



## **Responsible Conduct in Research (RCR): What you need to know to train your staff, fellows, and students**

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### Course Outline

Introduction and History of RCR

Identifying Program Goals and Teaching Methods

Nine Instructional Areas

- Applicable Regulations and University Policies
- Key Concepts for Students
- Case Study

Navigating Resources

## History of RCR Training

- Formal training relatively non-existent prior to 1980
- Several high-profile research misconduct cases occurred in late 1970s and early 1980s
- Focus became developing policies and procedures for handling allegations of misconduct, not RCR training
- By 1989 both PHS and NSF established basic definitions and procedures for responding to suspected cases of research misconduct

## History of RCR Training

- IOM report in 1989 recommended that universities should provide formal instruction in good research practices
- Traditional approaches provided by mentors “no longer adequate because of the size and complexity of the modern research environment”
- IOM turned to NIH for leadership and direction
- In 1990 NIH required a “program in the principles of scientific integrity be an integral part of the proposed research training effort” on all NRSA applications
- No required curriculum or standards were established
- But the era of formal RCR education was born

## History of RCR Training

- In the 1990s RCR education grew on its own
- Variability across universities in how pre-docs and post-docs were trained in RCR
- In 1995 DHHS *Report of the Commission on Research Integrity* recommended that each institution applying for a grant or contract add an assurance that it had an educational program in RCR
- ORI drafted and announced its intention to adopt a Policy on Instruction in RCR
- The ORI policy gave institutions flexibility in developing educational program, but it set minimum requirements with respect to nine core instructional areas
- FASEB, AAMC, Congress objected to the RCR policy and process
- ORI subsequently suspended the policy

## History of RCR Training

- In June 2000, NIH issued a policy for *Required Education in the Protection of Human Research Participants*
- Required institutions to document with each proposal that all investigators involved with human subject research have received education in the protection of human research participants
- Advent of free, web-based, computer-graded courses
- Since 2002, ORI has supported over 50 RCR resource development projects
- However, today there is still little agreement on:
  - How RCR instruction should be planned
  - Who should provide the instruction
  - How it should be supported
  - Who should be responsible for making sure that it is delivered

## Teaching RCR

### **Training Grant PIs**

25% instructors identified as teaching RCR by  
PI indicated that they, in fact, were not involved in  
teaching RCR

### **Who Does Teach RCR?**

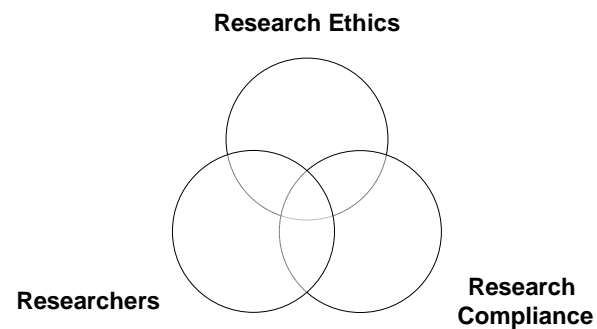
Researchers in variety of disciplines  
Administrators responsible for Research Compliance  
Research Ethics Departments?  
Primary Mission?

### **2002 Survey Early-Career and Midcareer Researchers**

25% felt less than well prepared to deal with ethical  
issues in their work

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## Teaching RCR



## Goals of RCR Education and Training

“...a well-trained researcher will understand that her or his responsibilities include the need to initiate conversations about the responsible dimensions of the practice of research, to seek perspective from others when something doesn't seem right or doesn't make sense, to nurture good conflict resolution skills to minimize the risk of misunderstandings and disputes, and to seek out help with mediation or arbitration of disputes that cannot otherwise be resolved.”

*Responding to Challenges...(Kalichman)  
Academic Medicine, Vol. 82, No. 9/September 2007 p.873*

## Baseline Trainee Knowledge of RCR

### **2004 RCR Survey of Graduate Trainees**

- 3 Competitive Health Sciences Universities
- 30 content questions and 12 demographic
- Completed prior to RCR training
- 251/401 test scores analyzed

**Scores ranged from 26.7% to 83.3% with a mean score of 59.5%**

Postdoctoral fellow scores did not vary significantly from graduate students

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## Possible Goal of Case RCR Program

For students to have knowledge of RCR core standards and principles and then be able to utilize their critical-thinking skills to:

1. Recognize when they have an ethical problem.
2. Know how to analyze the problem.
3. Come up with strategies for resolving it.

## Teaching RCR

Didactic Sessions – First-Year Students

Small Group Sessions with Faculty Facilitators

- Role Playing
- Testing
- Case Studies\*
  - Inductive
  - Illustrative
  - Cognitive Dissonance
  - Fostering Decision-making Skills

## Teaching RCR

### **Challenges In Utilizing Case Studies**

- Public Opinion Swap
- Participation
  - Creating “diversified” groups
  - “Safe” Environment

### **Bebeau Framework**

- Write an analysis prior to group discussion
- Re-write analysis after group discussion
- Facilitators give feedback on at least one written case analysis

## Teaching RCR Through Case Studies

“Developing a Well-Reasoned Response to a Moral Problem in Scientific Research”

*Moral Reasoning in Scientific Research: Cases for Teaching and Assessment*

Muriel J. Bebeau – University of Minnesota

- Issues or points of conflict
- Interested parties
- Consequences
- Obligations

Issues or points of conflict

**Describe the nature of the moral conflict beyond naming the issue. A dilemma, by definition, is a situation in which rights or obligations of interested parties conflict.**

Real-life dilemmas often present choices between equally unfavorable or disagreeable alternatives. A researcher who considers data enhancement to ensure continued funding for his lab sees a conflict between his obligation to report data honestly and his obligation to secure enough funds to keep his techs employed.

Interested parties

**Identify all parties who may have a stake in the decision of the person facing the ethical problem:**

- Person facing ethical problem
- Persons immediately affected (students, teachers, research subjects)
- Persons in the relevant institution
- Scientific community
- Society in general

## Consequences

**Identify both consequences that have a moderate to high probability of occurring and any very serious consequences even if there is a low probability of occurrence.**

Ex. Possibility that someone may die due to the release of a small amount of toxic substance during an experimental procedure may be remote, but the consequences may be so devastating that the potential benefit might not be worth the remote risk.

## Obligations

**When writing about obligations of professionals such as scientists, it is not enough to say that someone has a duty to do "x." You must say why they have that duty.**

Ex. Researcher who considers fabricating additional supporting data to speed publication of an exciting preliminary result that could be important in the treatment of viral disease.

*The scientist should not fabricate the data. Every scientist has a duty to report data truthfully because honesty is one of the most fundamental values of science.*

## Nine Instructional Areas

## Conflict of Interest – Policies and Regulations

### Federal Policies:

- OBJECTIVITY IN RESEARCH  
NIH GUIDE, Volume 24, Number 25, July 14, 1995  
<http://grants.nih.gov/grants/guide/notice-files/not95-179.html>

NIH Guidance Documents on COI  
<http://grants.nih.gov/grants/policy/coi/index.htm>

NSF Conflict of Interest Policy  
[http://www.nsf.gov/pubs/manuals/gpm05\\_131/gpm5.jsp#510](http://www.nsf.gov/pubs/manuals/gpm05_131/gpm5.jsp#510)

### Case Policy and Procedures

- **COI policy** – very general statement about expectations and process
- **COI procedures** – more detailed description of how COI is identified and addressed
- For details about both policy and procedures, go to:  
<http://ora.ra.cwru.edu/research/orc/coi/index.cfm>

## Conflict of Interest – Key Concepts

**COI policies: federal and university**

**Definition of Significant Financial Interest (SFI)**

**How SFI can create a COI situation**

- **Individual**
- **Institutional**

**COI procedures:**

- **Disclosure**
- **Review**
- **Management**
- **Monitoring**

**Elements of a COI management plan**

## Conflict of Interest – Case Study

Two Case professors have recently, with the help of the Case Tech Transfer Office, received a patent on intellectual property related to treating kidney stones. They have formed a company that has licensed this technology from Case. The company plans to conduct a clinical trial at University Hospitals (UH) with start-up money it has received from a venture capital firm. The company plans to enter into a clinical trial agreement with UH. One of the Case professors will be the principal investigator for this study. Are there any conflict of interest issues in this arrangement? If so, what are they and how can they be resolved, if at all?

## Mentorship - Policies and Regulations

There are no federal regulations or Case policy regarding mentorship

There are some national guidelines:

- National Institutes of Health Office of the Director, June 2002. A Guide to Training and Mentoring in the Intramural Research Program at NIH.
- National Academy of Sciences, National Academy of Engineering, and Institute of Medicine (1997): Adviser, Teacher, Role Model, Friend: On Being a Mentor to Students in Science and Engineering. National Academy Press, Washington, D.C.
- National Academy of Science (NAS), 2000. Enhancing the Postdoctoral Experience for Scientists and Engineers: A Guide for Postdoctoral Scholars, Advisors, Institutions, Funding Organizations, and Disciplinary Societies. Washington, D.C.: National Academy Press.

Case Human Participants in Research Policy states:

- Faculty member assigning research projects involving human subjects must take an active role in assuring that the subjects of student research are adequately protected
- Advisors will take an active part in preparing students for the role of researcher, instructing them in the ethical conduct of research, assisting them in completion of IRB application, and meet with them regularly to review work and progress

## Mentorship – Key Concepts

- Guston (1993) defines mentor as “that person directly responsible for the professional development of a research trainee”.
- According to Guston, professional development includes both the explicit conduct of scientific research and the implicit development of scientific standards.
- Ideal mentoring will:
  - Transmit both technical and professional skills
  - Shape career development
  - Assure that work is sound, honest and timely
- Obstacles to Good Mentoring:
  - Choice of mentor
  - Competing demands on mentor
  - Size of research team
  - Personalities
  - Power

## Mentorship and Training – Case Study

Bill, a graduate student, seeks advice about a problem with his thesis advisor from Professor John Smith, who is a member of his thesis committee.

As John knows, Bill and his thesis advisor have a difficult relationship. The causes are not entirely clear, but Bill is a very independent student, and the thesis advisor is known for his monumental lack of tact in dealing with students.

Nevertheless, the work done in the thesis advisor's lab is exciting and innovative, and Bill's project, in particular, has been highly successful.

Bill's question is this: He is preparing a paper reporting part of his thesis work. His good friend, Kim, who is a graduate student in a lab doing related work, has helped him a lot with the paper.

She has critiqued it from the initial draft, suggested an additional control experiment that Bill considers very helpful in presenting the results, and helped Bill to draft the discussion section.

Because of these contributions, Bill has offered her co-authorship.

However, this offer has been rescinded by his thesis advisor, who states Kim has no claim to authorship, and, further, that he objects to her having been involved in this way, "behind his back" without his knowledge or permission.

Bill feels that to deny her authorship is tantamount to plagiarism. He asks what he should do.

## Responsible Authorship – Policies and Regulations

No federal regulations

Journals and Professional Societies have developed authorship guidelines

Case has an Authorship Policy that was revised in 2005.

<http://ora.ra.cwru.edu/ospa/policies/CaseAuthorshipGuidelines.pdf>

Case policy stipulates the following:

- Only include as authors those who have contributed substantially
- All authors must have contributed to the development of the manuscript
- All authors must be sufficiently familiar with the conduct of the research
- It is the responsibility of the author corresponding with the journal or conference to see that all authors approve the final form
- All contributors accepting authorship must also accept the responsibility of avoiding unnecessary duplicate journal publication of similar material
- Contributions such as provision of standard materials, performance of incidental assays, use of facilities, routine patient care, do not justify authorship
- For large group projects, it is important at the outset that all members of the research team understand and agree to these principles of authorship
- Disputes or questions concerning authorship should be brought for resolution to the Dept. Chair, Dean, or Provost

## Responsible Authorship – Key Concepts

### Principles of Authorship:

- Authors must have participated sufficiently in the work so as to take public responsibility for its content
- Authors must be willing to respond to questions about the work
- Authors must have made substantial contribution to all of the following:
  - conception and design, or acquisition of data, or analysis and interpretation of data
  - drafting the article or revising it critically
  - final approval of the version to be published
- The following are not sufficient to justify authorship:
  - participating solely in acquisition of funding
  - participating solely in collection of data
  - supervising the overall activities of the research group

## Responsible Authorship – Key Concepts

### Principles of Primary Authorship

- The primary author (i.e., first author) is generally chosen based on an evaluation of that individual's contribution to the conception, planning and execution of the study
- Generally done after the work has been performed, but before the paper is written
- According to Houk and Thacker (1990), the primary author satisfies one or more of the following:
  - Originality of contribution
  - Major intellectual input
  - Major feature of manuscript
  - Greatest overall contribution

## Responsible Authorship – Case Study

You are part of a lab that has just concluded research on the efficacy of a new drug treatment for childhood asthma. At the next lab meeting you are to discuss authorship for the resulting publication. Which of the following individuals should be included as authors?

- The lab manager who contributed by offering a few suggestions from time to time, but whose role was largely to maintain the lab
- A post-doc who is no longer a part of the lab, but who wrote much of the protocol and obtained significant funding from a drug company for the project
- You and several other graduate students who did the majority of the work and analysis
- A biostatistician who helped the lab with the finer points of various analyses
- The PI who has been rather “hands off” on this project
- A representative from the drug company who made substantial contributions

## Data Management – Policies and Regulations

### Federal Policies and Guidance Documents:

- NIH Data Sharing Policy  
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>
- National Science Foundation Policy on Dissemination and Sharing of Research Results.  
[http://www.nsf.gov/pubs/policydocs/pappguide/nsf08\\_1/aag\\_6.jsp](http://www.nsf.gov/pubs/policydocs/pappguide/nsf08_1/aag_6.jsp)
- Federal Acquisition Regulations (FAR) - 48 CFR Part 27 (For contracts awarded by the Federal government); §27.403 Data rights—general 52.227-14; Rights in Data – General  
<http://www.arnet.gov/far/>
- HIPAA Privacy Rule  
<http://privacyruleandresearch.nih.gov/>
- OHRP, HHS. Guidance on Research Involving Coded Private Information or Biological Specimens, August 10, 2004.  
<http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>

### Case Policies:

- Data Custody Policy
- Intellectual Property Policy
- Human Research Protection Policy
- Confidentiality terms in contracts
- Non-disclosure Agreements

## Data Management – Key Concepts

Why is data management important?

- Integrity of research
- Intellectual property protection
- Ensuring confidentiality
- Compliance with sponsor's requirements

What are the issues to be considered for the following data management practices?

- Data Acquisition
- Data Analysis
- Data Sharing
- Data Retention

Who owns the data?

- Universities have generally been silent on the subject of data ownership
- Many universities have addressed the topic indirectly through intellectual property policies
- Ownership terms can often be stipulated by contracts with the sponsor
- Faculty generally own copyright to "learning material"

## Data Management – Case Study

A graduate student finally finishes his dissertation work (based on a group project with his adviser) and takes a position at another institution. The faculty member, while signing off on the work, does not think the data is worthy to be published (although a draft manuscript has been submitted). The graduate student does not take the data with him, but makes a request later to get a copy of his data and some other data from the project (including some software code). The faculty adviser refuses to let the former graduate student have the data.

## Peer Review – Policies and Regulations

### Federal Policies and Guidance Documents

- NIH Peer Review Policies and Practices  
<http://grants2.nih.gov/grants/peer/>

### Journal Policies

- New England Journal of Medicine  
<http://content.nejm.org/cgi/content/full/343/20/1485>
- Nature  
[http://www.nature.com/authors/editorial\\_policies/peer\\_review.html](http://www.nature.com/authors/editorial_policies/peer_review.html)

### Case Policies and Practices

- No specific Peer Review Policy
- Ancillary policies:
  - Code of Conduct  
[http://www.case.edu/president/audit/Code\\_of\\_Conduct.pdf](http://www.case.edu/president/audit/Code_of_Conduct.pdf)
  - Conflict of Interest Policy
  - Regulatory Committee Policies (e.g., IRB, IACUC, IBC)

## Peer Review – Key Concepts

### Expertise

- Same discipline, but not in direct competition with author or PI
- Junior vs. senior researcher

### Conflict of Interest

- Material under review too close to own work
- Author or PI from your institution, department, a past or present collaborator, your mentor
- Material under review focused on technology in which you have a financial interest

### Confidentiality

- Can you share a manuscript or proposal with someone else?
- Can you incorporate information from manuscript or proposal in your own research?

### Other Ethical Concerns

- Research misconduct, e.g., plagiarism
- Human subject or animal welfare non-compliance

### Time

- Reviews need to be done in a timely fashion
- Peer review takes time and is generally unfunded

## Peer Review – Case Study

A graduate student alleges that a faculty advisor has instructed him and his fellow graduate students to read an NIH grant that the faculty member received to review and to “identify things that could benefit their research”. The faculty advisor states that he was giving the graduate students an opportunity to assist in the review of a grant – something they will have to do when they graduate.

## Collaborative Science – Policies and Regulations

### Federal Policies and Guidance Documents

- NIH Roadmap – Research Teams of the Future  
<http://nihroadmap.nih.gov/researchteams/>
- NSF Cross-cutting/Interdisciplinary Programs.  
<http://www.nsf.gov/home/crssprgm/>

### Case Policies and Procedures

- No formal policy on collaborative science
- Various ancillary policies:
  - Conflict of Interest
  - Data Custody Policy
  - Authorship Policy
  - Intellectual Property Policy
  - Code of Conduct
  - Terms in sponsored research agreements including subcontracts

## Collaborative Science – Key Concepts

### What is collaborative research?

- Collaboration usually involves two or more researchers within an institution or in different institutions, working either in the same field or in different scientific fields or sectors of the economy

### What is spurring the increasingly collaborative and multidisciplinary nature of research?

- Funding sources
- Researchers need complementary skills
- Ease with new telecommunications technologies, e-mail
- Technology-transfer between academia and industry fostered by the Bayh-Dole Act
- Evidence that collaborations will improve progress

### What are some of the potential problems with collaborative research?

- Difference in style of investigators
- Difference in style of research across disciplines
- Differences between academic and industrial research with respect to sharing of data and results
- Ethical considerations may affect research across institutions and nations; there may be differences in issues such as disclosure of conflict of interest and standards for clinical research

## Collaborative Science – Key Concepts

### What are the ways to enhance collaboration?

- Communication first, second, and throughout
- Discussing in advance who will do what in a project; understanding that this might change as the research evolves
- Discussing authorship in advance
- Discussing data in advance
- Discussing intellectual-property issues in advance
- Managing accountability

### What is the institutional role in the collaborative process?

- Technology-transfer offices
- Grants-and-contracts offices
- Clinical-trials offices

## Collaborative Science – Case Study

A collaborative research venture involves institutions from the United States and a foreign country. Although the study will be conducted abroad, U.S. researchers' protocol underwent their institutional IRB review, while there is no such requirement for their foreign colleagues. As the study is underway, a situation threatens the promise of confidentiality for participants and thus the integrity of the research design. These participants are HIV positive patients receiving care, and who are citizens of the foreign country.

Although the foreign investigators inform their U.S. counterparts that they are providing the National Health numbers of patients in order for outside laboratories to be paid, these researchers do not exhibit concern since they are not obliged to follow the same regulations as U.S. researchers. Dr. Alexie Filipnova (co-principal investigator) and Dr. Syd Shingles, the U.S. researchers, discuss what they perceive as a threat to data integrity with a representative of the foreign research team, Dr. Raymond Lagarde.

## Research Involving Human Subjects (Participants)

### Regulation and Policy

- DHHS
  - 45 CFR 46
- FDA
  - 21 CFR 50, 56, 312, 600, 812
- Faculty Handbook
  - University Policy on Human Research Protection
- Local IRB Policy and Procedures
  - Case IRB (Nursing, Dentistry, Social Science)
  - Case Cancer IRB
  - University Hospitals Case Medical Center IRBs
  - The MetroHealth System IRB
  - Cleveland Clinic IRB
  - LS Veterans Affairs Medical Center IRB
  - <http://ora.ra.cwru.edu/research/orc/Case%20IRB%20System/Index.cfm>

## Research Involving Human Subjects (Participants) – Case Study

Dr. Rome wants to conduct a study of the effects of grandparents introducing reading to their three-year-old grandchildren. He is planning to obtain the participants' informed consent and wants to do follow-up with the children's parents in two years when the children begin kindergarten. Dr. Rome also plans to conduct an Internet search for contact information in order to find any of the parents who relocate over the course of the study.

What, if anything, does Dr. Rome need to do regarding the informed consent?

What ethical issues, if any, are there regarding the use of the Internet to locate contact information?

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## Research Involving Human Subjects (Participants)

- Why should some research on humans be exempted from regulation?
- IRBs must include at least five members and include one scientist, one non-scientist, and a member who is neither affiliated with the institution nor related to someone affiliated with the institution. What other criteria could be used to identify necessary members for IRBs?
- What should subjects know about proposed research and their protection before they enroll as subjects or participants?
- What other principles could be used for evaluating the ethics of human subjects research besides respect for person, beneficence, and justice?
- Should subjects be allowed to enroll in experiments or studies that either promise no direct benefit to them or cannot provide them with the opportunity to withdraw completely?

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## Research Involving Human Subjects (Participants)

### Key Concepts

Identifiable Private Information  
Vulnerable Populations  
Consent Process  
Ethical Recruitment

## Research Involving Animals

### Regulation and Policy

- PHS
  - Policy on Humane Care and Use of Laboratory Animals
- USDA
  - Animal Welfare Act
- Case Institutional Animal Care and Use Policies
  - <http://casemed.case.edu/ora/iacuc/>

## Research Involving Animals – Case Study

Dr. C is interested in the neurochemistry of aggressive behavior. He knows that a rat given para-chlorophenylalanine (PCPA) will display aggressive behavior toward adult mice, attacking and killing them. PCPA depletes serotonin by inhibiting tryptophan hydroxylase. Based on these and other observations, Dr. C believes that aggressive behavior appears when serotonin is no longer able to achieve a balance with other neurochemical agents. At this point, he wants to know which of the serotonin receptor subtypes are involved in mediating and modulating this behavioral response.

To this end, he proposes to administer a number of agents known to have an effect on serotonergic transmission; the administration will either be subcutaneous, if the agent is known to cross the blood-brain-barrier, or intraventricular, if the agent is known not to cross the blood-brain-barrier. Agents are selected to be either agonists or antagonists of different serotonin receptor subtypes. Once the agent is administered, the experimenter will attempt to elicit aggressive behavior by administering PCPA. A mouse will be introduced into the enclosure with the rat to act as a potential "prey." It is presumed that some but not all of the agents will affect the aggressive behavior. By observing which agents affect the behavior, he can determine which receptor subtype is involved.

## Research Involving Animals – Case Study

The IACUC has reviewed the protocol for these experiments, and communicated a concern that Dr. C indicated that the "prey" animal is "usually" killed instantly during an attack. He has argued that there is little potential for pain in the prey because they are normally killed instantly by a bite to the neck. The IACUC is concerned that animals not instantly killed may experience pain. In response to the IACUC, Dr. C has indicated that, should the prey not be killed instantly, he will immediately sacrifice them by cervical dislocation. The IACUC was also concerned that the rat might be bitten by the mouse during the attack and therefore suffer some pain. The investigator has indicated that he will watch for that carefully and either treat the rat or sacrifice it, depending upon the severity of the wound.

Another concern of the IACUC was the choice of object for the aggression. Why, they wondered, couldn't the investigator substitute crickets or frogs or rubber mice or a cotton ball or something else? The investigator responded that the response of the rat is different for objects other than mice or, in some cases, it may not respond at all. Previous studies have used mice; he wants to be able compare his results with those of previous experiments.

## Research Involving Animals – Case Study

Dr. C argues that these experiments are important because they may suggest improved methods of aggression control in humans.

- Do you think that the investigator has adequately designed the experiments to minimize pain and suffering by all animals involved?
- What more would you recommend?
- If you were a member of the IACUC, how would you vote on this protocol? Why?
- Are there some "gut" issues here that do not have to do with animal welfare?

**Michael D. Mann, Ph.D., University of Nebraska Medical Center**

## Research Involving Animals – Key Concepts

Selecting and Utilizing Animal Models

Reviewing IACUC Protocols and Function of Committee

Pain and Distress

Society and Activists

## Research Misconduct – Regulation and Policy

[http://ori.dhhs.gov/policies/federal\\_policies.shtml](http://ori.dhhs.gov/policies/federal_policies.shtml)

- DHHS – Office of Research Integrity
  - 42 CFR Parts 50 and 93
- National Science Foundation
- Department of Energy
- Department of Labor
- Department of Transportation
- Department of Veteran Affairs
- Environmental Protection Agency
- National Aeronautics Space Administration
- National Endowment for the Humanities

## Research Misconduct

### **Faculty Handbook**

- University Policy for Responding to Allegations of Research Misconduct

<http://www.case.edu/president/facsen/frames/handbook/CASEFH2006.pdf>

**Research misconduct** means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or in reporting research results

...must report allegations to Research Integrity Officer in the Case Office of Research Compliance

## Research Misconduct

**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.

## Research Misconduct – Case Study

Julio Cruz and Samantha Bergen are both graduate students working with Dr. Mark Chan, an eminent environmental chemist. Although both are in their fourth year of study, neither has published a manuscript. Both are beginning to worry that if they do not publish soon they will not be able to obtain good postdoctoral positions.

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, because even the synthesis and some properties of the intermediate molecule are unique enough to be published in an important journal, such as Nature.

## Research Misconduct – Case Study

Although only small amounts of RG198 are available, Julio and Dr. Chan agree that they must push ahead and work quickly. In order to help Julio as he works on manufacturing more RG198 for the next set of experiments, Dr. Chan recruits Samantha to assist Julio in some analyses. Samantha has not been very successful with her project, which involves transforming asbestos into a non-toxic compound, and Dr. Chan feels that performing the analyses will teach her some skills that she could apply to her own project. Dr. Chan promises her a second authorship on the paper if the results of her analytic studies pan out. Although Julio does not think highly of Samantha, believing her to be sloppy, he wants to move ahead with his research. He gives her the RG198 in two batches for the analytic studies.

Samantha completes the first set of analyses on the first batch and is excited by the results, which verify three of the four chemical groups that RG198 is supposed to have. On the next batch, Samantha performs another set of experiments, using another analytical tool that will identify the fourth chemical group. On the day she is doing the first experiment on the second batch of RG198, she phones Julio from the analytical facility across the street from the lab 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.

## Research Misconduct – Case Study

Julio asks Samantha to save the remaining material from the second batch, telling her that he will perform the second round of analyses. But when Samantha comes back to the lab a few hours later, she does not give him the leftover RG198. 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. Samantha tried to reassure Julio by showing him the graphical readout from the instruments from the experiments on the second batch, pointing to the results for the fourth chemical group.

Dr. Chan is ecstatic about the findings, and tells Julio to quickly write up a manuscript. Julio doesn't want to accuse Samantha of manipulating research results, but later in the day he looks through her research notebook and sees a written procedure and data for the first batch of experiments. For the second batch, he sees that she has put only the readout in the notebook, which looks too clean to him. It also has no accompanying text. He wonders what might have happened. Perhaps she used a reference sample and some mechanical manipulation to make the fourth chemical group peak appear so pure.

## Research Misconduct – Case Study

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 in Nature, but in the next several months other scientists who repeat his synthesis are finding different spectra than what he reported in his second batch of experiments. During that time, Julio has been able to synthesize more of the compound, and even succeeds in making WX5. When he repeats the analysis on the fourth chemical group in RG198, he finds a different spectral pattern from what Samantha found and what was published. He believes that she must have done something to the data.

### ***Columbia University RCR Course***

#### **Acknowledgement**

This case was adapted from Schrag B, "Research Ethics: Cases and Commentaries," Vol. 3. Prepared under NSF Grant No. SBR 9241897.

## Research Misconduct – Key Concepts

- How can the pressure to publish influence the conduct of research?
- Was it appropriate for Dr. Chan to promise Samantha second authorship based on performing some assays?
- Trust is one of the central issues in science. What might Julio have done to feel better about working with Samantha if he didn't think highly of her?
- At this point, it remains unclear whether Samantha has done anything wrong, even though she did not follow Julio's instructions to let him do the second analytic experiment. What action should Julio take?
- Data collection and management are important issues in the responsible conduct of research. Independent of the possibility that Samantha might have engaged in manipulating research data, what is the major problem in the way she kept her laboratory notebook?
- What is misconduct? If it is found that Samantha engaged in misconduct, is Julio also guilty of misconduct, because he did not report his concerns earlier?
- If science is self-correcting, as it is in this case study, why are there federal laws and regulations against misconduct?
- It seems clear that there was a problem with Samantha's data. What should Julio do now?

## Research Misconduct – Key Concepts

- Have you ever taken shortcuts to produce results under pressure-filled conditions?
- How do you think you would feel about accusing a colleague of misconduct?
- Do you know whom you would speak to in case you had suspicions of misconduct by a graduate student, postdoctoral fellow, laboratory head, or department head?

## Navigating Resources



<http://compliance.case.edu>

or

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## Goals of RCR Education and Training

“In short, it is not enough merely to teach information and skills. Promoting positive attitudes depends on evidence that responsible conduct is highly valued both by those teaching RCR and by the institution in which research is being conducted.”

*Responding to Challenges...(Kalichman) Academic Medicine, Vol. 82, No. 9/September 2007 p.873*

## Next Steps?

Spring Seminar Series  
-RCR Sessions

Thank you for your attention!

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