

# Common Ethical Issues in Medical Research and Publication

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### **Historical background**

Research changes the world, and it changes itself throughout the years. New things, including ethics of research, its implementation process always copes with the changing human behavior.

In the early 1960s, most notably in the United States, instances of unethical medical research was reported over the volunteers, especially those who were vulnerable or terminally sick, were treated with obvious disrespect and exposed to significant risks of harm. Among these were the infamous project conducted at the Brooklyn Jewish Chronic Disease Hospital. Here elderly patients with some disability, live cancer cells were injected which was considered as offensive! It was unclear that required informed consent of patients was sought or not! A study of infectious hepatitis C at the Willowbrook home for children with mental retardation, who were deliberately infected with hepatitis C, not only raised serious concerns in public, but also jeopardized the reputation of noble medical profession. In 1966, Henry Beecher's article, 'Ethics and Clinical Research,' in the New England Journal of Medicine reported 22 examples of medical research that did not follow the standard of ethics in treating the patients. Another incident happened in USA with nearly 40 years (1932-1972) duration; the U.S. National Health Service conducted a research titled the 'Tuskegee Study of Untreated Syphilis in the Negro Male.' About 600 black men were studied for syphilis. Among them, 399 had syphilis. The participants were never informed that they were involved in a research, and no informed consent was taken from them. Such unethical incidents necessitated the dire need of informed consent from participants. It was researchers' responsibility to be satisfied that the adequate information was supplied to the volunteers of research to meet all criteria of performing a research project.

The passion for success can also result in the coercion of human subjects to participate in the research. Another important aspect is misrepresentation or incomplete information of the medical facts to the patients in getting their consent signed for their participation in the research. In World War II, Nazi physicians performed medical experiments of injections of live viruses on prisoners, forceful immersion of people in ice water and compelling prisoners to ingest poison. In 1946, the War Crimes Tribunal at Nuremberg probed this and pronounced punishment against 16 of such physicians/administrators, including death sentence to seven of them. There are a number of international ethical codes that act as guiding factors for facilitating an ethical research. The World War-II Nazi episode of prisoners led to emergence of the first international code of research ethics named as Nuremberg Code. This code has acted as a basis for all the subsequent codes of ethics that emerged later on. Under this code, a set of 10 directives were issued in order to satisfy moral, ethical and legal concepts in the conduct of human subject research.

### **Introduction**

Research is the basement of knowledge which makes the building block of human civilization, and this is an integral part of progress. In the fast-expanding field of biomedical research, this has improved the quality and quantity of life. Historically, medical doctors are the privileged part of society who have an easy access to get the confidential and personal information regarding their health, diseases, and disabilities and they can use the information to carry out the research. Moreover, medical researchers have also enjoyed immunity from accountability due to high public involvement for science and medicine. This has resulted in some researchers conducting unethical researches. For instance, in World War II, medical doctors had conducted unethical experiments on human in the name of science,

resulting in harm and even death in some cases.<sup>1</sup> More recently, the involvement of pharmaceutical industry in clinical trials have raised issues about how to safeguard patient's care and to ensure the published research findings are objective.

In the light of these ethical controversies, the **Declaration of Helsinki** was established to inform formal statement of ethical principles published by the World Medical Association (WMA) to guide the protection of human participants in medical research. The Declaration of Helsinki was adopted in 1964 by the 18th WMA General Assembly, at Helsinki. Although not without its controversies, it has served as the standard in medical research ethics.

Though this is not legally binding documents, it may govern the biomedical research and has established the research work not to harm the human mentally and physically it has many versions that changes, modifies or improves the terms and principles of ethical research. As the declaration was expanded and made more prescriptive, it became more controversial, which caused some organizations to alter some of its standards or abandon it entirely. Committee on Publication Ethics (COPE) was also founded in 1997 to address the breaches of research and publication ethics.

### **Ethical issues in research**

Ethical issues matters in following fields of research:

- Study design and ethical approval
- Data analysis
- Authorship
- Conflict of interest
- Redundant publication and plagiarism
- Social and clinical value
- Scientific validity
- Fair subject selection

### **1. Study design and ethics approval**

According to COPE, "good research should be well adjusted, well-planned, appropriately designed, and ethically approved. To conduct research to a lower standard may constitute misconduct." This is an important criterion, but it means that a researcher has big responsibly to ensure quality of research. To achieve this, a research protocol should be developed carefully, and agreed to by all contributors and collaborators, and the precise roles of each team

member should be defined in initial period, including matters of authorship and publications. Research should seek to answer specific questions, rather than just collect data.

It is essential to obtain approval from the Institutional Review Board, or Ethics Committee, of the respective organizations for studies involving people, medical records, and anonymised human tissues. The research proposal should discuss potential ethical issues pertaining to the research. The researchers should pay special attention to vulnerable subjects to avoid breach of ethical codes (e.g. children, prisoners, pregnant women, mentally challenged, educationally and economically disadvantaged). Patient information sheet should be given to the subjects during recruitment, detailing the objectives, procedures, potential benefits and harms, as well as rights to refuse participation in the research. Consent should be explained and obtained from the subjects or guardians, and steps should be taken to ensure confidentiality of information provided by the subjects.

### **2. Data analysis**

It is the responsibility of the researcher to analyze the data appropriately. Data should be collected with informed consent and protecting the volunteers. Intentional omission of result may cause misinterpretation and mislead the readers. Fabrication and falsification of data do constitute misconduct. For example, in a clinical trial, if a drug is found to be ineffective, this study should be reported. Sometimes researchers hide the negative report and this leads the research to fabricated result or hypothesis. This happens partly by pressure from the pharmaceutical industry which funds the clinical trial. To ensure appropriate data analysis, all sources and methods used to obtain and analyze data should be fully disclosed. The discussion section of a paper should mention any issues of bias, and explain how they have been dealt with in the design and interpretation of the study.

### **3. Authorship**

There is no universally agreed definition of authorship. It is generally agreed that an author should have made substantial contribution to the intellectual content, including conceptualising and designing the study; acquiring, analyzing and interpreting the data. The author should also take

responsibility to certify that the manuscript represents valid work and take public responsibility for the work. Finally, an author is usually involved in drafting or revising the manuscript, as well as approving the submitted manuscript.

The ICMJE recommends that authorship be based on the following 4 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 reviewing 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.

Contributors who meet fewer than all 4 of the above criteria for authorship should not be listed as authors, but they should be acknowledged. Examples of activities that alone (without other contributions) do not qualify a contributor for authorship is acquisition of funding; general supervision of a research group or general administrative support; and writing assistance, technical editing, language editing, and proofreading. Those whose contributions do not justify authorship may be acknowledged individually or together as a group under a single heading (e.g. "Clinical Investigators" or "Participating Investigators"), and their contributions should be specified (e.g., "served as scientific advisors," "critically reviewed the study proposal," "collected data," "provided and cared for study patients," "participated in writing or technical editing of the manuscript").

#### 4. Conflicts of interest

Actually this is the conflict between science and the researcher. The researcher or the issues they published is not for public interest but he or a specific company or business firm or a group of people become benefitted by this type of research. These conflicts also include political, academic or financial interest. Financial interests may include employment, research funding, stock or share ownership, payment for lecture or travel, consultancies and company support for staff. This issue is especially pertinent in biomedical research where a substantial number of clinical trials are funded by pharmaceutical company.

Such interests, where relevant, should be discussed in the early stage of research. The researchers need to take extra effort to ensure that their conflicts of interest do not influence the methodology and outcome of the

research. It would be useful to consult an independent researcher, or Ethics Committee, on this issue if in doubt. When publishing, these conflicts of interest should be declared to editors, and readers will judge for themselves whether the research findings are trustworthy.

#### 5. Redundant publication and plagiarism

Redundant publication occurs when two or more papers, without full cross reference, share the same data, discussion points, or conclusions. However, previous publication of an abstract during the proceedings of meetings does not preclude subsequent submission for publication, but full disclosure should be made at the time of submission. This scenario of a research paper is called 'Self-plagiarism'. Actually the fact is hidden that the study was previously done and new one is copy only. Now a day, publication is important criteria for promotion and grant or funding for work. So researchers are under intense pressure to publish their work, which leads them to do such unethical activities; same paper is constructed in different language with new authorship!!

Therefore, it is important to disclose all sources of information, and if large amount of other people's written or illustrative materials is to be used, permission must be sought.

#### Conclusion

It is the duty of the researcher to ensure that research is conducted in an ethical and responsible manner from planning to publication. Researchers and authors should familiarize themselves with these principles and follow them strictly. Any potential ethical issues in research and publication should be discussed openly within the research team. If in doubt, it is advisable to consult the respective institutional review board (IRB) for their expert opinions.

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