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Avoiding Being Penalized: Research Misconduct

Office for the Protection of Research Subjects (OPRS)

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This series of booklets is adapted from the Collaborative Institutional Training Initiative (CITI) Responsible Conduct of Research online course available at www.citiprogram.org

Also available in the RCR Series:

Using Animal Subjects in Research

Collaborative Research

Peer Review

Data Management and Acquisition

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Mentoring Student Researchers

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Responsible Authorship and Publication

About the Source Material

The Collaborative Institutional Training Initiative (CITI) web based education program, developed by the University of Miami and the Fred Hutchinson Cancer Research Center, offers training in Human Subjects Research, the Responsible Conduct of Research, and Good Clinical Practice. CITI is currently used by over 1130 participating institutions and facilities from around the world and offers online course material in more than seven different languages. CITI RCR was developed with public funds and thus allowed access to material used to create these booklets.

Introduction to Research Misconduct

USC faculty, staff, and students are expected to conduct research in accordance with the highest ethical standards and all relevant regulations. The university does not tolerate misconduct in any aspect of research and will investigate all such allegations. Responsible conduct of research is expected of all university faculty members (including part time and visiting faculty), staff, other employees, (such as postdoctoral scholars), and students who propose, conduct, or report research on behalf of the university regardless of funding or source.

This booklet provides an overview of research misconduct including historical and contemporary examples, guidelines on reporting misconduct, and a brief description of the investigatory process. The booklet includes reference lists and case studies on research misconduct.

Ethical Obligations in Research

While ethical conduct of research fulfills a moral imperative it also leads to better research results because it requires attention to the details of research, including quantitative and statistical techniques, and to more thoughtful, predictable collaboration among investigators. The credibility of the research process and results depend on the maintenance of the highest ethical standards throughout the process.

Adherence to responsible conduct of research (RCR) guidelines will help an investigator avoid departures from accepted ethical research practice and prevent the serious deviations that constitute research misconduct.

(adapted from *The Guidelines for Ethical Practices in Research,* http://www.pitt.edu/~provost/ethresearch.html)

What is Research Misconduct?

Statement on Research Misconduct:

> "Advances in science, engineering and all fields of research depend on the reliability of the research record, as do benefits associated with them in areas such as health and national security. Sustained public trust in the research enterprise requires confidence in the research record and in the processes involved in its ongoing development."
>
> (Office of Science and Technology Policy—OSTP, Federal Record,12/6/09)

The OSTP coordinated federal agency input to create a unified definition of misconduct to ensure research dependability, to maintain public support, and to unify policies across the federal government. The definition below applies to all agencies and all recipients of funds from federal agencies. The two federal agencies that support the majority of research in academia, the National Science Foundation (NSF) and the National Institute of Health (NIH), have implemented the OSTP definition.

The OSTP's definition states: “research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.” USC adheres to this definition.

- **Fabrication** is making up data or results and recording or reporting them.

- **Falsification** is manipulating research materials, equipment, or processes, 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.

  Plagiarism examples:

  - Investigators, during the peer- review process, taking ideas from others' grant proposals or articles and including them in their own publications.

  - Students taking material from the internet verbatim, without attribution, during write-ups of research or other scholarly work.

  - Faculty taking dissertation material from students and including it in publications without giving due credit.

Research misconduct does not include accidental error or honest misinterpretation of results.

Office of Research Integrity (ORI)

The HHS Office of Research Integrity (ORI) promotes integrity in the biomedical and behavioral research that is supported by U.S. Public Health Service (PHS), which includes research at about 4,000 institutions worldwide. ORI monitors institutional investigations of research misconduct and facilitates responsible conduct of research (RCR) through educational, preventive, and regulatory activities. ORI carries out its responsibility by developing policies, procedures and regulations related to the detection, investigation, and prevention of research misconduct and the responsible conduct of research. ORI is also responsible for implementing activities and programs to teach the responsible conduct of research, promote research integrity, prevent research misconduct, and improve the handling of allegations of research misconduct.

Historic Cases of Research Misconduct

Throughout the history of scientific research, there has been speculation regarding the authenticity of data recorded by several famous scientists:

- **Isaac Newton** may have adjusted calculations to fit observations.

- **Gregor Mendel**'s results with pea plants

were cleaner than what is observed experimentally, indicating that he might have changed the data.

- **Robert Millikan**, in a research paper describing the charge of an electron, failed to mention that he eliminated some of the data points. He did not provide an explanation of why the data was deleted in the publication.

- **Louis Pasteur** failed to cite in his studies that he used the vaccine against anthrax made by a competitor, saying instead that he used his own vaccine to inactivate the bacilli.

More Recent Examples of Research Misconduct

Thereza Imanishi-Kari, David Baltimore, and Margot O'Toole; hearings and regulations

This infamous case began in 1985, when Margot O'Toole, a postdoctoral researcher at Tufts University, could not validate the findings of work soon to be published by her employer, Thereza Imanishi-Kari, in the journal ***Cell***. A co-author on the paper was Nobel Prize winner, David Baltimore, of MIT. O'Toole came to believe that Imanishi-Kari manipulated research data. She presented her evidence of misconduct to committees at Tufts and at MIT. Both committees ruled that misconduct had not occurred, but concluded that Imanishi-Kari had been sloppy in her research. An NIH committee, convened to review the case at the time, also cleared Imanishi-Kari.

But this was not the end of the Imanishi-Kari case. Walter Stewart and Ned Feder, two scientists from the NIH who were involved in exposing misconduct, became involved in the case. They believed that the committees and the NIH did not do an adequate job of revealing problems with the Imanishi-Kari paper.

In 1991, the NIH's misconduct division, the Office of Scientific Integrity, found that significant portions of the data were fabricated. As a result, Thereza Imanishi-Kiri was banned from receiving federal grant money for 10 years and David Baltimore resigned from his presidency of Rockefeller University. The whistleblower, Margot O'Toole, was ostracized by the science field.

The ORI (OSI reborn in HHS as the Office of Research Integrity) upheld the OSI decision regarding the Ishmani-Kiri case, but in 1996, the ORI appeals board overturned the ORI decision. The board said that it had not been proved that Imanishi-Kari falsified the scientific record but rather that she was guilty of sloppy scientific practices.

Soon afterward, regulations concerning the management of misconduct allegations were announced by the NIH and the NSF; they included provisions for protecting the rights of those who report misconduct, provisions for protecting the rights of the accused, and also a provision for an appeals process.

Reference: http://www.hhs.gov/dab/decisions/dab1582.html

Eric T. Poehlman Ph.D. Case
In March 2005, the Office of Research Integrity (ORI) found that a former professor in the Department of Medicine at the University of Vermont College of Medicine, Eric T. Poehlman, Ph.D., engaged in research misconduct by misleading and deceptive practices in proposing, conducting, and reporting the results of research.

In an NIH grant application, Dr. Poehlman falsified preliminary data purportedly obtained in a longitudinal study of aging. He falsified measurements and altered specific data during the conduct of longitudinal aging research. Over a period of several years, Dr. Poehlman reported the falsified data from these studies at professional meetings and in published results. He repeatedly falsified and fabricated data to support his hypotheses and reported the non-existent longitudinal study and related publications in NIH grant applications. He also provided false reports to the University's Investigation Committee.

As a result, Dr. Poehlman voluntarily agreed to exclude himself permanently from serving in any advisory capacity to the Public Health Service and to exclude himself permanently from any contracting or subcontracting with the US Government. He agreed not to petition for reversal or reduction of the scope of the agreements and to send ORI-written letters of retraction for ten published journal articles.

On June 28, 2006, Eric Poehlman was sentenced to 366 days in jail.

Reference: http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-05-040.html

Scott Reuben, MD
Prominent anesthesiologist Scott Reuben, MD pled guilty in early 2010 to falsifying research on the use of analgesics such as celecoxib (*Celebrex*; Pfizer) and rofecoxib (*Vioxx*; Merck) for postoperative pain management.

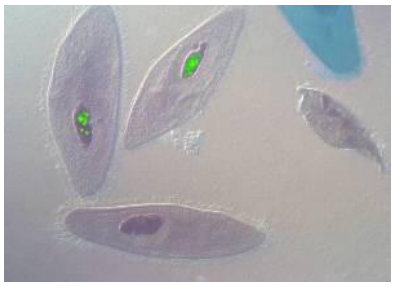
Pfizer paid for a clinical study of Dr. Reuben's on the perioperative use of celecoxib as part of multimodal analgesia for outpatient anterior cruciate ligament reconstructive surgery. Dr. Reuben reported in 2 articles published in the journal *Anesthesia & Analgesia* that he had treated 200 patients in the trial – 100 with placebo and 100 with celecoxib – and achieved success with multimodal analgesia therapy.

However, Dr. Reuben later admitted that he had not enrolled any patients in the trial but instead, had simply made up the findings. *Anesthesia & Analgesia* and other medical journals have retracted more than 20 articles by Dr. Reuben containing fabricated data, according to the publication *Anesthesiology News*.

Dr. Reuben was sentenced in June 2010 in a Boston, Massachusetts federal court to 6 months in prison for healthcare fraud.

Reference: www.medscape.com – “Anesthesiologist Sentenced to 6 Months for Faked Research”

Preventing Research Misconduct



Researchers share public concerns for the prevention of research misconduct because advances in and public support of research depend on the reliability of the research record. Sustained public trust in the research enterprise requires confidence in the research record and the processes Involved in its ongoing development. Occurrence of research misconduct has serious consequences for all involved – respondents, co-workers, complainants, institutions, sponsors, patients, and journals.

Suggestions for preventing and identifying research misconduct:

- The P.I., Lab director, etc. must establish a climate in the lab in which scientific integrity (and the reasons for it) are emphasized
- All staff must be thoroughly trained in integrity principles and in conducting their portion of the protocol
- The P.I. and other supervisors must maintain strong communication with staff and a “presence” in the study setting, verifying personally at least a sampling of the research records
- Staff should be questioned about data alterations in the research record (overwrites, erasures, whiteouts, changes in electronic records)
- If possible, request informed consent permission to re-contact the patient for quality control reasons, and follow up with a sampling of these patients
- Keep staff workloads reasonable
- Protocols should be designed with realistic requirements that can be met by both staff and patients
- Data forms should be as simple as possible, yet with clear designation of the required information
- In on-going studies, if possible, train more than one staff member to do follow-up
- Any alterations on data forms must be done by striking through the original entry (no whiteout or writing over) and initialing and dating the new entry

- Copies of all laboratory reports should be retained by originating facility (to be spot checked on routine and special audits)

- Protocol sponsors should not pay bonuses based on number of patients enrolled, nor should investigators accept such bonuses.

-Peter H. Abbrecht, M.D., Ph.D. from the Office of Research integrity (ORI), from PowerPoint presentation: "Comprehending Research Misconduct and Malfeasance" (http://www.endo-society.org/about/ethics/upload/11.ppt).

How common is research misconduct?

Data on research misconduct were not collected until the 1990s. The rate of overall research misconduct in the United States has been estimated to be one case per 100,000 researchers, given two million active investigators in the United States.

The number of allegations received by ORI (217 in 2007 and 201 in 2008) is lower than the 2004-2006 average of 271, but still above the 1992-2007 average of 198. As at the NSF, concerns also have been raised about settlements of cases by institutions without being reported to the federal government. This creates a low estimate of the total number of misconduct cases.

Whistleblowing: Reporting Research Misconduct

Government regulations require institutions to have policies and systems in place so that individuals are able to report misconduct confidentially and without fear of retaliation.

According to a 1995 ORI study, more than two-thirds of all whistle-blowers reported experiencing at least one negative outcome as a direct result of their whistle-blowing including pressure to drop allegations, facing counter- allegations, ostracism by colleagues, and reductions in research support levels. Some said that they were fired or were denied promotions. For the whistle-blowers who did not experience a negative consequence as a result of coming forward, more than 90% said that they would do it again. Surprisingly, 75% of those who did suffer a negative outcome from reporting an allegation of misconduct also said that they would do it again. The full report of the 1995 ORI-funded study is available at http://ori.hhs.gov/documents/consequences.pdf.

A 2006 paper describes the ORI's experience with individuals who report allegations of research misconduct. The paper examines the legal framework, the role of individuals who report allegations, and responsibilities of institutions and ORI in an effort to provide guidance for handling the allegations effectively. The full paper is at http://ori.hhs.gov/documents/Complainantarticle-Pascal-8-06.pdf.

What are Some Guidelines for those who Report Misconduct?

People who report allegations of misconduct ("whistleblowers") are protected by rulings from state governments and the federal government. The First Amendment protects the freedom of speech of someone who reports an allegation of misconduct. Also, the False Claims Act of 1986 protects whistle-blowers. The act, which was originally developed during the Civil War to protect the government from fraudulent contractors, awards a whistle-blower 15% to 30% of the resulting settlement in a case of misconduct. The act also provides for remedies if it can be shown that a whistle-blower suffered a discriminatory action in retaliation for the allegation brought under the legislation. There are also new federal guidelines proposed by HHS to protect whistle-blowers.

Some guidelines for those who report allegations of misconduct:

1. ***Documentation:*** When making an allegation of misconduct, documentation of who did what, and when they did it, will provide the best chance for a fair and timely resolution of the allegation.

2. ***Rules and procedures:*** Because the federal government has minimal requirements about how institutions should handle misconduct, institutions have some leeway in applying the regulations. As soon as someone is involved in an allegation, he or she should review institutional procedures on the issue. A whistle-blower needs to know who should be apprised of the allegation, what constitutes evidence for or against an allegation, how the evidence should be obtained, who will review the allegation, what the whistle-blower's role will be, and how much time the process is expected to take.

3. ***Perspective:*** People with little experience in research should seek guidance before making allegations of misconduct. What might appear to be a serious action could be a misunderstanding. It might be appropriate to talk to peers, senior researchers in a team, an ombudsperson, or the individual in question.

4. ***Dispute resolution:*** Some allegations of research misconduct might be resolved through other means, such as conflict resolution. This involves dealing with a problem as soon as possible; striving for an agreement rather than disagreement; emphasizing the problem, not the people involved; and using a third party, such as an ombudsperson, to clarify issues if necessary.

5. ***Motivation of a whistle-blower:*** Whistle-blowers should be aware that they may suffer retribution for their actions and that institutions are responsible for a misconduct inquiry and investigation. They should also distinguish between facts and speculation and not guess at the motives of others. Whistle-blowers should ask questions rather than draw conclusions.

*Michael Kalichman, Director of the University of California San Diego Research and Ethics Program. “Seven Key Components of Good Peer Review”: Responsible Conduct of Research: An Introductory Guide (2001)

Follow-up to a Claim of Misconduct

According to the Office of Science and Technology Policy (OSTP Policy) "federal agencies (Public Health Services Policy; National Science Foundation Policy) have ultimate authority for issues of misconduct for federally funded research, **BUT** research institutions bear primary responsibility for the prevention and detection of research misconduct and for the inquiry, investigation, and adjudication of research misconduct alleged to have occurred in association with their own institution." (see USC Scientific Misconduct Policy: http://ooc.usc.edu/policy-scientific-misconduct)

Defining inquiry, investigation, and adjudication

Inquiry is the assessment of whether the allegation has substance and whether an investigation is warranted. **Investigation** is the formal development of the factual record and the examination of the record leading to dismissal of a case or to a recommendation for a finding of research misconduct or to other remedies. During the **resolution** phase, recommendations are reviewed and corrective actions, such as sanctions, are determined.

In order for an action to be termed "misconduct", the action must have been committed intentionally or knowingly or in reckless disregard of known practices. The allegation must be proved by **a preponderance of the evidence**, which means determining whether the claim or fact is more probably true than not true. The standards of "clear and convincing evidence" and "beyond a reasonable doubt" require a much higher burden of proof.

Government agencies typically rely on institutions to make the initial response to allegations of misconduct. Agencies also generally refer to the institutions any allegations of misconduct that are made to them. Occasionally, agencies will perform their own inquiries into or investigations of allegations. Under certain circumstances, agencies may undertake investigations or act quickly to protect the public interest, such as when public health and safety are at stake.

Requirements to report to a federal agency

Research institutions have to notify an agency or agencies if the inquiry into an allegation of misconduct involving federally funded research leads to sufficient evidence to proceed to an investigation. When an investigation is complete, the institution is required to forward a copy of the evidence, the investigative report, recommendations made to the institution's adjudicating official, and the subject's written response to the recommendations. Institutions must also inform the agency about the decision of the adjudicating official and about any corrective action taken.

If, during an inquiry or investigation, there is any immediate risk to public health or safety, the research activities should be suspended. If there may be violations of criminal or civil law, or if allegations are made public prematurely, the institution must notify the federal agency.

Safeguards for whistle-blowers and subjects of allegations

Institutions must provide appropriate safeguards to those reporting misconduct and those who are subjects of misconduct allegations. People who report allegations of misconduct in good faith must feel that they can report allegations confidentially and without fear of retribution. Likewise, subjects of allegations should feel that the filing of an allegation will not stop their research or bring other undue adverse action against them. Subjects of allegations also should have their rights protected, with allegations kept confidential, and have timely written notification of the allegations made against them, a description of the allegations, reasonable access to data and other evidence supporting the allegations, and the opportunity to respond to allegations and findings of research misconduct. It is important that the appeals processes be part of the institutional process for handling allegations.

The PHS's "Policies on Research Misconduct" require institutions to protect whistleblowers, witnesses and members of inquiry and investigation committees. See http://ori.hhs.gov/documents/42_cfr_parts_50_and_93_2005.pdf.

In 1995, ORI issued "Guidelines for Institutions and Whistleblowers: Responding to Possible Retaliation Against Whistleblowers in Extramural Research" for responding to retaliation complaints. See http://ori.hhs.gov/misconduct/Guidelines_Whistleblower.shtml

Sanctions

Sanctions against those found guilty of research misconduct can include:

- Taking appropriate steps to correct the research record.
- Issuing letters of reprimand.

- Imposition of certification requirements to ensure compliance with the terms of a grant.
- Suspension or termination of a grant; and/or personal suspension or debarment.
- Restitution of funds

Institutions are required by the regulations to impose sanctions on those found guilty of research misconduct. The regulations do not proscribe specific sanctions. The ORI releases a description of cases of research misconduct with a guilty finding in the Federal Register, the ORI Newsletter, the ORI Annual Report, and on the ORI web site. In addition, the findings appear in the NIH Guide to Grants and Contracts and in the media, such as newspapers and magazines. In addition, the PHS may impose administrative sanctions. See http://ori.hhs.gov/misconduct/admin_actions.shtml

Agencies also may issue additional sanctions beyond those of the institution. If criminal or civil fraud violations have occurred, the agency will refer the findings to the appropriate organization for review.

Conclusion

The government has adopted specific laws and regulations concerning research misconduct. It is the responsibility of those involved in research to become familiar with the procedures so that they know what to do if misconduct is observed and so they can be vigilant of their own behavior. Research misconduct can have devastating consequences to the perpetrator, the person who reported the misconduct, and the institution where it occurred. Research may ultimately be self-correcting and the scholarly literature may be fixed, but a tarnished reputation never disappears.

Case Studies

I. "Editing and Crediting" - Plagiarism

A student Lin did all his previous work in China and is now in his second year of our Graduate School Program. He is enjoying his studies, is very successful with his course work, but still worries about the quality of his written English. In the spring, he is asked to write a paper about "Intelligence Testing from Binet to the Present" in an advanced Psychology course. He reads many sources, and uses some of the language from review articles that he has read. He cites the reference but does not use quotation marks around the "borrowed" language.

1. Why is this wrong?
2. How important is it for the English grammar and syntax to be correct?
3. If important, how can a foreign student or faculty member achieve the needed level?

A year later, Juan is writing a proposal for his Second Exam. He knows how careful he must be about plagiarism and exercises such care. However, still worried about his English, he asks his roommate to edit the English (not the historical elements) of his proposal. At his exam his committee accuses him of plagiarism.

1. Was Lin wrong to get editing help?
2. What is the faculty responsibility here?
3. What should Lin do?

II. Crediting

Dr. Rev Revson is a post doc in the Department of Education at Big Time University. Rev's advisor Dr. Jones gets a paper to review from the ***Journal of Adult Learning*** and asks Rev to read the paper and write the review. Rev does this. Later in the year, at a meeting, the associate editor from the journal is talking to Dr. Jones, Rev's boss, and they are talking about one of the rather good ideas that Rev had put into the review. Rev feels kind of bad, but cannot quite figure out the wrongs and rights of having done the review in the first place, and not getting credit for the idea.

1. What do you think?
2. How should ideas be credited in different situations?
3. Why is credit important?

II. In the Field, No One Will Know

LaToya Johnson and Sandra Rajeev are first-year graduate students in social work at a major research institution in New York City. They are working with Dr. Francine Lockheart, who specializes in studying the effects of homelessness on children. Dr. Lockheart has received a major federal grant to study the education of homeless children in New York City compared with children who are poor but have more steady housing. The study will follow children over a five-year period, from the fifth to the tenth grade.

A significant part of the grant involves fieldwork, in which investigators must go to homeless shelters and obtain informed consent from parents so that they and their children can participate in the research project for the duration of the study. Researchers must get permission to review the educational records of the children, and also must get the same informed consent and approvals from the parents of the children who have homes. Part of the study involves parents filling out a survey of information about themselves and the children with an interviewer. Another part involves an educational test of the children, to validate the school records. Both the survey and the test are specifically designed to be performed in the field.

1. How do you think the testing aspect of the research project could have been improved?

   Although adding another person to participate during testing administration would increase the initial cost of performing the research, having such a person online would prevent the costs of having to redo the testing, should a problem be discovered later on. Recording each interview and test is another way to prevent the possibility of fabrication or falsification.

2. Why is it important to obtain the same informed consent and approvals from both the parents of the children who have homes and those who do not?

Resources

USC Scientific Misconduct Policy
http://ooc.usc.edu/policy-scientific-misconduct

Office of Research Integrity (ORI)—Research Misconduct
http://ori.dhhs.gov/education/products/rcr_misconduct.shtml

ORI Guidelines for Institutions and Whistleblowers: Responding to Possible Retaliation Against Whistleblowers in Extramural Research
http://ori.hhs.gov/misconduct/Guidelines_Whistleblower.shtml

CITI Program
www.citiprogram.org

Scientific Misconduct Blog
http://scientific-misconduct.blogspot.com/

Public Health Services (PHS) Policies on Research Misconduct
http://ori.hhs.gov/documents/42_cfr_parts_50_and_93_2005.pdf

National Science Foundation (NSF)-Misconduct
http://www.nsf.gov/oig/misconscieng.jsp

USC Contacts

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http://stevens.usc.edu/

Health Research Association (HRA)
1640 Marengo Street, 7th Floor
Los Angeles, CA 90033
Tel (323) 223-4091
Fax (323) 342-0947
Web: http://www.health-research.org/

IRB Student Mentor
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https://oprs.usc.edu/education/mentor/

Office of Contracts and Grants-UP
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http://www.usc.edu/research/dcg/

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