



Research Misconduct: Practical Impacts for the Sponsored Research Office

NCURA Region IV Spring Meeting

April 26, 2010

Denise McCartney

Associate Vice Chancellor for Research Administration

Federal Definition of Research Misconduct

“Research misconduct is defined as fabrication, falsification, plagiarism in proposing, performing or viewing research or in reporting research.”

Multiple Agency Policies:

DHHS

NSF

Energy

EPA

NASA

etc.

Purpose of Federal Regulations & Policy

- Ensure the integrity in research
- Ensure the public trust
- Provide a framework by which allegations of misconduct in research or research training may be investigated

Research Misconduct

Federal Law requires that all institutions that receive federal funds have policies and procedures for dealing with and reporting allegations of research misconduct for federally funded research and proposals submitted to federal agencies.

What Is Misconduct?

**FABRICATION
FALSIFICATION
PLAGIARISM**

Allegations are investigated under the Institution's [Research Integrity Policy](#).

Fabrication, falsification, or plagiarism

Fabrication

Making up data or results and recording or reporting them

Falsification

Manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented

Plagiarism

Using another person's ideas, processes, results, or words without giving appropriate credit

Plagiarism

A particular problem for students educated outside the United States. In the US, you MUST:

- use quotation marks “ ” around all text taken from another source **even when the author of that source is your mentor, your boss, or an author of the current manuscript**
- use footnotes, endnotes, or internal documentation to cite each and every existing source from which any ideas are used or information is taken

Plagiarism of
Words

Plagiarism of
Ideas

Self Plagiarism

Findings of Research Misconduct Require

- Significant departure from accepted practices of relevant research community and
- Misconduct is committed intentionally, knowingly or recklessly and
- Allegation proven by preponderance of evidence.

Error vs. Misconduct or Misbehavior

To be research misconduct or misbehavior, the behavior needs to be performed:

- ✓ Knowingly
- ✓ Intentionally
- ✓ Recklessly



(Office of Science and Technology Policy)

Research Relies on Trust

- Principal investigators are rarely supervised
- Even data collectors are rarely line-of sight
- Research relies on researchers to:
 - Develop and employ unbiased research methods
 - Honestly and accurately report a study's methods, data handling and analyses.

Research Environment

- Increasing competition for federal funds
- Increasing pressure from NIH and NSF for institutions receiving Federal support to demonstrate that they have in place training for all trainees in RCR
- Increasing engagement by Congress in issues of conflict of interest
- Breaches of research integrity continue to increase nationally.

Research Misconduct Activity: 1993-2006 (ORI)

| Year | Institutions reporting activity | Institutions reporting new cases | New allegations | New cases |
|------|---------------------------------|----------------------------------|-----------------|-----------|
| 2006 | 111 | 81 | 151 | 86 |
| 2005 | 113 | 66 | 137 | 92 |
| 2004 | 101 | 63 | 120 | 81 |
| 2003 | 106 | 82 | 136 | 105 |
| 2002 | 99 | 71 | 163 | 83 |
| 2001 | 78 | 61 | 127 | 72 |
| 2000 | 82 | 60 | 103 | 62 |
| 1999 | 72 | 46 | 89 | 63 |
| 1998 | 67 | 41 | 69 | 54 |
| 1997 | 73 | 48 | 92 | 64 |
| 1996 | 88 | 54 | 127 | 70 |
| 1995 | 96 | 61 | 104 | 81 |
| 1994 | 79 | 50 | 89 | 64 |
| 1993 | 73 | 53 | 86 | 77 |

Sanctions Are Severe

□ Institution Sanctions Examples:

- Require education
- Suspension of research support
- Retraction of publications
- Return of award funds
- Termination/Loss of tenure

□ Agency Actions:

- Notification of journals/correction of published research
- Imposition of certain assurance requirements
- Termination of an award or return of award funds
- Suspension or debarment
- Investigations of potential criminal or civil fraud

The Investigation Must Be Fair

1. Investigations usually initiated with an allegation of wrong doing
2. Institutional Inquiry
 - Notification of the person charged in the allegation
 - Sequestering of data and research records
 - Record and transcribe all witness interviews
 - Person charged receives transcripts
 - Complete in 120 days
 - Submit written report
 - Maintain confidentiality
3. Institutional Investigation
 - Formal development of factual record
 - Rights to counsel
 - Person charged has the right to review the draft report and comment
4. Impose sanctions if finding of misconduct

Why is this Important for a Sponsored Research Office?

Academic Research Institutions have a Shared set of Values:

- ✓ Honesty
- ✓ Accuracy
- ✓ Efficiency
- ✓ Objectivity

Why is this Important for a Sponsored Research Office?

- ☐ Institutional Assurance of Compliance:
 - Initial certification
 - Annual reporting
- ☐ Report Allegations of Wrongdoing
- ☐ Educational Responsibilities
- ☐ Public Perception
 - Reputational
 - Trust

Why is this Important for Sponsored Research Office?

Grant management Issues:

- Charges to Grants
- Personnel Changes
- Pending proposals or proposals being developed
- Grant Close out or Transfers
- Debarment
- Institutional Reputation
- Patents based on research findings
- Others

Case Study

Dr. Zookeeper has a NIH RO I to study honey production in bees for use in skin ailments. His postdoc contacts the University of Wax Compliance Office and alleges that Dr. Zookeeper is manufacturing the honey data by purchasing honey from the grocery store and adding it to the hives to increase the production numbers to support his scientific hypothesis.

Case Study

Dr Zookeeper's very successful lab is comprised of:

- 2 postdocs (including the 1 raising the concerns)
- 3 Graduate Students
- 1 laboratory supervisor
- 2 other research staff
- 1 secretary

Case Study

The Postdoc is very concerned because he has based his own grant application on this data.

The institution launches a research misconduct investigation and finds Dr. Zookeeper has falsified the data of his research in this ROI as well as at least two others. Dr. Zookeeper resigns.

Case Study

What are the Institution's Next Steps towards:

- The Postdoc who raised the allegation
- The other postdocs and grad students
- The staff
- The NIH
- The ORI
- The journals which published the findings

Clinical Case Study

The IRB performs a routine review of the research records of a nursing home clinical trial to study the impact of chocolate candy on resident blood pressure. As part of its review, the IRB identifies that two of the patients in the trial died before the date of the signatures on the informed consent. The consents has been witnessed by the clinical research coordinator. The IRB notified the Vice President for Research.

What are some potential next steps?

What are Some Strategies to Reduce Research Misconduct?

- Responsible Conduct of Research (RCR) Education
- Mentoring
- Clearly Communicated Institutional Values
 - Code of Conduct
- Policies and Procedures
- Encourage Reporting of Suspected Violations
 - Hotlines
- Sanctions

QUESTIONS

Contact Information

Denise McCartney

mccartnd@wustl.edu

314-747-6274