Navigating the Minefields of Research Integrity

Aubrey R Morrison, MD
Chair of the Committee on Research Integrity
Washington University in St. Louis
Federal Law requires that all institutions that receive federal funds have policies and procedures for dealing with and reporting allegations of research misconduct.
RESEARCH ENVIRONMENT

• Increasing pressure from NIH and NSF for institutions receiving Federal support to demonstrate that they have in place training for all trainees in RCR

• Breeches of research integrity continue to increase nationally.

• Increasing engagement by Congress in issues of conflict of interest

• Education in RCR is the right and appropriate thing to do.
WHAT IS THE RESPONSIBLE CONDUCT OF RESEARCH?

Fundamental part of the research process Requires:

- responsible and ethical behavior in proposing, performing, and reporting research
- honoring professional commitments to other researchers, the scientific community, and society
- assuring that the rights, interests, and dignity of research subjects are protected
Research Relies on Trust

- Principal Investigators are rarely supervised
- Even data collectors are rarely line-of-sight supervised

Research relies on researchers to:
1. Develop and employ unbiased research methods
2. Honestly and accurately report a study’s methods, data handling and analyses.
SHARED VALUES

• Honesty
• Accuracy
• Efficiency
• Objectivity
To be research misconduct or misbehavior, the behavior needs to be performed

- Knowingly
- Intentionally
- Recklessly

(Office of Science and Technology Policy)
Washington University’s *Research Integrity Policy* defines research misconduct as:

1. Fabrication, falsification, or plagiarism (FFP) in proposing, performing, reviewing or reporting results
2. Knowing violations of federal and/or institutional rules or regulations governing the conduct of research involving human research participants that are serious or continuing
3. Violations of the University’s *Policy for Authorship on Scientific and Scholarly Publications*. 
A finding of research misconduct requires that:

• There be a significant departure from the accepted practices of the relevant research community

• The research misconduct be committed recklessly, knowingly, or intentionally

• The allegation be proven by a preponderance of the evidence
The most serious ethical violations are defined as research misconduct.

FABRICATION
FALSIFICATION
PLAGIARISM

Engaging in these practices will result in severe penalties and sanctions. Allegations of research misconduct are investigated under the Research Integrity Policy.
Fabrication, falsification, or plagiarism (FFP)

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 in the research record

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
Washington University’s Policy for Authorship on Scientific and Scholarly Publications

Restricts authorship to only those who:
• make a significant contribution to the scholarly effort,
• draft, review, or revise the manuscript, and
• approve the final manuscript.

Honorary or courtesy authors are not permitted.

“Ghost” writers are not permitted.

All authors are responsible for work submitted under their name.
Anatomy of an Investigation

Receipt of an allegation

RIO decides if allegation has merit

Formation of RIIP

Committee on Research Integrity (RIO, 2 Chairs, 3 senior faculty)
University counsel, Representative from RECO

Executive Vice Chancellor for Research
Dean
(Dean decides sanctions)

Office of Research Integrity (ORI)
The Washington University Policy on Research Integrity was revised effective November 4, 2010, and can be accessed on the newly developed Research Integrity website at the following URL:

http://research.wustl.edu/ComplianceAreas/ResearchIntegrity/Pages/default.aspx

The Policy complies with all the elements of Federal Regulations 42 CFR 59 and 93 and includes:

- Confidentiality
- Allegation assessment and investigation process
- Protections from retaliation
- Rights and Responsibilities
Research Integrity Website

In addition to policies and regulations, the RI website provides further information on:

1. How to report an allegation of potential research misconduct
2. Rights and responsibilities of individuals involved in research misconduct proceedings
3. Protections from retaliation for individuals involved in research misconduct proceedings

http://research.wustl.edu/ComplianceAreas/ResearchIntegrity/Pages/default.aspx
## Research Misconduct Activity: 1994-2008 (ORI)

<table>
<thead>
<tr>
<th>YEAR</th>
<th>Institutions Reporting Activity</th>
<th>New Allegations</th>
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<tbody>
<tr>
<td>2008</td>
<td>135</td>
<td>201</td>
</tr>
<tr>
<td>2007</td>
<td>131</td>
<td>183</td>
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<td>2006</td>
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<td>1995</td>
<td>96</td>
<td>104</td>
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<tr>
<td>1994</td>
<td>79</td>
<td>89</td>
</tr>
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![Graph showing trend of research misconduct activity from 1994 to 2008](image)
A survey suggests that many research misconduct incidents in the United States go unreported to the Office of Research Integrity. Sandra L. Titus, James A. Wells and Lawrence J. Rhoades say it's time to change that.
### SUSPECTED MISCONDUCT: 201 CASES OBSERVED BY 164 SCIENTISTS

<table>
<thead>
<tr>
<th>Type of misconduct</th>
<th>Number of cases</th>
</tr>
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<tbody>
<tr>
<td>Fabrication or falsification</td>
<td>120 (59.7%)</td>
</tr>
<tr>
<td>Plagiarism only</td>
<td>73 (36.3%)</td>
</tr>
<tr>
<td>Unknown</td>
<td>8 (4.0%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Rank of those suspected*</th>
<th>Number of cases</th>
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<tbody>
<tr>
<td>Professor or senior scientist</td>
<td>44 (21.9%)</td>
</tr>
<tr>
<td>Associate professor or scientist</td>
<td>28 (13.9%)</td>
</tr>
<tr>
<td>Assistant professor or scientist</td>
<td>34 (16.9%)</td>
</tr>
<tr>
<td>Postdoctoral fellow</td>
<td>50 (24.9%)</td>
</tr>
<tr>
<td>Graduate student</td>
<td>29 (14.4%)</td>
</tr>
<tr>
<td>Other (includes 1 unknown)</td>
<td>24 (11.9%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>How it was discovered</th>
<th>Number of cases</th>
</tr>
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<tbody>
<tr>
<td>Directly observed</td>
<td>23 (11.4%)</td>
</tr>
<tr>
<td>Observed products</td>
<td>53 (26.4%)</td>
</tr>
<tr>
<td>Told first, then observed</td>
<td>60 (29.9%)</td>
</tr>
<tr>
<td>Other direct evidence</td>
<td>30 (14.9%)</td>
</tr>
<tr>
<td>Other</td>
<td>30 (14.9%)</td>
</tr>
<tr>
<td>Don’t recall</td>
<td>1 (0.5%)</td>
</tr>
<tr>
<td>No answer</td>
<td>4 (2.0%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Was it reported?</th>
<th>Number of cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes, reported by responder</td>
<td>49 (24.4%)</td>
</tr>
<tr>
<td>Yes, reported by someone else</td>
<td>67 (33.3%)</td>
</tr>
<tr>
<td>No, not reported</td>
<td>75 (37.3%)</td>
</tr>
<tr>
<td>Don’t know</td>
<td>5 (2.5%)</td>
</tr>
<tr>
<td>No answer</td>
<td>5 (2.5%)</td>
</tr>
</tbody>
</table>

* Eight cases identified more than one person involved in incident.
Research Misconduct

Questionable Research Practices (QRP)

Responsible Research
QUESTIONABLE RESEARCH PRACTICES

Less than responsible research

Conduct that falls short of the commonly accepted practices of the relevant scientific community

Nick Steneck, ORI
QUESTIONABLE RESEARCH PRACTICES

Examples

• Misrepresentation of credentials

• Inadequate record keeping

• Withholding reagents and plasmid constructs from colleagues after they have been used and published in peer reviewed journals.
“PHOTOSHOP”

The Good

The Bad

The Ugly
DATA MANAGEMENT INCLUDES:

- Data Collection
- Record Keeping
- Data Analysis
- Data Ownership
- Data Storage/Retention
- Sharing Data

(Magnus and Kalichman, 2002)
Case Vignette: Data Ownership

Dr. Smith works at The University and is the Principal Investigator on a large research project that is funded by the National Institutes of Health (NIH). However, while Dr. Smith wrote the original grant proposal, he does very little day-to-day work on the project. Instead, the Research Director, Betsy, oversees all aspects of the project, including staff supervision and all data management activities. In addition, Betsy has been lead author on several publications about the project's research findings.

Who owns the project and its data?

__ The PI, Dr. Smith
__ The Research Director, Betsy
__ The University
__ The National Institutes of Health
__ No one person or organization
Answer:

The University. Despite the PI's and the Research Director's work on the project, the sponsoring institution typically maintains ownership of a project's data as long as the PI submitted the grant through that institution and is employed by them. However within the sponsoring institution, a PI is generally granted stewardship over the project data; he/she may control the course, publication, and copyright of any research, subject to institutional review.
Bayh-Dole Act
Enacted on December 12, 1980, the Bayh-Dole Act (P.L. 96-517, Patent and Trademark Act Amendments of 1980) created a uniform patent policy among the many federal agencies that fund research, enabling small businesses and non-profit organizations, including universities, to retain title to inventions made under federally-funded research programs. This legislation was co-sponsored by Senators Birch Bayh of Indiana and Robert Dole of Kansas. The Bayh-Dole Act was especially instrumental in encouraging universities to participate in technology transfer activities.
REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

Policy  Beginning on December 1 2000, the NIH requires education on the protection of human research participants for all investigators submitting NIH applications for grants or proposals for contracts or receiving new or non-competing awards for research involving human subjects.

This announcement also reminds institutions of their responsibility to oversee clinical investigators and Institutional Review Boards (IRB).
YOUR PROFESSIONAL RESPONSIBILITY

Maintaining the integrity of research performed at Washington University is everyone’s responsibility.

There is **never** a justification for engaging in research misconduct.

“That’s how my boss told me to do it” is not a valid excuse!
RCR Educational Resource

Program for the Ethical and Responsible Conduct of Science and Scholarship

For more information, please visit
http://PERCSS.wustl.edu
Vice Chancellor for Research
Evan Karasch, MD PhD
314.362.7010
kharasch@wustl.edu

Aubrey R Morrison MBBS
Chair Committee on Research Integrity
314.454.8495
amorriso@dom.wustl.edu

Receives allegations of research misconduct
Provides confidential advice to individuals concerned about possible instances of research misconduct