Major misconduct case: Eric Poehlman, Ph.D.
University of Vermont

Chris B. Pascal, J.D., Director,
Office of Research Integrity (ORI)
The initial allegations arose when Dr. Poehlman provided a colleague, about a week apart, two versions of a spreadsheet containing physical, dietary, energetic, and metabolic data on elderly men and women seen twice, on average, about six years apart.

In the complainant’s own words:
The incident that triggered my suspicions occurred in late September, 2000 - I was asked by Dr. Poehlman to write a paper from a longitudinal database (Protocol #678). The paper was to examine the effects of age on lipids in men and women... When I presented him with the data, he was not satisfied with the results and asked for the database in order to verify data entries and check for what he described as "reversed" datapoints, ... It was my belief that I was mistakenly given a “true” version of the dataset originally and then given the manipulated version the second time...
The Scope of the Misconduct

- The following two slides provide a brief glimpse of the massive scope of Dr. Poehlman’s alterations in the data base for the longitudinal study of aging, protocol #678.
Dr. Poehlman’s changes to total energy expenditure values included many fabrications (blue) and reversals of visit one and visit two values (red).

The net effects were to greatly inflate the number of subjects and to reverse the apparent effect of aging.

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Dr. Poehlman’s changes to glucose involved near complete reversal of T1 and T2 values, allowing him to claim that glucose levels rose with age when the real data showed the opposite.

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**Mean** | 98.94 | 87.94 | 87.79 | 99.90  
**S.D.** | 8.85  | 10.67 | 9.21  | 10.13  
**Count** | 143.00 | 126.00 | 137.00 | 136.00
Additional Issues

- Dr. Poehlman claimed to have conducted a longitudinal study of the menopause transition involving 35 women seen twice six years apart.
- This study was reported in a 1995 paper in the *Annals of Internal Medicine* and five follow-up papers as well as in many grant applications.
- The study was not conducted: Dr. Poehlman falsified the number of subjects at T1 and never saw the women a second time.
The data from the Annals paper claimed to show that the menopause transition quickly leads to undesirable changes in weight, fat mass, resting metabolic rate, leisure time activity, and waist-to-hip ratio.

None of these conclusions were legitimate (although cross-sectional studies have suggested that changes do occur eventually).

Additional fabricated results from this study were reported in later papers and grant applications.
Additional Issues (cont)

- The UVM investigation, ORI, and the U.S. Attorney’s office determined that Dr. Poehlman falsified data in additional papers and grant applications in areas as wide ranging as Alzheimer’s disease, the effect of endurance training on RMR, and the effects of hormone replacement therapy on post-menopausal women.

- Many of these false claims were also made in talks given by Dr. Poehlman, some of which were documented, allowing findings of scientific misconduct to be made.
Dr. Poehlman’s obstruction efforts

- Starting immediately after being accused of misconduct, Dr. Poehlman aggressively attempted to obstruct the University investigation, and subsequently the Government’s review.
- He accused his young colleagues of having falsified the 678 database.
- He went to Federal court to attempt to block UVM from notifying ORI of the pending investigation.
During the investigation, he solicited letters of support from collaborators and former technicians who claimed that they had helped with the longitudinal menopause study; these claims resulted from Dr. Poehlman’s false assurances and edits of the letters, and they placed these witnesses in legal jeopardy.

Dr. Poehlman submitted falsified and fabricated documents to the UVM committee in an effort to show that the 35 women in the menopause study had visited the GCRC a second time.
Additional Findings Made by ORI in its Oversight Review Include:

- Dr. Poehlman provided yet another falsified version of the Protocol 678 spreadsheet to a witness (W1) in the fall of 2000, suggesting that W1 write a review.

- W1 and Dr. Poehlman then wrote a review article that included falsified results about the decline in RMR upon aging.

- Dr. Poehlman also gave falsified TEE and body composition data to another witness (W2) in August 2000 to provide him with data for a presentation to be given in September 2000.
Why did it take so long to discover?

- The reality is that an established and renowned principal investigator with this volume of complex data could easily generate and propagate false values for months, even years, without anyone catching on (UVM Report, p. 19)
Summary

- Dr. Poehlman falsified and fabricated data in NIH grant applications and in published articles over a 10 year period with NIH funding of almost $3 million.

- Counting two USDA applications, he provided falsified and fabricated preliminary data to government agencies in 17 different competitive and non-competitive applications.
The misconduct affected studies related to disease prevention, including research on the health of older men and women, the effect of diet, exercise, menopause status, hormone replacement, and disease status.
The University of Vermont made 22 findings of scientific misconduct in areas represented by 3 GCRC protocols. ORI confirmed 21 of the findings made by UVM and made 35 additional findings in the same plus 2 additional areas (5 protocols).
Publications Identified for Retraction/Correction


Published Papers


Assurance

- Assurance on application form PHS 398, #15
- Principal Investigator/Program Director Assurance: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.
This is what led to Dr. Poehlman pleading guilty to a felony.
What is the involvement of the Vermont U.S. Attorney

- Defended civil litigation brought by Dr. Poehlman to prevent mandatory reporting of misconduct investigation to ORI
- Opened civil and criminal fraud investigations into Dr. Poehlman’s research activities, assisted by ORI and HHS OIG
- Decided that false claims of Dr. Poehlman warranted a criminal charge and personal monetary settlement of $180,000
- Dr. Poehlman still subject to possible criminal sentence
ORI actions and the Whistleblower’s role

- ORI/ASH actions against Dr. Poehlman include lifetime debarment from Federal research funding and retraction/correction of ten published papers.

- The whistleblower in this case later filed a qui tam suit under Federal fraud laws and received a relator’s share of 12% ($22,000) of the Federal recovery of $180,000.
Dr. Poehlman’s Misconduct

- What is the impact on the scientific community?
- What is the impact on the public?
- What are some lessons learned?
- What can your institution do to prevent or reduce research misconduct?
ORI Homepage

- At [www.ori.hhs.gov](http://www.ori.hhs.gov) see the original documents in this case, including the redacted UVM investigation report
Responding to Allegations of Misconduct

Chris B. Pascal, J.D.
Director, ORI
Seven Steps to Success

- Design a good system
- Be prepared
- Follow the defined process
- Consult counsel
Success (cont)

- Understand the **BIG** PICTURE
- Attend to small details
- Focus on integrity, not just misconduct
Rights and Obligations of Whistleblowers and Respondents

Chris B. Pascal, J.D.
Director, Office of Research Integrity
Whistleblower role as complainant

- Know your facts
- Know the definition of research misconduct
- Identify PHS jurisdiction over the allegation
- Disclose to responsible officials
- Maintain confidentiality
- Protect yourself
Whistleblower role as witness

- Provide evidence
- Cooperate with institution
- Understand need for objectivity
- Accept the outcome
Protection from retaliation

- PHS regulation states that institutions will undertake “diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations” of research misconduct. 42 CFR 50.103(d)(13)

- Allegations which are made falsely or in reckless disregard for the truth are not in good faith
Institutional obligations to whistleblower

- Protect from retaliation
- Maintain confidentiality for whistleblower
- Offer opportunity for review and comment on inquiry and investigation
- Do a fair, quality job on the allegation
- If retaliation occurs, take serious steps to correct the situation
ORI Whistleblower Guidelines

Offers three options for institution:

- Investigation by institution
- Binding arbitration
- Settlement
- Any other process that meets regulatory requirement may also be used
Protections for respondents

- Notice of allegations
- Access to evidence; opportunity to respond
- Review and comment on inquiry and investigation reports
- Confidentiality
- Fair, objective process with appropriate expertise
Obligations of respondent

- Provide data and other evidence to institution
- Cooperate with inquiry or investigation
- Avoid retaliation
- Protect confidentiality of whistleblower
- Understand the process and protect yourself
Exonerated respondent

- Institutions must undertake “diligent efforts, as appropriate, to restore the reputation of persons alleged to have engaged in misconduct when allegations are not confirmed” 42 CFR 50.103(d)(13)
- MAINTAIN CONFIDENTIALITY!
Restore reputation

- Send letters to involved parties informing them that misconduct was not found
- Remove material from personnel file
- Treat the exonerated respondent as a member in good standing in the academy
- Other steps appropriate to the circumstances