Speakers

- Alan R. Price, PhD, *Price Research Integrity Consultant Experts-- P.R.I.C.E.*
- Mary D. Scheetz, PhD, *Research Integrity Consulting, LLC*
- Debra M. Parrish, JD, *Parrish Law Offices*
Types of Misconduct

US Federal Agency Definition
• **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:** the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Other Types of Misconduct

- **Dual Submission/Self-Plagiarism/Salami Science**: Publishing the same, mostly unchanged, works in more than one publication
- **Lack of Informed Consent**: publishing data from experiments on humans without having consent for the experiment
- **Misappropriation of Data**: stealing the data of others to produce your “own” work
Motives

“...the perpetrators
(1) were under career pressure,
(2) knew, or thought they knew, what the result would be if they went to all the trouble of doing the work properly, and
(3) were in a field in which individual experiments are not expected to be precisely reproducible. Simple monetary gain is seldom, if ever, a factor in scientific fraud.”

State of the Art

Since 2001 the number of papers published in research journals has increased 44%, the number retracted papers has increased 15 fold (1)

Retraction notices:
- 2001 - 22
- 2006 - 139
- 2010 - 339

(1) Thomas Reuters Web of Science, August, 2011.
Retraction Examples due to Scientific Misconduct Findings

- A decade of valuable cancer research at the Mayo Clinic was erased when institutional investigation found research was fabricated.
- 17 papers published in 9 journals had to be retracted.
- Plans to commercialize the work have been halted.
Retraction Examples, Continued

- Lancet retracted Wakefield (1998) study linking vaccines to autism

- Ramifications: Children not receiving vaccines due to findings

- Measle cases spiked

- Author stripped of his medical license

- Many parents still decline to vaccinate due to paper findings
Retraction Examples, Continued

Schön scandal (Germany) papers retracted:

8 in Science
6 in Physics Review
7 in Nature
Common concerns echoed by editors:

- Don’t have enough resources to address scientific misconduct
- Perception that “it won’t happen to me” (2)
- Trouble shoot when it arrives

Reality Check for Editors

What Editors Cannot Do:

- Adjudicate authorship disputes
- Prevent scientific misconduct
- Conduct investigations
Preventative Measures

Instructions to Authors (IA)

CSE 2011 Meeting, study findings

Only 25% journals address research integrity / scientific misconduct

Most IA address mechanics of paper

Well written IA can serve as critical deterrent for scientific misconduct

Tools for the Trade

Software tools for detection / prevention:
- Cross Check
- Photoshop
- Turnitin
- iThenticate (blog and software for plagiarism detection)
What editors can do!

- Be aware of existing resources!
  - CSE – Council of Science Editors
  - WAME – World Association of Medical Editors
  - COPE – Committee on Publication Ethics
  - ORI – Office of Research Integrity
  - NSF – National Science Foundation
  - Retraction Watch - blog dedicated to education readers about retractions
What editors can do! continued....

- Carefully review / update IA
- Prevent publication misconduct through educating via IA
- Notify appropriate authorities when necessary (oversight agencies, institutions)
- Correct the literature as soon as possible
Questions?

Mary Scheetz, Ph.D.
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Webinar for CSE Editors
August 23, 2011

"THE OFFICE OF RESEARCH INTEGRITY & MISCONDUCT CASES - INTERACTIONS WITH JOURNAL EDITORS"

Alan Price, Ph.D.
Consultant, CEO of P.R.I.C.E.
Former Associate Director for Investigative Oversight, ORI, HHS, U.S. Government
Office of Research Integrity
U.S. Public Health Service, D.H.H.S.

- ORI receives & assesses allegations involving NIH and other HHS funding.
- Refers allegations to institutions on falsification, fabrication, and plagiarism in proposing, conducting, reporting, and reviewing research.
- Conducts investigative oversight on institutional investigation reports.
- Takes follow-up actions, including debarment and retractions of papers.
HHS Office of Research Integrity

Research Misconduct Regulation

• Original HHS regulation, 1989
  – 42 CFR Part 50

• Revised HHS regulation, 2005
  – 42 CFR Part 93

• Requires institutions to notify ORI and send reports on investigations

• Requires institutions to assist ORI, with evidence to support possible HHS research misconduct findings
Institutions, and ORI, receive F/F/P allegations from individuals:

- scientists, staff, postdocs, and students working as involved laboratory staff.
- readers who questioned papers, reports, or grant and fellowship applications.
- investigative reporters and public advocates/activists who question results.
- editors, or reviewers for their journals, who questioned submitted manuscripts - editors can seldom investigate alone.
ORI ENCOURAGES INTERACTIONS WITH EDITORS ON QUESTIONED PAPERS

**Example:** Robert Daroff, Editor of *Neurology*, received 1988 allegations of falsification of traces of facial motor control in a Parkinson patient, by Professor James Abbs, Ph.D., Univ. of Wisconsin.

Abbs convinced UWI inquiry committee that the traces were from a different patient, whose full records were missing. Daroff and others did not accept that, & asked NIH/ORI for investigation (delayed for years after Abbs filed for injunction in federal court to block the ORI investigation).

Editor Daroff retracted the paper himself in 1996 after ORI made findings and Abbs settled case.
ORI ENCOURAGES INTERACTIONS WITH EDITORS ---- NIH MEETING

- **OSI Editors’ Workshop**: at NIH Cloister in 1990:
  - 25 editors of top biomedical and medical journals invited to discuss with OSI officials and each other how to handle allegations of misconduct with their journals;
  - Led to numerous private interactions with editors on ORI cases.
- ORI welcomes calls from editors for advice or assistance; editor will decide follow-up actions.
ORI standard process on retractions and working with editors

• ORI negotiates settlement agreements require that a person who committed F/F/P-misconduct to submit ORI-approved retraction/correction letters to editors.

• Editors need to balance a desire for speed and correction of literature vs. ORI’s need for a complete process under the Regs.

• Editors as direct complainant to institution may thus get more information on status and outcome (rather than waiting for ORI)
ORI working with editors on retractions – issues and problems

- However, some chief scientists and institutional officials have already informed editors of need for retraction, before ORI is involved – this is best done by naming the person who did the F/F/P.
- Some individuals request just an erratum or comment be published, not a retraction.
- One individual’s attorney asked an editor to “un-retract” editor’s retraction (“wait for ORI”).
- Coauthors are often concerned that an individual’s retraction did not “fix the blame.”
- Some individuals submit corrections before findings of FFP are made, hoping to avoid a later statement on their blame for misconduct.
ORI working with editors on retractions – issues and problems

- One individual agreed to the retraction, then denied any misconduct on Internet.

- Some editors required that all coauthors sign retractions, allowing the person who did F/F/P to “refuse” -- and thus “block” the publication of the retraction.

- In some cases, the institutional research integrity officer cosigned the retraction with the other coauthors (or alone), so the editor accepted that for publication.
ORI working with editors on cases

- A few editors asked ORI for direct assistance when reviewers or staff experts detected possible image falsification. ORI scientists gave advice on whether evidence warranted referral to university.

- Once in seeking outside independent experts for ORI investigation, where editor had reported a reviewer discovered a falsified image, I asked the editor’s help, to ensure I would not ask that reviewer to serve (& breach confidential status).

- Once I requested an editor hold on to a copy of a manuscript (which the complainant/coauthor said he had requested be withdrawn), since it was not clear that the corresponding author/respondent would provide it for investigation.
Advice for editors on misconduct cases

- Council of Science Editors White Paper, Promoting Integrity in Scientific Journal Publications:

- Managing Allegations of Scientific Misconduct: ORI Guidance Document for Editors:

- ORI Learning Tool for Research Integrity and Image Processing [for editors, interviewing one]:

- http://www.councilscienceeditors.org/files/presentations/2011/12_Krueger.pdf; and

- ORI online forensic image analysis tutorials:
  - http://www.cmc2.tv/forensic/
Contact ORI, or me, for advice

Office of Research Integrity
Phone 240-453-8800
Web:  http://ori.hhs.gov

• Alan Price, Ph.D., Price Research Integrity Consultant Experts
• Phone 512-483-1574
• Web:  www.researchmisconductconsultant.com
Research Misconduct: Legal Issues for Editors

Debra M. Parrish

August 23, 2011
Defining/Shaping Legal Cases
Gallo

- Obscured the origin of the virus and cell line
- Breach of authorship cell line sharing obligation
- Amended the French abstract
- Refused to send virus/cell to competitors
- Journal asked to provide evidence of peer-review
- The politics of prosecution
Poisson

Journals do not have a need to know

Perpetuating the fabrication

Electronic tagging

Resulting litigation

The politics of prosecution
Poehlman

- Qui tam action
- Criminal investigation
- Early retraction/correction – breach of confidentiality?
- The politics of prosecution
Hwang

- The perils of whistle blowing
- The perils of authorship
- Institutional politics
- Media frenzy
- Public understanding of science
- The politics of prosecution
Suits/Threats Against Journals

- Plagiarism vs. copyright infringement

- Gross dereliction of duty, fraud and conspiracy to defraud (with regard to publishing a plagiarized and falsified research article)

- Coercion, fraud and conspiracy to defraud (with regard to rejecting a "Letter to the Editor/Corrective Advertising")

- Intentional infliction of emotional distress

- Willful violation of the Lanham Act § 43(a), 15 U.S.C. § 1125(a)

- Violation of the Sherman Antitrust Act, 15 U.S.C. §§ 1,2
Suits/Threats by Journals

- Copyright violation
- Black listing
- FOIA
Legal Issues Journals Consider

- Breach of confidentiality
  - Peer review
  - ORI regs
- Producing documents during investigation
- Retracting/Correcting while minimizing legal exposure
Research Misconduct and Editors

Questions?