RESEARCH MISCONDUCT AND HUMAN SUBJECT'S RESEARCH

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TOPICS

• What is Research Misconduct (RM)?
• When IRB Noncompliance constitutes RM
• Why people commit RM?
• How to prevent RM in Human Subjects Research
• Office of Research Integrity and Compliance
• Questions
WHAT IS RESEARCH MISCONDUCT?

Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results, according to 42 CFR Part 93.
WHAT IS RESEARCH MISCONDUCT?

Fabrication is making up data or results and recording or reporting them.
WHAT IS RESEARCH MISCONDUCT?

Illustrative case: Eric Poehlman

- Pleaded guilty of lying on grant applications
- Fabricated a decade’s worth of data about obesity, menopause, and aging
- Served time in prison for this crime
Falsification is the manipulation of research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
WHAT IS RESEARCH MISCONDUCT?

Illustrative case: Marc Hauser

- As the only person in the world working with tamarins, his research made replication impossible
- Comparing monkeys to human infants
- When others in lab analyzed the data, they found opposite results
- Dr. Hauser has voluntarily agreed for a period of three (3) years, beginning on August 9, 2012
Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
ILLUSTRATIVE CASE: YIBIN LIN, PH.D

- Falsified, fabricated, and plagiarized the whole content of six (6) papers and eight (8) manuscripts,
- Falsely created fictitious author names and affiliations without listing himself as an author to disguise himself from being the offender, and submitted them for publication in bioRxiv and medRxiv, open access preprint repositories, by falsely assembling random paragraphs of text, tables, and figures from previous publications and manuscripts to improve his citation metrics.
WHAT IS RESEARCH MISCONDUCT?

Research misconduct does not include honest error or differences of opinion.

Authorship issues can be confused as plagiarism cases.
Research integrity issues that represent Noncompliance could become RM

- Deviation from approved exclusion/inclusion criteria
- Unsupervised student research
- Altered eligibility test results
- Discrepancy between records and medical chart
- Fast Accrual

PRIM&R webinar “Conduct of Research: What IRBs Need to Know”, Fariba Houman, PhD, CIP and Julie F. Simpson, PhD, October 25, 2018
WHEN IRB NONCOMPLIANCE MAY CONSTITUTE RM

Fabrication/Falsification

- Tests, participants, data, consent forms, dates
- Interviews, payment, sample

Detrimental Research Practices

- Sloppy data, unsigned consent forms
- Unreported, misreported SAEs, or changes to protocol, undisclosed COIs

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WHEN IRB NONCOMPLIANCE MAY CONSTITUTE RM

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<td>Wakefield (1998-2010)</td>
<td>COI; poor study design, misleading publicity</td>
<td>Rise of measles cases, vaccination mistrust</td>
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<td>Lacour (2015)</td>
<td>Survey fabrication, inadequate collaborator oversight, falsified payments</td>
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WHY PEOPLE COMMIT RM?

• **Personal Drivers**
  - “pressured to make a good paper publication”
  - “I was terrified of failing”

• **Society/Institution**
  - “I was scared at my PI who was going to yell at me”
  - “I need a paper in a high-profile journal to get a faculty position”
HOW TO PREVENT RM IN HUMAN SUBJECTS RESEARCH

• Ensure that COI is followed and completed
• Analyze your culture and research environment
• Know who you can call if needed
• Say no! Speak up!
• QA audits
• Consult the ORIC if you have any questions/concerns
CONTACT US

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QUESTIONS
• PRIM&R webinar “Conduct of Research: What IRBs Need to Know”, Fariba Houman, PhD, CIP and Julie F. Simpson, PhD, October 25, 2018
• NIH webpage - Research Misconduct – Definitions
• “Poehlman's case” New York Times
• Case Summary: Lin, Yibin (ORI)