

Research and Authorship Responsibilities

By

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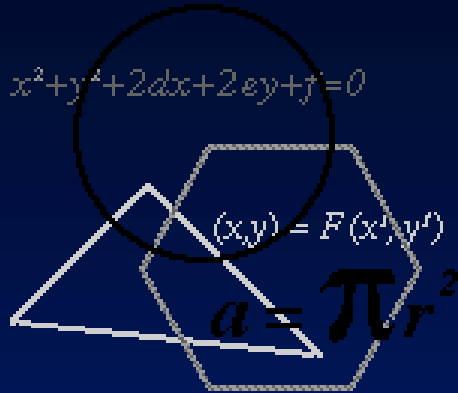
Chair, Medical Ethics Committee, UMMC



The research-publication enterprise is ultimately based on trust

- ❑ Society trusts that scientific research and publications are truthful and without bias
- ❑ A breach of that trust has far-reaching negative impact on the scientific community
- ❑ Inculcation of responsible and ethical conduct among young researchers and authors should be a key concern for academic mentors and editors





Biomedical Research and Ethics

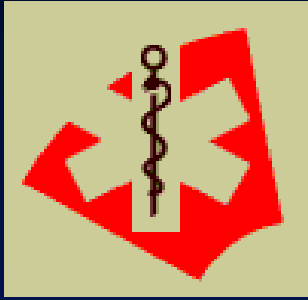
- ❑ Historically scientific/ biomedical researchers have enjoyed immunity from accountability
 - ◆ High public regard for Science & Medicine
- ❑ Blemished image of biomedical research
 - ◆ Biological research on vulnerable subjects in WW II
 - ◆ WMA Declaration of Helsinki (1964)
- ❑ Accountability is now a necessary facet of developed Society



Accountability in Research by Peer/Public Review

- ❑ Clinical Practice – Code of Professional Conduct
- ❑ Biomedical Research
 - ◆ Ethics Committee/IRB Approval
 - ◆ Animal Care Committee
- ❑ Journal requirements
 - ◆ Editorial policies





Declaration of Helsinki

- ❑ Most widely accepted guideline on medical research involving human subjects
- ❑ Developed by World Medical Association in June 1964
 - ◆ 1964 (Helsinki): Preventive measures in reaction to WW II biomedical research atrocities
 - ◆ 1975 (Tokyo): Statement of ethical principles to guide medical doctors engaged in clinical research
 - ◆ Revisions: Adaptations to expanded scope of biomedical research. 1983 (Venice); 1989 (Hong Kong); 1996 (Somerset West, South Africa); 2000 (Edinburgh); 2008 (Seoul, Korea).



ICH Harmonised Tripartite Guidelines for Good Clinical Practice

❑ Based on Declaration of Helsinki

◆ Respect for the dignity of the person

- Right to information
- Informed consent
- Right to refuse or withdraw from study

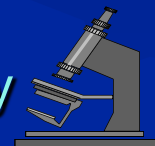


◆ Research should not over-ride the health, well-being and care of subjects

- Benefits should outweigh risks

◆ Principle of justice

- Benefits & burdens of research be distributed fairly among subjects



RESEARCH MISCONDUCT

❑ Fabrication

- ◆ Making up of data or results

❑ Falsification

- ◆ Manipulating research materials, equipment or processes
- ◆ Changing or omitting data or results (or images) so that research findings are not true

❑ Plagiarism



Advantage of authorship

- ❑ Academic advancement
- ❑ Social prestige
- ❑ Financial advantage



What are the common problems related to authorship?

Authorship criteria

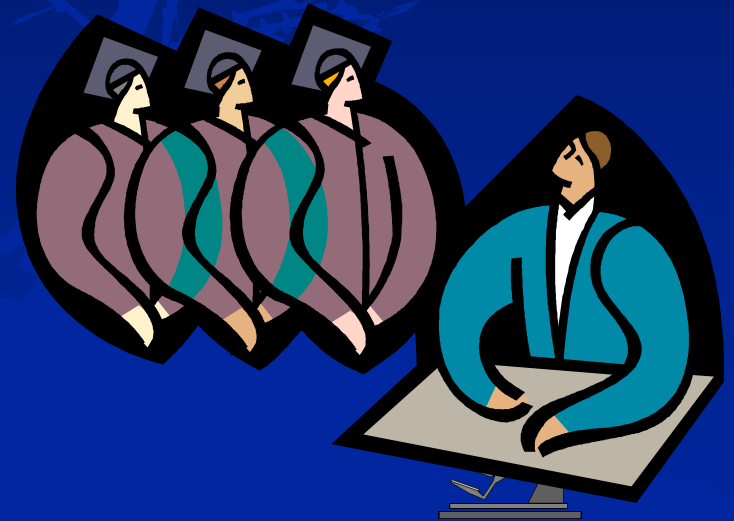
Authorship responsibilities



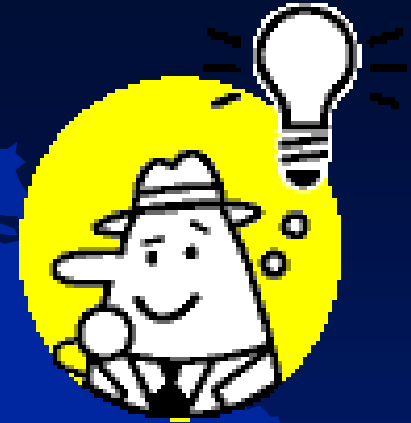
AUTHORSHIP

COMMON UNETHICAL PRACTICES

- ❑ Unjustified authorship
- ❑ Political authors
- ❑ Exclusion of valid co-worker



Criteria for authorship



- ❑ Made substantial contributions to the intellectual content
 - ◆ Concept and design
 - ◆ Acquisition of data
 - ◆ Analysis and interpretation of data



Criteria for authorship

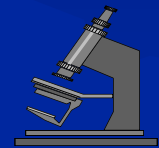


- Certify that manuscript represents valid work
 - ◆ Vouch for validity of data
 - ◆ Take public responsibility for the work



Criteria for authorship

- Approve submitted manuscript
- ◆ Involved in drafting or revising the manuscript



Multiple authors

- ❑ Authors should be those who accept direct responsibility for the manuscript
- ❑ Editors may ask for disclosure of roles
- ❑ Order of authorship should be joint decision of co-authors
- ❑ Increasingly, authorship of multi-centre trials attributed to group
 - ◆ All members of group listed as authors should fulfill criteria for authorship
 - ◆ Others listed in acknowledgements
 - ◆ Group name identified and indexed

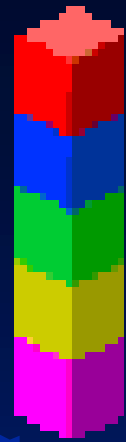


Ethical Responsibilities of Authors

- ❑ Submitted work based on scientifically sound, ethically conducted research
 - ◆ ICH-GCP guidelines
 - ◆ Declaration of Helsinki
 - ◆ Ethics committee (IRB) approval
 - ◆ Animal care committee approval
- ❑ Manuscript accurately reflect design and conduct of study
- ❑ Privacy and confidentiality of research subjects
- ❑ Rightful acknowledgements made
- ❑ Declare all potential conflicts of interest



OVERLAPPING PUBLICATIONS



❑ Duplicate submission

- ◆ Simultaneous submission of manuscript to two or more journals

❑ Redundant publication

- ◆ Submission that overlaps substantially with already published work
- ◆ Salami publication
- ❑ Does not apply to oral & poster presentations at conferences
- ❑ Does not apply to secondary publication in different language with permission of Editors











