Protecting the Integrity of Science
Scientific Misconduct

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Researcher admits fraud in grant data

Ex-Vermont scientist won nearly $3m from US

By Carey Goldberg and Scott Allen, Globe Staff | March 18, 2005

The Boston Globe
SCIENTIFIC MISCONDUCT

Researcher Faces Prison for Fraud in NIH Grant Applications and Papers

In the most extensive scientific misconduct case the National Institutes of Health (NIH) has seen in decades, a researcher formerly at the University of Vermont College of Medicine in Burlington has admitted in court documents to falsifying data in 15 federal grant applications and numerous published articles. Eric Poehlman, an expert on menopause, aging, and metabolism, faces up to 5 years in jail and a $250,000 fine and has been barred for life from receiving any U.S. research funding.

Scientists say the falsified data—including work in for total cholesterol, insulin, resting metabolic rate, and glucose” were falsified or fabricated, said a statement Poehlman signed last week. In an effort to portray worsening health in the subjects, DeNino tells Science, “Dr. Poehlman would just switch the data points.”

After DeNino filed a formal complaint, a university investigative panel looked into Poehlman’s research and uncovered falsified data in three papers. These included a much-cited 1995 Annals of Internal Medicine study that suggested hormone replacement therapy could prevent declines in energy expenditure and increases in body fat during menopause. In that paper Poehlman presented metabolic data on 35 women taken 6 years apart. Most of the women did not exist, according to the statement Poehlman signed. (In 2003 the paper was retracted.) Poehlman left Vermont in 2001, before the investigation ended, for the University of Montreal. He left there in January and now lives in Montreal.
Research scam makes waves

A Norwegian doctor’s fabrication of cancer research is making waves far beyond Norway’s borders. The fraudulent research may have led to faulty treatment of cancer patients, international investigations have been launched into how the fraud could have occurred, and top Norwegian officials all the way up to the ministerial level are desperately trying to control the damage.

The editor of the respected magazine, *The Lancet*, in which the fabricated article was published, calls the fraud “the worst the research world has seen.”

Richard Horton told Oslo newspaper *Aftenposten* that he also can’t understand how the Oslo doctor’s 13 co-authors and colleagues on the fraudulent cancer research project could have been duped as well.

Horton claims at least six of the doctor’s co-authors corresponded with *The Lancet*, and were highly involved with the substance of the article.
Research cheats may be jailed

State officials have been considering imposing jail terms on researchers who fake their material, but the proposal hasn't seen any action for more than a year. More is expected now, after a Norwegian doctor at the country's most prestigious hospital was caught cheating in a major publication.

Newspaper Aftenposten reported Monday that a commission led by medical professor Magne Nylenna of the Norwegian University of Science and Technology (NTNU) in Trondheim submitted its findings to the state Ministry of Health in December 2004. Commission proposals included a call for jail terms of up to one year for anyone caught forging medical research.

Norway's Radiumhospital has been rocked by a research scandal that may threaten its credibility.
NUCLEAR PHYSICS

Researchers Raise New Doubts About ‘Bubble Fusion’ Reports

Bubble fusion is again generating heat, but not the kind Rusi Taleyarkhan was hoping for. Last week, Purdue University in West Lafayette, Indiana, announced that it was launching a review into allegations that Taleyarkhan—a nuclear engineer at Purdue and the field’s chief proponent—had obstructed the work of Purdue colleagues by removing shared equipment, declining to share raw data, and trying to stop them from publishing results that countered his own published work.

The allegations, which Purdue University Provost Sally Mason calls “extremely serious,” were first made public in last week’s print and online issues of Nature. The review also follows a meeting in Taleyarkhan’s lab, attended by other researchers trying to replicate his work, at which Taleyarkhan attempted to demonstrate bubble fusion in action. Sev-
CHEMISTRY

Columbia Lab Retracts Key Catalysis Papers

For synthetic chemists working to craft new molecules, a carbon atom surrounded by hydrogens can be as hard to handle as a greased pig. Undaunted, in recent years researchers have scrambled to devise schemes for plucking select hydrogens off carbon and replacing them with other atoms that offer an easier handhold. A pioneer of this subfield, known as C-H activation, Columbia University chemist Dalibor Sames has developed a wealth of advances along with his group members. But some of the lab’s results are now in doubt.

Last week, the Journal of the American Chemical Society (JACS), a leading chemistry journal, printed corrections for three papers from the Sames lab. Two of the papers on C-H activation catalysts were fully retracted, and part of a third was withdrawn. In each case, the retractions say that the work was disavowed after Sames group members could not reproduce the results following the departure of Bengü Sezen, a former Sames group graduate student, who was the lead author of the two retracted papers and a co-author of the third. JACS Editor Peter Stang says the corrections came at the request of the Sames group. Sames did not reply to repeated phone and e-mail messages from Science.

Susan Brown, Columbia's director of public affairs, says the university has launched a review of the case, but that she cannot comment on its scope or timing. “It’s our policy not to comment on reviews while they are ongoing, so the integrity of the process can be maintained,” Brown says.

In an e-mail exchange, Sezen, who is now a Ph.D. candidate in the group of University of Heidelberg molecular biologist Elmar Schiebel, according to the group’s Web site, says the retractions came as a surprise. “Professor Dalibor Sames or anyone else from Columbia University did not contact me regarding the retractions,” she says. For the two retracted papers, Sezen named two other Sames group members who she says repeated her work while she was out of town. For the third paper, Sezen says her contribution was “limited to an intellectual one.” But Kamil Godula, one of the Sames group members Sezen cited, says in an e-mail that the reactions worked only when Sezen was in town. The other Sames group member Sezen mentioned did not return messages from Science.

Justin Du Bois, a synthetic chemist at Stanford University in California, calls the retractions “a bit of a blow” to the subfield of C-H activation: “These were definitely important papers,” he says. Sezen has at least five publications on C-H activation with Sames in addition to those corrected in JACS. Benjamin Lane, a former Sames group member now working as a chemist with the pharmaceutical company Biogen in Cambridge, Massachusetts, says some of Sezen's work has been replicated and has been used by chemists in the pharmaceutical industry. Says Lane, “She has done some good things and made an impact on the field.”

—ROBERT F. SERVICE
SCIENTIFIC COMMUNITY

Bias Claim Stirs Up Ghost of Dolly

A hearing into a scientist’s claim that he was the target of harassment and racial discrimination has put under a microscope the lab where Dolly the sheep was cloned. It also has prompted the man widely recognized as Dolly’s creator, Ian Wilmut, to give detailed evidence on who deserves credit for the successful experiment—and precisely how much. In testimony, Wilmut gave himself less than a third of the credit.

The investigation arises from a suit brought by molecular biologist Prim Singh. He charges that Wilmut, then a researcher at the Roslin Institute in Midlothian, U.K., bullied him and stole his ideas. Seeking $1.74 million, he claims that Roslin passed him over for promotions because of his race and forced him to quit after he lodged a complaint against Wilmut in 2003. Wilmut and Roslin have denied the charges. (A previous discrimination claim that Singh filed was dismissed last year.) Singh did not work on the Dolly project, but testimony in his case provides an inside view of the team that pulled off one of the world’s most famous biology experiments.

An employment tribunal in Edinburgh began hearing testimony from Singh and other witnesses in November 2005, but it was testimony last week from Wilmut himself that caught wider attention. Singh’s lawyers questioned Wilmut about the famous paper describing Dolly, published in Nature in 1997. Wilmut, who is now at the University of Edinburgh, was lead author and has received most of the public credit. But in court he said that he had neither developed the key technology nor conducted the experiments that led to Dolly’s birth. When Singh’s lawyer asked him if the statement “I did not create Dolly” was true, Wilmut answered “Yes.” He said he played a coordinating role in the project but that his colleague Keith Campbell, now at the University of Nottingham, deserved “66%” of the credit for the breakthrough.

Other members of the team offered independent views to journalists covering the case. Bill Ritchie, a technician at Roslin, says he and Karen Mycock, another technician, did the nuclear transfer procedures. But neither is listed as an author on the paper. Alan Colman, now CEO of ES Cell International in Singapore, who was working at Roslin’s sister institute PPL Therapeutics at the time of the Dolly experiments, says that authorship questions on the paper were controversial from the start. He says Ritchie and Mycock made important contributions to the project, but adds that Wilmut did not take an undue share of the credit. “Ian conceived the program, worked on it for many years, and hired the right people to get it done,” he says.

Roslin itself, meanwhile, is planning a complete makeover and change of location. After a positive scientific review last fall, says director Harry Griffin, Roslin has been approved to join a new outfit in 2009 called the Edinburgh Bioscience Research Centre at the University of Edinburgh School of Veterinary Studies. The U.K. government is pledging $60 million to the merger, which will also bring in experts in prion diseases from the nearby Institute for Animal Health. Griffin says its leaders aim to raise another $52 million for a research facility employing 500 scientists. He would not comment on the Singh case.

—GRETCHEN VOGEL AND ELIOT MARSHALL

With reporting by John Bohannon.

Murky origins. A discrimination hearing has reignited old resentments among the team that cloned Dolly the sheep.
New drug trial puts six men in intensive care
17:08 15 March 2006
NewScientist.com news service
NewScientist.com staff and AFP

Six men are in hospital intensive care – two of them in critical condition – after participating in trials of a new drug intended to treat chronic inflammatory conditions and leukaemia.

When drug trials go horribly wrong
By Elisabeth Rosenthal International Herald Tribune
SUNDAY, APRIL 9, 2006

LONDON In February, when Rob O. saw the text message pop up on his cellphone from Parexel International - "healthy males needed for a drug trial" for £2,000 - it seemed like a harmless opportunity to make much-needed cash.

to speak for this article on condition his family name not be used, took part in a study that has sent shock waves through the research world and has caused regulators to rethink procedures for testing certain new drugs.
Korean stem-cell case, Woo-suk Hwang

Who Is Telling the Truth?
Hwang Defends Stem Cell Work; Coauthor Repeats Fabrication Claim

By Kim Tae-gyu
Staff Reporter

Korea’s cloning scientist Hwang Woo-suk contended his team did create several tailor-made stem cells and will prove the authenticity of the medical potential-laden cells in about 10 days.

During a press conference Friday at Seoul National University (SNU), Hwang apologized for disputes over the stem cell research and said he had requested the withdrawal of the stem cell paper in question featured by U.S. journal Science in May.

However, the 52-year-old geneticist rebuffed the claim of his close aide Roh Sung-il, head of Mizmedi Women’s Hospital, who argued on Thursday that Hwang admitted the stem cells were fake.
Public response…

- Scott Fitzgerald's opener to The Great Gatsby, "the rich are different from you and me..." is most aptly applied today to an elite corps of rich academic scientists.
- Academia once symbolized a fortress of intellectual integrity and the pursuit of science and higher education for the common societal good.
- Today, a brazen culture of lawlessness is pervasive at major academic medical centers that have been caught engaging in fraud, research misconduct, misappropriation of money, falsification of records—even fraudulent reports about phantom clinical trials.

August 17, 2005
Research community response…

- **Five long-standing assumptions/generalizations**
  - Serious misconduct in research is rare
  - Self-regulation keeps improper behavior in check
  - Research misconduct is difficult to detect
  - Research misconduct cannot be prevented
  - Apart from misconduct, standards for integrity in research are high

- **Objectives:**
  - Explore whether these assumption/generalizations are accurate
  - Suggest policy changes needed to foster higher standards for integrity in research
How common is research misconduct?

• Definitions of misconduct vary:
  ✓ Government definition = fabrication, falsification and plagiarism
  ✓ Research institutions have broader definitions, e.g. add:
    - Financial mismanagement
    - Failure to comply with research regulations
    - Failure to maintain confidentiality
  ✓ Researchers view other behaviors as troubling:
    - Failure to report data, including contradictory data
    - Using other’s ideas without giving credit
    - Deceptive data interpretation

• Prevalence of misconduct ~ definition
  ✓ Broader definitions → greater prevalence (more misconduct)
  ✓ FFP = narrow definition → lower estimates of prevalence
What is known about prevalence?

Scientists behaving badly

To protect the integrity of science, we must look beyond falsification, fabrication and plagiarism, to a wider range of questionable research practices, argue Brian C. Martinson, Melissa S. Anderson and Raymond de Vries.

• **Martinson, *Nature* (June 2005)**
  - Goal: factors that influence research behavior
  - Method:
    - Developed peer-based list of major offenses
    - Survey to 6,000+ researchers (3,000+ response)
    - Major question: “have you done … in last three years?”

• **Results**
  - Major offenses, ca. 0.3%
  - Questionable Research Practices (QRP) ca. 5-15% or higher
Data from other recent studies

  ✓ Survey, 442 biostatisticians, 37% response
  ✓ 51% knew about fraud in medical research
   ▪ 26% involved FF
   ▪ 31% directly involved in projects with misconduct
  ✓ Estimates of rate, .69% → .80% (.25% standard)

  ✓ Survey, 305 new medical consultants, 64% response
   ▪ 55.7% observed misconduct (FF lower)
   ▪ 5.7% committed misconduct in the past
   ▪ 18% would commit in future
   ▪ 17% had research ethics training
Studies continued

- **Gardner, Contemporary Clinical Trials (2005)**
  - ✓ Authors pharmaceutical clinical trials (64% response)
  - ✓ 1% reported target article misrepresented the research
  - ✓ 5% reported fabrication in a study they had participated in over the last 10 years
  - ✓ 17% knew personally of fabrication in a study over the last 10 years

- **Rossner, Journal of Cell Biology**
  - ✓ 8 in 800 papers had serious improper digital image manipulation

*Technology seen abetting manipulation of research*

By Gareth Cook, Globe Staff | January 11, 2006

An explosion of new digital image technology has left many of the world's top biology journals vulnerable to fraud, scientists say.
How common is research misconduct?

- **Standards for significance?**
  - “rare disease” ~ 1 in 200,000 / year
  - 2 M researchers → 10 cases / year
  - ORI & NSF confirm on average twice this number annually
  - Confirmed cases underestimate actual cases by factor of 10 or more
    - Some researchers suspect but do not report misconduct
    - Some journals find but do not report misconduct
    - Some research institutions do not pursue rigorous investigations

- **Research misconduct is not “rare”**
  - depending on definition, FFP could taint > 1 in 1,000 researchers
  - 2 M researchers → 2,000 cases / year
  - Studies of research behavior confirm these estimates!
Does self-regulation keep misconduct in check?

**NEWSTRACK**

**Purdue investigates professor's research**

WEST LAFAYETTE, Ind., March 8 (UPI) -- Purdue University is reportedly investigating the research of Professor Rusi Taleyarkhan, who said he produced nuclear fusion in a tabletop experiment.

- **Key mechanism is thought to be replication**
  - Purdue case driven primarily by inability to replicate
  - Bell Labs/ Schön Case, inability to replicate raised questions
    - *Co-authored dozens of papers on superconductivity*
    - *Other researchers could not replicate his results*
    - *Bell Labs appointed investigation (Beasley) committee*
    - *16 papers found to have fraudulent data*
      - *Science retracted 7 papers, Nature retracted 8*
  - **Failure to replicate raises questions; does not guarantee discovery**
  - **Schön’s misconduct discovered by reviewers & readers, no co-authors**
Quality control in research

Review settings

- Regulatory enforcement
  ✓ IRB, IACUC, audits…
- Funding peer review
- Publication peer review
- Replication
- Application
  ✓ IND, patents, copyrights…

Other review and detection
How is misconduct detected?

- Hwang case

- Other review and detection

PI

Graduate Students

Postdocs

Graduate Students

Staff

TV Station/Blogs

News reports

Co-author withdraws

Duplicate images discovered

More news reports

Official Review

University investigation
Discovery of research misconduct

- **Who discovers**
  - ✓ Research mentors/advisors
  - ✓ Students & research staff
  - ✓ Grant peer reviewers
  - ✓ Journal editors & peer reviewers
  - ✓ Clinical trial auditors
  - ✓ Journal readers
  - ✓ Government auditors

- **Process of discovery**
  - ✓ Part of regular review process
  - ✓ Accidental discovery

- **Self-regulation works, but has serious weaknesses**

- Early/pre-publication
- Late/post-publication
Is misconduct difficult to detect?

- Hwang case, some obvious problems
  ✓ “In another example, [Schatten] reported that he was told by Dr. Hwang in the middle of January, 2005 that some contamination of the cells had occurred. Dr. Schatten’s reaction was apparently to accept Dr. Hwang’s assurance that this problem was a minor nuisance.

  ✓ Dr. Schatten did not extrapolate to conclude that if new cell lines had to be started in middle or late January there would not have been enough time to grow and analyze them by March 15, the date of the first manuscript submission.” (Pittsburgh Report)

- More attention to supporting data (or lack thereof) might have led to earlier discovery
Misconduct is often not subtle or clever

- **Obvious mistakes**
  - Sudbø reported results from trials that had not been conducted, did not vary patient data
  - Schön repeated figures, reported unrealistic results
  - Hwang did not falsify “supportive” data
- **Inattentive co-authors and collaborators**
  - Poehlman, MD co-author did not track patients
  - Batlog did not verify Schön’s experiments or look at his equipment
  - Schatten did not look carefully at the data
- **More “organized skepticism” (Mertonian norm) would improve quality control**
Can misconduct be prevented?

• Francis Collins / Amitav Hajra case
  ✓ UM MD/PhD student, went to NIH with Collins
  ✓ Fabricated/falsified data in 5 papers

• Collins role
  ✓ “Collins was praised for the forthright way he handled the case of misconduct, which had been discovered by a reviewer of a paper that Hajra had submitted to the journal Oncogene.” (Cell, March 10, 2006)

• Might have been detected earlier if not prevented by regular checks of laboratory notes
  ✓ “[the experience] caused me to become more skeptical, which is something I am not entirely happy about.”
Is integrity in research otherwise high?

Research behavior

Misconduct ~ 0.1% $\leftrightarrow$ 1%

QRP ~ 10% $\leftrightarrow$ 50%

High or highest standards ??
Questionable Research Practices

• Identified in name by NAS, 1992
  “Questionable research practices do not directly damage the integrity of the research process and thus do not meet the panel's criteria for inclusion in the definition of misconduct in science.

• Felt to have minimum consequence
  … they deserve attention because they can erode confidence in the integrity of the research process, violate traditions associated with science, affect scientific conclusions, waste time and resources, and weaken the education of new scientists.”

  (NAS, Responsible Science, 1992, p. 28)
Findings in the Martinson study

<table>
<thead>
<tr>
<th>Ten Top Behaviors</th>
<th>All</th>
<th>Mid</th>
<th>Early</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Falsifying or ‘cooking’ research data</td>
<td>0.3</td>
<td>0.2</td>
<td>0.5</td>
</tr>
<tr>
<td>2. Ignoring major aspects of human-subject requirements</td>
<td>0.3</td>
<td>0.3</td>
<td>0.4</td>
</tr>
<tr>
<td>3. Not properly disclosing involvement in firms whose products are based on one’s own research</td>
<td>0.3</td>
<td>0.4</td>
<td>0.3</td>
</tr>
<tr>
<td>4. Relationships with students, research subjects or clients that may be interpreted as questionable</td>
<td>1.4</td>
<td>1.3</td>
<td>1.4</td>
</tr>
<tr>
<td>5. Using another’s ideas without obtaining permission or giving due credit</td>
<td>1.4</td>
<td>1.7</td>
<td>1.0</td>
</tr>
<tr>
<td>6. Unauthorized use of confidential information</td>
<td>1.7</td>
<td>2.4</td>
<td>0.8</td>
</tr>
<tr>
<td>7. Failing to present data that contradict one’s own previous research</td>
<td>6.0</td>
<td>6.5</td>
<td>5.3</td>
</tr>
<tr>
<td>8. Circumventing certain minor aspects of human-subject requirements</td>
<td>7.6</td>
<td>9.0</td>
<td>6.0</td>
</tr>
<tr>
<td>9. Overlooking others' use of flawed data or questionable interpretation</td>
<td>12.5</td>
<td>12.2</td>
<td>12.8</td>
</tr>
<tr>
<td>10. Changing the design, methodology or results of a study in response to pressure from a funding source</td>
<td>15.5</td>
<td>20.6</td>
<td>9.5</td>
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</tbody>
</table>

= Federal definition of misconduct
## Martinson continued

<table>
<thead>
<tr>
<th>Other behaviors</th>
<th>All</th>
<th>Mid</th>
<th>Early</th>
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<tbody>
<tr>
<td>11. Publishing the same data or results in two or more publications</td>
<td>4.7</td>
<td>5.9</td>
<td>3.4</td>
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<tr>
<td>12. Inappropriately assigning authorship credit</td>
<td>10.0</td>
<td>12.3</td>
<td>7.4</td>
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<tr>
<td>13. Withholding details of methodology or results in papers or proposals</td>
<td>10.8</td>
<td>12.4</td>
<td>8.9</td>
</tr>
<tr>
<td>14. Using inadequate or inappropriate research designs</td>
<td>13.5</td>
<td>14.6</td>
<td>12.2</td>
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<tr>
<td>15. Dropping observations or data points from analyses based on a gut feeling that they were inaccurate</td>
<td>15.3</td>
<td>14.3</td>
<td>16.5</td>
</tr>
<tr>
<td>16. Inadequate record keeping related to research projects</td>
<td>27.5</td>
<td>27.7</td>
<td>27.3</td>
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</tbody>
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- Practices felt likely to occur and adversely impact research

<table>
<thead>
<tr>
<th>Issue</th>
<th>Weight</th>
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<tbody>
<tr>
<td>Over-interpretation of “significant&quot; findings in small trials</td>
<td>83</td>
</tr>
<tr>
<td>Selective reporting based on p-values</td>
<td>80</td>
</tr>
<tr>
<td>Selective reporting of outcomes in the abstract</td>
<td>76</td>
</tr>
<tr>
<td>Subgroup analyses done without interaction tests</td>
<td>75</td>
</tr>
<tr>
<td>Negative or detrimental studies not published</td>
<td>68</td>
</tr>
<tr>
<td>Putting undue stress on results from subgroup analysis</td>
<td>68</td>
</tr>
<tr>
<td>Inappropriate subgroup analyses</td>
<td>64</td>
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<tr>
<td>Selective reporting of (i) subgroups (ii) outcomes (iii) time points</td>
<td>64</td>
</tr>
<tr>
<td>Selective reporting of positive results/omission of adverse events data</td>
<td>60</td>
</tr>
<tr>
<td>Failure to report results or long delay in reporting</td>
<td>60</td>
</tr>
<tr>
<td>Post-hoc analysis not admitted</td>
<td>59</td>
</tr>
<tr>
<td>Giving incomplete information about analyses with non significant results</td>
<td>56</td>
</tr>
<tr>
<td>Analysis conducted by the sponsor of the trial</td>
<td>54</td>
</tr>
</tbody>
</table>
Adverse impact of QRP > FFP

- Impact of FFP is limited
  - Relatively few “major” cases
  - Little evidence of misleading the course of science
  - Some positive outcomes

- Impact of QRP is significant
  - Duplicate publication distorts meta-analyses

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THE CHRONICLE OF HIGHER EDUCATION

Today's News

Many Experts Who Worked on Manual of Mental Disorders Have Ties to Drug Industry, Study Finds

By AMY RAINEY

Friday, April 21, 2006
Conflict of Interest Studies

- Bekelman (2003), *JAMA*
  - Meta-analysis of 37 COI studies (1,000s of trials)
  - Positive correlation (3.60 OR), industry sponsorship & positive outcomes
- Lexchin (2003), *BMJ*
  - Meta-analysis of 30 COI studies
  - Positive correlation (4.05 OR), industry sponsorship & positive outcomes
- Friedman (2004)
  - 398 publications, *NEJM* and *JAMA*
  - Correlation (2.35-2.64 OR), industry/positive outcomes
Conclusions and recommendations

• Research agree that standards for integrity should be high

• Evidence suggests that standards fall short of this mark
  ✓ FFP is not rare
  ✓ QRPs are fairly common & have serious adverse impacts
    ▪ Undermine the objectivity and accuracy of the research record
    ▪ Waste public funds
    ▪ Erode public confidence
    ▪ Discourage careers in research/science

• Two options for raising standards for integrity
  ✓ Improved self-regulation
  ✓ More effective government regulation
Improved self-regulation

☆ Improved quality control
  ✓ Better supervision and mentoring
  ✓ More careful review (grant, publication, promotion)
  ✓ Report suspected problems (FFP, QRP, Adverse events…)

◆Clearer, more specific guidelines
  ✓ Authorship
  ✓ Conflict of interest
  ✓ Data management, interpretation, and storing
  ✓ Digital images

◆Better training
  ✓ Basic introduction to responsible research practices
  ✓ On-going, across-the-training spectrum reinforcement
More effective government regulation (I)

Strengthen problem assessment

- Identify practices & behaviors that:
  - Waste research funds
  - Undermine the usefulness and objectivity of findings
  - Weaken public confidence in research
  - Mislead policy making
  - Adversely impact public health and safety

- Establish regulatory priorities based on risk/impact assessment, not arbitrary definitions (i.e. FFP)

Areas for support, coordination and education

- Funding agencies (finish adoption of 2000 OSTP definition)
- Quality assessment and audit offices (AHRQ, FDA …)
- Inspectors General (better education & coordination)
- Research on Research Integrity (increase funding)
More effective government regulation (II)

Broaden government authority if institutional and professional commitments do not improve

• Areas for support, coordination and education
  ✓ Replace “plagiarism” with “practices that significantly compromise the accuracy and objectivity of the research record, waste public funds, or endanger human lives”
  ✓ Extend obligations to report misconduct to scientific journals that publish government-supported research
  ✓ Strengthen RCR training requirements
    ▪ However accomplished, all researchers should be introduced to the fundamental of the responsible conduct of research
questions & information

nsteneck@umich.edu