

# Conflicts of Interest in Research:

Exploration and Case Studies of Managing Col in Research and Development

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## Disclosure

I am currently employed as an independent consultant for several small Medical Device companies, primarily in strategic advisory roles and customer education.

Palette Life Sciences, AirTagarders, Imatrix

I'm paid at an hourly rate consistent with AAPM guidelines with no stock or performance bonuses.

I'm also a voting member of the AAPM Ethics Committee, and helped craft portions of the Code of Ethics as a member of TG-109.

## The Problem With Conflicts of Interest (Col)

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### Money and Power (appear to) create Bias

Interests with **Financial** incentives appear especially problematic

- Developing a product when you will benefit from its success
- Advising a company how to handle a problem or create a solution – or serving on the board
- Investments in a company
- Being employed by a company (full-time, or part-time consulting)
- Accepting research grants, travel reimbursements, honoraria or other in-kind perks

Interests stemming from **Authority, Power or Influence** are also problematic

- Leadership in multiple committees or organizations
- Access to Confidential or Privileged information create a conflict
- Contributing to papers, presentations = "gift of opportunity" and inclusion




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### Gifts make the receiver feel obliged to give something in return



#### Did Free Pens Cause the Opioid Crisis?

Article by: [Randy L. Brinkley](#) and [Joseph C. Salamone](#) | [Healthcare Business](#) | [July 10, 2018](#)



Repeated Nudges drive direction, consciously or unconsciously.




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### See the System Imperfections That Drive Bias

Medical Physicists are some of the hardest working people I know.

- That drive comes from a combination of
- needing your creative work to be recognized
  - feeling you must live up to the investment society has placed on you
  - competition, between individuals, institutions and companies.

This can power creativity. It makes our field better!

But, it can also

create a wish to please funders and your university, sometimes at the expense of objectivity.




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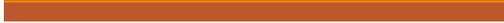
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## Solutions for Managing Conflicts of Interest (COI)



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### Inventory your Interests



What do you "want" to succeed? Which entities support you?  
- employment, funding, travel, prestige, esteem, professional alignment

Who do you feel flattered by, or indebted to?

Not all interests are "in conflict" with primary duties, but be aware of how they bias your behavior

- You ability to see these biases will make you better!
- Unbiased research, and unbiased leadership is a worthy goal in itself

Identify which interests may compete with AADM's interests, or may appear to

- Appearances, in the absence of other information, may implicate
- By declaring them, you acknowledge them, and imply you can be trusted to manage them

Having interests that conflict usually stems from completely legitimate duties and activities

There is nothing inherently unethical or unlawful  
-- unless you engineer to profit from them, or appear to do so.



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### Dealing with Conflicts: Identify, Prevent, Manage

- **Identify:** Inventory of vested interests
- **Prevent:** If you see that paths are going to intersect, don't go there.  
- E.g. If you're on the Editorial Board of a journal, reconsider joining a University library committee that recommends journal subscriptions.

**Manage:** handle the situation once it manifests

*Always*

**Declare** -- Be transparent.

*Occasionally*

**Recuse** -- excuse yourself from a decision where you cannot be impartial

Usually temporary while the issue is being resolved by others: Sit out of meeting, refrain from expressing opinion or voting

*Sometimes*

**Resolve or Eliminate** the conflicting interests by staying active in only one or the other positions

- Direct stock or financial holdings.
- Hedge position.
- OK, Refuse gifts or offers to pay for expenses (increasingly often)



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## How to Construct Col Disclosures

Goal: Be proactive and transparent about the ideas/things you are vested in.

Straightforward, simple and precise wording, covering:

1. Past and Present funding and/or other resources related to the project
2. Role
3. Future Incentives. Future incentives are stock, options, or other bonuses related to the performance of the product/company in the marketplace.

"Jane Doe has been the recipient of research (travel) grants from Company A, while participating in the (direction/design/development/evaluation) of Product B. She receives no other financial bonus or incentives."  
 Or "She holds stock in Company A and receives a portion of profits from Product B."

Ask: What would you be embarrassed of, or need to defend, if it were discovered later??"

**The specific amounts and degree of detail that is appropriate will be context-sensitive. Expect more rigor when more influence is at stake. Seek or ask for guidance if specific direction is not given.**




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## Example Case Studies For Managing Conflicts of Interest (Col)




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## Col – to Declare or not to Declare

Example 1: Company X has provided you with a free version of their product to do an evaluation of it. Do you declare this "gift" in the subsequent manuscript?

Example 2: Your retirement portfolio includes an index fund, and after researching what the fund invests in, you determine that some large Diagnostic Imaging Companies are held. Do you need to declare this in your AAPM presentation?

Example 3: Your spouse works for Company A in your field. Your assets are joint. As you are submitting your ASTRO abstract, do you declare the interest in their employer?




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## Case Study: CHEERS study



- A highly regarded institution proposed a 10-year, \$100 M study to NIH
- Hypothesis: 1 drink per day can reduce heart disease and diabetes risk
- Funded: mostly by Anheuser-Busch, InBev, Heineken and other alcohol companies through donations to a private foundation that raises money for the NIH
- Design: PI and NIH were in close contact with funders regarding design of the study, but the protocol was "highly vetted" and reviewed. Trial was approved with full funding.
- What issues might be present? Or APPEAR to be present?
- The New York Times completed an investigation and ran story in March 2018. The story accused NIH employees of courting the alcohol industry, including giving talks strongly suggesting that the study's results would endorse moderate drinking as healthy.
- The study had attracted 105 participants and spent \$4 million before it was suspended.
- Trial was closed a few months after the NYT story.
- "Personnel actions" were taken against employees that violated policies.

Appearances Matter. An Apparent Col, real or not, can destroy public trust.

## Case Study: P-Hacking the Data

Data Analysis: P is the statistical significance variable.  
 A p-value of 0.05 or less is the long-accepted common standard for publication  
 in the era of Big Data, it can be tempting to p-hack to support your desired hypothesis!

Let's pick an example from a social science, that leads to strong "nudge" feelings for a desired outcome  
 Hypothesis: "The U.S. economy is affected by whether Democrats or Republicans are in office"

Before data is collected, variables need to be well-defined... because the nuances can change the answer.

Interest #1 : Find data to support your hypothesis

Interest #2: Make it into a publishable manuscript

Try it! <https://fivethirtyeight.com/features/science-snt-broken/#part1>

## Algorithm Red vs Algorithm Blue



<https://fivethirtyeight.com/features/science-snt-broken/#part1>

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### Case Study: Licensing IP

A researcher has an exceptional treatment planning algorithm and creates intellectual property (IP). A patent is issued, and the University is negotiating the license rights to a hot new start-up company for product development.

- Can the researcher invest in the company?
- What if the researcher is also the founder of that start-up company?

Idea: **Elimination** of conflict by not investing during negotiations. If researcher is a founder, **Recusal** from terms of negotiation.




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### What if you don't manage your CoI?

**Career and Reputation**

- Risk undeclared bias → irreproducible or misleading research results
- Risk of setting back the progress of science and patient care

**Punitive measures:**

- Violation of AAPM Code of Ethics, as well as any employer requirements
- If a complaint is lodged, could result in revocation of AAPM/ASTRO membership

**The failure to effectively manage such conflicts results in**

- **greater risk of personal and public mistrust**
- **reduced confidence in research results**
- **diminished public and patient support for medical research.**




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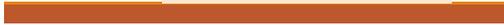
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### The Research Community System




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## Summary

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Conflicts of interest are pervasive in medical research, they are not inherently unethical.

Conflicts are not **only financial**, they can also be related to career advancement or power.

If you aren't actively keeping inventory and managing your conflicts, you are vulnerable bias.

Bias often operates on an unconscious level, impairing judgement.

**No one is free of bias or conflicts.** However, working together as a system where everyone has different biases, the research forefront can advance effectively.

This area is rapidly evolving further methods for managing conflicts and bias. Expect it to be context-specific. **Stay current on disclosure recommendations** and research practices.



## Thank You

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## Why are there so few Studies with Null Results?

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It has long been argued that Null studies are less publishable.

A more objective view comes from a 2015 [study published in PLOS ONE](#)

Followed how many **null results** were found in trials funded by the National Heart, Lung and Blood Institute

- before and after researchers were required to **register their protocols** at a public website
- Rule introduced in 2000 in part because of a general sense that researchers were subtly altering their work — after it was begun — to achieve positive results.
- In the 30 years before 2000, **57 percent** of trials published showed a "significant benefit."
- Afterward, only **8 percent** did.
- Conclusion: Researchers themselves suppress Null Results





## Solutions – Pro Moves for Data Analysis

### Create a Validation Process for your lab

- In house – split data into 2 independent groups,
  - Test your hypothesis on each one
  - Use separate data for literature based for hypothesis formation
- Get a collaborating group to independently validate your hypothesis with their own data
  - Write this into grant as a last step, provide another group funding to independently validate
    - Amit Sawant et al., [NCI CA1 09102: Personalized Motion Management for truly 4D Lung Stereotactic Body Radiotherapy](#)
    - Highly recommended practice for Senior Research Funding

### Be aware of & follow AAPM guidelines for research

- Code of Ethics, Ethics committee
- Newly forming Institute for New Technology Assessment, non-profit
- Guidance papers emerging on several topics

