Creating a Positive Environment for Fostering Research at MUSC

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Learning Objectives

- What constitutes research misconduct?
- What steps does MUSC take towards preventing research misconduct?
- How would someone report potential research misconduct?
- What is the process for addressing an allegation of potential research misconduct?
- What protections are affirmed for "whistleblowers"?



Definition of Research Misconduct

The US Health and Human Services (HHS) Office of Research Integrity defines Research Misconduct in 3 Categories:

- 1. Fabrication
- 2. Falsification
- 3. Plagiarism



What is Research Misconduct?

Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.



1) Fabrication

Fabrication is making up data or results and recording or reporting them.



2) Falsification

Falsification is 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

Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Note: This does not include most authorship disputes.

Visit the Office of Research Integrity Website



Why do otherwise intelligent people commit research misconduct?

Career Pressure

- Scientists depend on a good reputation for funding, this relies on the publication of high-profile papers.
- "Publish or Perish"
- This may motivate desperate (or fame-hungry) scientists to fabricate results.

Ease of Fabrication

- Results are difficult to reproduce accurately. .. if a scientist does falsify data, they can expect to get away with it – or at least claim innocence....
- No "scientific police", investigations are made by experts in science but amateurs in dealing with criminals. ..Relatively easy to cheat and difficult to know how many fabricate data.

The Very Nature of Research Selects For Driven Individuals

http://cliparts.co/speed-limit-sign-clip-art

startrek-boldlygo.jpg

http://www.pbase.com/csw62/image/51296041



Lack of integrity leading to findings of research misconduct are increasingly in the news

- University Suspects Fraud by a Researcher Who Studied Red Wine
- "A charge of widespread scientific fraud, involving 26 articles published in 11 journals, was leveled by..."

Lack of integrity leading to findings of research misconduct are increasingly in the news (Continued)

- An Unwelcome Discovery
- "...fabricating more than a decade's worth of scientific data on obesity, menopause and aging, much of it while conducting clinical research as a tenured faculty member at the University of Vermont."

Common lapses in research integrity in human subjects research

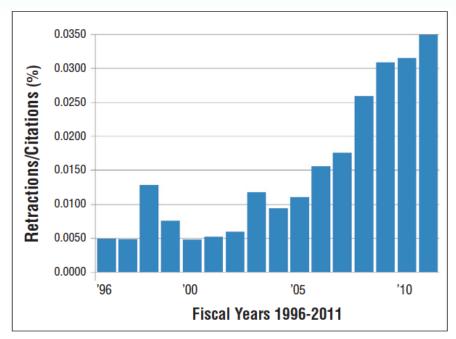
- Failure to report all data
- Fabrication of data to match number of reported subjects
- Falsification of data on study report forms
- Failure to report all adverse events/reactions or serious adverse events/reactions related to the study

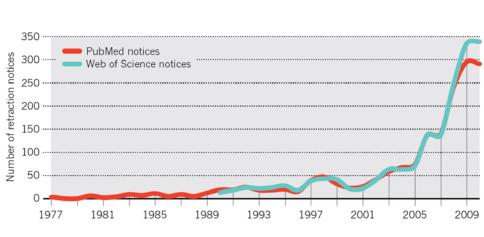
"A large percentage of allegations of misconduct received by ORI involves clinical research." John Dahlberg, HHS Office of Research Integrity

Titus et al. Nature 453:980-982



Is unethical behavior in conducting research getting worse or ... is there a greater awareness of its impact?







http://ori.hhs.gov/images/ddblock /dec_vol21_no1.pdf

https://www.nature.com/news/2 011/111005/pdf/478026a.pdf



The impact of research misconduct in an investigator's lab is devastating to all

Leading Edge

Analysis

Cell

The Aftermath of Scientific Fraud

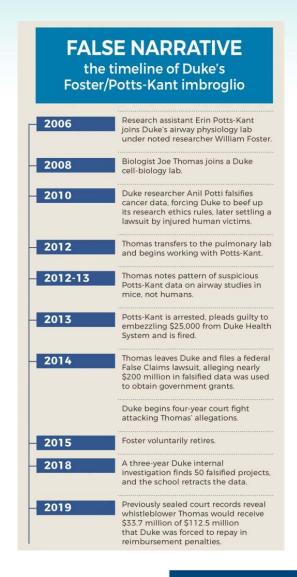
Scientists who have come face to face with scientific misconduct consider its consequences years later.



Research Misconduct Findings Can be Very Expensive for Universities



Duke Misconduct Case: Timeline





NIH Requires Training in the Responsible Conduct of Research (RCR)

Training in the responsible conduct of research (RCR) is required of all postdocs, graduate students, and students doing summer research projects (K-awardee faculty, too)

- Data acquisition, management, sharing and ownership
- Human subjects
- Animal welfare
- Research misconduct
- Publication practices and responsible authorship
- Mentor/trainee responsibilities
- Peer review
- Collaborative science
- Conflict of interest and commitment



Nine pitfalls of research misconduct

Academic leaders must audit departments for flaws and strengths, then tailor practices to build good behavior C. K. Gunsalus and Aaron D. Robinson.



A TABLE OF TRAGEDIES

Temptation

"Getting my name on this article would look really good on my CV."

Rationalization

"It's only a few data points, and those runs were flawed anyway."

Ambition

"The better the story we can tell, the better a journal we can go for."

Group and authority pressure

"The PI's instructions don't exactly match the protocol approved by the ethics review board, but she is the senior researcher."



A TABLE OF TRAGEDIES

Entitlement

"I've worked so hard on this, and I know this works, and I need to get this publication."

Deception

"I'm sure it would have turned out this way (if I had done it)."

Incrementalism

"It's only a single data point I'm excluding, and just this once."

Embarrassment

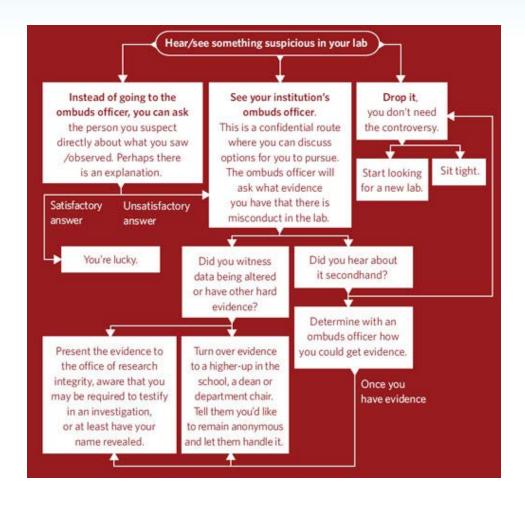
"I don't want to look foolish for not knowing how to do this."

Stupid systems

"It counts more if we divide this manuscript into three submissions instead of just one."



What do I do if I suspect misconduct?





If problems arise...

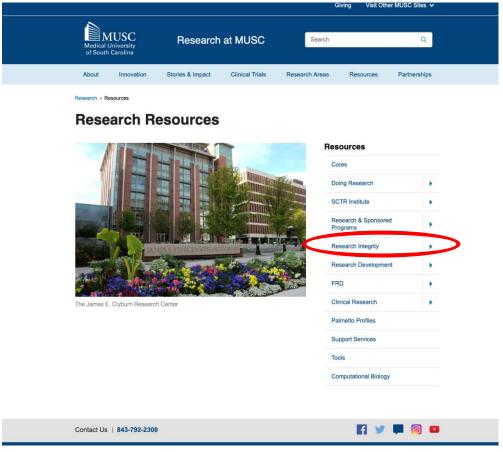
First: "May I speak with you confidentially?"

Last: "Thank you for letting me speak with you

confidentially."



The Research Integrity Committee Investigates Potential Research Misconduct



MUSC Research



Process for Addressing an Allegation of Research Misconduct

- 1. Research Integrity Officer receives complaint.
- 2. Complainant interviewed by the inquiry committee.
- 3. Respondent notified in writing of the allegation and pertinent data records sequestered.
- 4. Respondent interviewed by, and present evidence to, inquiry committee.



Process for Addressing an Allegation of Research Misconduct

- 5. Deciding Official receives inquiry report and determines if an investigation is warranted, and if so notifies PHS ORI within 30 days.
- 6. Complainant interviewed by the investigation committee.
- 7. Respondent interviewed by the investigation committee.
- 8. Any individuals pertinent to the investigation interviewed.



Process for Addressing an Allegation of Research Misconduct

- 9. Investigation committee submits findings and recommendations to Research Integrity Officer, who reports to the Deciding Official.
- 10. If misconduct has been found, the Deciding Official determines what administrative actions are appropriate and reports to the PHS ORI.
- 11. The PHS ORI determines whether or not to accept the Deciding Officials report. If the report is not acceptable, the investigation continues until the PHS ORI is satisfied.
- 12. The PHS ORI may post findings of research misconduct on their website.



Principles of ORI Whistleblower's Bill of Rights

- 1. Whistleblowers are free to disclose lawfully whatever information supports a reasonable belief of research misconduct as it is defined by PHS policy,
- 2. Institutions have a duty not to tolerate or engage in retaliation against good-faith whistleblowers,
- 3. Institutions have a duty to provide fair and objective procedures for examining and resolving complaints, disputes and allegations of research misconduct,
- 4. Institutions have a duty to follow procedures that are not tainted by partiality arising from personal or institutional conflict of interest or other sources of bias,
- 5. Institutions have a duty to elicit and evaluate fully and objectively information about concerns raised by whistleblower,
- 6. Institutions have a duty to handle cases involving alleged research misconduct as expeditiously as possible without compromising responsible resolutions, and
- 7. At the conclusion of proceedings, institutions have a responsibility to credit promptly, in public or private as appropriate, those whose allegations are substantiated.

MUSC Compliance Hotline 800-296-0269

Whistleblower Guidelines



Office of Clinical Research Website

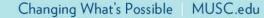


RCR Casebook: Stories about Researchers Worth Discussing

This casebook was funded through the ORI RCR Resource Development Program to James M.

- . Case One: My Lab Boss Put His Name on My Papers and Proposals







Useful Website on Research Integrity

- National Center for Professional & Research Ethics
- National Institutes of Health
- Retraction Watch
- US Public Health Service
- Office of Research Integrity



Everyone is important in a team

"Innovation provides the seeds for economic growth, and for that innovation to happen depends as much on collective difference as on aggregate ability. If people think alike then no matter how smart they are they most likely will get stuck at the same locally optimal solutions. Finding new and better solutions, innovating, requires thinking differently. That's why diversity powers innovation."

Scott E. Page, Professor, University of Michigan

