Navigating the Minefields of Research Integrity

Aubrey R Morrison, MD
Chair of the Committee on Research Integrity
Washington University in St. Louis
National Biomedical Research Portfolio

- Clinical Research
- Translational Research
- Basic Research

NIH - $28B

- Clinical Research
- Translational Research
- Basic Research

Private Sector - $59B
>80% of NIH Budget funds:

- 350,000 research personnel
- 3,000 institutions
- 50 states and territories
- 90 countries around the world
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

“The scientific research enterprise, like other human activities, is built on a foundation of trust. Scientists trust that the results reported by others are valid. Society trusts that the results of research reflect an honest attempt by scientists to describe the world accurately and without bias.


“The successful conduct of research in a free society depends on trust between the scientific enterprise and the public, trust in the integrity of the discovery process, and especially trust in the safety of patients and healthy volunteers who participate in the process. In recent years, this essential trust has been shaken by a number of highly publicized events: tragic deaths of patients enrolled in clinical trials, high-profile allegations of financial conflicts of interest, and scientific misconduct by a few investigators.”

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)
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 human participant research that are serious and ongoing
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 and intentionally

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

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
Publication is considered the primary currency of the academician. It is one of the major criteria by which researchers are evaluated, both for hiring and promotion purposes and by other groups for funding and membership to societies.

Failure to understand and exhibit ethical standards will damage your reputation and chances for career advancement.

Ethical lapses may also lead to personal and professional penalties.
"I didn't exactly write the article, but...well, I didn't exactly do the research, either."
All collaborators share some degree of responsibility for any paper they coauthor. Some coauthors have responsibility for the entire paper as an accurate, verifiable report of the research. These include coauthors who are accountable for the integrity of the data reported in the paper, carry out the analysis, write the manuscript, present major findings at conferences, or provide scientific leadership to junior colleagues. Coauthors who make specific, limited, contributions to a paper are responsible for their contributions, but they may have only limited responsibility for other results. While not all coauthors may be familiar with all aspects of the research presented in their paper, all collaborators should have in place an appropriate process for reviewing the accuracy of the reported results.

Nicholas Cozzarelli, Editor in Chief – PNAS (2004)
RECENT VIOLATIONS OF THE PUBLIC TRUST

- 2005 Woo Suk Hwang, fabricated and falsified Stem Cell lines.  
- 2005 Eric Poehlman fabricated and falsified data from clinical aging studies.  
  June 28, 2006, Eric Poehlman was sentenced to 366 days in jail.
- 8-2006 40 Ohio U Engineering grad students accused of plagiarism. Revocation of degrees
- 8-2006 Ward Churchill, Professor of Ethnic Studies at the University of Colorado. Fired for Research Misconduct.
- 9-1-06 Elizabeth Goodwin. Resigned from the faculty at U. of Wisconsin at Madison - falsification and fabrication of data.  
  Graduate students found false data in NIH grant proposal.
- 9-29-2011 Judy Mikovits was fired over work of another researcher and which was published in Science in 2009. She was subsequently arrested as a fugitive from justice on 11-18-2011.
Retractions
(JME, 37, 2011)
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

Vice Chancellor for Research
Dean
(Dean decides sanctions)

Office of Research Integrity (ORI)
The Washington University Policy on Research Integrity

http://www.wustl.edu/policies/research.html

Includes all the elements of Federal Regulations 42 CFR 59 and 93

- Confidentiality
- Data sequestration
- Data availability
Commentary

Nature 453, 980-982 (19 June 2008) | doi:10.1038/453980a;
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Repairing research integrity
Sandra L. Titus¹, James A. Wells² & Lawrence J. Rhoades³

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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.
## RESEARCH MISCONDUCT ACTIVITY: 1994-2008 (ORI)

<table>
<thead>
<tr>
<th>YEAR</th>
<th>Institutions Reporting Activity</th>
<th>New Allegations</th>
</tr>
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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>
</tr>
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<td>2006</td>
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<td>151</td>
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<td>2005</td>
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<td>2002</td>
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<td>1995</td>
<td>96</td>
<td>104</td>
</tr>
<tr>
<td>1994</td>
<td>79</td>
<td>89</td>
</tr>
</tbody>
</table>
### Type of misconduct

<table>
<thead>
<tr>
<th>Type of misconduct</th>
<th>Number of cases</th>
</tr>
</thead>
<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>

### Rank of those suspected*

<table>
<thead>
<tr>
<th>Rank of those suspected</th>
<th>Number of cases</th>
</tr>
</thead>
<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>

### How it was discovered

<table>
<thead>
<tr>
<th>How it was discovered</th>
<th>Number of cases</th>
</tr>
</thead>
<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>

### Was it reported?

<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
Figure 3C. To make the images in line 4: take out the corresponding image from line 2, rotate it 90 degrees counter clockwise, then increase the size by about 50%.

Now take the resulting large images and cut the right top corner to get the corresponding images in lane 4.
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.
The Bayh-Dole Act (1980) (35 USC §200) allowed non-profit organizations and small businesses to retain title to inventions arising from federally funded research.

- It is the policy and objective of Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development;...to promote the collaboration between commercial concerns and non-profit organizations, including universities...

- to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against non-use or unreasonable use of inventions;...
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!
In *Advice to a Young Scientist*, Medawar (1979) made the following statement.

“*I cannot give any scientist of any age better advice than this: the intensity of the conviction that a hypothesis is true, has no bearing on whether it is true or not.* The importance of the strength of our conviction is only to provide a proportionately strong incentive to find out if the hypothesis will stand up to critical evaluation”.
RCR Educational Resource

For more information, please visit http://PERCSS.wustl.edu
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Receives allegations of research misconduct
Provides confidential advice to individuals concerned about possible instances of research misconduct
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.