

Introduction to Research Integrity

(AKA “Responsible Conduct of Research”
or “Research Ethics”)

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My Definition:

- **“Responsible Conduct of Research” is the conduct of research by people thoughtfully attuned to the ethical dimensions of their work, who care about doing the right thing, and who know how to address ethical issues that arise.**

“I’m a good person. Why do I need to worry about research ethics?”

- It’s true that most of us do the right thing most of the time.**
- It’s true that we can’t do much about bad people determined to do evil things.**
- However, research ethics isn’t just – or even mostly - about bad people doing bad things.**

It's also about imperfect people doing imperfect things:

- Following acceptable practice we later deem wrong
- Accident
- ‘Misdemeanor’ -level wrongs (e.g., taking shortcuts)
- Missing something, especially with new methods or technology
- Becoming involved in ethics violations via the wrongs of others
- Sometimes the right thing to do just isn't clear
- Self-deception and other psychological tendencies

Professional Pressures in Academia

- Publish or perish
 - Tenure/employment
 - “Keeping up” with peers
 - Securing grants
 - Being first to a discovery
- All of these encourage shortcuts and “misdemeanors,” or worse

Example: professionally acceptable practice

- “Example 18. Melanoma was transplanted from a daughter to her volunteering and informed mother, ‘in the hope of gaining a little better understanding of cancer immunity and in the hope that the production of tumor antibodies might be helpful in the treatment of the cancer patient.’ ”
- “Since the daughter died on the day after the transplantation of the tumor into her mother, the hope expressed seems to have been more theoretical than practical, and the daughter’s condition was described as ‘terminal’ at the time the mother volunteered to be a recipient.”

- “The primary implant was widely excised on the twenty-fourth day after it had been placed in the mother. [The mother] died from metastatic melanoma on the four hundred and fifty-first day after transplantation. The evidence that this patient died of diffuse melanoma that metastasized from a small piece of transplanted tumor was considered conclusive.”
- Beecher, H. 1966. “Ethics and Clinical Research.” *NEJM* 274(24), 1354-1360. (This paper has many such examples, published by physicians with the most prestigious credentials, in the most prestigious journals.)

‘Misdemeanor’ -level wrongs we may try to justify or shortcuts we take (see cases 1,2,5)

- Case 1: “sharing authorship [is] the norm” in a lab in another country where you do research. Should you list authors who haven’t done much on your paper?**
- Case 2: Conducting research based on work you see in the course of confidential review, then trying to beat that group to print with the results.**

- Case 5: A graduate student presents his work at a meeting. One attendee asks him to discuss his work in detail over dinner, and later publishes a paper using the student's method.

Sometimes the right choice isn't clear (see case 6)

- Case 6: Grad students in a lab read a newspaper story about a researcher at their institution. They want to write a letter to the newspaper pointing out several errors in the reporting, but their supervisor/professor prohibits them from doing so because it may make them look guilty. What should they do?

Sometimes we have to think about the implications of an action in order to see the research ethics issues (see case 3)

Case 3: A graduate student writes notes in the laboratory notebooks in his native language (not English) so that he has privacy from the senior technician. Is this acceptable?

What are the moral foundations of research?

- Doing good for humans, animals, the planet, future generations, etc. via the pursuit of truth and knowledge
- Our duty to respect individuals
- Our possible duties to animals
- Our obligations to society

→ Various obligations derive from these foundations, and they can be in tension with one another.

Example: Ethical guidelines stemming from research as the pursuit of truth

- “The truth, the whole truth, and nothing but the truth.”
 - The truth: Be honest about your research.
 - The *whole* truth: Omission of parts of research findings might constitute research misconduct or violate other moral norms.
 - *Nothing but* the truth: It’s also dishonest to “puff” results by adding irrelevant or misleading information, or overstating the significance.

To whom do we owe the truth, and why?

- The public, for its funding support
- Individual research participants, out of respect for their autonomy
- Colleagues and collaborators, whose research may be based on our research
- Funding institutions, for giving us resources
- Research institutions/universities (our employers), for employment, resources, and because their reputations can be affected by what we do
 - Clearly, many obligations of research stem from its nature as the pursuit of truth and knowledge.

Some areas of research ethics:

1. Research misconduct (falsification, fabrication and plagiarism)
2. Collaboration issues (authorship, data ownership and management)
3. Peer review
4. Conflicts of interest or obligation
5. Complicity and funding sources
6. Animal subject research
7. Human subject research

1. Research misconduct:

The National Science Foundation definition

Research misconduct means fabrication, falsification, or plagiarism in proposing or performing research funded by NSF, reviewing research proposals submitted to NSF, or in reporting research results funded by NSF.

(1) Fabrication means making up data or results and recording or reporting them.

(2) Falsification means 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.

(3) Plagiarism means the appropriation of another person's ideas, processes, results or words without giving appropriate credit.

Research misconduct does not include honest error or differences of opinion.

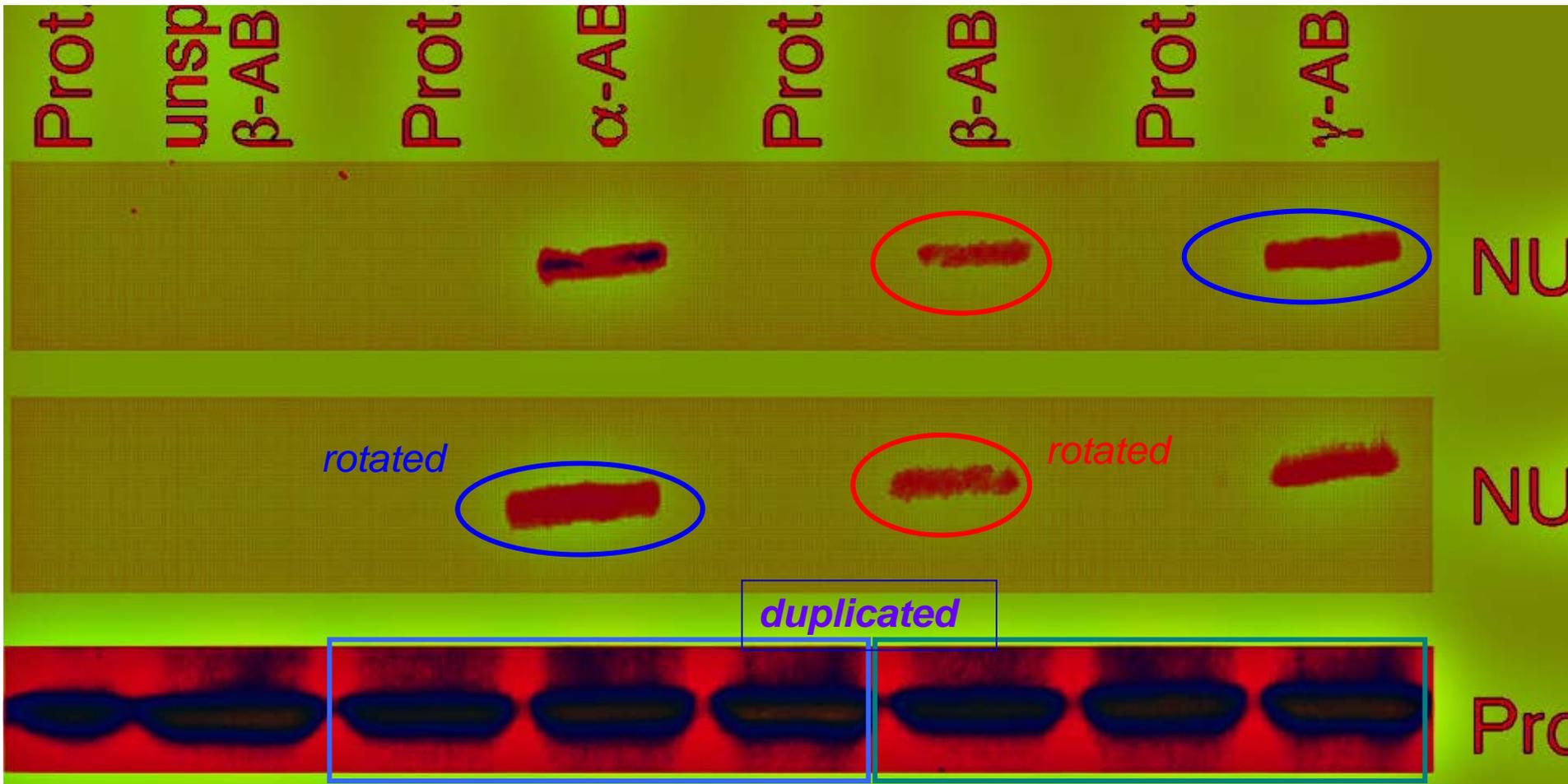
- From NSF regulations, section 689.1

Examples of research misconduct:

- Image manipulation
- Data fabrication or falsification
- Data omission/suppression
- Plagiarism from the work of another - could also be ideas gleaned from peer review and used as one's own work
- Sabotage
- See case 5 (case 2 may also be an example of this)
- See www.retractionwatch.com for many examples of articles retracted from journals

Image Manipulation Example

(from <http://www.councilscienceeditors.org/events/annualmeeting07/presentations/Krueger.ppt>)



2. Collaboration issues

What kinds of research ethics issues can you think of that might stem from collaboration?

- * Authorship
- * Intellectual Property
- * Different levels of methodological rigor
- * Recordkeeping issues
- * Calculation issues

Collaboration Issues Example 1:

Authorship Credit

- *The following individuals contributed in some way to the work reported in a manuscript to be submitted for publication. Who should and should not be listed as an author, and in what order?*
- 1) Lab chief** – Contributed to the design of the experiments, and analysis and interpretation of the data; edited several drafts of the manuscript.
 - 2) Program director** – Obtained the funding for the research project, including the salaries, supplies and equipment necessary for the research.
 - 3) Technician** – Trained graduate student in the techniques used for their research; did all of the surgical procedures and some of the biochemical analyses.
 - 4) Postdoctoral fellow** – Questions arising from their research spurred the lab chief to examine this research topic. Contributed to discussions regarding the design of the experiments and the analysis and interpretation of the data.

[case continues on next slide]

(Authorship credit continued)

5) Graduate student – Contributed to the design of the experiments; conducted the experiments; responsible for most of the analysis and the interpretation of the data; wrote the first draft of the manuscript, and edited several subsequent versions.

6) Undergraduate research assistant – Performed some of the sample analysis.

7) Glassware washer – Employed special procedures for washing and sterilizing glassware to meet the strict requirements in the experimental protocol.

8) Animal caretaker – Provided specialized care needed to ensure the survival of the animals in the study.

9) Departmental colleague – Read a complete draft of the manuscript and provided extensive comments on both the organization and style.

10) Colleague at another university – Shared with the lab chief a unique reagent that they (the colleague) had developed, was not commercially available, and was central to the experiments.

•BA Fischer & MJ Zigmond

•Survival+@pitt.edu

Collaboration Issues Example 2: Management of and Access to Data

- Who 'owns' the data, and who can make use of it in the future?
- Can lab notes and materials be taken off-site?
- What responsibilities do lab workers/student assistants have in documenting lab work?
- See cases 3, 4, and 5

3. Peer Review

- What do you do if you learn something from reviewing a manuscript that could help your own research?
- What can you do to protect your intellectual property during the review process?
- Can graduate students read manuscripts on behalf of their professors?

4. Conflict of interest

- A situation in which one experiences conflicting pulls from one's personal interests and from one's professional obligations.
- Most direct example: being paid to say something untrue.
- Indirect example: Knowing that if you say something positive about a company that gave you a grant, you may be more likely to get a grant from them again in the future.
- Another indirect example: A funding agency may stipulate that they have a right to decide whether you can publish your findings or may delay publication.
- 'Ghostwriting' and 'ghost management' in the medical literature is rampant and raises these questions.

4. (cont' d) Conflicts of Obligation

- Having duties to 2 or more parties at the same time.
 - For example, the duty to research and the duty to teach
- Not to mention obligations to one's family, friends and self (e.g., how should you spend your time off?).

5. Complicity and funding

- Moral issues beyond scientific misconduct can arise depending on one's field of research and funding source.
- Examples:
 - stem cell research
 - dual-use biological agents
 - weaponizeable technology/DoD funding

6. Animal subject research

- May we use animals in research?
- What are the arguments for or against?
- Are there limits to how we might treat them, and if so, what are they, and what justifies these limits?
- Quick lesson in animal subject research: the “3 Rs”:
 - Refine: refining experiments to cause less pain and distress
 - Reduce: reducing the number of animals used if possible
 - Replacement: replace higher-order animals with lower-order ones

7. Human subject research

- May we use human subjects in research?
- Under what conditions?
- Nuremberg Code: the first attempt to answer these questions with guidelines for the use of human subjects of research.
 - First sentence: **The voluntary consent of the human subject is absolutely essential**

Conclusion

- Thinking about research ethics can't *make you* a good person.
- But a study of research ethics can offer a “map” of ethical issues so that you recognize them when you encounter them.
 - It can't solve the problems you might have, but it is very helpful to have advance warning of where the perils lie.
 - It will also help you recognize when you (or someone you know) are entering or in the middle of an ethically challenging situation so that you can avoid it or address it. “Prophylactic ethics” is a much better approach than crisis management!

Bottom Line:

- You must actually *think* about the ethical components of what you do. Rules give very little guidance in tricky situations.

Research Ethics and Leadership

- Leaders set the tone; they don't just "get along, go along." You may go on to help run a lab, department, institution, or system in which the importance of responsible conduct of research is a part of the culture.
- Becoming a thoughtful, ethically-attuned researcher helps you develop leadership skills in your field, mentor others, and see issues others miss.

- I'm just a tour guide. Your professors really know about the ethics in your field.
- But they, like others, can tend to think of ethics as “separate” from the “real work” of the field, or forget to teach it to their students.
- Sometimes, YOU need to start the conversation.

Suggested references

- Office of Research Integrity: ori.hhs.gov
- “The Lab” interventional video about research misconduct: ori.hhs.gov/thelab
- Retraction Watch: retractionwatch.com

The Ethics of Authorship and Publication

Case 1

Dr. Warren is the editor of *Biomedical Methodologies*, an 8-year old quarterly journal with an international readership and pool of authors. Dr. Warren has just sent an issue's final proofs to press when he receives an e-mail from Dr. Hannah, one of the issue's authors. Dr. Hannah is a rising star in her field. Her paper compares three variations on a particular research method as used in the United States and two European centers. Dr. Hannah collected her European data from the published literature while working as a visiting fellow in two prominent research institutes. In both settings she worked with little supervision or collaboration, but she established good personal relationships with the other researchers there.

Dr. Hannah wants to make a late correction to her article, adding four more authors. A few weeks before she had enthusiastically sent copies of her author's proofs to the directors of the two European labs where she had worked. That morning, however, Dr. Hannah received a stern letter from the director of the second facility informing her that sharing authorship credit was the norm in his country. Dr. Hannah now fears that she erred seriously in not listing both center directors and her two office mates as authors despite their having had almost no role in designing the project and none in writing the paper. She is worried that any future European collaboration depends on adding their names to the paper.

The journal's policy is that authors take responsibility for assigning authorship, yet Dr. Hannah acknowledges that her attribution will be false. She has also cited the paper elsewhere as hers alone – "forthcoming" in the journal. Practically, the entire article will have to be reset to add four names and their affiliations, adding potentially significant expense and delay to its publication.

Should Dr. Warren add the additional names to the title page?

Case 2

Members of the Grand Old State University (GOSU) Biology Department had recently submitted a large, complex program project grant to the National Institutes of Science, and Professor Kane, chair of the Biology Department at Competitive State University (CSU), was part of the site visit team. Professor Kane was impressed by the department's research in support of the grant application. GOSU researchers reported that one particularly exciting patch clamp study using frog skin had recently been accepted for publication in the *American Journal of Biology*. It demonstrated a new single-channel protein that actively transported a specific molecule that had been found polluting the water in local streams. This transport proved toxic to the skin cells. The article speculated that this newly discovered channel might be involved with the recent death of frogs in the region.

When Professor Kane returned to CSU, he mentioned this work and the forthcoming article to Dr. Tristan and his graduate student Yazmin, who were working on a similar patch clamp system. That afternoon, Dr. Tristan asked Yazmin to see if she could repeat the results that Professor Kane had described. Knowing the details of the work at GOSU, Yazmin had no trouble repeating the experiment, and she wrote it up for Dr. Tristan. The next Monday Yazmin was dismayed when Dr. Tristan showed her a Brief Report that he had written using her patch clamp data. He intended to submit it to the *Aquatic Pathobiology Journal* with both of them as authors. The *Aquatic Pathobiology Journal* was edited by one of

Dr. Tristan's friends and typically had a short turnaround time before publication. Dr. Tristan expressed confidence that they could beat the GOSU team's study into print.

When Yazmin had initially repeated the GOSU patch clamp experiment, she had had no intention to use the data for publication. Yet now she was reluctant to confront her PI about his unauthorized knowledge of the GOSU study and was somewhat eager to get her name on this easy paper directly related to her own research.

How should Yazmin respond to Dr. Tristan's plans for publication?

Management of and Access to Scientific Data

Case 3

Joseph is a second-year doctoral student in microbiology who entered the program with a master's degree from his native country. He works in a large lab with several other students, fellows, and technicians. Their PI travels frequently, and Carol, a senior technician, is in charge of almost all of the lab's day-to-day activities.

Joseph originally expected a close working relationship with his new adviser, and was disappointed that they seldom saw each other. He was also surprised that Carol wanted to review his work every week. She routinely examined his notebooks and questioned his methods, results, analysis, and plans for future experiments. Carol seldom gave feedback other than short critical notes like "this can't be right." After several weeks, Joseph asked Carol whether she was unhappy with his work. Carol replied that she was not dissatisfied but rather that she was responsible for the students when the PI was away. She found that reviewing students' lab notebooks was the best way to measure their progress. None of the other students complained, but Joseph resented having his work checked by a technician, and her supervision felt like an invasion of his privacy.

One afternoon, in the middle of a complex experiment, Joseph had an idea for a new procedure that he outlined in a mix of his native language and English. Later that week, when Carol reviewed his notebook, she said nothing about the strange notation. Joseph recognized that he could maintain some privacy by taking notes in his native language.

Now at the end of the year, Joseph keeps roughly half of his records in his native language with enough basic documentation in English to satisfy Carol that he is making progress.

Are Joseph's record-keeping methods acceptable?

Case X 4

Darlene is an advanced graduate student at State Land-grant University. She is about to finish her dissertation on the cloning of a gene and the biological actions of the protein it produces. A manuscript describing her results has already been accepted for publication in a competitive journal. When Darlene started graduate work at State, she had elected to work with Dr. Goforth because his laboratory was well supported by NIH funds, he had an impressive publications record, and he had supervised several Ph.D. students who had gone on to good academic positions. Darlene has always gotten along well with Dr. Goforth and is sorry to be leaving his lab.

Darlene has been offered a postdoctoral fellowship at another university. Her future mentor has requested that she bring samples of various biological reagents that she had produced during her doctoral training so that they could continue to develop her research in this area. However, when Darlene asked Dr. Goforth about how best to take the samples with her, Dr. Goforth not only refused to let her have samples but also told Darlene that she had to leave her computerized database and laboratory notebooks at State as well. Darlene was so stunned by this response that she couldn't even think to ask why.

How can Darlene ethically retain access to dissertation research data and the biological tools that have been the foundation of her work? How should she respond to Dr. Goforth's refusal to let her take essential data and materials with her?

The Work of the Academic Scientist

Case X 5

Sean is a fourth-year graduate student in Dr. Murray's research group who is purifying a newly discovered enzyme from beef heart. Both he and Dr. Murray think this enzyme should be important to the metabolic integrity of the heart.

Dr. Murray encourages her students to communicate openly with other researchers and to present their work at meetings whenever possible. When Sean presented his dissertation work in a 10-minute talk at a regional meeting, he received good comments from several members of the audience. One listener, Dr. Frank, invited Sean to dinner that night to talk about their common research interests. Over dinner Dr. Frank asked Sean many questions about his work with Dr. Murray. True to Dr. Murray's philosophy, Sean talked openly with Dr. Frank. When dinner was over, Sean told Dr. Frank that he had enjoyed their conversation and looked forward to an ongoing professional exchange.

Three months later, Sean learned that Dr. Frank had published a paper in *Online Biological Notes* about a very similar enzyme from sheep lung. Although the purification reported by Dr. Frank was less extensive than the one that Sean had accomplished, Dr. Frank's paper reported some kinetic properties of the sheep lung enzyme that were to have been a major part of Sean's dissertation.

Sean is devastated and afraid that his dissertation research has been wasted. How should Sean proceed with his dissertation? What should Sean tell Dr. Murray about Dr. Frank's article?

Case ~~7~~ 6

Marie and Leon are second-year graduate students working under Dr. Ortega, a prominent scientist whose research team includes several trainees at various points in their studies. The lab has a very collegial atmosphere that Marie and Leon enjoy. They typically have worked under the supervision of Charles, a postdoctoral fellow who will take a tenure-track position at another university at the end of the year.

One morning, the newspaper carries a front-page story that a researcher from the university's medical school is under investigation for scientific misconduct. No one in the lab can talk about anything else as they try to figure out from the article what could have happened. Charles, Marie, and Leon identify a number of errors in the reporter's discussion of the basic science behind the case. Charles is adamant that researchers need to support each other and science itself against uneducated lay critics, and he is eager to dispute the article. Together the three draft a letter to the editor of the newspaper pointing out the problems with the original story and disagreeing with the reporter's conclusions about the medical school researcher's actions.

Before mailing the letter, they take it to show Dr. Ortega. Surprisingly, Dr. Ortega is very critical of the letter and their desire to respond to the newspaper article. "You're right that the article is very misleading, but I can't let you submit this," says Dr. Ortega. "Everything that is sent out of this lab for publication reflects on me, this department, and this university. We can't get involved in this mess or it will look as if we know something about the guy's work. We don't really know what he was doing, and I don't even understand that much about the field. But once the press gets your letter, there will be no end to the calls, and we may all be treated like suspects. I'm sorry, but this is for the authorities to sort out."

How should the three trainees respond to the newspaper article in light of their advisor's objections?