



## Practical Strategies for Dealing With 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.

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## 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

### 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/>

## 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

#### 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

#### 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 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

### 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 1<sup>st</sup> visit and never saw the women a 2<sup>nd</sup> 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.



In common law, a writ of qui tam is a writ whereby a private individual who assists a prosecution can receive all or part of any penalty imposed. [www.en.wikipedia.org/wiki/Quitam](http://www.en.wikipedia.org/wiki/Quitam)



## 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.



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# 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>

## 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>

**Questions?**