

Managing Conflicts of Interest in Health and Medical Research

Dr Nitya Phillipson
Head of Governance & Integrity
Health Translation Queensland

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Disclosures

- MCRI Head of Integrity- responsible for Col management at MCRI
- No financial or non-financial Col
- AI use
 - Used GPT-4 to give me ideas for the questions and definitions, used these as starting point and then re-wrote.
 - Used Elicit to summarise the current literature on Col in Health and Medical Research, then manually checked and read the relevant literature.

What will we cover today

- Role of Australian Code & Guides in supporting Col management
- Definition and types of Col
- Some famous cases & consequences
- How to manage Cols
- What can organisations do
- Activities along the way.

Why is the Head of Integrity managing Col portfolio?

Australian Code for the Responsible Conduct of Research (2018)

- Expectation that research is to be conducted responsibly, ethically and with integrity
- 'The Code' sets out the principles and responsibilities that underpin the conduct of Australian research.
- Supported by guides with details on how to comply with the Code and specific topics like Col
- Compliance with this Code is a requirement for the receipt of funding by NHMRC and ARC



Responsible Conduct of Research

Principles

1

HONESTY

in the development, undertaking and reporting of research

2

RIGOUR

in the development, undertaking and reporting of research

3

TRANSPARENCY

in declaring interests and reporting research methodology, data and findings



4

FAIRNESS

in the treatment of others

5

RESPECT

for research participants, the wider community, animals and the environment

6

RECOGNITION

of the right of Aboriginal and Torres Strait Islander peoples to be engaged in research that affects or is of significance to them

7

ACCOUNTABILITY

for the development, undertaking and reporting of research

8

PROMOTION

of responsible research practices

Principles of the The Code

Conflicts of Interest

“a situation where an independent observer might reasonably conclude that the professional actions of a person are or may be unduly influenced by other interests”



Types of Col

Financial

- When personal or institutional financial gain could influence decisions.

Non-Financial (Personal or Ideological)

- When personal beliefs, loyalties, or relationships affect judgment.

Relational

- When close relationships could create bias.

Institutional COI

- When the organisation itself has interests that may affect research conduct or reporting.



Types of Col

Actual Conflict of Interest

- A situation where a researcher's judgement or actions *are directly influenced* by a competing interest.

Example:

- A researcher receives consultancy fees from a medical device manufacturer whose products they are evaluating.

Potential Conflict of Interest

- A situation where a competing interest *could* influence, or be seen to influence, a researcher's decisions in the future.

Example:

- A researcher involved in drafting policy while pursuing patents in the same field.



Types of Col

Perceived Conflict of Interest

- A situation where a reasonable person *might think* a researcher's judgement could be influenced, even if it is not.

Example:

- A hospital ethics committee member reviewing a protocol led by their close colleague or friend.



One in four?

One in four medical researchers fails to declare conflict of interest, study claims

Lucy Carroll and Liam Mannix
March 13, 2022 – 12.15am

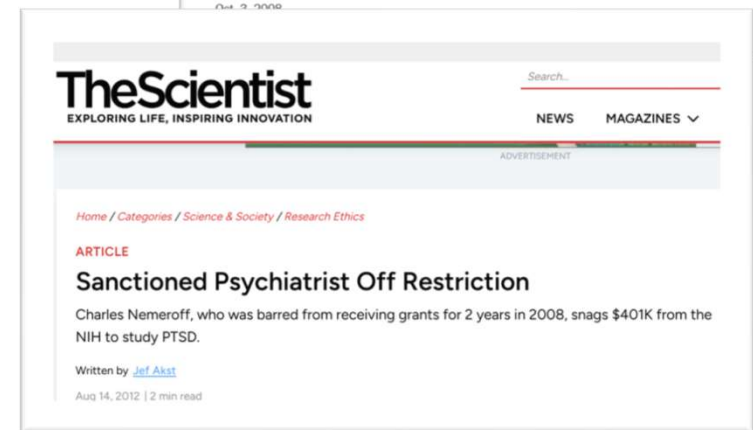
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Flood, L., Mintzes, B., Chiu, K. et al. Australian Clinical Trial Authors' Declarations of Industry Ties. *J GEN INTERN MED* 37, 3196–3198 (2022). <https://doi.org/10.1007/s11606-022-07466-9>

- Looked at companies' reports of payments & compared these reports with authors' self-reported conflicts between January and August 2020.
- One in four Australian authors in 120 trials had at least one undeclared conflict, average value of undisclosed payment at almost AU \$9000.

Charles Nemeroff - Undisclosed Pharma Payments

- Prominent US psychiatrist, then Chair at Emory University.
- Senate probe found he failed to disclose over US\$1 million in personal payments from pharma companies while conducting NIH-funded research.
- Some payments related to drugs he was actively evaluating in his research
- In 2008 NIH temporarily suspended Emory (org not person) from applying for new grants.
- Sparked major reforms in US COI disclosure policies.

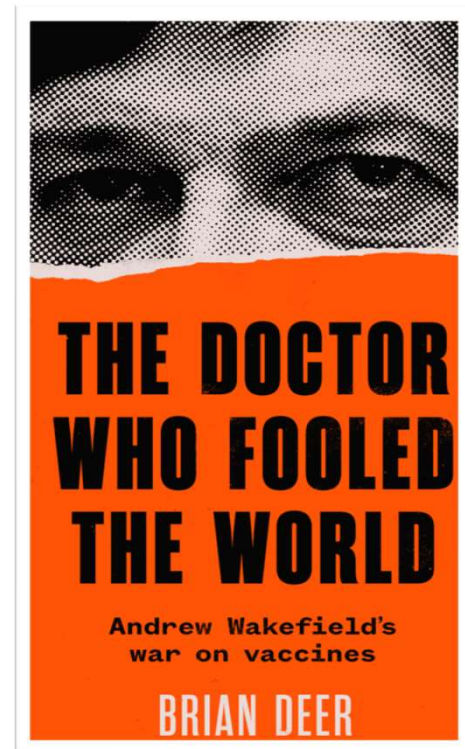


<https://www.the-scientist.com/sanctioned-psychiatrist-off-restriction-40609>

<https://www.nytimes.com/2008/10/03/health/03iht-04drug.16674357.html>

Andrew Wakefield - MMR Vaccine Fraud

- 1998 *Lancet* study linking MMR vaccine to autism.
- Published a study of 12 children suggesting MMR vaccine caused autism.
- Study triggered vaccine scares, sharp fall in immunisation rates, and ongoing public health harms.
- Later investigations revealed falsified data and undisclosed conflicts.
- AW was paid by lawyers preparing lawsuits against vaccine manufacturers.
- Had filed a patent for an alternative measles vaccine
- Did not disclose these conflicts to *The Lancet*, his institution, or readers.
- *The Lancet* fully retracted the paper in 2010 and this has been WIDELY refuted
- Case is now cited worldwide as a catastrophic example of undisclosed COI + misconduct.



Consequences

- Harm patients and participants
- Lead to sanctions, retractions, or legal consequences



Sanctions & Legal consequences

- Research misconduct
 - Serious breach of the code that is intentional, reckless or negligent.
- Corrupt conduct
 - Dishonesty or concealment: Failing to disclose relevant interests that could influence decisions or actions.
 - Breach of public trust: Acting in a way that erodes confidence in fair, transparent, and ethical processes.
 - Misuse of resources or authority: Directing funding, research outcomes, or opportunities based on hidden personal or institutional interests.
- Fraud
 - Deception for financial gain.

Consequences

- Harm patients and participants
- Lead to sanctions, retractions, or legal consequences
- Undermine trust in research..

What does this teach us...

Disclosure is non-negotiable

- All actual, potential, and perceived conflicts must be declared.

Management is essential

- Conflicts do not automatically equal misconduct — poor disclosure and handling do.

Institutions share responsibility

- Need robust systems for declaring, monitoring, and managing conflicts. Public health organisations are obligated to report corrupt conduct.

Public trust is fragile

- Failure to manage COIs can harm participants, damage institutions, and undermine science globally.

Better practice when it comes to Col?

1. disclose all relevant interests and
2. look at whether these constitute a
conflict of interest and
3. manage the Cols identified.

Review > Intern Med J. 2019 May;49(5):574-577. doi: 10.1111/imj.14233.

Conflicts of interest: new thinking, new processes

Paul A Komesaroff ^{1 2}, Ian Kerridge ², Wendy Lipworth ²

Affiliations + expand

PMID: 30693633 DOI: [10.1111/imj.14233](https://doi.org/10.1111/imj.14233)

Komesaroff PA, Kerridge I, Lipworth W. Conflicts of interest: new thinking, new processes. Intern Med J. 2019 May;49(5):574-577. doi: 10.1111/imj.14233. PMID: 30693633.

Better Practice when it comes to Col?

1. disclose all relevant interests and
2. look at whether these constitute a conflict of interest and
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'interest' as 'a commitment, goal, obligation or duty related to a particular social role or practice'.

'conflict of interest' as the condition that arises when two coexisting interests directly conflict with each other: that is, when they are likely to compel contrary and incompatible outcomes.

[Review](#) > [Intern Med J.](#) 2019 May;49(5):574-577. doi: 10.1111/imj.14233.

Conflicts of interest: new thinking, new processes

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Step 1 Disclose relevant interests

- Disclose all relevant interests
- Relevant interest \neq Col

Some examples (should be related to your work):

- Competitive research funding
- Consultancy work
- Paid and unpaid membership of boards or advisory committees
- Paid speaking engagements
- Personal relationships
- Direct payment to you by a sponsor or funder of research
- Shareholdings

Step 2 Do these = a Col?

- Not all disclosures = a Col
- Allows you to systematically think about them and see interdependencies
- Allows for future strategies and disclosure plan

Consider whether they are real, potential or perceived:

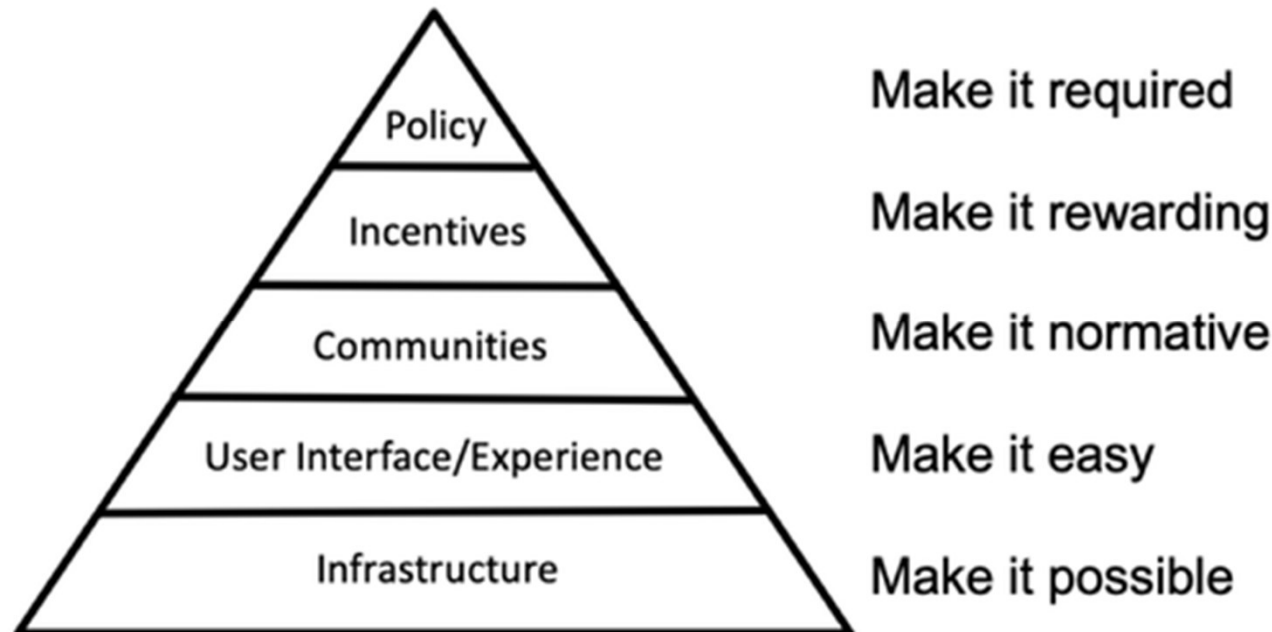
- Your personal relationship with head of sales at thermofisher.. Perceived- but becomes relevant if you deal with them (or you're the head of procurement, then real)
- Direct payment to you by a sponsor or funder of research.. May not be an issue until you run a trial for them..
- They may trigger other policies e.g gift register

Step 3 Manage your Col

- Think beyond disclosure
- Make manage plan specific & practical
- Create disclosure templates to assist with regular disclosing

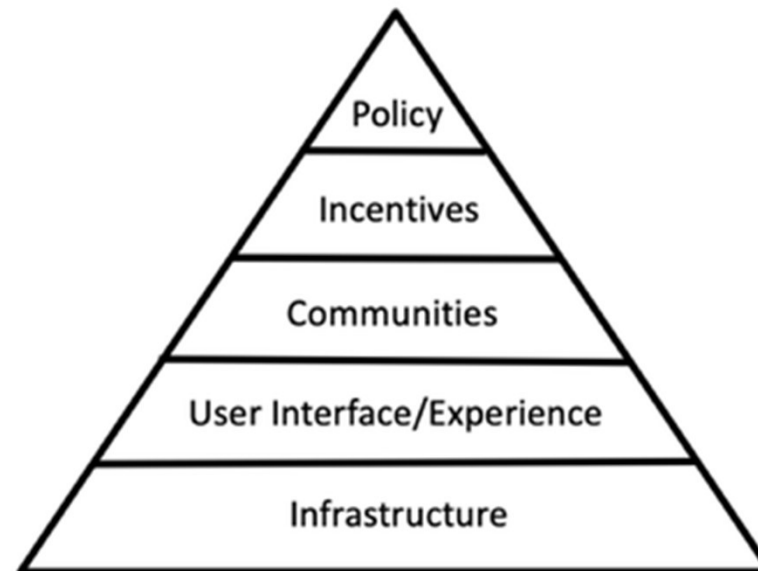
- Recusal or withdrawal from decisions
- Limit or avoid certain relationships
- Separate roles or modify responsibilities
e.g. treating clinician does not recruit or consent own patients, keep data/personnel blinded
- Independent oversight
e.g. appoint an independent statistician get specific peer review to look for potential bias
- Use external or additional monitoring
e.g. a trial with commercial funding uses an independent data monitoring committee to review safety and efficacy.

What can organisation do?



Make it possible & easy

- Make the Col form simple and easy to do
- Help researchers who need to chat it
- Remind them to update it



Make it required

Make it rewarding

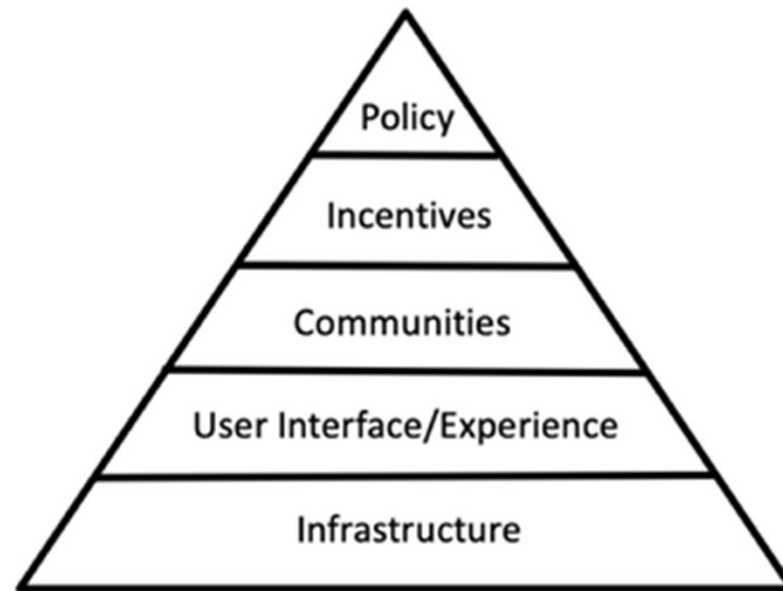
Make it normative

Make it easy

Make it possible

Make it normative

- Get leadership to do it publicly
- Consider COI Placeholder
 - Powerpoint presentations
 - Agenda templates
 - Minutes templates
 - Grant checklists



Make it required

Make it rewarding

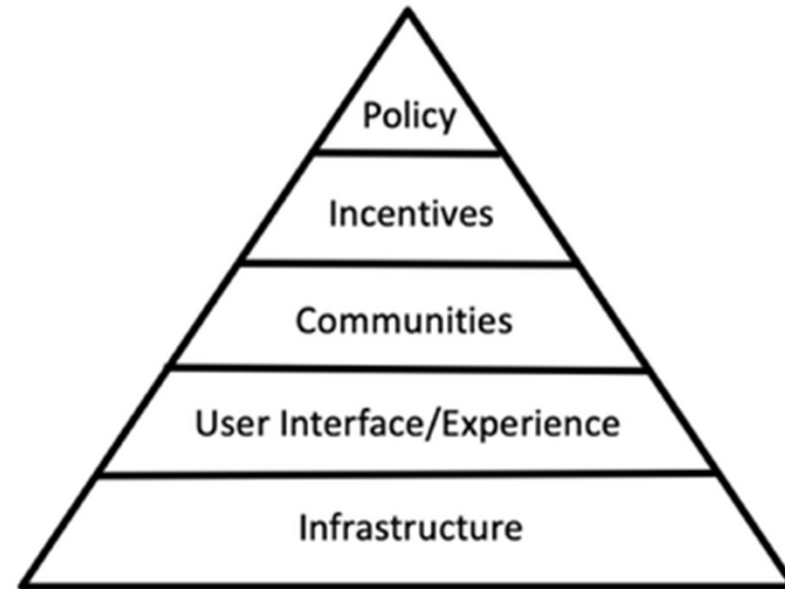
Make it normative

Make it easy

Make it possible

Make it rewarding

- Try not to make it a big deal to disclose
- Consider Research Integrity awards
- Embed into hiring & promotions



Make it required

Make it rewarding

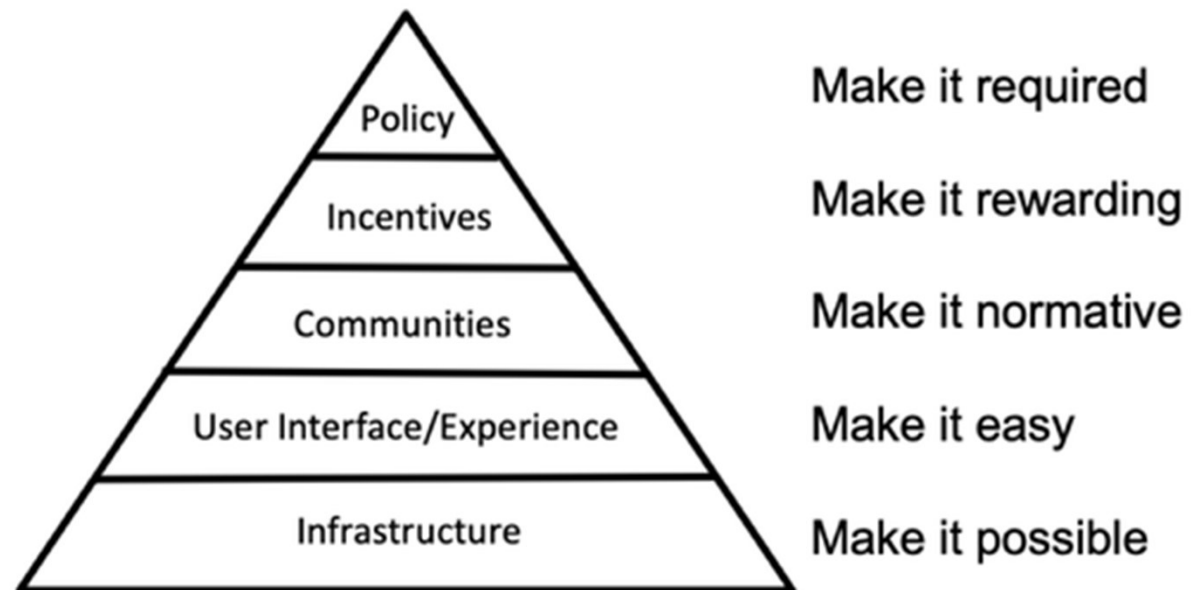
Make it normative

Make it easy

Make it possible

Then make it required

- Write that policy document!



Take home message

- **COIs aren't inherently bad**, They're realities of modern research. What matters is how we acknowledge and manage them.
- **Disclosure is just the start**
- **Accountability is a shared commitment.** Individuals, teams, & organisations have a role in fostering good COI culture
- **It's never been this hard, nor this important**
 - Today's research environment is more complex than ever.
 - Trust is fragile and precious.

<https://theconversation.com/storm-clouds-ahead-scandals-that-have-rocked-australian-politics-216825>
<https://www.theguardian.com/us-news/2025/jun/16/trump-conflict-of-interest>

'This is the looting of America': Trump and Co's extraordinary conflicts of interest in his second term

Bitcoin, internet, EVs, private dinners for hire - the list of pay-for-play and quid quo pro goes on, and on ... and on

- 'I have never seen such open corruption': Trump's crypto deals and loosening of rules shock observers




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Thank you!
Please reach out: Integrity@mcri.edu.au