

SASBT Abstract Writing Series

Ethics and Authorship

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Definition

Research Ethics refers to a diverse set of values, norms & institutional regulations that help constitute and regulate scientific activity



Some History ... Nuremberg Code

- A well-known chapter in the history of research with human subjects - The [Nuremberg trials](#): Prosecution of Nazi physicians from 1945 to 1946 for their unethical human experimentation during World War II
- Among the charges were that German physicians conducted medical experiments on thousands of concentration camp prisoners without their consent. Most of the subjects of these experiments died or were permanently crippled as a result.
- Initiated public discussion of research ethics involving human subjects.
- As a direct result of the trial, the Nuremberg Code was established in 1948, stating that “The voluntary consent of the human subject is absolutely essential,” making it clear that subjects should give consent and that the benefits of research must outweigh the risks.

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

The Nuremberg Code (1947)

Permissible Medical Experiments

The great weight of the evidence before us to effect that certain types of medical experiments on human beings, when kept within reasonably well-defined bounds, conform to the ethics of the medical profession generally. The protagonists of the practice of human experimentation justify their views on the basis that such experiments yield results for the good of society that are unprocurable by other methods or means of study. All agree, however, that certain basic principles must be observed in order to satisfy moral, ethical and legal concepts:

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, overreaching, 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 reasonably 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 justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
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.

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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.

Tuskegee Syphilis Study (1932-1972)

- Well-known chapter in history - research project conducted by the U.S. Public Health Service.
- 600 low-income African-American males, 400 of whom were infected with syphilis, **were monitored for 40 years**. Free medical examinations were given; however, subjects were not told about their disease.
- Even though a proven cure (penicillin) became available in the 1950s, the study continued until 1972 with participants being denied treatment. In some cases, when subjects were diagnosed as having syphilis by other physicians, researchers intervened to prevent treatment.
- Many subjects died of syphilis during the study. The study was stopped in 1973 by the U.S. Department of Health, Education, and Welfare only after its existence was publicized and it became a political embarrassment.

National Research Act (1974)

- Because of the publicity from the Tuskegee Syphilis Study, the National Research Act of 1974 was passed.
- The National Research Act created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.
- This commission was tasked with identifying the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects.
- It was also tasked with developing guidelines that should be followed to assure that such research is conducted in accordance with these ethical principles.



Research Ethics



Issues related to ethics in research

- ☐ Plagiarism
- ☐ Data
- ☐ Authorship and other publication issues
- ☐ Research with animals
- ☐ Research with human subjects
- ☐ Research conduct and misconduct
- ☐ Misuse of privileged information
- ☐ Conflict of interest (COI)
- ☐ Institutional review board (IRB) approval

Got Ethics?



Research Ethics



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Publication Ethics Checklist

Approval and Consent

- Do you have approval of the relevant Regulatory Authorities, Institutional Review Board and Ethics Committee?
- Have you registered your clinical trial?
- Have you documented Informed Consent?

Data Accuracy Falsification Fabrication

- Is there manipulation of material, equipment, process or data?
- Have you double-checked data for accuracy?

Is there any lurking fake data?

Plagiarism and Self-Plagiarism

- Have you used your own prior work or copied others' work?
- If so, have you cited these correctly?
- Do you have written permission for reproduced material, figures or tables?

Submission Fraud

Is there simultaneous submission to two journals?

Have you published the entire work or part of it (salami-slicing) already?

Have you excessively cited your own publications?

Ethics of Authorship

- Have you included all the authors in a specific pre-agreed order?
- Do you have an agreement with co-authors?
- Are the co-authors aware of the contents of the publication?
- Have they had access to, and hold themselves responsible for the data and its interpretation?
- Is there any Ghost Author or a "Guest Author"?

Conflict of Interest

Have you declared relevant interests and relationships that could be seen as influencing your findings (whether financial or scientific)?



Let's hear some of your questions...

Authorship

The currency of research...

- Most important for academic career
- Not only number of articles but also quality of work and author position in articles

But, a source of hurt feelings

- Recognition of collaborators



Authorship

Potential problems

- Omission of those who merit authorship (or should have been offered the opportunity)
- Inclusion of those who do not merit authorship
- Order of authorship

Authorship Order

First Author: Took the lead in the data analysis plan and writing of the paper

Second Author: Contributed less than the first author, but more than all other authors, with the possible exception of the senior author

Senior Author: Someone who has provided significant scientific guidance to the study and to the paper

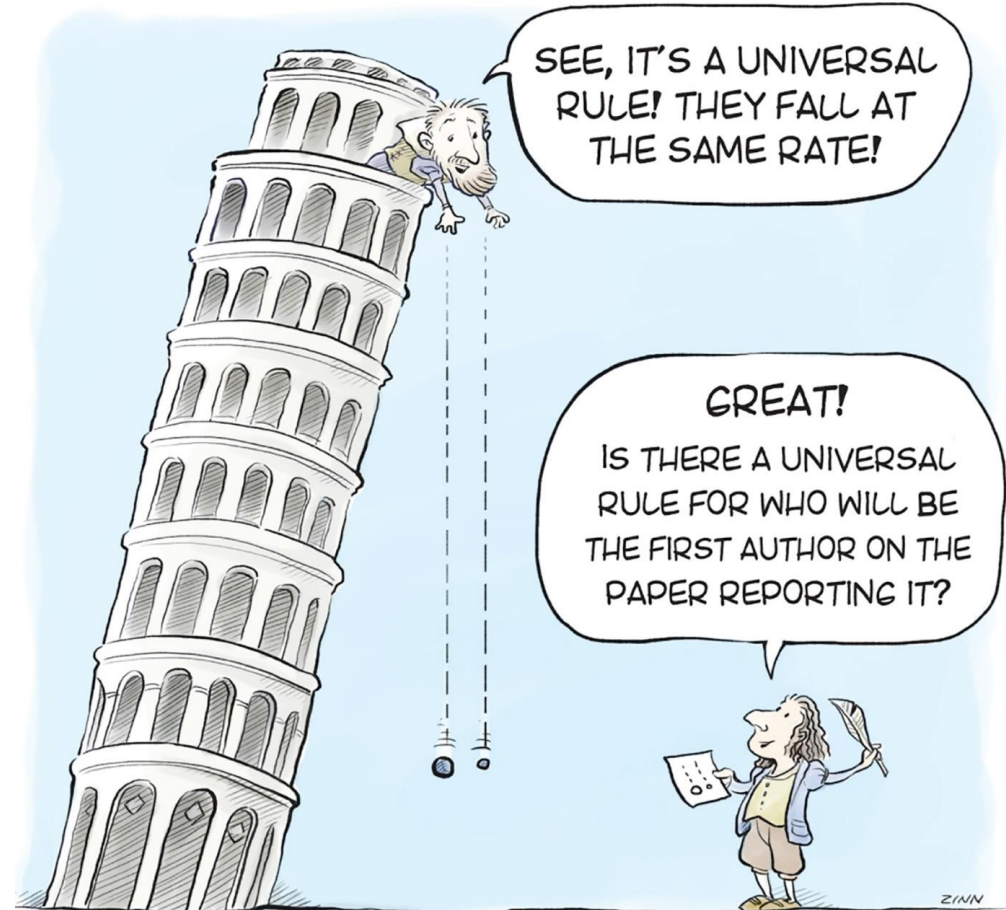
After Second Author and before Senior Author: Listed in the order of the amount of contribution on the paper

Corresponding author: Can be anyone but responsible to responding to editors comments

Huge Importance

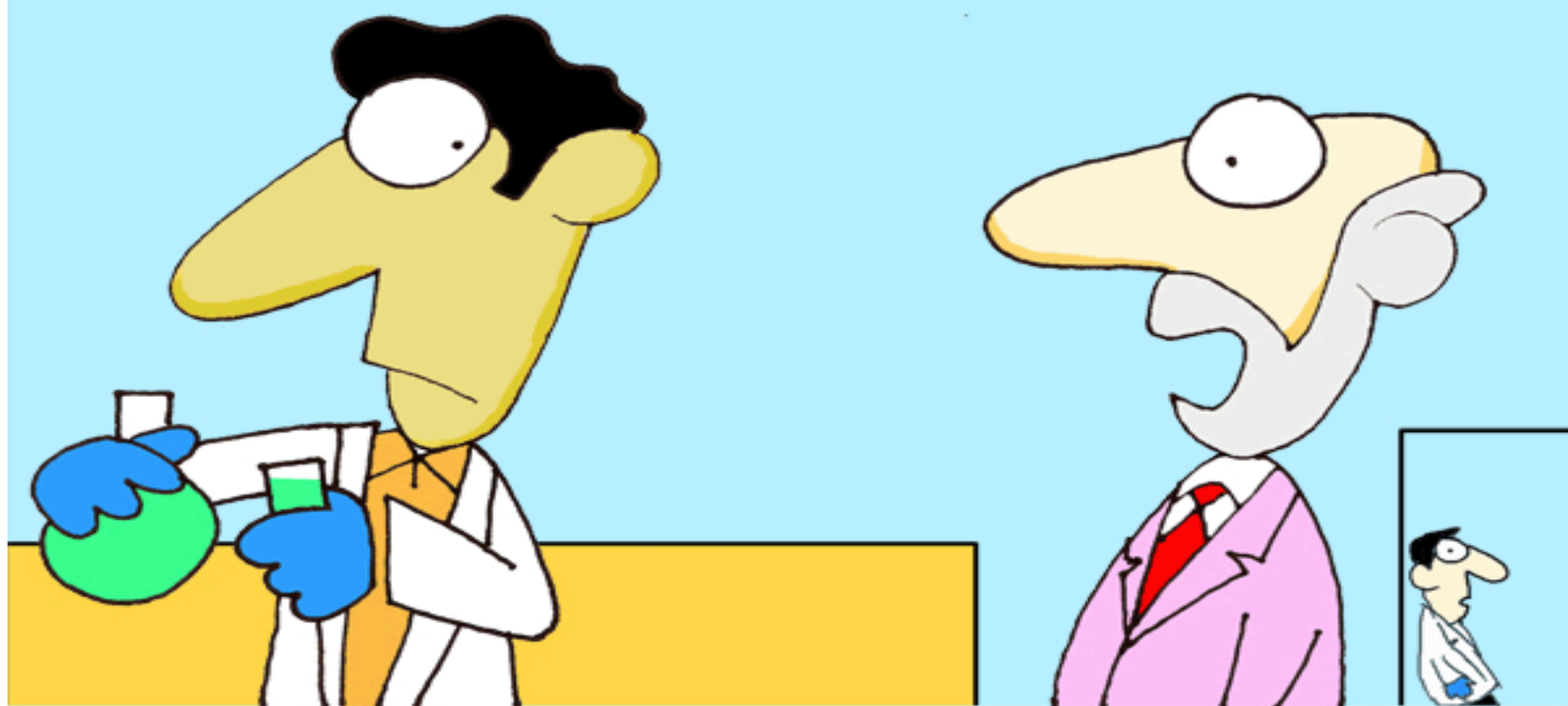
Clarify authorship as early as possible

- Discuss authorship early in the design of the study
- Agree from start who first and last (senior) author will be
- In the absence of organizational guidelines - Establish principles for authorship (Review from time to time)
- Have clear expectations
- Give everyone a chance to say what they commit to



Guest Authorship

- Someone named as an author but did not contribute in a meaningful way to the design, research, analysis or writing of paper
- Several varieties
 - Often well known and respected leaders in the field who are paid for use of their name
 - Gift authorship accepted to boost CV, AS REPAYMENT FOR FAVORS
 - Sometimes scientists agree to trade authorships by each placing their name on the others papers so each appear more productive
 - Some department supervisors, heads, managers are named as authors simply by virtue of seniority or departmental tradition



“No, it’s my wife’s turn to be the first author
on **your** paper.”

What is a Ghost Author

- a. A person who had the idea for the research, but contributed a little more
- b. A person who has made substantial contribution to the research, but passed away before the article / abstract was submitted for publication
- c. A person who has made a very small contribution to the research and is named as an author
- d. A person who has made substantial contribution to the research but is not named as an author**

GHOST AUTHORSHIP:
BE AFRAID...
BE VERY AFRAID

**WARNING
THIS COULD HOBBLE
YOUR CAREER**



Authorship

- Journals are cracking down
 - Frowning on non-contributors
 - Frowning on “ghost authors”
 - Frowning on “gift authorship”
- Usually up to 6 authors acceptable
 - Some require written statement for more than 6 authors

Criteria for authorship

- International Committee of Medical Journal Editors (ICMJE)
 - Established in 1978 in Vancouver
 - Established common criteria for publication of scientific articles in health sciences
 - Established clear criteria for authorship in 1988

<http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>

ICMJE: Criteria

- **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

Authorship criteria (CDC)

- Authorship credit should be based on three conditions, **all of which** must be met:
 - (i) **Substantial contributions** to conception and design, or acquisition of data, or analysis and interpretation of data;
 - (ii) **Drafting** the information product or **revising** it critically for important intellectual content; and
 - (iii) **Final approval** of the version to be published.
- Acquisition of funding, general supervision of researchers/authors, or review and approval of an information product, by themselves, **do not** justify authorship.

Written justification of authorship

Example

Factors Associated with HIV infection in Married or Cohabiting Couples in Kenya: Results from a Nationally Representative Study. Kaiser R, Bunnell R, Hightower A, Kim AA, Cherutich P, Mwangi M, Oluoch T, Dadabhai S, Mureithi P, Mugo N, Mermin J for the KAIS Study Group

Author contributions

Conceived and designed the experiments: RK RB AH AAK MM TO SD PM PC NM JM.

Performed the experiments: RK RB AAK PC MM TO SD PM JM.

Analyzed the data: AH.

Contributed reagents/materials/analysis tools: RK RB AH AAK.

Wrote the paper: RK RB AH JM

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Few Rules

- Co-authors must know that they are co-authors and formally agree to it!
- Co-authors must (should) formally approve the final paper before it is submitted.
- This applies to abstracts as well.
- Supervisors on dissertations and thesis should always be considered for co-authorship

Authorship and ethics in publishing scientific work

1. Who is an author and who merely gets thanked?
2. What determines the order of authorship?
3. What if different people contribute in different ways, not just more or less?
4. How do we include the supervisor who may have played a different role entirely?
5. Can supervisors bully students and other “less powerful” people into including them as authors when they do not deserve it?



References

- <https://www.unlv.edu/research/ORI-HSR/history-ethics>.
- <http://www.cirp.org/library/ethics/nuremberg/>