

---

# Conflicts of Interest and Error and Negligence

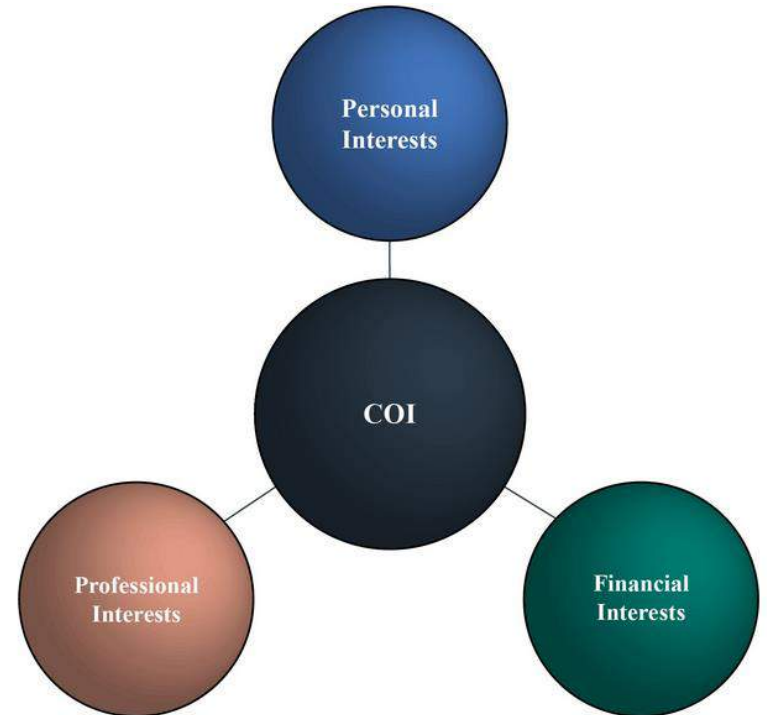
Sept. 17, 2018

RCR Course

# Conflict of Interest (COI)

---

- Legal term encompassing a variety of behaviors or actions involving personal gain or financial interest
- Any circumstance where personal, professional, financial, or other private interests of a person or institution compromise or have the potential to compromise the exercise of professional judgment or obligations, or may be perceived as doing so
- All of us have to file an annual financial conflict of interest disclosure with NIH



# Types of COIs

---

- **Gifts and gratuities**
  - Vendors use inducements to establish product recognition and to convince clients of the merits of their products. “These modest gifts and gratuities have become routine, accepted, and expected.”
  - Where do we draw the line? A magnet, a book, a lunch, a Red Sox game?
- **Compensation**
  - Speaker’s fees, honoraria, conference fee waivers, travel accommodations.
  - Consultantships: “A scientist-consultant must not transmit to a private business any information, records, or materials generated as a result of research sponsored by philanthropic foundations or government agencies unless the same information, records, or materials are made readily available to the scientific community in general.”

# Types of COIs

---

- **Multiple pay for one job**
  - Example: Federal grant supports a project and the PI is also in a paid leadership position of a company that supports a similar project in his/her lab
- **Nepotism**
  - Want to ensure equal opportunity to employment
  - Some organizations prohibit members of the same family from working in the same department. This can severely hinder two-career families.
  - What about people working as postdocs/staff scientists in the lab of their spouse?

# Types of COIs

---

- **Scientific conflict of interest**
  - Editor delays publication by a competitor
  - Reviewers uncritical of manuscripts favorable to a method or product in which they have a personal interest
  - Reviewing a proposal from a former student, close friend, or someone at the same institution
  - Expert witness for pay accused of giving misleading information.
  - But if trying to eliminate any and all perceived COIs, can sometimes exclude the most qualified scientists from giving important input.
- **Academic conflict of interest**
  - Using reputation or resources of employer for personal gain
  - Wealthy donor trying to influence research directions

# Types of COIs

---

- **Insider trading**
- **Institutional conflict of interest**
  - Involves IP and the financial interests of private companies
- **Equity Interests**
  - Start-up companies to commercialize research
  - Important to disclose possible COI to university administrators
- **Institutional prerogatives**
  - Universities may try to hide/suppress complaints about scientific misconduct and COIs, fearing a loss of grant funding and loss of prestige

# ACS and RSC COI Policies

---

- Both ACS and RSC require a statement describing any financial conflicts of interest or lack thereof is published with each manuscript. The statement should describe all potential sources of bias, including affiliations, funding sources, and financial or management relationships, that may constitute conflicts of interest.
- When recommending reviewers, authors should avoid reviewers with whom they have a COI (but as we discussed last week, if a significant amount of time has passed, disclosing the potential COI may not exclude that person from becoming a reviewer)

<http://pubs.acs.org/page/policy/ethics/index.html>

<http://www.rsc.org/journals-books-databases/journal-authors-reviewers/author-responsibilities/#code-of-conduct>

# MIT COI Policy

---

- MIT policy requires that researchers disclose certain financial interests, which disclosure enables MIT to determine if a financial interest creates a conflict of interest or the appearance of a conflict of interest. **The existence of a conflict or the appearance of one does not imply wrongdoing on anyone's part** and does not necessarily mean that a researcher may not retain his or her financial interest and undertake the affected research. Some conflicts must be eliminated, but often MIT can work with the researcher to manage a conflict or the appearance of a conflict so that the research can continue in a way that minimizes the possibility of bias in the research and preserves the objectivity of the research. Proper management of a conflict depends on full and prompt disclosure.
- **When in doubt, disclose.**



# Managing COIs

---

- **Elimination.** A financial COI may be eliminated by divestiture of equity interests; termination of the relationship that gives rise to the significant financial interest (such as consulting); abandoning the proposal; terminating the sponsored project; and similar measures
- **Management.** If the investigator does not want to eliminate a financial COI or the appearance of a financial COI and the institutional official determines that it can be managed, the investigator must develop a written management plan. The COI officer will assist the investigator in developing the plan.
  - Public disclosure to human participants or when presenting research
  - Appointment of independent monitor or oversight committee
  - Expedited dissemination of results so related entity does not receive preferential access

# Research Misconduct

---

- *Fabrication, falsification, or plagiarism* in proposing, conducting, reviewing or reporting research; that
- Seriously deviates from professional norms in that discipline,  
AND
- Has been committed intentionally, knowingly or recklessly;  
AND, that
- Has been proven by a preponderance of the evidence (more likely than not)

Misconduct does not include honest error or honest differences in interpretations or judgments of data. Significant departure from accepted ethical practices of the relevant research community will be treated as violations of the Academic Faculty and Administrative Professional Manual or of the Graduate School Academic Integrity policy.

# NSF: CFR Part 689

---

- (a) Research misconduct means fabrication, falsification, or plagiarism in proposing or performing research funded by NSF, reviewing research proposals submitted to NSF, or in reporting research results funded by NSF.
- (1) ***Fabrication*** means making up data or results and recording or reporting them.
- (2) ***Falsification*** means manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- (3) ***Plagiarism*** means the appropriation of another person's ideas, processes, results or words without giving appropriate credit.
- (4) Research, for purposes of paragraph (a) of this section, includes proposals submitted to NSF in all fields of science, engineering, mathematics, and education and results from such proposals.
- (b) Research misconduct does not include honest error or differences of opinion.

# Motivation Behind Misconduct

---

- David Goodstein (Caltech): “In the cases of scientific fraud that I have looked at, three motives, or risk factors have always been present. In all cases, the perpetrators,
  - were under career pressure;
  - knew, or thought they knew what the answer would turn out to be if they went to all the trouble of doing the work properly, and
  - were working in a field where individual experiments are not expected to be precisely reproducible.”
- Usually, motives are self-interested

# How Common is Research Misconduct?

- 2005 survey of thousands of NIH-funded scientists:

“ Our findings suggest that US scientists engage in a range of behaviors extending far beyond falsification, fabrication and plagiarism.”

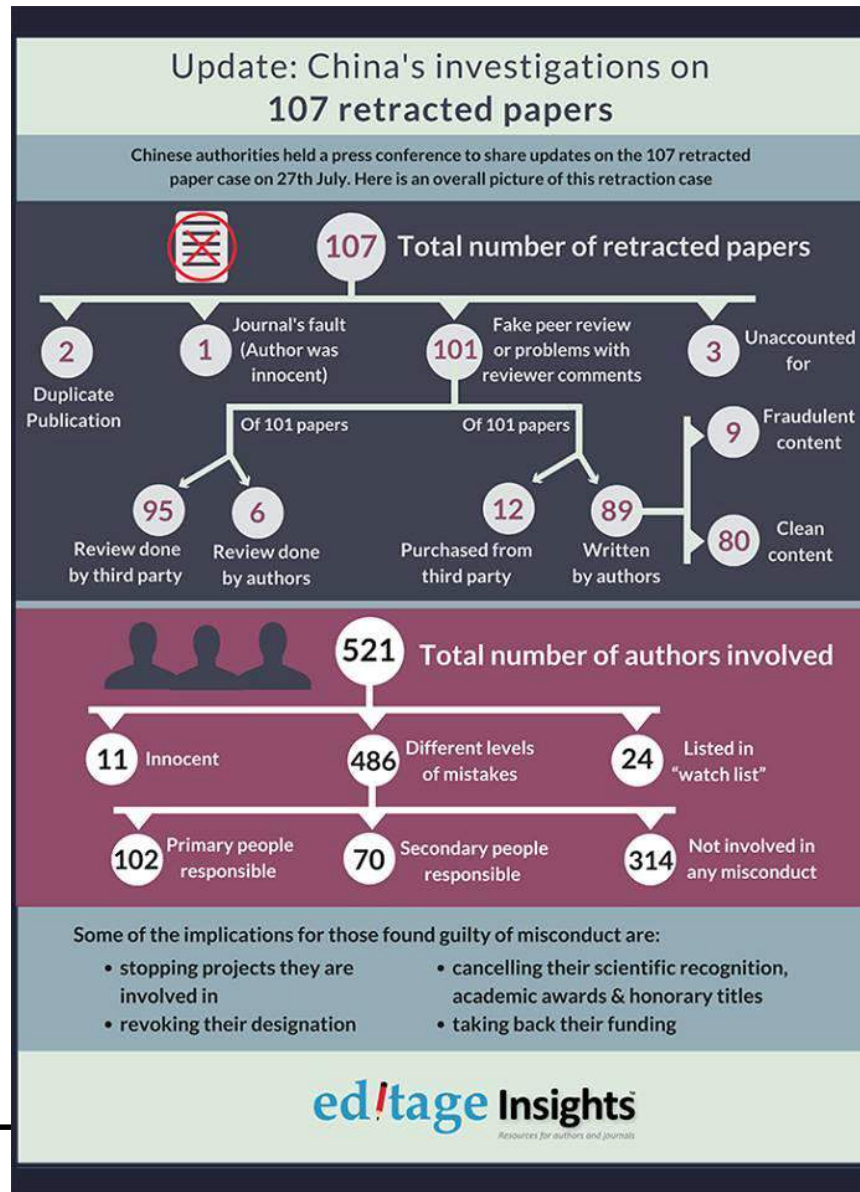
“Certain features of the working environment of science may have unexpected and potentially detrimental effects on the ethical dimensions of scientists’ work.”

**Table 1 | Percentage of scientists who say that they engaged in the behaviour listed within the previous three years (n = 3,247)**

Top ten behaviours	All	Mid-career	Early-career
1. Falsifying or 'cooking' research data	0.3	0.2	0.5
2. Ignoring major aspects of human-subject requirements	0.3	0.3	0.4
3. Not properly disclosing involvement in firms whose products are based on one's own research	0.3	0.4	0.3
4. Relationships with students, research subjects or clients that may be interpreted as questionable	1.4	1.3	1.4
5. Using another's ideas without obtaining permission or giving due credit	1.4	1.7	1.0
6. Unauthorized use of confidential information in connection with one's own research	1.7	2.4	0.8 ***
7. Failing to present data that contradict one's own previous research	6.0	6.5	5.3
8. Circumventing certain minor aspects of human-subject requirements	7.6	9.0	6.0 **
9. Overlooking others' use of flawed data or questionable interpretation of data	12.5	12.2	12.8
10. Changing the design, methodology or results of a study in response to pressure from a funding source	15.5	20.6	9.5 ***
<b>Other behaviours</b>			
11. Publishing the same data or results in two or more publications	4.7	5.9	3.4 **
12. Inappropriately assigning authorship credit	10.0	12.3	7.4 ***
13. Withholding details of methodology or results in papers or proposals	10.8	12.4	8.9 **
14. Using inadequate or inappropriate research designs	13.5	14.6	12.2
15. Dropping observations or data points from analyses based on a gut feeling that they were inaccurate	15.3	14.3	16.5
16. Inadequate record keeping related to research projects	27.5	27.7	27.3

Note: significance of  $\chi^2$  tests of differences between mid- and early-career scientists are noted by \*\* ( $P < 0.01$ ) and \*\*\* ( $P < 0.001$ ).

# How Common is Research Misconduct?



# Fabrication: Marc Hauser

---

- Evolutionary biologist Marc Hauser resigned from Harvard in 2011 after being found guilty of scientific misconduct. He had been considered a leader in his field.
- A federal report alleged that:

“Hauser **fabricated** data in a 2002 Cognition paper that was later **retracted**, which examined monkeys’ ability to learn patterns of syllables. He never exposed monkeys to a particular sound pattern described in the experiment, despite reporting the results in a graph.”

“In two experiments, researchers measured monkeys’ responses to patterns of consonants and vowels, a process called “coding” their behavior. Hauser **falsified** the coding, causing the results to pass a statistical test used to ensure that a particular finding was not just a chance result. Colleagues coding the same experiments came up with different results. Hauser “acknowledged to his collaborators that he miscoded some of the trials and that the study failed to provide support for the initial hypothesis,” the report said.”

# Fabrication: Marc Hauser

---

- “[Cognition editor Gerry] Altmann said that Hauser had made positive contributions to his field, but that the shortcuts described in his experiments were unacceptable. Informally, he said, the field now recognizes some of his findings—such as the one that was retracted from the journal Cognition in 2010—as unlikely to be successfully repeated, but no formal investigation is planned of his vast body of work.”
- How does fabrication affect a researcher’s reputation?
- Hauser has neither denied nor admitted to research misconduct, only “mistakes.” What responsibilities should researchers have in the wake of misconduct allegations?

<https://www.boston.com/uncategorized/noprimarytagmatch/2012/09/05/for-mer-harvard-professor-marc-hauser-fabricated-manipulated-data-us-says#>

---



# Fabrication and Falsification: Recent Example

---

- A former NIH postdoc recruited to a tenure-track position last year committed multiple acts of misconduct in two papers, according to the U.S. Office of Research Integrity. The two papers — a 2016 paper in *Cell* and a 2015 paper in *PNAS*

“Shortly following publication, a lab with whom we had shared reagents noticed that cell lines that were supposed to be stably expressing GFP-FMN2 were not. We subsequently found that a western blot in the paper had been inappropriately manipulated and that multiple cell lines were not as reported. When we constructed and validated new cell lines and reagents, our attempts to reproduce critical results in the paper were unsuccessful.”

The infractions included using **fabricated primary data, and selectively omitting or including data points.**

“The misconduct occurred while she was completing a postdoc in the Cell Biology and Physiology Center at the National Heart, Lung, and Blood Institute. Last year, The Cancer Prevention and Research Institute of Texas (CPRIT) announced that Skau was among eight targets of a recruitment grant; the grant, totaling \$2 million USD, was designed to help entice her to accept a tenure-track position at the University of Texas Southwestern Medical Center.”

# Plagiarism

---

- “In scientific writing, perhaps the most widely recognized unethical lapse is plagiarism. Plagiarism can occur in many forms and some of the more subtle instances, while arguably unethical in nature, may not be classified as scientific misconduct by federal agencies such as the National Science Foundation (NSF) or the Office of Research Integrity (ORI). Nevertheless, the ethical professional is expected to operate at the highest levels of scientific integrity and, therefore, must avoid all forms of writing that could be conceptualized as plagiarism.” --Roig
- Two elements
  - *Attribution*
    - › Attribute specific idea or words to another
  - *Documentation*
    - › Site the source of the idea or words
- “Common knowledge” does not need to be attributed or documented
- Definition of plagiarism is not static
  - Definition changes across time and space

# There are many ways to plagiarize

---

- Many types of plagiarism exist; some are obvious and some are not. A writer must know what constitutes plagiarism because ignorance of the facts will not excuse him or her from the consequences. The University of Pittsburgh's undergraduate plagiarism policy (University of Pittsburgh, 2008) lists examples of plagiarism:
- Copying text "as is" **without quotation** marks and with no citation or source.
- Reordering the elements of the source text **without citation**.
- Copying pieces (sentences, key phrases) of the source text **without citation**.
- Paraphrasing **without citation**.
- Reproducing information that is not common knowledge or self-evident **without citation**.
- Incorporating an idea heard in conversation **without citation**.
- Using your own past material or another student's material as a new idea **without citation**.
- Paying for another to contribute to your work **without citation**.
- Using software or online translators to translate material **without citation**.
- Paying someone else to do your work, purchasing material, or translating from someone else's material (web-based or hard copy). (Calvano, 2011, p.1)

# There are many ways to plagiarize

---

- Self-plagiarism occurs when authors reuse their own previously written work or data in a ‘new’ written product without letting the reader know that this material has appeared elsewhere.
  - Redundant and duplicate publications
  - Data fragmentation / data augmentation
  - Text recycling
- Other “misdemeanor” unethical writing practices
  - Relying only on the abstract for content of a cited source
  - Citing sources that were not read or thoroughly understood

# COI Case Study I

---

- Dr. Zhang is funded by a federal research grant to study the effect of physical tension on the production of hormones by endocrine cells in culture. She is assisted in this project by her research assistant, Mr. Singh. Dr. Zhang and Mr. Singh design a culture dish with a flexible bottom. After the endocrine cells have attached to the flexible bottom of the culture vessel, it is possible to stretch the cells, subjecting them to physical tension. Dr. Zhang wants to purchase 100 of these custom-designed vessels, with immediate delivery. Mr. Singh tells Dr. Zhang that he has two brothers who own a small plastics fabrication business, and they could produce the customized dishes quickly. Dr. Zhang prepares a sole-source purchase request for the custom dishes, at a cost of \$7500, charged to her federal grant. The fiscal administrator denies the requisition on the grounds that this purchase constitutes a conflict of interest. Dr. Zhang argues that the selection of this supplier is justified because they are getting a special rate and rapid delivery because of Mr. Singh's relationship with the company. The issue is brought to you for resolution. Who is affected by this action and how? What are the potential benefits or negative consequences of this transaction?

# COI Case Study II

---

- Ms. Jobs is completing her degree at Research University. She has conducted some successful and exciting research in the laboratory of Dr. Keene. Dr. Keene's project was supported in part by a research contract with Innovations, Inc. Dr. Keene and the members of his laboratory developed new, rapid, accurate assays that can be adapted to kits for direct sale to the public. Innovations, Inc., is considering developing and marketing these kits but has not made a definite decision. Leaper Enterprises offers Ms. Jobs a position in a new unit of the company to apply her training to develop kits based on the technology that she learned and helped develop in Dr. Keene's laboratory. Discuss any conflict Ms. Jobs may have in accepting a position in a company that competes with Dr. Keene's sponsor. How is the situation altered if Ms. Jobs was paid or not paid by funds from Innovations, Inc., while a student?

# Twitter from Benjamin Kerr @evokerr

---

- “I am really proud of a grad in our group, but not for the reasons most commonly shared on Twitter... She got some very tough experimental results that cast serious doubt on an exciting interpretation of a long-term project. Despite how much effort she had invested & how hard the results were to process, she conducted careful & creative follow-up work to figure things out. Sadly, *the challenging results were real and our earlier exciting interpretation evaporated*. The reasons we were misled were very subtle, but she untangled them. Further, she fully embraced how the results could change the project. Of course, she was upset (as was I) but she took genuine solace in understanding what was actually happening in her system, and that she had figured it out. In addition to her incredible resilience, she showed how she appreciates science as a process, rather than a product. *Although efforts like hers are sometimes unsung, they are at the very core of what it means to be a scientist*: to wrestle with data, to reconcile discord between data and a model, and to countenance the abandonment of a model when the data demands it. *I think we need to continually recognize that being a scientist requires courage to take challenging data seriously, strength to design and execute follow-up research that may destroy your pet ideas, and a commitment to honestly integrate everything to form new ideas*. These foundational elements aren't always easy to implement, but it is possible to embrace all of these things- a grad in our group did just that, and I'm very proud of her.
- **How could the situation have been avoided?**
- **At what point did the situation get out of control?**
- **How should/does the public view of science influence our research and how we report it?**