal, Meeting, & Institutional Requirements



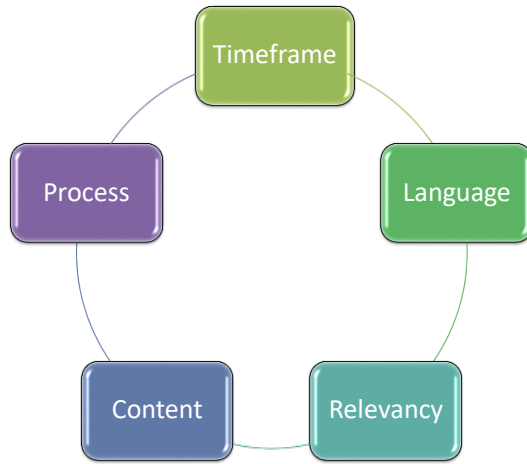
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The Conundrum



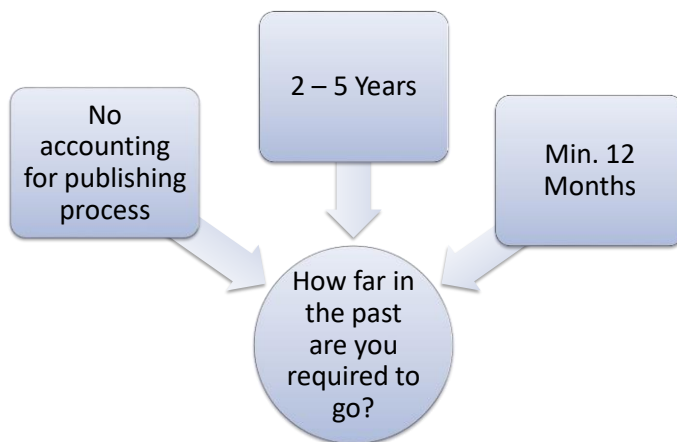
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Variability in Disclosure Requirements for Journals & Meetings



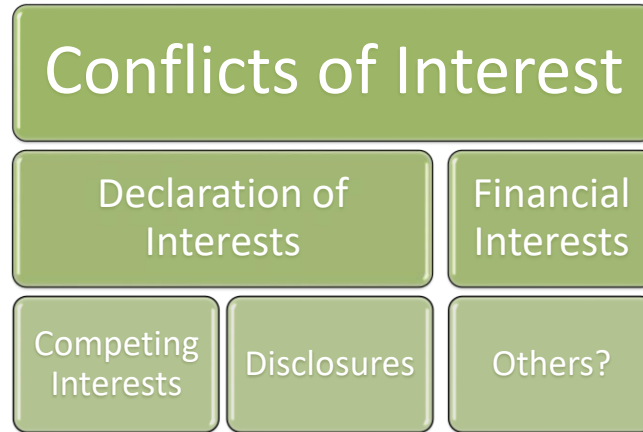
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Timeframe



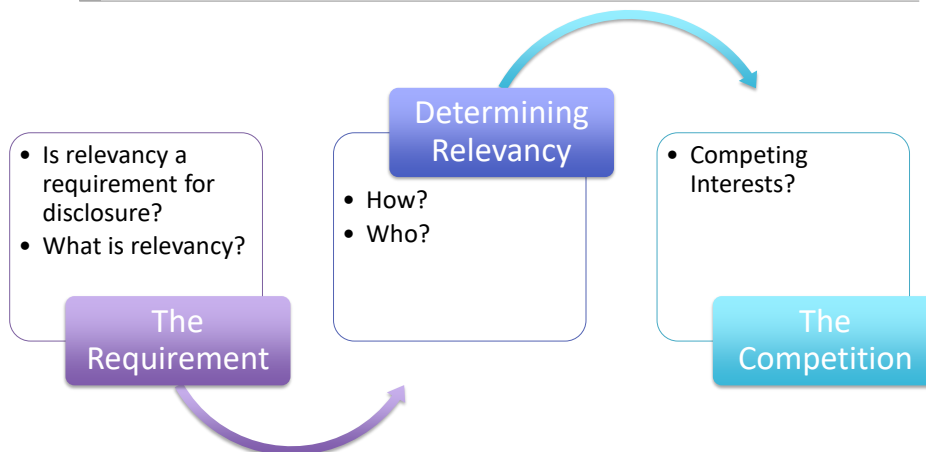
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Language



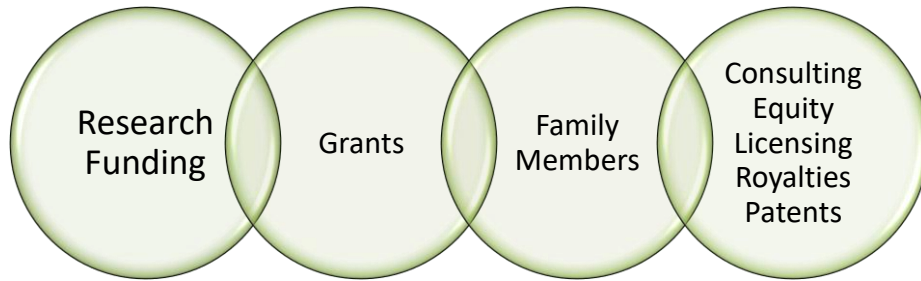
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Relevancy



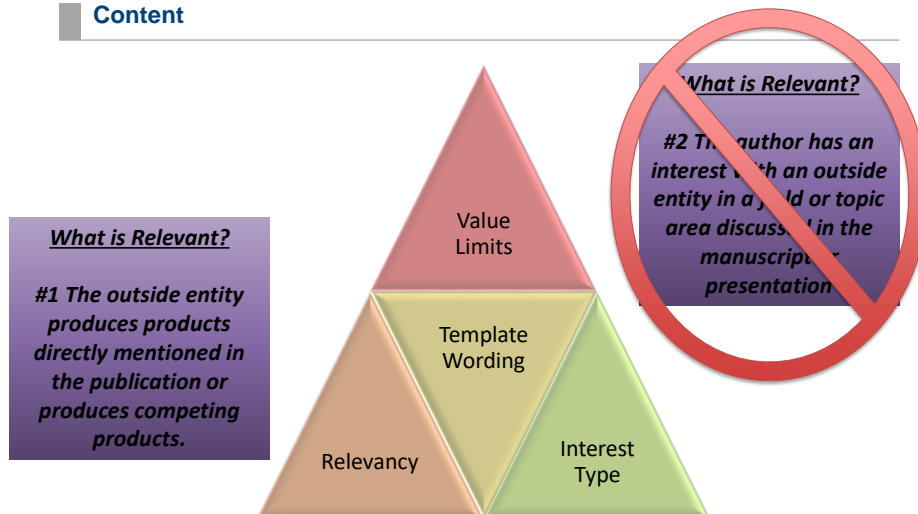
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Types of Interests



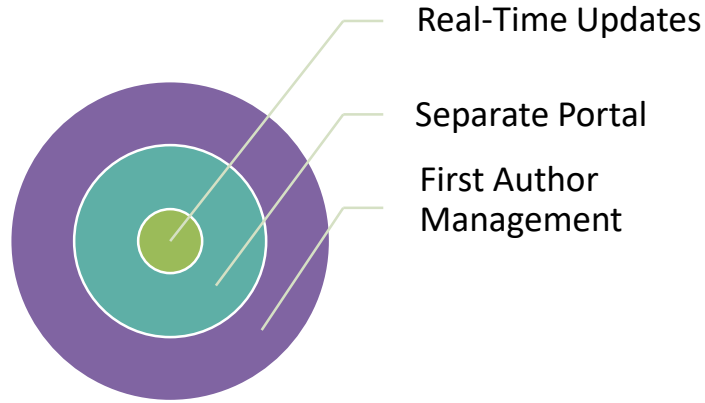
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Content



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Process



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Training & Ensuring Compliance

Training for Authors

Awareness of situations that lead to missing disclosures

- Human error
 - Is the corresponding author aware of the needed disclosure?
 - Was the disclosure present in the final submission?
 - Do the other authors make similar disclosures?
- Lack of awareness of the COI
 - Ensuring Management Plan is clear and specific
 - Management Plan monitoring and other touchpoints
 - COI training
- Inaccurately assessing relevancy
 - Rationalizing why a disclosure is not relevant
- Issues with Journal's requirement
 - Journal rejects disclosure
 - Variation/assumptions of journal requirement

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Training for Administrators

Sensitivity to context

- Gather full story
- Publication date compared with the issue date of Management Plan
- Attempts to disclose

Skillset to review

- Consistently determine what interests are relevant
- Funding sources and manufacturers
- Research content relevancy

Strategy for Management Plan monitoring

- Reminds individuals of the conflict and Management Plan
- Discuss Management Plan compliance at COI review
- Provide guidance on how to best comply with Management Plans and journal requirements

Appreciate the Limitations

- CMS Open Payments of limited value
- Avoid concepts like “potential COI” or “potential non-compliance” in determinations

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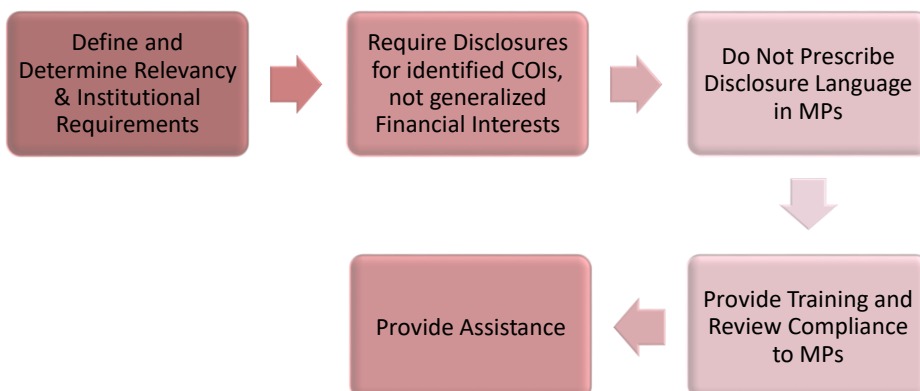
Reviewing for Compliance

- Management Plan monitoring within one year of issuing MP
 - Investigators may provide examples of appropriate disclosure
- Review recent publications within the last year or since the last review of the COI
 - Generate list of publications from standard source (e.g. PubMed)
 - Filter list by publication date
 - Review abstracts and Methods to identify relevant publications
 - Confirm appropriate disclosure was included
 - **Reach out** to understand why a disclosure was omitted
- Compliance reviews for instances of MP non-compliance
 - May require updating disclosure in manuscript
- Establish a policy for SOP for the COI Office to use for manuscript/presentation review to ensure consistency

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Recommendations



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