Responsible Conduct in Research: Research Misconduct

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What we’re trying to avoid!

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MY FIRST FRAUD KIT

PERFORM DECADES OF SCIENTIFIC FRAUD!
No experimentation necessary.

- Learn to falsify data like a pro!
- Avoid pesky peer review scrutiny!

CONTENTS
Objectives

- Introduce the concept and issues surrounding research misconduct

- Review of case studies on research misconduct allegations

- To better understand the regulations and Tulane University policies and procedures applicable to research misconduct
Background

- Prior to World War II, little public funding for research existed.

- Today, public funds support 1/3 of all research and development in the United States and 1/2 of all basic research.

- As public funding for research has grown, interest by the public, through its elected officials, has resulted in increased regulation and oversight of research.
Federal Laws on Research Misconduct

- Public concern over research misconduct initially arose in the early 1980’s

- At the time, research institutions sometimes ignored or covered up potential misconduct problems rather than investigate them

- In December 2000, the Office of Science and Technology Policy adopted a federal policy on research misconduct
Public Health Service Policies on Research Misconduct

- Public Health Service (PHS) Policies on Research Misconduct 42 CFR 93

- All institutions receiving PHS funding must have written policies and procedures for allegations of research misconduct

- Covers any entity that applies for a research, research-training or research-related grant or cooperative agreement with the Public Health Service (PHS)

- All allegations of research misconduct are handled by Office of Research Integrity (ORI)
Purpose of Research Misconduct Policies

- Establish definitions for research misconduct

- Outline procedures for reporting and investigating misconduct

- Provide protection for whistleblowers and persons accused of misconduct
PHS-mandated Institutional Procedures

- The designation of an individual authorized to receive and investigate allegations of misconduct (Research Integrity Officer)

- Provisions for an initial inquiry to determine if allegations have merit

- Provisions for a formal investigation to determine the truth of the allegations

- The designation of an individual authorized to adjudicate the conclusions of the investigation and impose administrative actions to redress the misconduct or to vindicate the person charged (DO)

- Provisions for reporting findings to ORI
Office of Research Integrity

- Develops policies, procedures and regulations related to the detection, investigation, and prevention of research misconduct and the responsible conduct of research

- Reviews and monitors research misconduct investigations conducted by applicant and awardee institutions, intramural research programs, and the Office of Inspector General in the Department of Health and Human Services (HHS)

- Recommends research misconduct findings and administrative actions
Office of Research Integrity

- Provides technical assistance to institutions that respond to allegations of research misconduct

- Implements activities and programs to teach the responsible conduct of research, promote research integrity, prevent research misconduct

- Conducts policy analyses, evaluations and research to build the knowledge base in research misconduct, research integrity, and prevention

- Administers programs for: maintaining institutional assurances, responding to allegations of retaliation against whistleblowers
Office of Research Integrity

- According to the Federal Office of Research Integrity ("ORI"), in general terms, Responsible Conduct in Research ("RCR") is good citizenship applied to professional life.

- Researchers who conduct and report their work honestly, accurately, efficiently, and objectively can achieve RCR.
ORI Recommendations on Misconduct

- Adopt zero tolerance
- Protect whistleblowers
- Clarify how to report
- Train the mentors
- Model ethical behavior
What is Research Misconduct?

- The Department of Health and Human Services defines research misconduct as: fabrication, falsification, or plagiarism in proposing, performing, or reviewing research results.
Research Misconduct

3 CATEGORIES OF SCIENTIFIC MISCONDUCT:

1. Fabrication
   Making up data.

2. Falsification
   Distorting data.

3. Questionable Research Practices:
   Cooking data, mining data, concealing conflicts of interest.
Research Misconduct

**Fabrication:** making up results and recording or reporting them

**Falsification:** manipulation of research materials, equipment, or processes, or changing or omitting results such that the research is not accurately represented in the record

**Plagiarism:** the appropriation of another’s ideas, processes, results, or words without giving proper credit
Criteria for Research Misconduct

- Represents a **significant departure** from accepted practices

- Has been committed **intentionally**, or **knowingly** or **recklessly**; and

- Can be proven by a preponderance of evidence

\[ \text{mouse} + \text{ink} = \text{Research Misconduct} \]
Research misconduct does not include honest error, misinterpretation of results or differences of opinion.
Top “BAD” Behaviors

- Fabricating or ‘cooking’ research data
- Ignoring major aspects of human-subject requirements
- Not properly disclosing involvement in firms whose products are based on one’s own research
- Relationships with students, research subjects or clients that may be interpreted as questionable
- Using another’s ideas without obtaining permission or giving due credit (plagiarism)
Bad behaviors (continued)

- Unauthorized use of confidential information in connection with one’s own research

- Failing to present data that contradict one’s own previous research

- Overlooking others' use of flawed data or questionable interpretation of data

- Changing the design, methodology or results of a study in response to pressure from a funding source

- Publishing the same data or results in two or more publications
Studies of Research Misconduct

Misconduct accounts for the majority of retracted scientific publications

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Fig. 1. (A) Number of retracted articles for specific causes by year of retraction. (B) Percentage of published articles retracted for fraud or suspected fraud by year of publication.

Fig. 2. Country of origin of publications retracted for fraud or suspected fraud (A), plagiarism (B), or duplicate publication (C).
Examples of Fabrication

- Creating data for experiments that were never done
- Making up subjects
- Splicing together different images to represent a single experiment
- Changing brightness and/or contrast of the image
- Any change that conceals information, even when it is considered not specific
- Showing only a very small part of the photograph so that additional information is not visible
Examples of Falsification

- Substituting one subject’s record for that of another subject
- Inflating the number of samples (animals, subjects, etc) that were used
- Deleting data points
- Altering images to appear better
- Altering images and using them multiple times
Why does misconduct occur?

- Career Pressure: Publish or Perish
- Desire to “get ahead”
- Character issues/Laziness
- Ease of fabrication
- Personal problems
- Cultural Differences
- ???
Frequency of Scientific Manuscript Retraction

Case Studies
Research Misconduct: Case Study 1

- Informed Consent documents for a research study contained multiple places for a participant to sign. Audit of study revealed that on some of the signed informed consents, signatures on one part of the form did not match signatures on another part of the form (i.e., some signatures appeared to be forged). Was this research misconduct?

- No. Why not?
Research Misconduct: Case Study 1

- Even though this was a noncompliance with federal regulations regarding obtaining informed consent, it was determined not to be “material failure” to comply with federal regulations, nor did it constitute falsification of data or plagiarism.

- The matter was reported to the appropriate federal agency as serious noncompliance but not as research misconduct.
Research Misconduct: Case Study 2

- Following a 5 year long research misconduct investigation at the University of Vermont College of Medicine, respondent admitted to falsifying data in 17 grant applications to the NIH and fabricating data in 10 publications over a period of 10 years.

- Was this Research Misconduct?

- Yes
Research Misconduct: Case Study 2

- Dr. Eric Poehlman banned forever from seeking or receiving public research money
- Retraction of 10 scientific papers
- Settlement terms dated June 8, 2006 of the case filed by the U.S. pursuant to the false claims act:
  - Prison sentence of 1 year and 1 day for falsifying data in a grant application.
  - Restitution payments of $180,000.00 to the United States
Research Misconduct: Case Study 3

- Case of De Domenico and Kaplan, U of Utah
- Editors of a journal expressed concerns over the data presented in manuscript published by the journal
- Concerns also raised by a collaborator from another Institution
- An internal review has discovered that, over five year period De Domenico “recklessly” fiddled with data in 11 papers
- 21 detected errors in 11 papers
- Committee could not prove intentional falsification by De Domenico
- Several papers retracted
- De Domenico fired / Kaplan retired
Research Misconduct: Case Study 4

• Researcher admitted to two counts of making false statements in connection with grant proposals and progress reports that contained false data, the result of rabbit sera that researcher intentionally spiked with human HIV antibodies to make it appear as if a vaccine was working.

• Was this research misconduct?

• Yes. Why?
Research Misconduct: Case Study 4

- Falsification of data
- Dong-Pyou Han, PhD, former Research Assistant Professor at Iowa State University
- After a one year investigation, Office of Research Integrity (ORI) and Dr. Han agreed to settlement in 2014. Dr. Han admitted the research misconduct and agreed to a three-year ban from receiving PHS funding.
- U.S. Senator Chuck Grassley expressed outrage at the terms of the settlement agreement.
Research Misconduct: Case Study 4

- U.S. brought a false claims action, and a settlement was reached
- University paid $496,832 to NIH to cover Dr. Han’s salary and benefits that had been paid with NIH funding
- As part of a plea agreement, Dr. Han, represented by a public defender, agreed to repay $7.2 million to NIH as restitution for NIH’s actual losses due to Dr. Han’s actions
- On July 1, 2015, Judge sentenced Dr. Han to 57 months in prison. Dr. Han is appealing
Research Misconduct: Case Study 5

• Co-investigator working on a project alleged that principal investigator created a hostile working environment and did not comply with reporting requirements of the grant.

• Was this Research Misconduct?

• - No. Why not?
Research Misconduct: Case Study 5

- The hostile working environment determined to be an employment issue

- The failure to comply with grant reporting requirements was determined not to be fabrication of data, falsification of data, or plagiarism.
Research Misconduct: Case Study 6

- Researcher removes outlier values and/or replaces outliers with mean values to produce results that conform to predictions.

- Research is published in four journals.

- Is this Research Misconduct?

- Yes!
Research Misconduct: Case Study 6

- David Anderson, former graduate student at University of Oregon at Eugene
- 3 years’ probation in 2015
- Probation includes supervision of PHS-supported research. Any institution employing him must certify his research in for PHS funding applications or publication.
- Must retract or correct four published papers involving his misconduct.
Research Misconduct: Case Study 7

- Graduate student includes falsified or fabricated data in two poster presentations, several laboratory meetings, and progress reports associated with federal grants.

- Is this Research Misconduct?
  - Yes!

- Is this Research Misconduct?
  - Yes!
Research Misconduct: Case Study 7

- Brandi Blaylock, former graduate student at Wake Forest School of Medicine knowingly presented falsified and/or fabricated data in two poster presentations, several laboratory meetings, and progress reports associated with NIH and National Institute of Drug Abuse grants.

- Reported 12 non-human primates responded to anti-abuse nicotinic acetylcholine and/or dopamine receptor selective compounds in self-selectivity assays for cocaine, methamphetamines or nicotine when the compounds were never given to the primates per protocol.

- Received 3 years’ probation in 2015.

- Probation call for supervision if she applies for or receives PHS support during probation. Any institution employing her must certify her research for PHS funding applications or publication.
Lessons Learned from Research Misconduct Cases

- Any person involved in research may be responsible for misconduct, regardless of rank or duties on the project.

- The majority of respondents have held technical positions and not doctoral degree holders.

- Common excuse for research misconduct: excessive work loads and/or time pressure.

- Scientific “divorces” are often bitter and irrational; however, the accusations usually do not constitute research misconduct.
Impact of Findings of Misconduct for Individuals and Institutions

- Degradation of the University’s reputation, loss of public trust

- Physical/monetary/psychological harm to employees, research subjects, students or trainees

- Additional regulatory oversight resulting in greater scrutiny, expanded programmatic requirements and greater institutional investments

- Suspension/disqualification of individual researchers

- Fines, penalties, punitive/compensatory damages, debarment and legal defense costs
Research Misconduct Processes at Tulane
Research Misconduct

- Policies listed in the faculty handbook and on Tulane Research Compliance website:

http://tulane.edu/asvpr/research-compliance.cfm
Research Misconduct Rights and Responsibilities

• If you discover research misconduct, contact the Research Compliance Officer for guidance. You have the right to remain anonymous and are protected from retaliatory acts.

• If you are accused of research misconduct, you are entitled to due process. Contact the Research Compliance Officer for guidance. That office is obligated to protect the confidentiality of the process.
Research Misconduct Process

Stages of the Process

- Submission of allegations
- Assessment
- Sequestration and notification to respondent of allegations
- Inquiry
- Investigation
- Formal finding
- Appropriate disposition
Investigation Process

- Investigation of a research misconduct allegation is a serious and lengthy process.

- Attempt an informal resolution, by speaking with supervisor or responsible academic officer (e.g., Chair, Dean, etc.).

- When the research involves PHS funding, the PHS Office of Research Integrity must be involved in the process and can override decisions of the university.
Misconduct Policy – Disposition

Examples of disciplinary actions include:

- Letter of reprimand
- Removal from the particular project
- Special monitoring of future work
- Suspension or expulsion (students)
- Termination of employment (staff)
- Dismissal of faculty member
Federal Research Misconduct Policy – disciplinary actions by sponsors

- Letter of reprimand
- Restrict expenditures under award
- Suspension or termination of award
- Require correction of research record
- Prohibition of individual as federal agency reviewer, advisor, or consultant
- Prohibition of individual and/or institution from receiving federal funds (debarment)
Research Oversight Committees at Tulane

- Institutional Review Board (IRB) – must approve all human subjects research: http://tulane.edu/asvpr/irb/index.cfm

- Institutional Animal Care and Use Committee (IACUC) – must approve all activities involving vertebrate animals: http://tulane.edu/asvpr/iacuc/index.cfm

- Institutional Biosafety Committee (IBC) – must approve all activities involving rDNA and select agents and toxins: http://tulane.edu/asvpr/biosafety/committee/index.cfm
Questions?

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