

Ethics in Research



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Acknowledgement:

Dr. Arun Shet, India Alliance Senior Fellow, St Johns Medical College & Hospital, Bangalore

Overview

- Introduction to research ethics
- Responsible conduct of research
- Examples of misconduct
- Authorship and peer review
- Ethical use of animals in research
- Ethical use of humans in research
- Discussion

Resources

- Web based resources
- Institutional resources – training courses
- Self learning courses and modules
- Textbooks
- Ethics focused articles in Pubmed
- Novels and perspectives addressing ethical issues

What makes research (un)ethical

- Handling of relations between researchers
- Handling of science
- Handling of the consequences of research
- Handling of human research subjects
- Handling of animals used in research



Ethics

- What is Ethics and why follow it?
- Principles of Ethics
- Types of scientific misconduct
- Motives for scientific misconduct
- Consequences
- Preventive measures

Morality and Ethics

Morals tell us what to do? – Mostly driven by the individual's principle

Norms for conduct that distinguish acceptable from unacceptable behavior. Mostly laid down in a profession/society.

Ethics tells us why and how to do it? – Driven by informal guidelines

Why follow ethics in research?

Pursuing Truth

- promotes knowledge, truth, and avoidance of error
- promotes trust, accountability, mutual respect, and fairness

Public money

- promotes accountability to the public
- build public support for research
- promotes moral and social values

Principles of Ethics

- Performing, evaluating and interpreting experiments with integrity and honesty
- Publishing the research and results with honesty
- Granting access to others to allow reproduction of the results
- Personal responsibility for the research
- Acknowledging the contributions of others

Case Study 1

An investigation conducted by Iowa University found that in the AIDS manuscript, Dr. Stricker selectively suppressed data that did not support his hypothesis, and reported consistently positive data whereas only one of four experiments had produced positive results.

He later clarified that the experimental dye did not work on those days when he got a negative result. **Acceptable?**

In another publication, Dr. Stricker reported that an antibody was found in 29 of 30 homosexuals, but not found in non-homosexuals – the actual data showed antibody in 33 of 65 non-homosexuals.

He admitted it was a typing error. **Acceptable?**

Scientific Misconduct

Data 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”

Data Fabrication

“is making up data or results and recording or reporting them”

Case Study 2 - Schön

Aftermath and Sanctions

In June 2004 the University of Konstanz issued a press release stating that Schön's doctoral degree had been revoked due to "dishonourable conduct".

In October 2004, he was deprived of his active right to vote in German research foundation (DFG) elections or serve on DFG committees for an eight-year period.

During that period, Schön will also be unable to serve as a peer reviewer or apply for DFG funds.

Between October 2002- March 2003

Science withdrew eight papers

Physical Review journals withdrew six papers

Nature withdrew seven papers

What is Plagiarism?

It is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Case Study 3 - Plagiarism

The Ohio University found that Dr. Freisheim submitted a research grant application to the NIH containing substantial portions plagiarized from another scientist's grant application, which he reviewed.

The investigation reviewed the handwritten draft, which Freisheim submitted and concluded that it had been written much later than purported by Dr. Freisheim.

The ORI concurred with the University's findings. Dr. Freisheim was debarred from receiving Federal grants or contract funds for a period of three years. He was also prohibited from serving on PHS Advisory Committees or review groups for the same period.

Outcome of Scientific Misconduct

- Loss of funding or employment
- Legal actions (fine or imprisonment)
- Psychological distress
- Damaged reputation
- Time-consuming and costly proceedings
- Adverse effect on scientific innovation and progress

Co-authorship in scientific research

- Publications central in researcher's CV
- Who gets to be on the papers and why, becomes a very important issue
- Much criticism about questionable practices
- Also criticism regarding major guidelines
- **To Discuss (suggestions):**
 - What guidelines are you aware of?
 - How is authorship determined in your lab?

Case Study 4 – Authorship Issues

Mr X, a US citizen, joined as a Post baccalaureate in JP's lab at NIH in 2009. He started studying an important protein called "ZIP" in Tuberculosis. ZIP was involved in ATP synthesis by the parasite. In 2010, Dr Y, from Srilanka, joined JP's lab as Post-doctoral Fellow. Although, Mr X and Dr Y were passionate about research, X was a biologist, whereas Y was a physicist. After five months of Y joining the lab, X came across a parasite whose growth rates were significantly less than the wild parasite. X informed this observation to Y; however, Y could not appreciate this and relate this finding to anything important. X informed this to JP and both jumped at it and knew there was a lot of hidden science in it.

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Case Study 4 – Authorship Issues

(contd.,)

The team thought of characterizing this mutant using biophysical techniques, because they hypothesized that the lower growth rates were because of a mutation in the gene coding for a protein, which resulted in the synthesis of a faulty protein. Dr Y because of his physics background, was asked to do biophysical studies and X to perform molecular biology experiments. Although Y was quite involved in carrying out the biophysical studies, he did not take much interest in understanding the biological aspects of the project, whereas X was very passionate and was always involved in intense discussions with JP about the project. Dr Y was sometimes involved in data analysis of the biophysical recordings while Mr X and JP discussed the biology part while writing the manuscript. When the studies were completed, the team published the work in Nature with Mr X as first author and Dr Y being the co-first author.

Case Study 5 – Dr Day's Lab

Dr Day has two labs, one in Sweden and another one in the UK. Sonali was a PhD student at Day's lab in UK. At around the same time, Brenda also joined Day's lab as a PhD student but in Sweden. They were both given projects on the same pathway but asked to study two different aspects of it. Sonali was hard working and put in a lot of effort and managed to finish her PhD within 3 years. She moved to a different lab as a post doc. She still had some of her work from PhD unpublished and was working with Day on the manuscripts in her free time. Brenda, on the other hand, had an extendable scholarship and took her time with the PhD. According to the Swedish higher education system, it was a requirement to have publications before one could be awarded a PhD. Even after 5 years, Brenda did not have enough results for even a single paper. With the intentions of helping out Brenda, Day decided to put Brenda as a co-author on Sonali's paper. In return, he offered to put Sonali's name as a co-author on Brenda's paper, if and when it gets published. *(continued on the next page)*

Case Study 5 – Dr Day's Lab

(contd.,)

When Sonali refused, he offered to put her as an equal first author on Brenda's paper. He tried to convince her by saying that Brenda needed their help to complete her PhD and she would be doing her a huge favor to her along with getting a first author paper in return.

Sonali was not happy with this situation at all but she started to feel guilty about not helping out Brenda. But when she discussed this with her colleagues in the lab, they told her that it is unethical of Day to even ask her that; if Brenda was good enough for a PhD, she would get a PhD out of her own work. Sonali realized that Day was only trying to help Brenda out of his good nature but it was not right. She finally told Day that she didn't want to be on Brenda's paper as she has not contributed towards the paper and that it is against her values and similarly she does not agree to Brenda being on her paper. Day did not push her any further and Sonali managed to publish her paper without Brenda's name on it.

ICMJE guidelines

- Substantial contributions to: the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work AND
- Drafting the work or revising it critically for important intellectual content AND
- Final approval of the version to be published AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved
- **To discuss (suggestions):**
 - Exemplify insufficient contributions for co-authorship
 - Are these criteria for scientific authorship reasonable?
 - Identify potential weaknesses
 - Give examples of flaws in current practices e.g. inclusions/exclusions

Insufficient grounds for authorship

- To be the leader of the research group
 - To supply the funding of the research
 - To be formal main supervisor of PhD student
 - To have collected data but not participated with critical input in the revision of the paper
 - To have done something other than research
-
- *Are you sure you want to discuss this?*

Research merits – order of authorship

- Meant to mirror relative contribution
- Known praxis: 1st, last, 2nd, 3rd
- But there are other interpretations
 - E.g. second to last honorable; last not very good; corresponding author most important
- Misrepresentative given reward system – Faculty funding (e.g. Funding agencies, Institutes of Science)
- Addressed to a certain extent by indicating each authors contribution in an article – journal dependent
- Guidelines yet to be formulated

Misconduct motives

- No clear idea of what research is about
- Attracted by the glamour of science
- Anxiety to produce results (publish)
- Negative criticism from superiors
- Jealous of others moving ahead

Case Study 6 - Bhrigu

Bhrigu, a Post-doctoral student over the course of several months at Michigan, had meticulously and systematically sabotaged the work of Heather Ames, a graduate student in his lab, by tampering with her experiments and poisoning her cell-culture media. A hidden camera exposed his acts.

Why did Bhrigu succumb to temptation of taking short cuts in Science?

Reasons for Misconduct

Bad Apple Theory

- Morally corrupt
- Economically desperate
- Psychologically disturbed, jealous, ego, etc.

Imperfect Environment Theory

- Insecurity (poor mentoring, lack of able leadership, role models, etc.)
- Over ambition due to unhealthy competition
- Isolation from colleagues (paper got rejected recently)

Possible remedies

Bad Apple Theory

- Morally corrupt – ???
- Economically desperate – Science gives good returns.
- Psychiatric Illness – Get this treated

Imperfect Environment Theory

- Insecurity – Acquire knowledge
- Publication Pressure - Focus on quality, not quantity
- Mentoring - More ratio of senior to junior scientists

Proper guidance and oversight

- Periodic review of scientific records
- Assessing workloads
- Ethics issues at all levels of education
- Education programs in professional schools etc.
- Incidental rewards designed to reinforce ethical conduct

Research ethics - Animals

What do you think?

The interests of animals carry -

- a) absolutely no moral weight,
- b) (somewhat) less moral weight than the comparable interests of humans,
- c) equal moral weight as the comparable interests of humans?

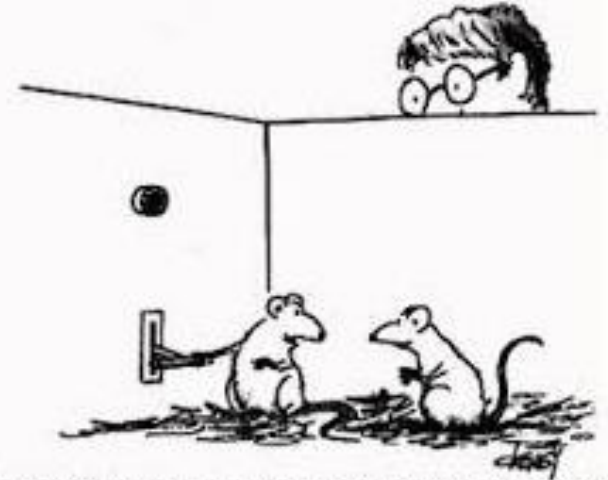
If you favor b) over c), what's the rationale?

Can research using animals be morally justified if c) is correct? How about b)?



Research ethics - Animals

- Most agree pain is contrary to the interest of any individual (human or animal) but that death is a harm only to humans.
- Are animals harmed by death (assuming it's instant, painless and unexpected)?
- If you think animals are not harmed by death as such, what is the ground for thinking humans are harmed by death?



It's a rather interesting phenomenon. Every time I press this lever, that post-graduate student breathes a sigh of relief.

To what extent does your field of work depend on the use of animals?

Can you envision work in your field without the use of animals?

Research ethics - Humans

The “Nuremberg Code” was established in 1948, stating that **"The voluntary consent of the human participant is absolutely essential"**.

The Nuremberg Code was the first international document which advocated voluntary participation and informed consent.

DECLARATION OF HELSINKI WMA 1964

Statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data:

- Research with humans should be based on the results from laboratory and animal experimentation
- Research protocols should be reviewed by an independent committee prior to initiation
- Informed consent from research participants is necessary
- Research should be conducted by medically/scientifically qualified individuals
- Risks should not exceed benefits

GCP guidelines; not legally binding.

Belmont Report's Three Ethical Concepts

Respect for persons, requiring researchers to obtain subjects' informed consent to study participation.

Justice, requiring equitable distribution of research burdens and benefits.

Beneficence, requiring that risks to human subjects be justified by the value of the knowledge the study is expected to generate.

Came in the setting of concerns raised over research participant abuse in the Tuskegee studies of syphilis.

What is the principle?

How is it applied?

Respect for Persons

- Individuals should be treated as autonomous agents
- Persons with diminished autonomy are entitled to protection.

Informed Consent

- Participants, to the degree that they are capable, must be given the opportunity to choose what shall or shall not happen to them
- The consent process must include three elements:
 - Information,
 - Comprehension, and
 - Voluntary participation

Beneficence

- Human participants should not be harmed
- Research should maximize possible benefits and minimize possible risks

Assessment of risks & benefits

- The nature and scope of risks and benefits must be assessed in a systematic manner

Justice

- The benefits and risks of research must be distributed fairly

Selection of participants

- There must be fair procedures and outcomes in the selection of research participants

Ethical Principles of Research

