Research Misconduct: A look at process and current trends

KERI GODIN
ASSOCIATE DIRECTOR OF RESEARCH COMPLIANCE
HMS OFFICE FOR ACADEMIC AND RESEARCH INTEGRITY
Research Misconduct Defined

**Fabrication** (making up results and recording or reporting them)

**Falsification** (manipulating research materials, data, or processes; or manipulating data such that the research is not accurately represented in the research record)

**Plagiarism** (the appropriation of another person’s ideas, results, or words without giving that person appropriate credit)

...in proposing, performing, or reviewing research, or in reporting research results.
What it is & importantly, what it is not

- Intentional
- Knowing
- Reckless

- Not an honest error
- Not a difference of scientific opinion
- Not a non-compliance related to human subjects or animal subjects
- Not misuse of research funds

- Significant departure from accepted research practice
- Proven by a preponderance of the evidence

Office of Research Integrity, 42 CFR, Sec. 93.104
William Fals-Stewart, Ph.D.

- Former University of Buffalo (UB) addictions researcher accused in 2004 of fabricating data – NIDA funded

- September 2007, three witnesses testified via phone on Dr. Fals-Stewart’s behalf: Project Director, Project Coordinator & Director of Quality Assurance

- Faculty panel determined “insufficient evidence” based on witness testimony

- Fals-Stewart sued UB for $4 million in US District Court → wrongful termination, tarnished reputation

- Submitted an affidavit including an email from a University of Miami professor re: misconduct allegations coming up during a conference
...and the truth emerges

- Witnesses were actors told they were participating in a mock trial
- U of Miami professor confirmed he did not send email
- Dr. Fals-Stewart arrested in 2010
- Charged with attempted grand larceny, three counts of perjury, three counts of identity theft, two counts of offering a false instrument and three counts of falsifying a business record

Maximum permissible sentence = 15 years in prison
Recent Enforcement Action: Dong-Pyou Han

- ISU Scientist, admitted to falsifying AIDS vaccine study data supported by multi-million dollar NIH grant
- Entered plea agreement (Feb. 2015), saying his subterfuge cost the federal government $7 - $20 million.
- In return for his guilty pleas to two felony charges of making false statements, prosecutors dropped two other charges; could face up to 10 years in prison
- ISU had to repay $496K; lost $1.4 in grant monies not yet paid
Process and Key Players

- **Complainant**
  - Journals
  - Anonymous
  - Proximal to accused (i.e., in lab, collaborator)
  - Received from federal agency
  - Retraction Watch

- **Respondent**
  - Anyone performing, proposing, reporting
  - Can be multiple respondents in a given matter
  - All levels of appointment can and have been respondents

- **Relevant Agency (NSF, ORI, DoD)**
  - ORI: Jurisdiction over PHS funded work
  - Informed when review reaches Investigation
  - Waits for institutional finding before own review

**Flowchart**
- Receipt of Allegation(s)
- Institutional Preliminary Assessment
- Inquiry
- Investigation
- Potential independent Investigation by ORI if RM found
Institutional responsibilities

- **Policy** for handling Allegations of Research Misconduct
- Assessment of all **good faith** allegations – Research Integrity Officer
- **Sequestration** of data by Institution & Notification of Accused
  - ALL potentially relevant data
- Appointment of impartial **faculty panel**
- Fair, objective, CONFIDENTIAL process
- Interviewing witnesses /Forensic analysis of Data
- **Reporting of advancement to investigation, findings of research misconduct** (PHS funded)
Costs of Misconduct

- Direct costs associated with handling research misconduct cases at the institutional level in the US exceed $110 million annually\(^1\)
- Estimated $525,000 per case\(^1\)
- Institutional reputation
- Repayment of sponsored funds
- Loss of productive faculty
- Impact on public health & trust in research

\(^1\)Michalek et al. (2010)
Not just an Academic Issue

- Public health is perhaps most at stake when medical research is found to be falsified or fabricated – A. Wakefield matter

- A 2011 article in *The Journal of Medical Ethics* reviewed ~200 papers that were retracted due to questionable data → the published research was tied to 28,000 patients, 6,573 of whom received treatment based on the research presented in the retracted papers (Steen, 2011).
ORI Data: 2012 Annual Report*

- ORI received 423 allegations in 2012
- 56% increase over the 240 allegations handled previous year
- Historical perspective: 1992-2007 average of 198 allegations
- 32/33 ORI Investigations involved allegations of falsification and/or fabrication

Current trends

- Fanelli’s 2009 *PloS One* article:
  - Nearly 2% of scientists admitted to falsifying or fabricating data a minimum of one time
  - Nearly 34% reported engaging in other forms of devious research practices
  - Approximately 14% of scientists surveyed witnessed colleagues’ manipulation or making up of data.

- Tavare’s 2012 *British Medical Journal* article:
  - 1 in 7 researchers in U.K. witnessed other investigators falsifying/fabricating data to increase publishing potential
Incidence of Misconduct: A look at rejections

*Source: Fang et al. (2012), Figure 1A, p. 17029.
Environmental Pressures

- Growing number of investigators vying for limited funds
  - Recent example: Imperial College London, Prof. Grimm*
- Decreasing federal research budget
- Promotions reliant on robust C.V.
- Incentives to publish
  - Prestige
  - Garner additional funding

*Source: https://www.insidehighered.com/news/2014/12/01/imperial-college-london-investigates-role-pressure-death-academic
Evolving Academic Research Environment

- Junior faculty at increased risk
Early and mid-career researchers account for 2/3 of research misconduct findings (Martinson et al., 2005)

Pressure to obtain external funding and federal research dollars to support one’s salary positively correlated with reports of serious misconduct (Martinson et al., 2009)

Professional stressors - being overworked & pressure to complete experiments/produce data with insufficient time allotted - correlated with research misconduct (Davis et al., 2007)
Evolving Academic Research Environment

- Junior faculty at increased risk
- Increase in Foreign-born researchers
Foreign-born Investigators

- Differing cultural norms (*Davis, 2003*)
- Lack of English proficiency (*Xiguang & Lei, 1996*)
- Fear of asking for help (*Davis, Riske-Morris and Diaz, 2007*)
- Lack of Responsible Conduct of Research training/oversight in country of origin (*Okonta and Rossouw, 2012*)
Evolving Academic Research Environment

- Junior faculty at increased risk
- Increase in Foreign-born researchers
- Mentoring increasingly challenging
Mentoring

- 62% of mentors had not established procedural standards (Wright et al., 2008)

- 73% had not reviewed the raw data generated by their trainees (Wright et al., 2008)

- “Improvement in the quality of mentoring in training programs” is the path to reducing misconduct at any given institution (Kornfeld, 2012)
Evolving Academic Research Environment

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- Mentoring increasingly challenging
- Data storage and presentation processes changing
Data Management

- Schreir and colleagues’ (2006) survey of 96 university officials charged with institutional oversight of research misconduct cases revealed that inquiries and investigations were “hampered by inadequate research records.”

- Martinson et al. (2005) similarly reported that 27% of the faculty investigators they interviewed openly confessed to “inadequate record-keeping related to research projects.”

- Schreier et al. (2006) lament the shortcoming of the present academic research environment, in which formal record-keeping standards are absent or woefully inadequate, peers rather than superiors teach newcomers record-keeping habits, and foreign investigators often record data in their native languages given insufficient standards dictating the importance of data retention in English.
Potential Consequences

- Retraction or correction of all pending and published papers and abstracts affected by the misconduct
- Reprimand, removal from project, rank and salary reduction, dismissal
- Restitution of funds to the granting agency
- Ineligibility to apply for Federal grants for years
- Public awareness & reputational harm – federal register/ORI website
- **Likely, the end of one’s research career**
Tools to spot-check data

- Forensic tools (http://ori.hhs.gov/forensic-tools)

- Plagiarism tools
  - eTBLAST: http://etest.vbi.vt.edu/etblast3/
  - Déjà vu: http://dejavu.vbi.vt.edu/dejavu/
  - Drop text in “Google” or Images in “Google Image”

- Image analysis – Photoshop
  - Advanced Forensic Actions: http://ori.hhs.gov/advanced-forensic-actions
  - Earlier versions available for Photoshop CS2 and 3 Forensic Droplets: http://ori.hhs.gov/droplets

- Other freeware available (More intensive image analysis)
  - Fiji (ImageJ): http://fiji.sc/Fiji
Which three lanes are the same?

Source: [http://ori.hhs.gov/samples](http://ori.hhs.gov/samples)
What evidence shows the 67 kDa band is the same data as the 32 kDa band?

Source: [http://ori.hhs.gov/samples](http://ori.hhs.gov/samples)
What more can administrator’s do?

- Encourage adherence to institutional Policy and sponsor-required data/record retention
- Assess lab sizes; mentor-mentee ratios
- Create a culture and environment where data sharing is expected, and data challenging is encouraged
- Follow your instincts; repeat offenders of non-compliance may be a red flag of substandard practices
- If you witness something concerning, don’t stay silent

Fake Peer Review

- Authors review own paper or 3rd party vendor reviews at a cost
- Widespread
  - Elsevier, Springer, Taylor & Francis, SAGE and Wiley
- The fall-out
  - As of last fall, about 110 retractions across several journals.
  - Then Elsevier added 16 more retractions
  - Then, in March 2015, Bio Med Central added 43

170 Retractions thus far...

Sources: [http://www.nature.com/news/publishing-the-peer-review-scam-1.16400](http://www.nature.com/news/publishing-the-peer-review-scam-1.16400)
Journals and NIH take action: Reproducibility in Science

- June 2014 – NIH/the Nature Publishing Group/Science held a workshop on reproducibility & rigor of research findings
- Over 30 basic/preclinical science journals represented in which NIH-funded investigators have most often published.
- The workshop focused on the common opportunities in the scientific publishing arena to enhance rigor and further support research that is reproducible, robust, and transparent.

http://www.nih.gov/about/reporting-preclinical-research.htm
References