



Research Misconduct

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Research Misconduct

Definitions for Reference

What is Research Misconduct?

The Fabrication, Falsification, or Plagiarism in proposing, performing or reviewing research or in reporting research results. It does not include honest error or differences of opinion.

Research Misconduct:

Regulatory Overview

Definition of F F P

- Fabrication is making up data or results and recording or reporting them.
- Falsification is 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 is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

NOTE: Applies to NIH funding and is considered the “best practice” definition for all research institutions. This is the definition that has been adopted by most institutions and is used with all research regardless of sponsor.

Research Misconduct

Definitions for Reference

- **Adverse action:** Any action taken by a covered institution or its members which negatively affects the terms or conditions of the whistleblower's status at the institution, including but not limited to his or her employment, academic matriculation, awarding of degree, or institutional relationship established by grant, contract or cooperative agreement.
- **Allegation:** Allegation means a disclosure of possible research misconduct through any means of communication. The disclosure may be by written or oral statement or other communication to an institutional or HHS Official.
- **Complainant:** An individual who makes an allegation or demonstrates an intent to make an allegation (or what is perceived to be an allegation) while a member of the institution at which the alleged research misconduct occurred.

Research Misconduct

Definitions for Reference

- Covered institution:** Any entity, whether individual or corporate, which applies for or receives funds under a research, research-training, or research-related grant or cooperative agreement under the PHS Act.
- Deciding official:** The official designated by the administrative head of a covered institution to make a final institutional determination as to whether retaliation occurred.
- Good faith allegation:** An allegation of research misconduct made with a belief in the truth of the allegation which a reasonable person in the whistleblower's position could hold based upon the facts. An allegation is not in good faith if made with knowing or reckless disregard for or willful ignorance of facts that would disprove the allegation.

Research Misconduct

Definitions for Reference

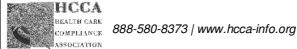
Institutional member, or member: A person who is employed by, affiliated with under a contract or agreement, or under the control of a covered institution. Institutional members include but are not limited to administrative, teaching and support staff, researchers, clinicians, technicians, fellows, students, and contractors and their employees.

Responsible official: The official designated by and reporting to the administrative head of a covered institution to establish and implement the institution's whistleblower policies.

Retaliation: Any adverse action or credible threat of an adverse action taken by a covered institution, or member thereof, in response to a whistleblower's good faith allegation of research misconduct. It does not include an institution's decision to investigate a good faith allegation of research misconduct.

Source for all definitions:

ORI Website



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Research Misconduct

Regulatory Overview

Office of Research Integrity (ORI)

- The Health and Human Services Secretary has delegated responsibility for addressing research integrity and misconduct issues related to PHS supported activities to the Office of Research Integrity (ORI).
- ORI monitors institutional investigations of research misconduct and facilitates the responsible conduct of research (RCR) through educational, preventive, and regulatory activities.

ORI Website: <http://ori.dhhs.gov/>



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Research Misconduct: An Overview

**“Whenever you do a thing, act as
if all the world were watching.”**

Thomas Jefferson

**“It is hard for an empty bag to
stand upright.”**

Benjamin Franklin

Research Misconduct

Regulatory Overview

What is “Research?”

- Research includes all basic, applied, and demonstration research in all fields of science, engineering and mathematics. This includes, but is not limited to, research in economics, education, linguistics, medicine, psychology, social sciences, statistics, and research involving human subjects and animals.

Fed. Reg. Vol. 65 No. 235, December 6, 2000

Office of Science and Technology Policy – Executive Office of the President:
Federal Policy on Research Misconduct

Research Misconduct

Regulatory Overview

NIH Definition of Human Subjects Research

1. Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies.
2. Epidemiologic and behavioral studies.
3. Outcomes research and health services research.

Source:

<http://cms.csr.nih.gov/ResourcesforApplicants/AdvicetoInvestigatorsSubmittingClinicalResearchApplications.htm>

Research Misconduct

Regulatory Overview

Findings of Research misconduct require that:

- There be a significant departure from accepted practices of the research community,
- The misconduct be committed intentionally, knowingly, or recklessly, and
- The allegation be proven by a preponderance of the evidence.

Research Misconduct

Regulatory Overview

Public Health Services (PHS) Policies on Research Misconduct; Final Rule

- Regulations at 42 CFR Parts 50 and 93 provide the scope of authority of the final rule:
 - HHS [US Department of Health and Human Services] has ultimate oversight authority for PHS supported research, and for taking other actions as appropriate or necessary, including the right to assess allegations and perform inquiries or investigations at anytime.
 - Each institution that applies for or receives PHS support for biomedical or behavioral research, research training or activities related to that research or research training must comply with this part.
- The Final Rule delegates responsibility for addressing research misconduct issues to the Office of Research Integrity (ORI).

Research Misconduct

Regulatory Overview

Public Health Services (PHS) Policies on Research Misconduct; Final Rule

- Regulations at 42 CFR Parts 50 and 93 provide the responsibilities of institutions for compliance. Institutions **must**:
 - Have written policies and procedures for addressing allegations of research misconduct that meet the requirements of this part;
 - Respond to each allegation of research misconduct for which the institution is responsible under this part in a thorough, competent, objective and fair manner;
 - Foster a research environment that promotes the responsible conduct of research, research training, and activities related to that research or research training;
 - Take all reasonable and practical steps to protect the positions and reputations of good faith complainants;
 - Provide confidentiality to all respondents, complainants, and witnesses.

Research Misconduct

Regulatory Overview

Public Health Services (PHS) Policies on Research Misconduct: Final Rule

- Regulations at 42 CFR Parts 50 and 93 provide the responsibilities of institutions for compliance. Institutions **must**:
 - Ensure the cooperation of respondents and other institutional members with research misconduct proceedings
 - Cooperate with HHS during any research misconduct proceeding or compliance review
 - Assist in administering and enforcing any HHS administrative actions
 - Have an active assurance of compliance

Institutions must file an Assurance to document that they will comply with these rules and report the results of any research misconduct Investigations to ORI.

(Note: this is in addition to an Assurance for Human Subjects Protection)

Research Misconduct Regulatory Overview

The signature on these documents establishes an assurance

Form Approved Through 11/30/2010		OMB No. 0925-0047	
Department of Health and Human Services Public Health Service		LEAVE BLANK - FOR USE ONLY	
Grant Application <small>Do not exceed character length instructions indicated</small>		Agency Group	Funding
TITLE OF PROJECT (do not exceed 50 characters, including spaces and punctuation)		Contract/Grant (Fiscal Year)	Case Number
2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION: <input type="checkbox"/> NO <input type="checkbox"/> YES (If YES, cite statute and/or rule)			
3. PRINCIPAL DIRECTOR/PRINCIPAL INVESTIGATOR Name: _____ Title: _____ 4. NAME (use the title): _____ 5. POSITION TITLE: _____ 6. DEPARTMENT/ SERVICE/ LABORATORY/ OR EQUIVALENT: _____ 7. MAJOR SUBDIVISION: _____ 8. TELEPHONE AND FAX (Area code, number and extension): TEL: _____ FAX: _____		9. HUMAN SUBJECTS RESEARCH <input type="checkbox"/> NO <input type="checkbox"/> YES (a) Research Exempt <input type="checkbox"/> NO <input type="checkbox"/> YES (b) Exemption No. _____ 10. RESEARCH ASSISTANCE NO. _____ (a) Original Title _____ (b) Non-abstract Phase II Clinical Trial <input type="checkbox"/> NO <input type="checkbox"/> YES 11. VETERINARIAN ASSISTANCE <input type="checkbox"/> NO <input type="checkbox"/> YES (a) Animal Welfare Assurance No. _____ 12. DATES OF PROPOSED PERIOD OF SUPPORT (month/year start/ended-yy/mm) _____ (a) Original Title _____ (b) Other Case ID _____ (c) Other Case ID _____ 13. TYPE OF ORGANIZATION: Name: _____ Address: _____ Public <input type="checkbox"/> Private <input type="checkbox"/> Federal <input type="checkbox"/> State <input type="checkbox"/> Local For-profit <input type="checkbox"/> General <input type="checkbox"/> Small Business <input type="checkbox"/> Non-profit <input type="checkbox"/> Socially and Economically Disadvantaged 14. ENTRY IDENTIFICATION NUMBER: _____ 15. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE Name: _____ Title: _____ Address: _____ TEL: _____ FAX: _____ E-mail: _____ DATE: _____ 16. APPROVAL/ OBSERVATION/ IDENTIFICATION AND NOTIFICATION - Leave this section blank unless you are being contacted by ORI to review your compliance with the PHS regulations. Do not exceed 50 characters. Do not include the name, title, or contact information of any individual or entity. Do not include the name, title, or contact information of any individual or entity. Do not include the name, title, or contact information of any individual or entity.	

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APPLICATION FOR FEDERAL ASSISTANCE		DATE SUBMITTED		Applicant number	
1. TYPE OF SUBMISSION a. Application <input type="checkbox"/> Pre-application <input type="checkbox"/> b. Contribution <input type="checkbox"/> Collaboration <input type="checkbox"/> Non-contractual <input type="checkbox"/>		2. DATE RECEIVED BY STATE		State Application number	
3. DATE RECEIVED BY FEDERAL AGENCY		Fiscal year number		4. TYPE OF APPLICANT (check all that apply)	
5. APPLICANT INFORMATION a. Legal Name: _____ b. Organizational Unit: _____ c. Division: _____ d. Address: _____ e. City: _____ f. State: _____ g. Country: _____ h. ZIP Code: _____ i. Phone Number (area and local): _____ j. Fax Number (area and local): _____		6. TYPE OF PROJECT a. New <input type="checkbox"/> Continuation <input type="checkbox"/> Revision <input type="checkbox"/> b. Revision, enter appropriate office or division (see back of form for description of office): _____ c. Other (specify): _____		7. NAME OF FEDERAL AGENCY	
8. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER: _____		9. TITLE (Name of Program): _____		10. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT: _____	
11. AREAS AFFECTED BY PROJECT (State, County, District, etc.): _____		12. PROPOSED PROJECT START DATE: _____		13. COMMERICAL OBJECTS OF PROJECT: _____	
14. ESTIMATED FUNDING: a. Federal: _____ b. State: _____ c. Local: _____ d. Other: _____		15. IS THIS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 13132 PROCESS FOR REVIEW ON DATE: _____		16. IS PROGRAM IS NOT COVERED BY E.O. 13372 OR PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW: <input type="checkbox"/> YES <input type="checkbox"/> NO	
17. IS THIS THE BERRY OF MY RESEARCH AND DEVELOPMENT? ALL DATA IN THIS AND OTHER DOCUMENTS ORIGINATED BY THIS AGENCY OR CONTRACTOR, THE DOCUMENT HAS BEEN FULLY AUTHORIZED BY THE GOVERNING BODY OF THE APPLICANT AND THE APPLICANT WILL COMPLY WITH THE ATTACHED ASSURANCE IF THE ASSISTANCE IS AWARDED. a. Signature of Principal Investigator: _____ b. Signature of Authorized Representative: _____ c. Signature of State: _____ d. Signature of Local: _____		18. SIGNATURE OF APPLICANT: _____ a. First Name: _____ b. Middle Name: _____ c. Last Name: _____ d. Title: _____ e. Telephone Number (area and local): _____ f. State: _____ g. Date Signed: _____		19. SIGNATURE OF STATE: _____ a. State: _____ b. Date Signed: _____	

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Research Misconduct Regulatory Overview

Institutions maintain their assurance by:

- Filing the Annual Report on Possible Research Misconduct that have been handled by their institution during the prior calendar year (*NOTE: The report is expected to be filed between January 1 and March 1 each year*),
- Submitting their policy for responding to allegations of research misconduct for review when requested by ORI,
- Revising their policy when requested by ORI to bring the policy into compliance with the PHS regulation, and
- Complying with the PHS regulations.

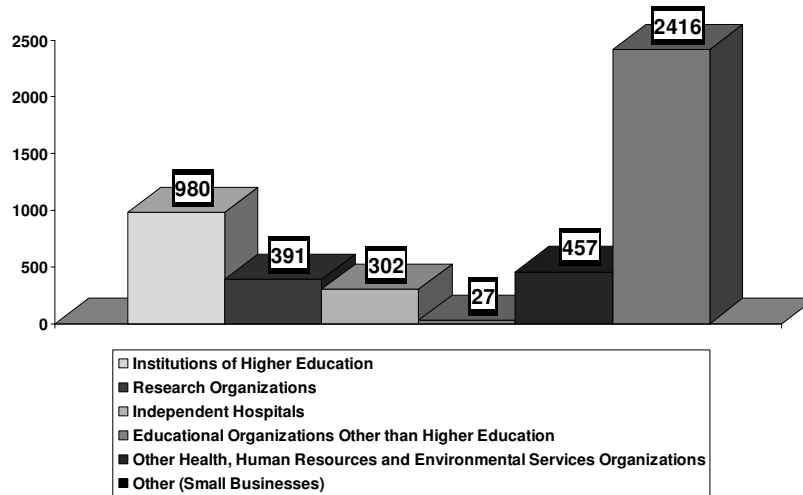
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Research Misconduct

Historical Overview

Number and Type of Institutions with Active Assurances, 2006



Research Misconduct

Regulatory Overview

Department of Health and Human Services Policy on Research Misconduct

- All institutions that apply for or receive PHS support for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training share responsibility for the integrity of the research process.
- Institutions and institutional members have an affirmative duty to protect PHS funds from misuse by ensuring the integrity of all PHS supported work, and primary responsibility for responding to and reporting allegations of research misconduct.

Subpart A- 42 CFR Part 93.100

Research Misconduct

Regulatory Overview

Examples of “Bad Science” *Not* Research Misconduct:

- Poor design, inappropriate experimental methodology
- Poor scientific assumptions
- Use of wrong statistical methodology
- Keeping poor research records
- Poor technique

Examples of Errors or Carelessness *Not* Research Misconduct:

- Misinterpretation of data
- Calculation errors
- Not checking chemical labels
- Miscalculations of amounts of solutions

Research Misconduct

Regulatory Overview

Frequently Asked Questions:

- Q: When did the new regulation become effective?
- A: The final rule became effective on June 16, 2005, 30 days after the date of its publication in the Federal Register (70 FR 28370).
- Q: Does the final rule apply retroactively?
- A: No, the final rule applies prospectively.

Source: <http://ori.dhhs.gov/policies/QA-Reg-6-05.shtml>

Research Misconduct

Regulatory Overview

Frequently Asked Questions:

- Q: What are the primary differences between the 2005 regulation, 42 CFR Part 93 and the old regulation, 42 CFR Part 50, Subpart A, regarding the policies on research misconduct?

- A: Several differences including:

Applicability: The new rule includes PHS intramural research programs and contracts that support research, research training or activities that are related to research or research training.

The new rule applies to an allegation that PHS-supported research involving journal peer review has been plagiarized. Section 93.102.

Limitations period: Moreover, because of the problems that may occur in investigating older allegations and the potential unfairness to the respondent in defending against them, the new rule is limited to research misconduct occurring within six years of the date on which HHS or the institution receives the allegation of misconduct, unless: conditions described in Section 93.105 are met.

Source: <http://ori.dhhs.gov/policies/QA-Reg-6-05.shtml>

Research Misconduct

Regulatory Overview

- A: (continued)

Burden of Proof: Consistent with the OSTP guidance that the exclusion of honest error or difference of opinion from the definition of research misconduct does not require HHS and the institutions to disprove possible honest error or difference of opinion, the new rule provides that these elements are an affirmative defense that the respondent has the burden of proving by a preponderance of the evidence. Sections 93.106(b)(1) and (2) and 93.516(b).

Institutional Responsibilities: The new rule describes in greater detail the responsibilities of the institutions in responding to allegations of research misconduct. Subpart C, Sections 93.300 - 93.319.

Hearing Process: The new rule sets forth a detailed hearing process that is modeled on the HHS Office of Inspector General (OIG) regulation, 42 CFR part 1005, that governs the hearing process for the exclusion of health care providers from Medicare and State health care programs. Subpart E, Sections 93.500 - 93.523.

Responsibilities of ORI and the ASH: The new rule changes the respective responsibilities of ORI and the Assistant Secretary for Health (ASH). Sections 93.400, 93.404, 93.500, and 93.523.

Research Misconduct

Regulatory Overview

Why is there heightened focus on Research Misconduct?

- An area of increased scrutiny
- DHHS must monitor the use of public funds
 - Protection from misuse and fraud
- DHHS must ensure the safety of research participants
 - Human research protections
- Recent questions of the integrity of the scientific method
 - Replicable, verifiable and transparent processes
- Recent questions about research data quality
 - Valid and clean
- Public Trust

Research Misconduct

Historical Overview

In 1999 ORI proposed that Responsible Conduct of Research policy requires training in 9 core areas:

- Data Acquisition, Management, Sharing and Ownership;
- Conflict of Interest and Commitment;
- Human Subjects;
- Animal Welfare;
- Research Misconduct;
- Publication Practices and Responsible Authorship;
- Mentor/Trainee Responsibilities;
- Peer Review; and
- Collaborative Science

ORI announced these training regulations on their website in 2000.

Research Misconduct

Historical Overview

Congressional Inquiry from Representative W. J. "Billy" Tauzin

- In response, the Office of Research Integrity (ORI) suspended new ethics training regulations on February 20, 2001, just months after they were announced on ORI's Web site.
- At the heart of the matter is whether ORI should have published the rules in the Federal Register, a repository of federal regulations and notices, instead of on the ORI Web site alone. In an official response to Tauzin, ORI Director Chris Pascal argued that the RCR regulations did not constitute new rules, but "[the document] was a natural extension of the pre-existing RCR requirement for NIH training grants."
- Outcome: It is highly recommended that institutions have a RCR policy, oversight of its administration, and SOPs that describe enforcement procedures within the organization.

Source:

http://sciencecareers.sciencemag.org/career_development/previous_issues/articles/0910/saved_by_the_bell_ethics_training_rules_put_on_hold

Research Misconduct

Historical Overview

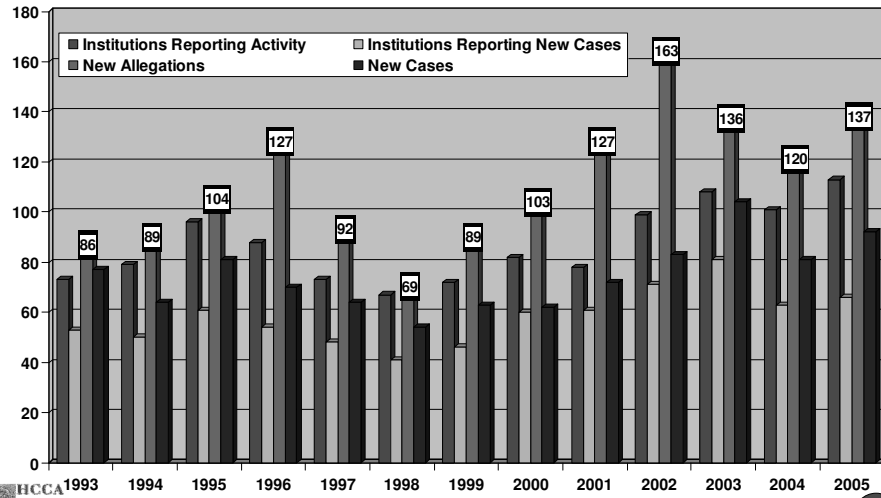
Prevalence of Research Misconduct as of 2006 (based on allegations brought to ORI)

- 266 allegations received by ORI. (265 in 2005)
- Opened 29 new cases; closed 35; 53 cases remained open at end of 2006.
- 15/35 closed had findings of RM and/or imposed administrative actions – 45% of closed cases had RM findings.
- Debarment or voluntary exclusion:
 - 10 cases for 4-5 years
 - 5 cases for 3 years
 - 1 for lifetime (2005)

ORI Annual Report 2006 (Published 5/07)

Research Misconduct Historical Overview

Research Misconduct Activity, 1993-2005



Research Misconduct Historical Overview

Prevalence of Research "Misbehavior"

- n=3,247

- Approximately 1.5% of researchers responded that they have falsified or plagiarized
- 33% admit to professional misbehavior

Journal Nature, June 9, 2005

**Research Misconduct
In Context
Part I**

**“The integrity of the game is
everything.”**

Peter Ueberroth, baseball commissioner, May 12, 1985

**“Success without honor is an
unseasoned dish; it will satisfy
your hunger, but it won’t taste
good.”**

Joe Paterno, head football coach of Pennsylvania
State University, a position he has held since 1966.

Research Misconduct In Context Part I

Most researchers have good intentions

- Pressures (including, in some cases, a lack of resources) and competition can lead to vulnerabilities in integrity. For example:
 - Deadlines and the rush to produce and publish results
 - Funding and financial incentives
 - Prestige and fame
 - Inadequate work environments
 - General frustrations and personal issues
 - Fear and anxieties related to all of the above

Research Misconduct In Context Part I

Research misconduct can result in a variety of actions by the government

- Debarment from federal funding or advisory relationships with federal agencies
- Involvement of other federal/local agencies (Department of Justice, etc.)
- Payment of restitution
- Retraction of publications
- Imprisonment
- When ORI reaches a conclusion of research misconduct, the findings (e.g. researcher's name) can become public

Research Misconduct In Context Part I

When research misconduct becomes public



Illustration by David Zinn

Research Misconduct In Context Part I

Examples of Research Misconduct

Jong Hyuk Park, Ph.D. – University of Pittsburgh (UP)

- Post doctoral fellow in Gerald Schatten's lab
- Collaborated with Woo Suk Hwang
- In 2007, the Office of Research Integrity (ORI) found that Dr. Park:
 - Intentionally and knowingly falsified various versions of two figures in a manuscript entitled "Rhesus Embryonic Stem Cells Established by Nuclear Transfer: Tetraploid ESCs Differ from Fertilized Ones" that was being prepared for submission to Nature;
 - Repeatedly misrepresented to the UP investigative panel the accuracy of one of the figures;
 - Presented the false figures as true to members of the laboratory; and
 - Falsified the record of revisions of the figures by deleting all prior versions from the laboratory server.

Research Misconduct In Context Part I

Examples of Research Misconduct

Jong Hyuk Park, Ph.D. – University of Pittsburgh

- ORI took the following action:
 - Debarred Dr. Park from any contracting or subcontracting with any agency of the United States Government and,
 - Prohibited Dr. Park from serving in any advisory capacity to PHS including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

Research Misconduct In Context Part I

Examples of Research Misconduct

Eric Poehlman, M.D – University of Vermont

- Research misconduct allegation the result of qui tam* disclosure.
- ORI found that Dr. Poehlman misrepresented data that were collected, and falsified information in a number of federal grant applications.
 - Represented metabolic data on 35 women.
 - Falsified number of subjects in 1st visit and never saw the women a 2nd time.
- Two year Investigation
- ORI referred the matter to the Department of Justice.
- In 2005 Dr. Poehlman entered into a Global Settlement:
 - Pleaded guilty to making a material false statement
 - Lifetime debarment from receiving federal funds
- In 2006 Dr. Poehlman was sentenced to imprisonment:
 - 366 days of jail-time followed by 2 years of supervised release
 - Ordered to pay \$180,000 in restitution.

Research Misconduct In Context Part I

Examples of Research Misconduct

US vs. Kornak

Former Research Assistant at Stratton VA Medical Center:

- Mr. Kornak plead guilty to numerous facts including:
 - Enrolling participants who did not qualify for the study.
 - Falsely stating and representing the results of [the study subject's] blood chemistry analysis which resulted in the death of a participant.
- Mr. Kornak plead guilty to three (3) criminal charges:
 - Making a material false statement
 - Mail fraud
 - Criminally negligent homicide
- In 2005 Mr. Kornak was sentenced to imprisonment:
 - 71 months of jail-time
 - Ordered to pay \$639,000 in restitution.

Research Misconduct In Context Part II

An important aspect of integrity is how we deal with errors and mistakes.

Errors and our response to them are part of the scientific process.

Research Misconduct In Context Part II

Case Study #1

Career vs. Responsibility

- Dr. José M. is beginning his fifth year as an independent researcher. His work is going well. He has published a number of important articles and secured a large grant for future work. Based on this progress, he expects his pending promotion review to proceed without problems.
- Late one afternoon a graduate student hands José two papers written by a senior colleague in his department. She has circled graphs in each of the papers that are clearly the same but reported as representing two different experiments. After checking the graphs carefully and reviewing the supporting data, José agrees that something is wrong. The senior colleague, who will almost certainly be a member of his promotion review, has either made a careless mistake or falsified information in a publication.
 - **What is the compliance issue in this scenario?**
 - **What should Dr. José do?**
 - **Do you think this is research misconduct?**



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*ORI Introduction to the Responsible Conduct of Research- Nicholas H. Steneck, PhD Illustrations by David Zinn
HTML Version, September 2006, updated from Revised Printed Edition, June 2004*

<http://ori.dhhs.gov/education/products/RCRintro/>

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Research Misconduct In Context Part II

Case Study #2

Truth or Consequences

- Finally, Julio's project starts to look promising. After many months of effort, he believes he has been able to synthesize RG198, a compound that is to serve as an intermediary in the formation of his thesis molecule, WX5, which he believes will degrade plastic in an environmentally sound way. Julio now has to repeat his experiment to make more RG198 and perform a series of analyses on the compound to verify some of its properties. Dr. Chan is very excited about Julio's progress, and tells him to repeat his experiment and to begin to write up the results. Dr. Chan recruits Samantha to assist Julio in some analyses. Julio gives her the RG198 in two batches for the analytic studies.

(continued on next slide)

Research Misconduct In Context Part II

Case Study #2

Truth or Consequences- continued

- Samantha completes the first set of analyses on the first batch and is excited by the results. On the next batch, she phones Julio and asks him if a contaminant might have gotten mixed up in the compound, since the spectral pattern is not what is expected for the molecule. She tells Julio that she obtained positive results and that her mistake in the original interpretation was due to tiredness, and to the fact that she had focused inadvertently on a reference sample, not on RG198. There is no way for Julio to validate her findings, since there is not enough RG198 left to do another run. Julio is unsure about whether he can trust Samantha's findings, but he proceeds to write up the manuscript about his synthesis of RG198 and its analysis by Samantha. The article is published, but other scientists who repeat his synthesis are finding different spectra than what he reported in his second batch of experiments.

- **What is the compliance issue in this scenario?**
- **What should Julio do?**
- **Do you think this is research misconduct?**

Discussion & Self Assessment

Research Misconduct

Discussion

How Does Your Institution Stack Up?

Please take a few minutes to jot down notes on your institutions compliance with the following:

- Written policies and procedures for addressing allegations of research misconduct
- Fostering a research environment that promotes the responsible conduct of research, research training, and activities related to that research or research training
- Provide confidentiality to all respondents, complainants, and research subjects
- Have an active Assurance of Compliance

How to Protect Your Researchers and the Organization from Allegations of Research Misconduct

Research Misconduct How to Protect Your Organization

Avoiding Pitfalls:

- Validation of study methodology or experimental design
- Objective oversight of statistical analysis
- Careful supervision and detailed communication with students and/or technicians
- Meticulous recording and review of data points
- Open reporting of results – internal meetings and external presentations
- Peer review and peer replication
- Seeking feedback from research community and peers

Research Misconduct

How to Protect Your Organization

Process:

- Develop an Effective Research Misconduct Policy:
 - Explicitly define the concept
 - Detailed roles and responsibilities
 - Research Integrity Officer
 - Appointed Committees
 - Overview of the Inquiry Process
 - Overview of Investigation Process
 - Notification of Determinations
 - Confidentiality
 - Protection from Retaliation
 - Duty to Report Statement
 - Mechanisms for Employee to Report Suspected Research Misconduct
 - Process for Appeals
 - Process for Notification of ORI
 - Record Retention
 - Restoration or Dismissal of Employees

How to Respond to Allegations of Research Misconduct

Research Misconduct

How to Respond to Allegations

Major Players

- Complainant:
 - A person who in good faith makes an allegation of research misconduct.
- Respondent:
 - A person against whom an allegation of research misconduct is directed or who is the subject of the misconduct proceeding.
- Research Integrity Officer or Institutional Official (person named to receive and respond to allegations of research misconduct):
 - The person responsible for protecting the integrity of the process as well as the following:
 - Complainants
 - Respondents
 - Witnesses
 - Insures Confidentiality
 - Protection of Sponsor resources
 - Committee Members

Research Misconduct

How to Respond to Allegations

Employee Obligation to Report and Obligation to Cooperate

- Expectation on researcher to report
- Reporter/Complainant/Whistleblower does not have to be right. Allegations must be brought in good faith
- Obligation on employees to cooperate with the Research Integrity Officer and any related review of the allegations.

Institutions should consider having an employee "Duty to Report Research Misconduct" policy.

Research Misconduct

How to Respond to Allegations

Document Process and Set Timeline

- Receive allegation report
- For each allegation there should be a "file" opened.
 - Log all activities related to the allegation.
 - Record and save statements, signature and inventory evidence.
- Institution / Institutional Officer selects the process for resolving the complaint
- Resolution of Initial Complaint
 - 60 day to complete Inquiry
 - 30 days to initiate Investigation after conclusion of Inquiry
 - 120 days to complete Investigation
 - 24 hours to notify federal sponsors of any reasonable indication of criminal activity or danger.

Research Misconduct

How to Respond to Allegations

Preliminary Assessment / Inquiry

- The Preliminary Assessment is the process by which the institution conducts an initial review of the evidence to determine whether an Investigation is warranted
- This "preliminary fact finding" is conducted by the RIO though it could be a committee.
- Criteria warranting an Inquiry:
 - Does the allegation fall within the definition of misconduct?
 - Does the allegation involved PHS support?
 - Is there sufficient evidence to proceed with an Investigation?
- Other key actions:
 - Obtain custody of the records
 - Inventory the records
 - Convene Inquiry committee
 - Interview respondent, complainant, witnesses
 - Keep records
 - Notify Respondent

Research Misconduct

How to Respond to Allegations

Preliminary Assessment / Inquiry

- Results of the preliminary assessment should be documented
 - Interim administrative actions should include protecting the funding in question and/or the public health
 - A report should contain
 - The allegation
 - Name and position of the Respondent
 - Evidence Reviewed
 - Basis for (not) recommending an Investigation
- Institution should provide the report to the Complainant and Respondent. The Respondent should be informed how to respond and be given the opportunity to respond (60 days).
- The Preliminary Assessment / Inquiry is **NOT** a final conclusion, but it could be if there is a confession or some other compelling reason to cease the review.

Research Misconduct

How to Respond to Allegations

Investigation

- Purpose: Detailed exploration to determine if research misconduct occurred, by whom, and to what extent.
- Institutions must report the Initiation of an Investigation to the Office of Research Integrity (ORI) within 30 days of the of the finding that an Investigation is warranted (only if PHS funds are involved).
- In addition to the above, Institutions conducting Investigations must:
 - Notify the respondent in writing of the allegations
 - Obtain custody of all research documents and other evidence
 - Ensure that all efforts are well documented
 - Ensure that the Investigation is fair and impartial

Research Misconduct

How to Respond to Allegations

Investigation

- The Investigation report should include the Inquiry findings and the following information:
 - The name and position of the respondent
 - A description of the allegations of research misconduct
 - PHS support (grant number, application, publications)
 - Rationale for the Investigation
 - Comments of the respondent and complainant
 - Work papers, records/evidence, interview data
- Once complete, notify the respondent

Research Misconduct

How to Respond to Allegations

Institutions must forward Investigation report to ORI

- The Investigation report should include all of the information contained in the Inquiry and the following
 - Institutional policies and procedures under which the Investigation was conducted
 - All research records and evidence
 - Statement of findings for each separate allegation
 - Comments
- The Investigation must be completed within 120 days of the start
 - Institutions may request (in writing) an extension from ORI
- Institutions should maintain records for at least 3 years after Inquiry/Investigation

Findings of Misconduct

Findings of Misconduct

HHS Responsibilities

- ORI review - ORI may respond to an institution's allegation of research misconduct at anytime
 - Conducting allegation assessments
 - Does allegation fall within the definition of research misconduct?
 - Does it involve PHS support?
 - Reviewing an institution's findings and process
 - Make a finding of research misconduct

Findings of Misconduct

HHS Responsibilities

- HHS administrative actions
 - ORI may propose administrative actions to the HHS
 - Notifies the respondent in a charge letter which includes ORI's findings of research misconduct
 - Suspension, debarment (from receiving Federal funds)
 - HHS debarment official issues a notice of proposed debarment or suspension as a part of the charge letter
- ORI assistance to institutions
 - Provide information, technical assistance, procedural advice regarding misconduct proceedings

Findings of Misconduct

- ! **Findings of misconduct might trigger notifications to licensing and certifying bodies, publications, law enforcement agencies including the DOJ and OIG, and other researchers and sponsors**

- ! **ORI may offer the respondent a voluntary settlement or they might debar, suspend or exclude respondents from participating in government programs**

Recent Case Summary #1

The U.S. Public Health Service (PHS) found that Lois Bartsch, Ph.D., former postdoctoral research trainee, engaged in research misconduct in research supported by National Cancer Institute (NCI), National Institutes of Health (NIH), grants P30 CA36727 and R01 CA77876 and National Center for Research Resources (NCRR), NIH, grant P20 RR016469. Specifically, PHS found that Dr. Bartsch:

- Falsified DNA sequence files by deleting a nucleotide and changing nucleotide designations and reported the altered file as the ACI rat p16Cdkn2a sequence with a CpG dinucleotide polymorphism in the upstream region to GenBank, in grant application CA118151, and in the poster presented to Cold Spring Harbor Laboratory (CSHL);
- Fabricated the claim in grant application CA118151 that GenBank entries for the human p16Cdkn2a gene had a CpG polymorphism near the transcription start site;
- Falsified the differential methylation of CpG dinucleotides near the transcription start site of p16Cdkn2a DNA and reported that tumor tissue was more methylated than normal tissue in ACI rats treated with estrogen and that the ACI allele was more methylated than the BN allele in tumor tissue from (BN x ACI)F1 animals treated with estrogen in grant application CA118151.



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Source: <http://ori.dhhs.gov/misconduct/cases/Bartsch.shtml>

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Case Summary #1

Continued

Dr. Bartsch has entered into a Voluntary Exclusion Agreement (Agreement) in which she neither admits nor denies ORI's finding of research misconduct; the settlement is not an admission of liability on the part of the respondent. In accordance with the terms of the Agreement, she has voluntarily agreed, beginning on April 15, 2008:

- To exclude herself from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in non-procurement programs of the United States Government referred to as "covered transactions" pursuant to HHS' Implementation (2 CFR Part 376 et seq.) of OMB Guidelines to Agencies on Government-wide Debarment and Suspension (2 CFR Part 180) for a period of two (2) years; and
- To exclude herself permanently from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant or contractor to PHS for a period of three (3) years.

Source: <http://ori.dhhs.gov/misconduct/cases/Bartsch.shtml>



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Recent Case Summary #2

The U.S. Public Health Service (PHS) found that J. Keith Hampton, MSN, APRN, former Clinical Research Associate, SLH, engaged in research misconduct in research supported by National Cancer Institute (NCI), National Institutes of Health (NIH), awards U10 CA69651, U10 CA12027, and U10 CA33601. PHS found that Mr. Hampton engaged in research misconduct by falsifying and fabricating data that were reported to the National Surgical Adjuvant Breast & Bowel Project (NSABP) and Cancer and Leukemia Group B (CALGB) cooperative research groups. Specifically, PHS found that:

1. For protocol CALGB 90206, Respondent:
 - (a) Falsified a patient's CT scan reports and registration forms and reported the falsified CT scan reports and registration worksheet to CALGB,
 - (b) Falsified a patient's performance status records (giving 80% performance status) and registration forms and reported the falsified performance status report and registration form to CALGB.

Source: <http://ori.dhhs.gov/misconduct/cases/Hampton.shtml>

Case Summary #2

Continued

2. For protocol NSABP B-35, Respondent:
 - (a) Falsified eligibility data related to hematology and chemistry assays and to the performance of a pelvic exam on one patient's registration form and reported the falsified registration forms to the National Cancer Institute Cancer Trial Support Unit (CTSU),
 - (b) Falsified pelvic exam eligibility on a second patient's registration form and reported the falsified registration form to the CTSU,
 - (c) Falsified hematology and chemistry assay eligibility on a third patient's registration form and reported the falsified registration form to the CTSU.
3. For protocol NSABP B-36, Respondent falsified a patient's multi-gated acquisition test (MUGA--a test of heart function) records, cardiac function, and registration forms, certified the patient's eligibility, and reported the falsified MUGA test, cardiac function, and registration forms to the CTSU.

Source: <http://ori.dhhs.gov/misconduct/cases/Hampton.shtml>

Case Summary #2

Continued

4. For protocol NSABP B-38, Respondent falsified hematology, chemistry, and MUGA eligibility for a patient on the registration form and reported the falsified registration form to the CTSU.
5. For protocol NSABP C-08, Respondent:
 - (a) Falsified urine protein/creatinine ratio eligibility for one patient on the registration form and reported the falsified registration form to the CTSU,
 - (b) Falsified urine protein/creatinine ratio eligibility for a second patient on the registration form and reported the falsified registration form to the CTSU,
 - (c) Falsified claims of the urine protein/creatinine ratio and PT(INR) eligibility for a third patient on the registration form and reported the falsified registration form to the CTSU.

Source: <http://ori.dhhs.gov/misconduct/cases/Hampton.shtml>

Case Summary #2

Continued

6. For protocol NSABP R-04, Respondent falsified a patient's colonoscopy report and eligibility at registration and reported the falsified colonoscopy report and registration form to the CTSU. Mr. Hampton has entered into a Voluntary Exclusion Agreement (Agreement) in which he has voluntarily agreed for a period of three (3) years, beginning on June 17, 2008:
 - (a) To exclude himself from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in non-procurement programs of the United States Government referred to as "covered transactions" pursuant to HHS' Implementation (2 CFR part 376 et seq.) of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (2 CFR part 180); and
 - (b) To exclude himself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant or contractor to PHS.

Source: <http://ori.dhhs.gov/misconduct/cases/Hampton.shtml>

After the Findings of Misconduct

- **When to seek Legal Counsel?**
- **Going on the offensive?**
- **Refocusing the research team?**
- **Repairing your reputation?**

Tools

- **Videos**
 - [The Role of the RIO](#)
- **Regulation**
 - [PHS Policies on Research Misconduct - 42 C.F.R. 93](#)
- **Sample Policies and Procedures**
 - [ORI Sample Policy and Procedures for Responding to Allegations of Research Misconduct](#)
 - [ORI Guidelines for Institutions and Whistleblowers: Responding to Possible Retaliation against Whistleblowers in Extramural Research](#)
- **Handbooks**
 - [ORI Handbook for Institutional Research Integrity Officers](#) - Being revised to comply with 42 C.F.R. Part 93

Resources

- **Office of Research Integrity**
 - <http://ori.dhhs.gov/>
- **CITI**
 - Course in the Responsible Conduct of Research
 - <https://www.citiprogram.org/rcrpage.asp>
- **University of Texas Health Science Center at Houston**
 - Research Misconduct Training Course
 - <http://www.uth.tmc.edu/orsc/training/ResearchMisconduct.html>
- **St. Jude Children’s Research Hospital**
 - Educating Clinical Staff in Clinical Research Data Collection and Data Management
 - <http://ori.dhhs.gov/education/products/stjude/content.htm>

“Most people say that it is the intellect which makes a great scientist. They are wrong: it is character.”

Albert Einstein

Questions?