

# Tales from the Dark Side: Case Studies in Research Misconduct

Office of Research Compliance 4<sup>th</sup> Annual Compliance & Ethics Symposium October 30, 2009 "Man lives in the sunlit world of what he believes to be reality, but there is, unseen by most, an underworld, a place that is just as real, but not as brightly lit, a dark side."

Introduction to *Tales from the Dark Side* TV Series, 1984-88, Laurel Entertainment, Inc.

### Overview of Presentation

- What is Research Misconduct?
  - FF & P
- Is this a monster I need to FEAR?
  - Does research misconduct really happen all that much?
- What do I do if I find the Research Misconduct Monster lurking in my lab?
  - Emory Policy Overview
- What can I do to head it off? (Garlic?
   Wolvesbane? Silver bullets?)
  - Case Studies for Discussion



## What Exactly is Research

## Misconduct?



### Research Misconduct =

 "Fabrication, Falsification or Plagiarism in proposing, performing or reviewing Research; submitting proposals for Research: or in reporting Research results. It does not include honest error or honest differences in interpretations or judgments of data"

• 42 CFR Section 93.103

### Research =

- "A systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) [including, but not limited to Research] relating broadly to public health by establishing discovering, developing, elucidating or confirming information about, or the underlying mechanism relating to, biological causes, functions or effects, diseases, treatments or related matters to be studied."
  - 42 CFR Section 93.222 (less italicized text)
  - Emory University Policy on Research Misconduct (Policy 7.8 at http://policies.emory.edu/7.8) (including italicized text)



### Fabrication =

- "Making up of Research data or results and recording or reporting them."
  - 42 CFR section 93.103



### 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 Records."
  - 42 CFR Section 93.103



## Research Records =

 "Those records of data or results that embody the facts resulting from scientific inquiry, including but not limited to, Research proposals, laboratory records (physical and electronic), progress reports, abstracts, theses, oral presentations, internal reports, journal articles, . . . "

- 43 CFR Section 93.224

## Plagiarism =

- "The appropriation of another person's ideas, processes, results or words without giving appropriate credit."
  - 42 CFR section 93.103



### Office of Research Integrity Policy on Plagiarism

"Many allegations of plagiarism involve disputes among former collaborators who participated jointly in the development or conduct of a research project, but who subsequently went their separate ways and made independent use of the jointly developed concepts, methods, descriptive language, or other product of the joint effort. The ownership of the intellectual property in many such situations is seldom clear, and the collaborative history among the scientists often supports a presumption of implied consent to use the products of the collaboration by any of the former collaborators.

For this reason, ORI considers many such disputes to be authorship or credit disputes rather than plagiarism. Such disputes are referred to PHS agencies and extramural institutions for resolution."

http://ori.dhhs.gov/policies/plagiarism.shtml





# Is Research Misconduct a Monster that I Really Need to FEAR?



## FEAR =

• F-- FALSE **E-- EVIDENCE** A-- APPEARING R -- REAL Veer Sharma f

## How Common is Research Misconduct?

- Cases at Emory on the Increase:
  - Total All New Cases:
    - 2005 -- 1
    - 2006 -- 2
    - 2007 -- 5
    - 2008 -- 9



- Use of new forensic tools by journals resulting in more allegations:
  - Plagiarism IThenticate, WCopyfind, MOSS
  - Image Manipulation Cadmus "Rigour" software

## How Common is Research Misconduct?

 "As computer programs make images easier than ever to manipulate, editors at a growing number of scientific publications are turning into image detectives, examining figures to test their authenticity.

. . .

Ten to 20 of the articles accepted by The Journal of Clinical Investigation each year show some evidence of tampering, and about five to 10 of those papers warrant a thorough investigation . . ."

Jeffrey R. Young, Journals Find Fakery in Many Images
 Submitted to Support Research, Chronicle of Higher
 Education, May 29, 2008.

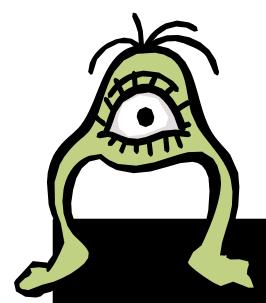
## How Common is Research Misconduct?

 "Research misconduct at U.S. institutions may be more common than previously suspected, with 9 percent of scientists saying in a new survey that they personally had seen fabrication, falsification or plagiarism.

The survey of 2,212 mainly biomedical scientists at 605 universities and other research institutions, published in the journal *Nature* on Wednesday, also showed that researchers are very reluctant to report bad conduct.

Thirty-seven percent of cases of suspected misconduct were never reported to the institution involved for investigation, perhaps due to fear of reprisals for turning in a colleague or a desire to protect the flow of research money."

 Will Dunham, Survey Suggests Research Misconduct is Common, Reuters, June 19, 2008 at <a href="http://www.reuters.com/article/scienceNews/idUSN18466264200806">http://www.reuters.com/article/scienceNews/idUSN18466264200806</a>



What do I do if I find the Research

Misconduct Monster lurking in my lab

or research group?

## Emory Policy on Research Misconduct

- Policy 7.8 at <a href="http://policies.emory.edu/7.8">http://policies.emory.edu/7.8</a>.
  - Allegations of fraud, falsification or plagiarism reviewed under process for Matters Involving Allegations of Research Misconduct
  - Allegations of violating other research related policies or rules reviewed under process for Matters involving Other Allegations
  - Projects funded by any Public Health Service units (e.g., NIH) also covered by regulations at 42 CFR Part 93
  - Projects funded by National Science Foundation also covered by regulations at 45 CFR Section 689.1 - .10.

## Reporting is Required

#### Responsibility to Report Research Misconduct or Regulation/Policy

<u>Violations</u>: immediately report any observed or suspected Research Misconduct or Regulation/Policy Violation to your supervisor, the chair or chief administrator of their department, the dean/director of your unit, or directly to the RIO. If an allegation is initially reported to any one other than the RIO, then that person, in turn, should report the allegation to the RIO. Similarly, if the RIO initially receives a report, then s/he should notify the appropriate Administrative Official and any other appropriate administrators and/or University committees or units that may have jurisdiction over the issue.

Policy 7.8 <a href="http://policies.emory.edu/7.8">http://policies.emory.edu/7.8</a>

## Emory's Code of Business Ethics and Conduct Policy

...is to ensure that employees operate in accordance with all applicable U.S. laws and regulations in carrying out all of their job responsibilities, and any responsibilities they have in connection with Federal Research/Contract Activities.

- Adhere to ethical principles
- Follow policies
- Report suspected violations
- Prohibits retaliation.

Policy 7.20 http://policies.emory.edu/7.20



### Research Misconduct Review Process

- Initial Review by RIO
- Administrative Official
- Inquiry
- Investigation
- Appeal
- Reporting to federal agencies, journals and others.



### To Establish Research Misconduct . . .

- It must be shown by a preponderance of evidence that:
  - Fraud, falsification or plagiarism occurred.
  - It was committed intentionally, knowingly or recklessly.
  - It was a significant departure from accepted practices of the research community.
  - It did not result from honest error or a difference of opinion.

### Not Sure if it's Research Misconduct?

• If unsure whether or not a particular incident or practice constitutes research misconduct or a regulation/policy violation, you may call the Research Integrity Officer (RIO) at (404) 727-2398 to discuss the matter confidentially and obtain guidance.



 Alternatively, reports or questions may be made anonymously by dialing the Trust Line. More information on the next slide about the Trust Line.

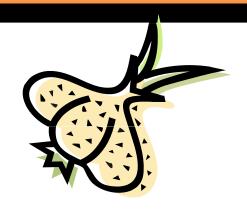
## **Emory Trustline**

- Anonymous reports can be made to the Emory University Trust Line at:
  - **-** 1-888-550-8850
- The Trust Line is operated by an independent third party who will maintain the caller's anonymity, while ensuring that the caller's report is routed to the proper individuals within the University/
- REMEMBER, if you make a good faith report of suspected research misconduct, there cannot be any retaliation for making the report.



What can I do to head off the
Research Misconduct monster?

(Garlic? Wolfsbane? Silver bullets?)





## CASE I: The Case of the Disappearing Subjects

Research coordinator collects data from subjects enrolled in study to track compliance with prescribed drug regimen. PI is at geographic site "A," and coordinator recruits subjects and collects data at geographic site "B." PI and coordinator have weekly teleconference. At end of study, coordinator resigns. PI begins to compile data for manuscript and finds that some of the subjects about whom data was collected were actually listed in other records as having not been eligible to participate ("screen failures"). Subsequent investigation shows that data for these subjects has been fabricated based on information gleaned from their medical records subjects were never enrolled in study.

## **Preventative Steps**

- Trust but verify!
- Regularly examine data collection forms and compare them against source documentation.
- Review standard methods for how data should be collected and recorded.
  - Sometimes the simplest rules are the ones that are forgotten first, e.g., no white out; log in and out of databases using your unique ID and password; lab notebook organization and data recording must be clear.

## CASE II: The Case of the Re-styled Gel

Journal kicks back article to PI stating that gel image that appears in article submitted for publication in 2009 as result from Experiment A, previously appeared in article published in 2006 as result from different Experiment B. Subsequent investigation reveals that multiple images of gels used in this article and other are "composites" made from cutting and pasting parts from other gels.

## **Preventative Steps**

- Lab supervisors Key to prevention is continuous communication, review and SUPERVISION.
- Lab associates Key to prevention is TRANSPARENCY in process and documentation; and
  - ASK QUESTIONS If you think that a supervisor has asked you to do something incorrectly, seek guidance.

## CASE III: The Case of the Sullied Solution

Researchers at Lab B attempt to reproduce research results using solution samples obtained from Lab A, but cannot do so. Researchers at Lab B analyze samples and determine that they have been contaminated with substance that would produce a false positive result. Further investigation reveals that Lab A inadvertently used incorrect solution when formulating samples that were sent to Lab A.

## **Preventative Steps**

- Develop and ensure implementation of rigorous lab procedures.
- Have processes in place for quality assurance and assessment.



## CASE IV: The Case of the Crafty Complainant

Researcher complained that PI had committed research misconduct by falsely reporting in manuscript for which researcher had participated in underlying research that certain technique had been performed on animals. Researcher provided copies of draft paper showing and computer records showing that technique had not been performed as stated in published manuscript. Investigation revealed that surgical logs kept during procedure confirmed technique HAD been done and documents provided by Researcher had been altered to support bogus claim of research misconduct.



## **Preventative Steps**

- Document management is key.
  - Put rigorous process in place to control versions of manuscripts. Know who wrote and edited what and when.
  - Lock down computers.
    - Avoid the "single lab computer" that everyone signs on to with one password.



## Weapon Against the Dark Side: Turn on the Light!

- Transparency, transparency, transparency!
- Supervision, supervision!
  - Check and re-check data that is collected.
  - Check source against reported results.
- Set the tone.
  - Research Integrity is Goal #1
  - Advise lab personnel to report suspect work.
- Training on appropriate research methods.
  - Neat, accurate and well-organized research records.

### **QUESTIONS:**

Office of Research Compliance

Research Integrity Officer (RIO): Kris West

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