Introduction to Research Ethics

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What is “research ethics” or the “responsible conduct of research”?

I'm a good person. Why do I need to worry about research ethics?

- It's true that we can't do much about the bad person who is 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, for a variety of reasons:
  - Socially acceptable practice we later deem wrong
  - Accident
  - 'Misdemeanor' -level wrongs that we try to justify
  - Missing something, especially with new methods or technology
  - One can become involved in research ethics violations through the wrongs of others
  - Sometimes the right thing to do just isn't clear
  - Self-deception and other psychological tendencies

Example: socially 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. She 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.)

More examples

- ‘Misdemeanor’ wrongs we may try to justify:
  - See cases 1 and 2
- Sometimes the case isn’t clear
  - See case 6

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 up one's results by adding irrelevant or misleading information, or overstating their 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

→ So 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.

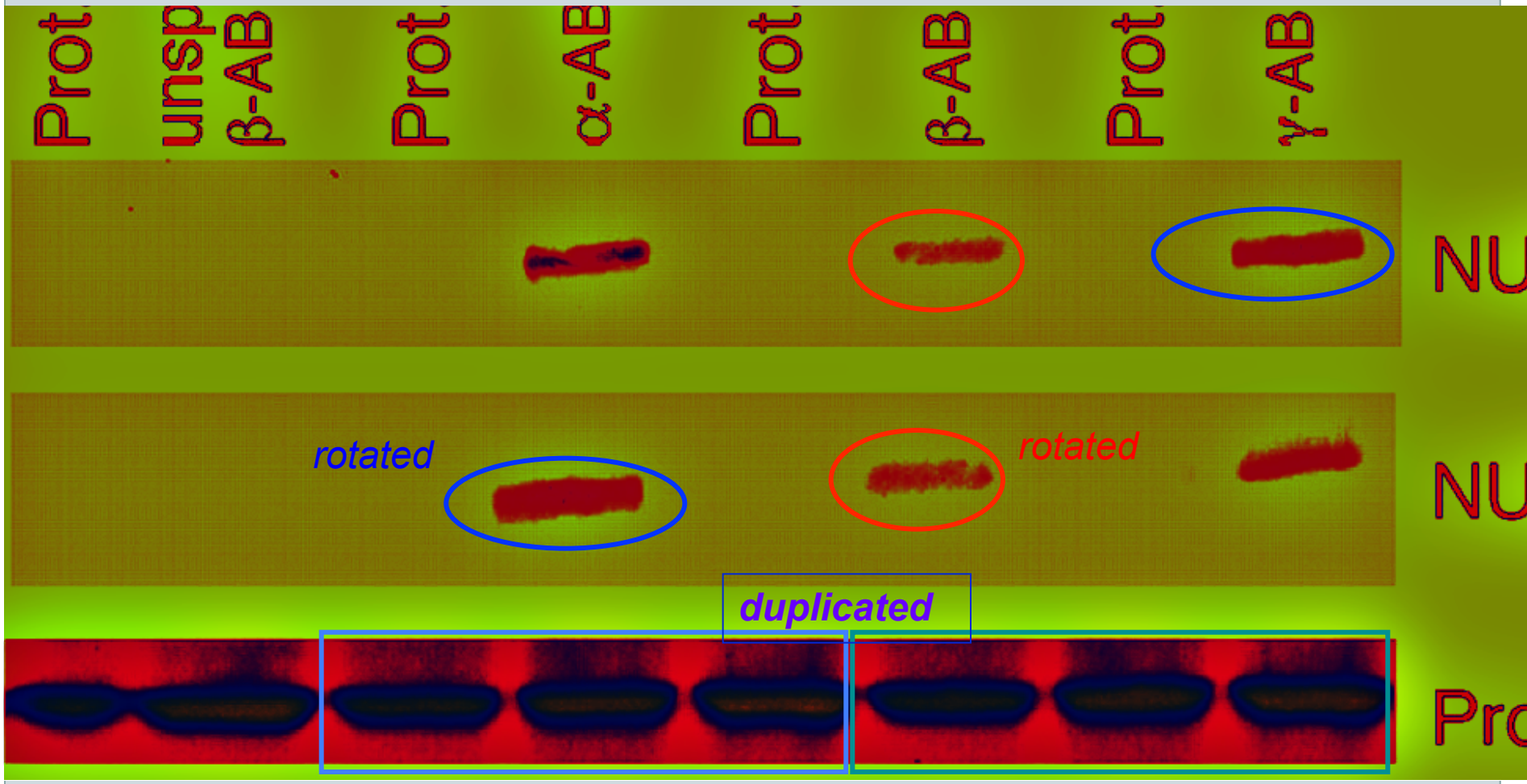
- From NSF regulations, section 689.1

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
- See case 5 (case 2 may also be an example of this)
- See www.retractionwatch.wordpress.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
* Rigor with which the experiment is conducted
* Good recordkeeping
* Accurate calculations

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 and 4

3. Peer Review

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

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 the duty to one' s family, friends and self

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

Nuremberg Code

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonable to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

Nuremberg Code, cont' d.

5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

- 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!

Suggested references

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