Announcements

**SOS**

May 14-SMART teams (here, n-1)
- SMART teams (MSOE): protein modeling and how to get involved
- Be a mentor to a HS student and teach them about protein modeling.

May 28-cancelled

What do you want to hear about at SOS? postdoc@mcw.edu

**Events**

- Hacking the academic job market
  - May 16th, noon-1:30, H4940
  - RSVP: cvc@mcw.edu

**Other**

- Join the PAC (Postdoc Advisory Committee)-contact Paris Eason
- Podcast suggestion: Beyond the lab (by Vanderbilt University)
- Join the Commons (Fall, 2018) learn how to solve challenges that face area business-contact Paris Eason
Overview

Noon-1pm: Lecture/panel
- Matt Richter, JD, MA, Corporate Compliance (30 min)
- Julie Tetzlaff, PhD, Assoc Dean Postdocs (5 min)
- Neil Hogg, PhD, Assoc Dean Grad Students (5 min)
- Ryan Spellecy, PhD, Assoc Prof IH&E (5 min)

Small group discussion

<table>
<thead>
<tr>
<th>Micro &amp; Immuno</th>
<th>Today</th>
<th>1-2pm</th>
<th>Micro &amp; Immuno conference room</th>
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</thead>
<tbody>
<tr>
<td>MSTP</td>
<td>April 26 lunch provided Led by Dr. B</td>
<td>1-2pm</td>
<td>HUB A7520</td>
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<tr>
<td>All others</td>
<td>Today</td>
<td>1-2pm</td>
<td>H1210/30/50</td>
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</tbody>
</table>
Matt Richter, JD, MA
MCW Corporate Compliance
Manager, Research Compliance
Medical College of Wisconsin
Research Misconduct

April 23, 2018

Neil Hogg, PhD
Matt Richter, JD
Ryan Spellacy, PhD
Julie Tetzlaff, PhD
Agenda

Hour 1
- Types of misconduct
- Definition of research misconduct
- Authority and MCW Policy
- How is an allegation reviewed?
- What do I do if I suspect research misconduct?
- Research misconduct and ethics
- For postdoctoral researchers
- For graduate students
- Questions

Hour 2
- Case Study
Types of Misconduct

- Discrimination or Harassment
  - Anti-Harassment and Non-Discrimination (MCW Policy AD.CC.050)
  - Prohibition on Sex Discrimination and Related Misconduct (AD.CC.080); - Investigations (AD.CC.090)

- Conflict of Interest
  - Conflict of Interest - General (AD.CC.030); - Health Care Industry Product Interactions (AD.CC.040); Financial Conflicts of Interest in Research (RS.GN.020)

- Misappropriation of Funds and False Claims
  - Federal/State – NIH, CDC, Medicare, Medicaid, etc...
  - Institutional/College – personal use

- Safety and Environmental
  - Hazardous Chemical Safety (RS.GS.040); Biological Safety Program (RS.GS.030)
  - Occupational Health and Safety

- Human or Animal Research
  - Oversight of the Care and Use of Vertebrate Animals in Research and Education (RS.AN.010); Reporting and Investigating Animal Welfare Concerns (RS.AN.020)
  - Research Involving Human Subjects and/or their Private Identifiable Information (RS.HS.010); Participation as Research Subject (RS.HS.030); Human Research Protection Program (RS.HS.040)

- Research Misconduct
  - Research Misconduct and/or Research Noncompliance (RS.GN.010)
Research Misconduct: Definition

- **Fabrication** is making up data or results and recording or reporting them.

- **Falsification** is 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** is the use of another person's ideas, processes, results, or words without giving appropriate credit.

- Research misconduct does not include honest error or differences of opinion.
Research Misconduct Criminal Actions are rare... but they do happen

<table>
<thead>
<tr>
<th>Name</th>
<th>Sentenced</th>
<th>Background</th>
<th>Criminal Charges</th>
<th>Result</th>
</tr>
</thead>
</table>
| Scott Reuben       | 5/24/10   | Anesthesiologist - Former Chief of acute pain at Baystate Medical Center, Springfield, MA | Falsified research studies, published in medical journals. Solicited and obtained research grants from pharmaceutical manufacturers but did not actually perform studies. Made up patient data and submitted data in various articles. | • Sentenced to 6 months in prison  
• $361,923 in restitution to drug companies  
• Forfeiture of $50,000 and a fine of $5,000 |
| Richard Fleming    | 4/24/10   | Cardiologist - President of Fleming Heart and Health Institute in Omaha, Nebraska | Submitted false research data about privately funded clinical study of benefits of soy chips to sponsor.                                                                                                           | • Pled guilty to one count of mail fraud  
• Sentenced to 5 years probation, 6 months of house arrest, 150 hours of community service  
• Restitution in the amount of $107,244                                                                 | |
| James Holland      | 3/31/09   | Oncologist - Physician and head of oncology at Stratton VA Medical Center, in Albany, NY. | Falsified histories of certain VA patients to allow them to be enrolled as participants in study who did not qualify; one unqualified patient died as a result.                                                | • Pled guilty to one count of information  
• Placed on 5 years probation  
• Restitution of $502,925 |
DHHS - Office of Research Integrity

Investigates Fabrication, Falsification, Plagiarism – Research Integrity


http://ori.hhs.gov/about-ori
MCW Corporate Policy RS.GN.010

Research Misconduct and/or Research Noncompliance

Research Misconduct

Purpose
To maintain appropriate standards to ensure a healthy and compliant research environment at the Medical College of Wisconsin (MCW), to protect Public Health Service (PHS) funds from misuse by ensuring the integrity of all PHS supported work, and to outline the process for responding to and reporting allegations of Research Misconduct.

Definitions
Allegation: A disclosure of possible Research Misconduct having taken place by any person involved in research at MCW. The disclosure may be made through any means of communication. It may be by a written or oral statement or

https://infoscope.mcw.edu/Corporate-Policies/Research-Misconduct-Research-Noncompliance.htm
Research Misconduct: Review Process

• **Assessment of Allegation**
  - Performed by Corporate Compliance Office
  - Purpose: To determine whether allegation meets required criteria for further review

• **Inquiry**
  - Performed by Corporate Compliance Office
  - Purpose: To review evidence, conduct interviews, consult with scientific or other experts, to determine whether to recommend institutional investigation.

• **Investigation**
  - Performed by Institutional Investigation Committee (at least 3 individuals appointed by the Dean), in consultation with Office of General Counsel
  - Purpose: To determine whether research misconduct has been committed.
What to do?

• Do I have to report it?
  ▫ Anyone with credible knowledge or reasonable suspicion that an incident of research misconduct has occurred is **required** to report the incident.

• Where / to whom do I make a report?
  ▫ Your Supervisor or Advisor
  ▫ Department or Section Chief or Chair
  ▫ Senior Associate Dean for Research, Dr. Ann Nattinger
  ▫ Dean of Graduate/Medical School, Dr. Joseph Kerschner
  ▫ Compliance Office (can always call if unsure what to do)
  ▫ **LAST RESORT** – when nothing works, report it externally to the federal office charged with research misconduct oversight: ORI

• How do I make a report?
  ▫ Oral or written
  ▫ Anonymous allegations are accepted
Confidentiality

- **Federal Whistleblower Protections**
  - Research Misconduct – rule requires that institutions have a policy that provides for some confidentiality and protections.

- **State Whistleblower Protections (WI Statute 146.997)**
  - State law prohibits retaliatory action by a health care provider (e.g. MCW) against an employee who in good faith reports:
    - Violation of state or federal law;
    - Violations of recognized clinical or ethical standards.

- **MCW Policy**
  - all parties involved with a report or review of possible research misconduct must keep identities confidential *to the extent allowed by law.*
Questions and Discussion
Julie Tetzlaff, PhD
Associate Dean of Postdoctoral Affairs and Graduate Student Career Development
Assistant Professor of Pathology
WHAT DRIVES PEOPLE TO COMMIT RESEARCH MISCONDUCT?

These quotes come from people who admitted to research misconduct in closed Office of Research Integrity cases. Research misconduct is never justified, but it is important to recognize potential drivers of misconduct to better understand how it might be prevented.

**POOR SUPERVISION**

“I was scared to go to [my PI], he used to scream & yell at me when things did not work as planned.”

**INADEQUATE TRAINING**

“AFTER TWO YEARS OF A POSTDOCTORAL FELLOWSHIP... I STILL DON’T KNOW HOW TO PROPERLY PUBLISH WESTERN BLOT DATA.”

**COMPETITIVE PRESSURES**

“I felt it was necessary to get a paper in a high-profile journal in order to get a faculty position.”

**PERSONAL CIRCUMSTANCES**

“I had been applying for a green card and felt pressured to make a good paper and get good publications.”

**INDIVIDUAL PSYCHOLOGY**

“Half of me wanted to make [my PI] proud. The other half was terrified of failing... so I fabricated a piece of data.”

Seek support from a mentor if stressors are impacting your work.
POSSIBLE RED FLAGS OF RESEARCH MISCONDUCT

TIME
- Usable data are only generated when there is a pressing deadline
- Experiments are completed faster than usual

RESULTS
- Data are too good to be true
- Findings can't be replicated by others in the lab

LACK OF TRANSPARENCY
- Raw data can't be produced when requested
- Research materials and protocols are kept hidden
- Work is mostly done when no one else is around

If you suspect research misconduct
contact your institution's Research Integrity Officer or ORI at AskORI@hhs.gov

ori.hhs.gov  @HHS_ORI  #ORIedu
Examples of research misconduct

• Data based on actual published cases from the Office of Research Integrity (ORI) website

• **Who committed the misconduct?**
  ▫ Graduate students
  ▫ Postdocs
  ▫ Post-bac research volunteers

• **Where was misconduct found?**
  ▫ Grant applications and progress reports
  ▫ Manuscripts (J. Neuro, Cell, Nature, PloS One, PNAS)
  ▫ Manuscript supplemental data
  ▫ Poster and oral presentations at conferences
  ▫ Data presentations at laboratory meetings
Real examples of research misconduct

• Manipulating instrument/reagents to get desired result
  • Manipulating error bars/bar graphs
    • *Removing outliers from data*
  • Omitting data points from analysis
• Performing different normalizations for different groups
  • Falsely reporting statistical significance
    • Mislabling images
• *Claiming to have run an experiment in triplicate (was only duplicate)*
  • Falsifying images by drawing in staining with Photoshop
• Claiming a drug was given to an experimental group when it was not
  • Falsely claiming to have generated a recombinant model
  • Falsifying laboratory notebooks and vivarium entry logs
Lasting Consequences

- Manuscript retraction
- Mandatory supervised research
- No funding from US government for several years, or ever
- Institution that employs the person must disclose the misconduct on every grant application
- MCW consequences—possible suspension, termination
Other consequences-PI relationship damage

My Mentoring Network
(adapted from materials at WEBS 2011/ www.facultydiversity.org)

ME and MY Priorities

Accountability for what MATTERS!! (subtopics may apply)

Professional Development (Outside of Scientific Sphere)

Sponsorship/ Promoters

Role Models

Emotional Support

Safe Space

Friends

Family

Other

Intellectual Community (ex: Paper or Grant Readers)

Access to Opportunities

0-25% Complete

25-50% Complete

50-75% Complete

75-100% Complete

External Mentors

Internal Mentors

Peer Mentors

1. Sr. (Dept.) Faculty

Department Colleagues

Professional Editor(s)

 Readers (see Intellectual Community)

Internal

External

https://advance.cc.lehigh.edu/mentoring-network-map
MCW RIO:
Dr. Ann Nattinger
Assoc. Provost for Research
Sr. Associate Dean for Research

RESEARCH TRAINEES
WHAT YOU NEED TO KNOW ABOUT RESEARCH MISCONDUCT

Misconduct Is Not Limited to Published Research
Research misconduct is fabrication, falsification, or plagiarism and can occur in publications, presentations, posters, and grant applications—whether they are funded or unfunded.

Research Misconduct Affects Everyone
Tainted research can have negative implications on individuals in the lab, the larger research community, and in the public’s trust in science.

There Is a Professional You Can Contact
Most institutions refer to this person as the Research Integrity Officer (RIO). You can contact your RIO about questionable practices.

Anyone Can Report Misconduct
Scientists are obligated to point out errors regardless of their position in the lab. The research community depends on you to report misconduct.

Institutions Have Policies to Protect All Involved
Every institution has a requirement to take all reasonable and practical steps to protect the reputation of those who report research misconduct and anyone falsely accused.

You Can Report Research Misconduct Anonymously
Anyone can contact ORI anonymously by phone or email to address concerns.

Learn more about responsible research at: ori.hhs.gov

1 For the full definition of research misconduct, see 42 C.F.R. § 93.103.
2 RIOs may have other titles, such as Chief Compliance Officer, Director of Compliance, Vice President/Dear of Research, or Director of Integrity.
3 Statistics based on closed ORI cases from 2011-2014. Trainees are students and postdoctoral fellows.
Neil Hogg, PhD
Associate Dean, Graduate Students
Professor of Biophysics
Graduate Student Handbook

Professional Misconduct Honest, ethical, and responsible behavior is as essential to the scientific and medical professions as is academic excellence and scholarship. For students, such behavior is necessary in all areas of the educational experience, including, but not limited to: academic course work, scientific research, ethical use of information and relationships with peers. *It is incumbent on all members of the academic community to uphold high standards, to monitor these standards, and to bring to appropriate College administrators concerns regarding dishonest, unethical, or irresponsible behavior.* With regard to graduate students, alleged violations shall be brought to the attention of the Graduate School Dean.
Academic Consequences:

Potential Sanctions:

1) Reprimand
2) Disciplinary Probation
3) Suspension
4) Dismissal
Your Thesis is a Publication

1) You cannot plagiarize in your thesis even from papers from your own group (Exception: papers on which you are an author).

2) You need permission to reproduce published figures in your thesis (Exception: papers on which you are and author)

3) Your thesis can be retracted by the institution if it is found to contain fraudulent data, plagiarism or other ethical violations.

4) Retraction of the thesis usually would involve revocation of the degree.
Ryan Spellecy, PhD

Ursulal von der Ruhr Chair in Bioethics
Associate Professor of Bioethics and Medical Humanities, and Psychiatry and Behavioral Health