

UC San Diego

RESEARCH COMPLIANCE AND INTEGRITY

Research Compliance and Integrity Hot Topics Session
October 9, 2024

UC San Diego

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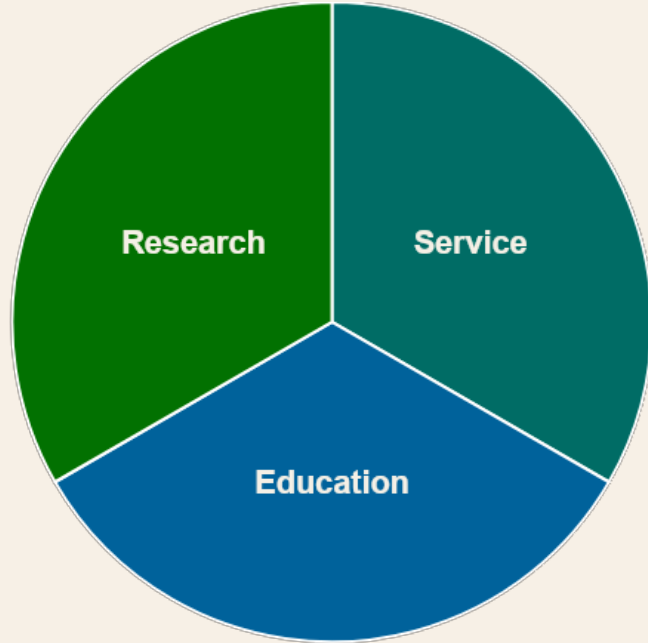
- Conflict of Interest (COI)
- Dual Use Research of Concern (DURC)
- Export Control and Facility Security
- Institutional Animal Care and Use Committee (IACUC)
- Research Ethics and Integrity (Research Misconduct)
- ClinicalTrials.gov, NIH Good Clinical Practices (GCP) and Responsible Conduct of Research (RCR) Compliance
- General Research Compliance Activities

Website: RCI.UCSD.EDU

Helpline: (858) 822-4939

Email: rci@ucsd.edu

UC San Diego Research Ethics Program



The Research Ethics Program fosters a campus learning community to examine the ethical, legal and social implications when planning, conducting and reporting research.

The Promise and Pitfalls of the Academic Research Ecosystem: Root Causes and Strategies for Improvement

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Director, UCSD Research Ethics Program

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Asst Professor, School of Public Health

Session Objectives

By the end of this session, you will know or be able to:

- Describe several examples research misconduct (fabrication, falsification and plagiarism (FFP)) and questionable research practices (QRPs)
- Apply an ecological systems model to explore possible root causes of FFP and QRPs
- Using the ecological systems model, know how each “layer” of the system can contribute to positive change to improve the “health” of the research ecosystem.

Briefing | Unreliable research

Trouble at the lab

Scientists like to think of science as self-correcting. To an alarming degree, it is not

The screenshot shows the NPR website interface. At the top, there is a navigation bar with the NPR logo (npr) on the left and links for NEWSLETTERS, SIGN IN, and NPR SHOP on the right. Below this is a dark grey navigation bar with icons and text for NEWS, CULTURE, MUSIC, PODCASTS & SHOWS, and a SEARCH icon. The main content area is white and features the word "EDUCATION" in a small font. Below it is the main headline: "Stanford president resigns after fallout from falsified data in his research". At the bottom of the article preview, it says "UPDATED JULY 20, 2023 · 6:36 PM ET".

The screenshot shows the AP News website interface. At the top, there is a navigation bar with the AP logo on the left and a menu icon followed by links for WORLD, U.S., ELECTION 2024, POLITICS, SPORTS, ENTERTAINMENT, BUSINESS, SCIENCE, FACT CHECK, ODDITIES, and NEWSLETTERS. Below this is a dark grey bar with a red dot and the text "Live updates: Baltimore bridge collapse", "RFK Jr. running mate", "Bird flu", "'Diddy' investigation", and "Israel-Hamas war". The main content area is black and features the text "U.S. NEWS" in a small font. Below it is the main headline: "Plagiarism probe finds some problems with former Harvard president Claudine Gay's work".

<https://apnews.com/article/harvard-president-plagiarism-claudine-gay-14330935453134c7c9c9a9c496020568>

<https://www.npr.org/2023/07/19/1188828810/stanford-university-president-resigns#:~:text=Stanford%20president%20resigns%20in%20wake%20of%20falsified%20data%20in%20academic%20papers%20%3A%20NPR&text=Food%20Stanford%20president%20resigns%20in%20wake%20of%20falsified%20data%20in%20academic,of%20his%20lab%20who%20did.>

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Retractions are on the rise (more than ever)!

nature

Explore content ▾ About the journal ▾ Publish with us ▾ Subscribe

[nature](#) > [news](#) > article

NEWS | 12 December 2023

More than 10,000 research papers were retracted in 2023 – a new record

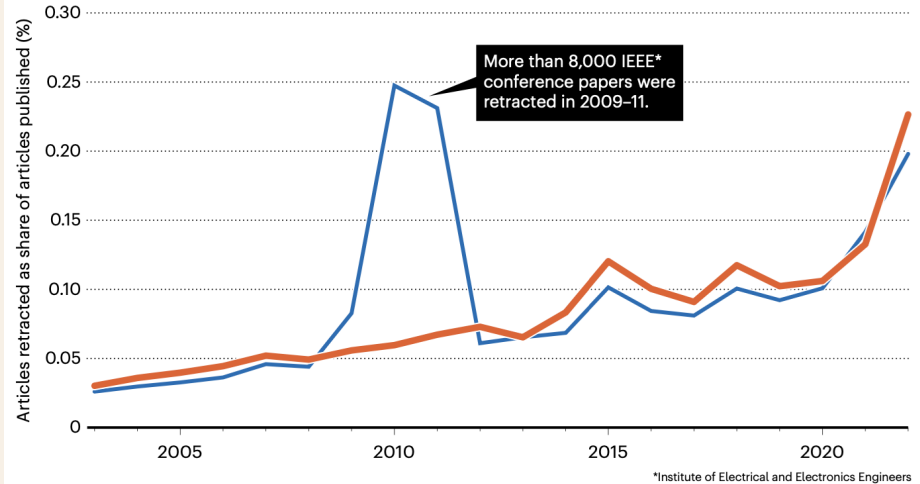
The number of articles being retracted rose sharply this year. Integrity experts say that this is only the tip of the iceberg.

<https://www.nature.com/articles/d41586-023-03974-8>

RISING RETRACTION RATES

The ratio of retracted papers to articles published has risen to above 0.2%.

— Including conference papers — Excluding conference papers





1-2% of all papers estimated to be fraudulent.

How many more don't get caught (lower tier journals)?

34-72% of researchers report 'questionable research practices'

Research Integrity

- Pre-registration
- Open data
- Open code
- Version control

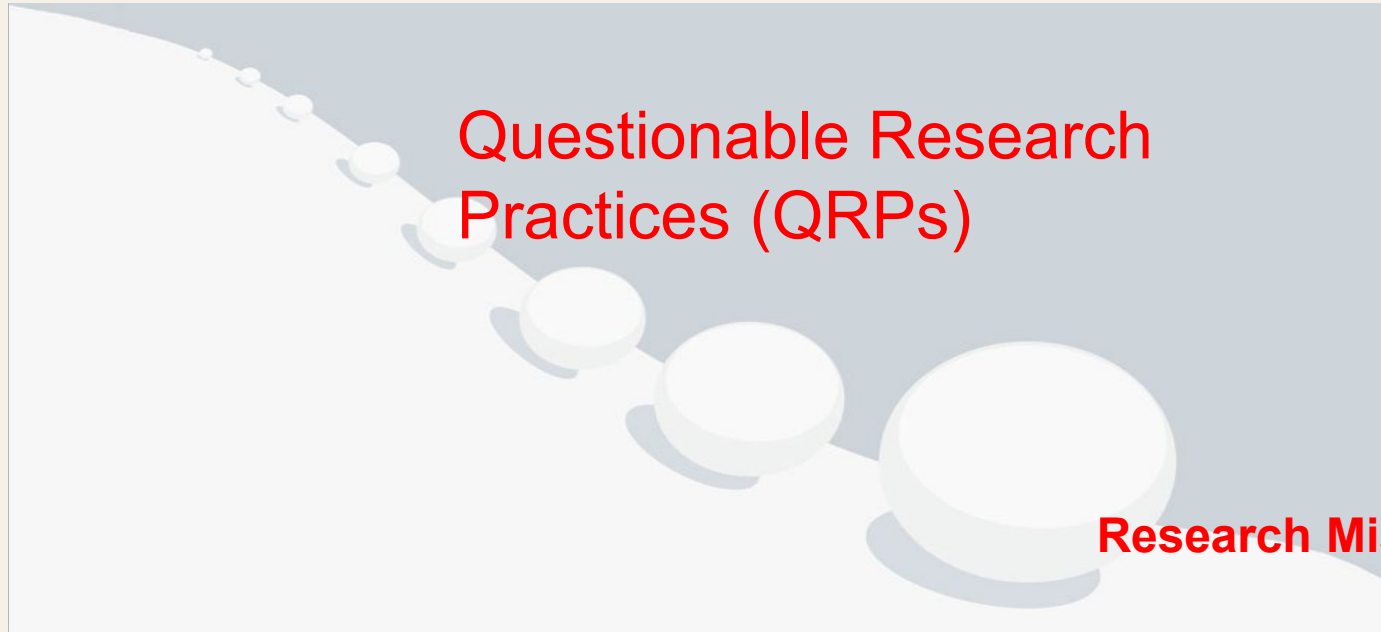
Questionable Research Practices

- P-hacking
- Inappropriate design, analysis, or validation
- Ghost authors
- Withholding contradictory data
- Misuse of peer review system

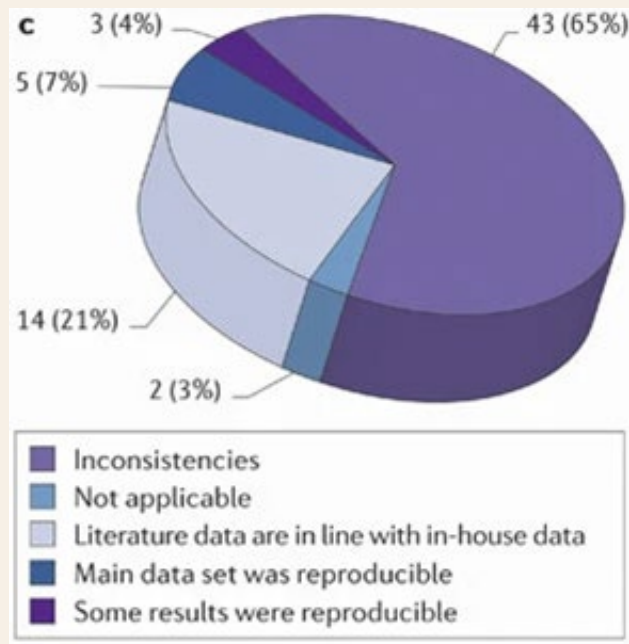
Research Misconduct

- Fabrication
- Falsification
- Plagiarism

Scientific Integrity



Pharma reproducibility studies

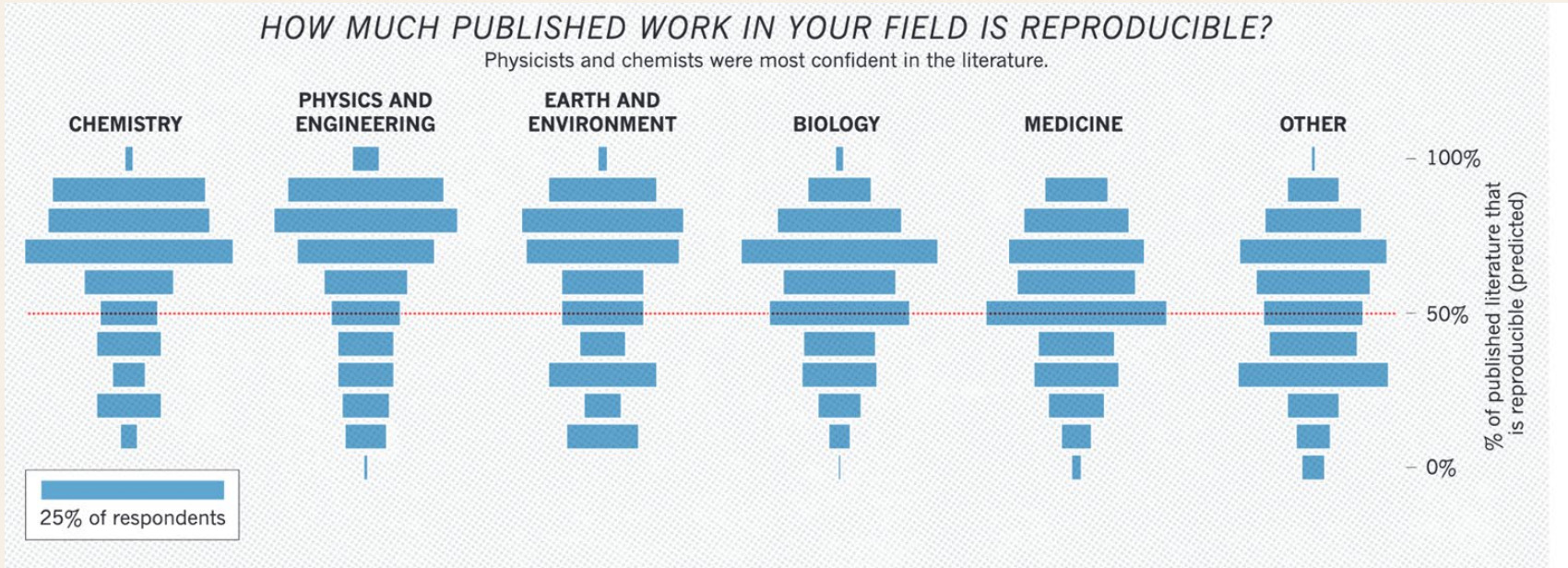


Journal Impact factor	Number of articles	Mean citations for non-reproducible articles	Mean citations for reproducible articles
High (>20)	21	248	231
Middle (5-19)	32	169	13

<https://www.nature.com/articles/nrd3439-c1>

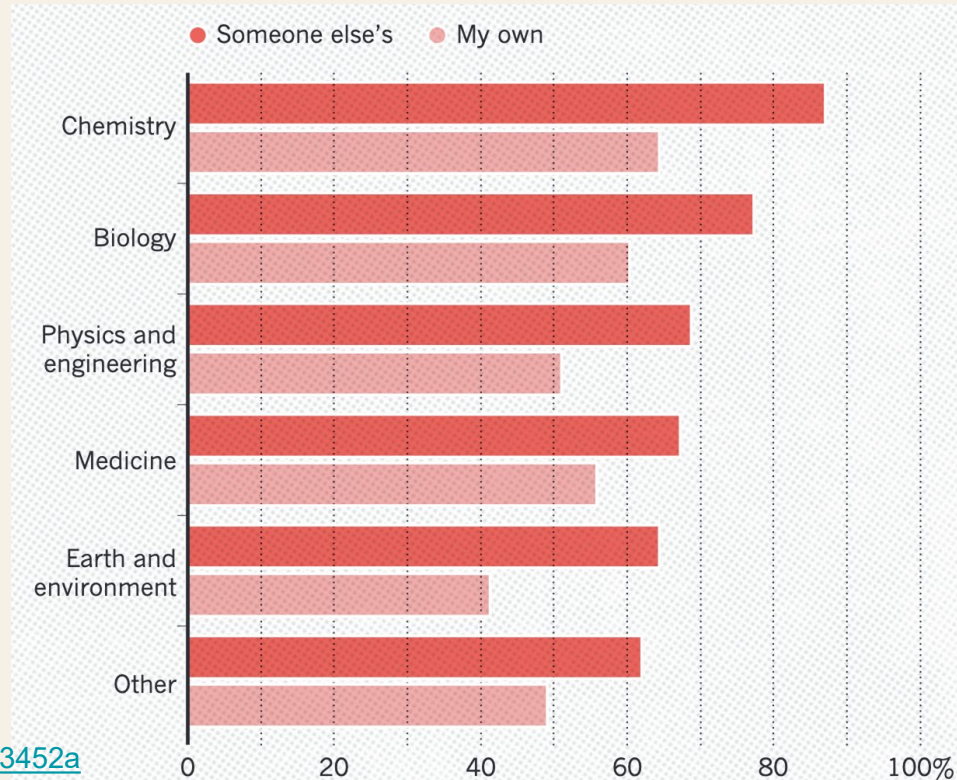
<https://www.nature.com/articles/483531a>

Nature survey of 1,576 scientists



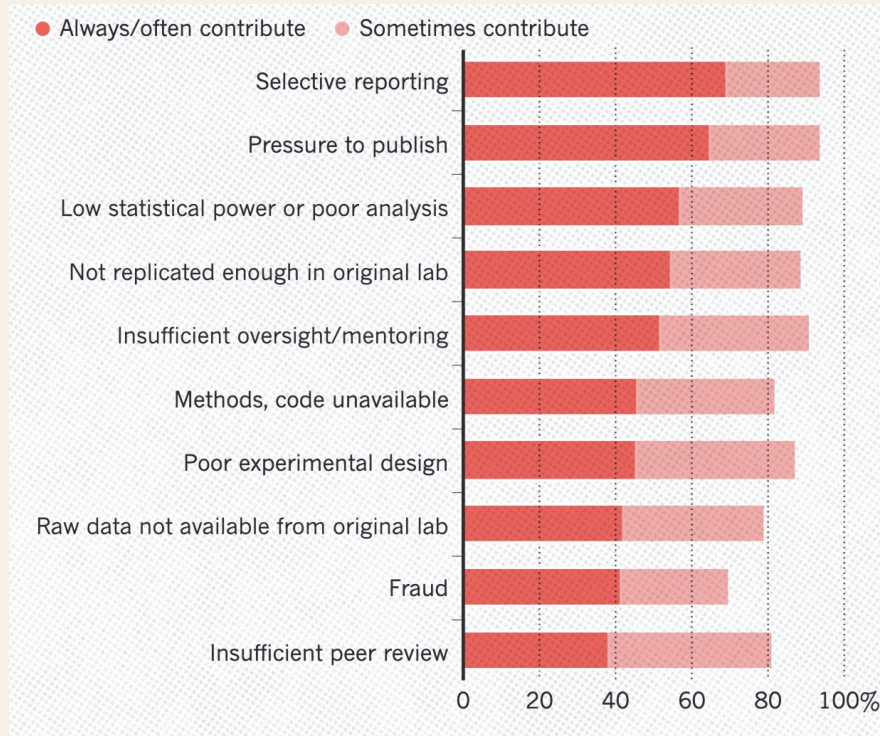
<https://www.nature.com/articles/533452a>

Have you failed to reproduce an experiment?



<https://www.nature.com/articles/533452a>

What factors contribute to irreproducible research?



<https://www.nature.com/articles/533452a>

Reasons for non-reproducible results

Part of the Scientific Process

1. Study differences
 - Design
 - Definitions/Methods
 - Population
 - Analysis
2. Strength of effect
3. Statistical power
4. Chance
(regression to the mean)

Sloppy Science

1. **Design:** Lack of methodological details, raw data, and research materials.
2. **Execution:** Misidentified or cross-contaminated materials.
3. **Management:** Mismanagement of datasets

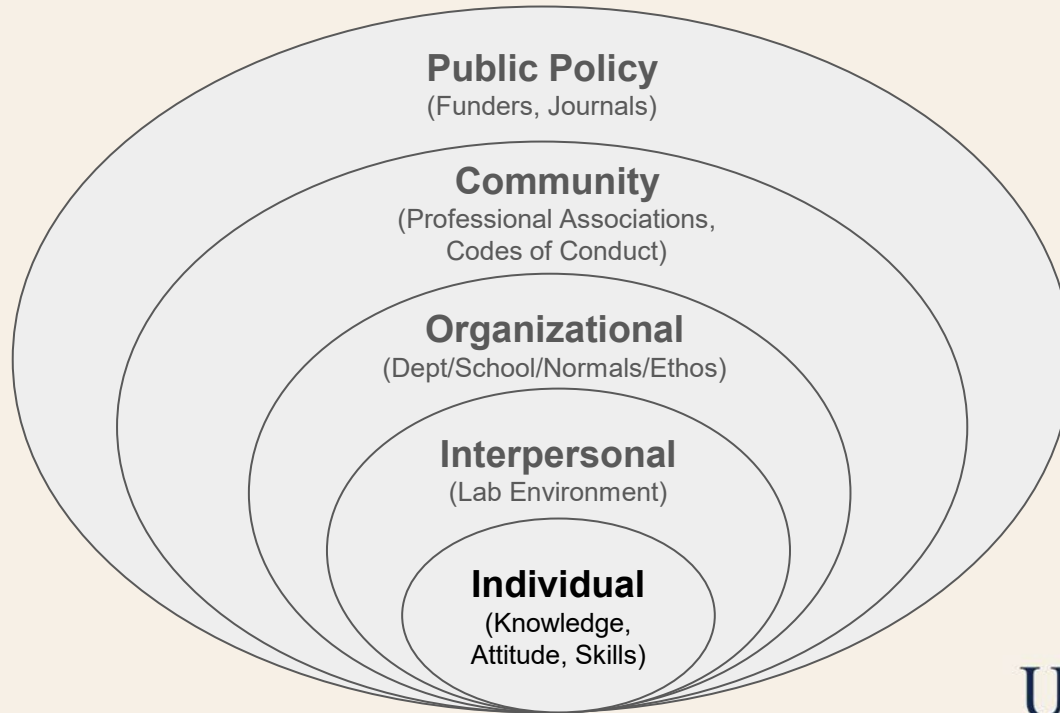
The System

1. **Culture:** A competitive culture that rewards novel findings and undervalues negative results (eg, publication bias)
2. **Psychological:** Cognitive bias
3. **External:** Conflicts of interest

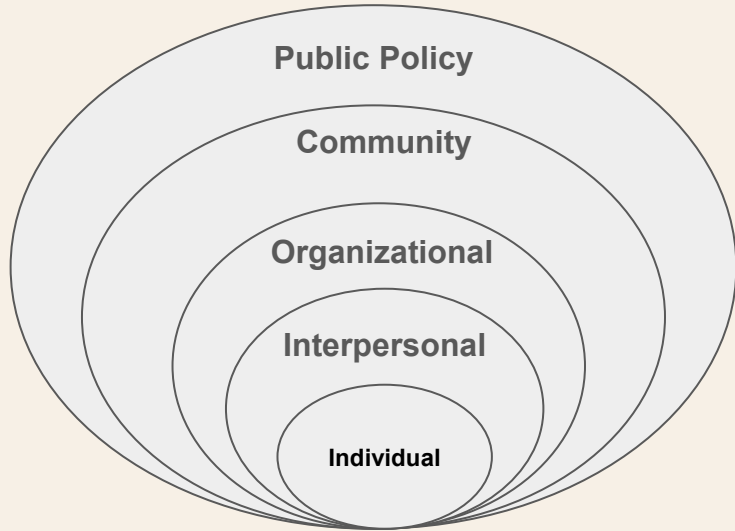
How can we change things?

Breaking down the problem

Behavioral/Social Ecological Systems Model



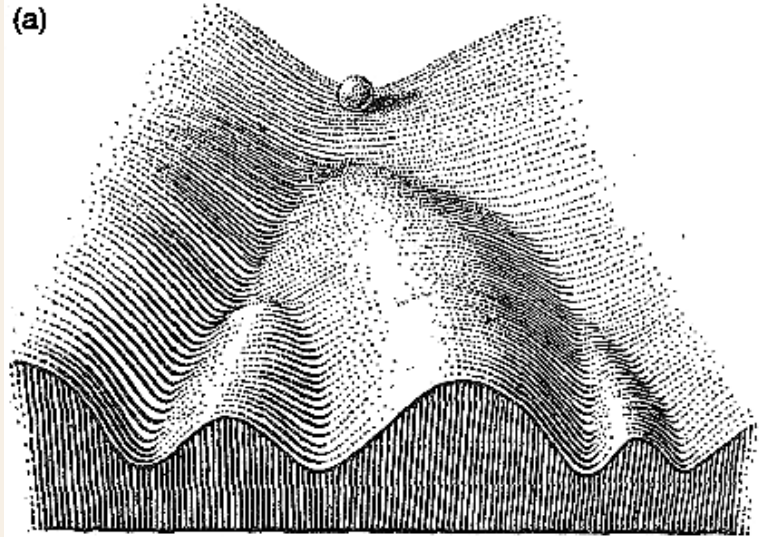
Ecological Model: Known “drivers”



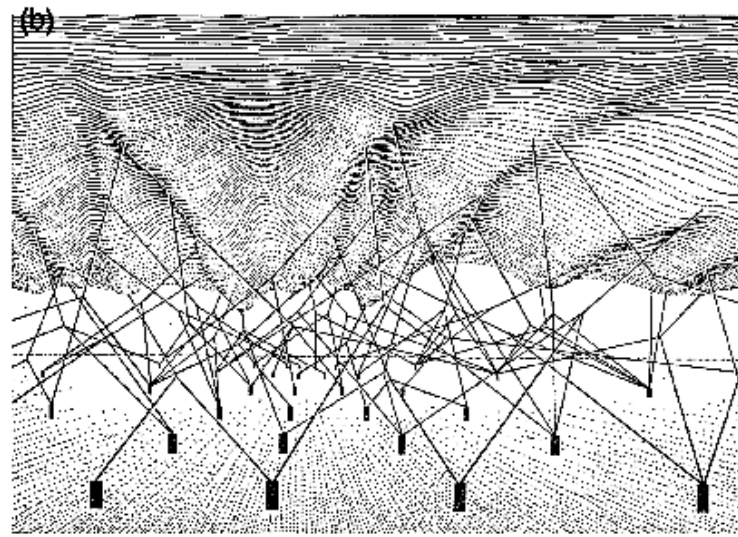
Grad student	Graduating and Job Hunt
PI	Time/Bandwidth and Funding
Reviewers	Limited time and Scope of duties
QC system	Formal checks are inadequate. Detailed checks are informal. Limited funding for ‘science sleuths’
3rd parties	Paper mills
Journals	Journal revenue
University & NIH	Reward system (“Publish or Perish”)

Structural landscapes change root causes

Waddington's Epigenetic Landscape



Systems settle in paths of least resistance.



Many factors shape the landscape.

Root causes & Structural solutions (SORDS)

Solution

Align incentives with values – not progress at all costs

Root causes



Drivers

POOR SUPERVISION “ I WAS SCARED TO GO TO [MY PI]. HE USED TO SCREAM & YELL AT ME WHEN THINGS DID NOT WORK AS PLANNED. ”	INADEQUATE TRAINING “ AFTER TWO YEARS OF A POSTDOCTORAL FELLOWSHIP... I STILL DON'T KNOW HOW TO PROPERLY PUBLISH WESTERN BLOT DATA. ”
COMPETITIVE PRESSURES “ I FELT IT WAS NECESSARY TO GET A PAPER IN A HIGH-PROFILE JOURNAL IN ORDER TO GET A FACULTY POSITION. ”	
PERSONAL CIRCUMSTANCES “ [I] HAD BEEN APPLYING FOR A GREEN CARD AND FELT PRESSURED TO MAKE A GOOD PAPER AND GET GOOD PUBLICATIONS. ”	INDIVIDUAL PSYCHOLOGY “ HALF OF ME WANTED TO MAKE [MY PI] PROUD. THE OTHER HALF WAS TERRIFIED OF FAILING... SO I FABRICATED A PIECE OF DATA. ”

Symptom



<https://ori.hhs.gov/what-drives-people-commit-research-misconduct>

<https://undsci.berkeley.edu/understanding-science-101/the-social-side-of-science-a-human-and-community-endeavor/the-scientific-community-and-misconduct/>

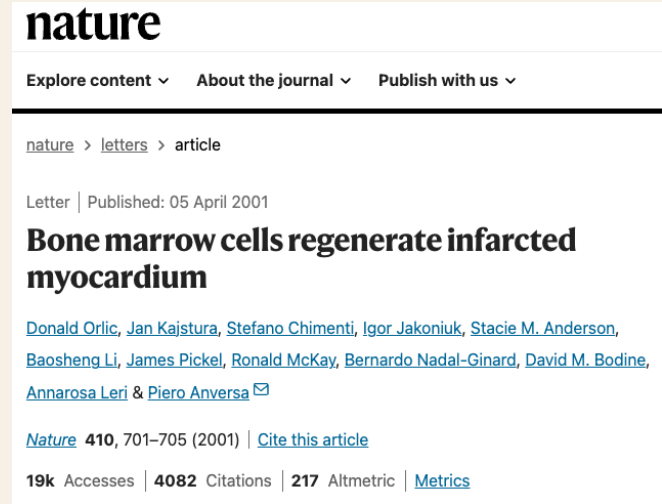
Case Study: Dr. Piero Anversa

Case study: Dr. Piero Anversa (Harvard)

- Anversa's [Nature publication in 2001](#) showed that stem cells can be used to regenerate damaged heart tissue.
- In 2013, he was accused of and later found to have falsified and/or fabricated data in 31 publications
 - Harvard refused to disclose which papers/journals
 - Only 19 of 31 papers retracted
 - Journals claimed to have handled the matter appropriately

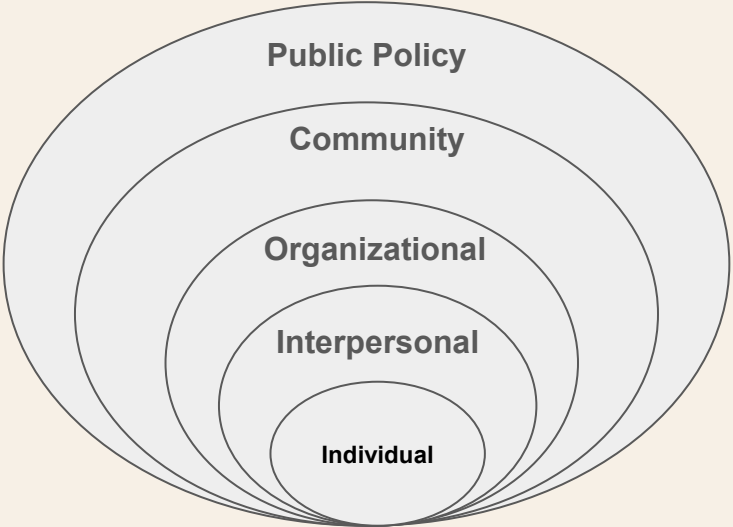
<https://www.nature.com/articles/35070587>

<https://www.reuters.com/investigates/special-report/health-hearts-stem-cells/>



The screenshot shows the top portion of a Nature article page. At the top is the 'nature' logo. Below it are navigation links: 'Explore content', 'About the journal', and 'Publish with us'. The breadcrumb trail reads 'nature > letters > article'. The article is identified as a 'Letter' published on '05 April 2001'. The title is 'Bone marrow cells regenerate infarcted myocardium'. The authors listed are Donald Orlic, Jan Kajstura, Stefano Chimenti, Igor Jakoniuk, Stacie M. Anderson, Baosheng Li, James Pickel, Ronald McKay, Bernardo Nadal-Ginard, David M. Bodine, Annarosa Leri, and Piero Anversa. Below the authors, there is a link to 'Cite this article' and a summary of metrics: '19k Accesses | 4082 Citations | 217 Altmetric | Metrics'.

Ecological Model: Drivers of misconduct



NIH	
<i>Nature</i> (Publisher)	
Journal reviewers	
Harvard	
Department	
PI	
Postdoc/GSR	

SORDS: Anversa case study (NIH)

Solution

Root causes

Drivers

Symptom

- Funding requirements:
 - Publish in approved journals
 - Data sharing committees
 - Funding penalties for violators (Authors, Journals, Institutions)
- *Carrots*: Incentives don't align with values
 - *Sticks*: Poor enforcement
- Infrastructure for QC left to the PIs
 - External incentives (funding, career advancement, fame) favor 'impact at all costs'
- Rising number of retracted papers

SORDS: Anversa case study (Journal)

Solution

- Non-profit or government-run “journals”
- Refine review process
 - More reviewers
 - Broader expertise
 - Focused requests
 - Include data sharing/checking

Root causes

- Journals are a business (*ie*, profits matter)
- Journals consider themselves as a publication platform (QC is responsibility of authors)
- Reviewer bandwidth & expertise

Drivers

- High impact papers (“firsts”) are valued
- Lack of safeguards

Symptom

- Rising number of retracted papers

SORDS: Anversa case study (PI)

Solution

- Lab management training and/or hiring
- Incentivize more values than 'productivity' and impact (eg, reproducibility, data usage)

Root causes

- Indicative of future productivity
- “Being the first” (exciting and fast) >>> “Getting it right” (mundane and slow)
- No lab management training or infrastructure support

Drivers

- Job security: publication pressures (number and impact)
- Limited bandwidth
- Lack of safeguards
- “Point of no return”

Symptom

- Data falsification and fabrication

Are institutions incentivized to allow or quash misconduct?

- Anversa brought in \$32.7M (direct) and \$17.9M (indirect) in funding after 2001.
 - NIH spent >\$588M on research in this area
 - >\$259M of which was awarded after the research fraud was made public.
 - AHA spent \$73M on this area of research
 - 5,000 people worldwide (including babies) received stem cells in their hearts during this period.
- Epilogue: Dr. Anversa's institution paid the NIH \$10M

How do we make misconduct “bad for business?”

Consequences of irreproducibility of research

1. Harms the public
2. Lowers scientific output efficiency -> Slows scientific progress
3. Wastes time and money -> Erodes the public's trust in scientific research

Estimated cost of irreproducible preclinical research in the U.S. = **\$28B/year**

<https://www.nature.com/articles/d42473-019-00004-y#ref-CR3>
<https://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.1002165>

Conclusion

- Research misconduct is on the rise. (Existential threat to science).
- Incentives are not always aligned with the values of the scientific community.
- All parties in the research ecosystem have a role to play in reducing Questionable Research Practices.
 - In turn, that may reduce activities that lead to Research Misconduct.

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Discussion

How would you rate your own research ecosystem? (1=Bad ... 10=Great)

What do they do well?

What change would have the greatest positive impact?

COMMUNICATIONS

- Research Compliance and Integrity Helpline: (858) 822-4939, rci@ucsd.edu
 - RCI Office Hours, Tuesdays from 11-12: <https://calendly.com/ucsdrciooffice>
- Conflict of Interest Helpline: (858) 534-6465, info-coi@ucsd.edu
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<https://blink.ucsd.edu/sponsor/rci/research-compliance-hot-topics.html>
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