

ETHICS IN MEDICAL RESEARCH

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Medical ethics is a system of moral principles that apply values and judgments to the practice of medicine. Medical ethics has a long history from Hippocrates to the present. Many experiments were conducted in the 19th and 20th centuries on patients without their consent and with out concern for the patients'well-being and clearly violated fundamental human rights. "Beginning in the 1930s, 399 men signed up with the U.S. Public Health Service for free medical care. The service was conducting a study on the effects of syphilis on the human body. The men were never told they had syphilis. They were told they had "bad blood" and were denied access to treatment, even for years after penicillin came into use in 1947. By the time the study was exposed in 1972, 28 men had died of syphilis, 100 others were dead of related complications, at least 40 wives had been infected and 19 children had contracted the disease at birth." [Tuskegee Study].

During the Nuremberg War Crimes Trials, 23 German doctors were charged with crimes against humanity for "performing medical experiments upon concentration camp inmates and other living human subjects, without their consent, in the course of which experiments the defendants committed the murders, brutalities, cruelties, tortures, atrocities, and other inhuman acts."

Following World War Two, some of these physicians were tried and convicted by a special tribunal at Nuremberg in 1947, Germany. The basis of the judgment is known as the Nuremberg Code, which has served as one of the foundational documents of modern research ethics. There are ten principles of this Code and one of them is the requirement of voluntary consent of participant. The World Medical Association(WMA) was also established in the same year.

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To bound physicians in ethical obligations WMA adopted a set of Principles for Those in Research and Experimentation in 1954. This document was revised over the next ten years and eventually was adopted as the Declaration of Helsinki (DoH) in 1964. It was further revised in 1975, 1983, 1989, 1996, 2000 and 2008. The DoH is a concise summary of research ethics.later on many other detailed document on research ethics have been produced. The American Sociological Association (ASA) adopted a formal code of ethics in 1969.The National Research Act (1974) was Passed by Congress for the purpose of protecting human subjects participating in experiments.

Ethical factors :The responsibility for ethical research ultimately lies with the individual researcher. Ethical Factors are : i) No Pressure (Never any pressuring of participants). ii) Safety (Safety of participants essential. iii) Credit (Every researcher must receive precise, appropriate credit). iv) Communication (One should try to make results known to participants). v) Ill Usage of Research (One should be conscious of possible bad uses of research.)

Informed Consent : The first principle of the Nuremberg Code reads as follows: "The voluntary consent of the human subject is absolutely essential." The researcher has to explain the study and offer to answer questions.Participation is always voluntary.The researcher has to provide participants with copy of informed consent form (if relevant). He should maintain Confidentiality (Anonymity) tell participants who is conducting study, Why was subject singled out for participation? Any benefits for the participant to be expected? Any potential risks, and how have these been managed?

Special Populations & Coercion:

Children and mentally retarded lack necessary competence to resist coercion. Others may be Indirectly Coerced are Students,Prison Inmates, Employees, Military Personnel,The Homeless and Welfare Recipients

Institutional Review Board (IRB):

Paragraph 15 of the DoH stipulates that every proposal for medical research on human subjects must be reviewed and approved by an independent ethics committee before it can proceed. Most Colleges/universities have IRBs Chittagong Medical College has an Ethical Review Committee. Bangladesh Medical Research Council has an Ethical Committee.

Questions Asked by IRBs:***About the Investigator***

- Who is the primary investigator, and who is supervising the study?
- About Research Participants
- What are general characteristics of participants (e.g. age, sex etc.)?
- Any special characteristics of participants (e.g. children, alcoholics, mentally retarded etc.)?
- Any other institutions/individuals cooperating/cosponsoring the study?
- What is general state of health (mental and physical) of the participants?
- How will subjects be selected for, or excluded from, participation in this study?

About the Procedure

- What will the subjects be asked to do, or what behaviors will be observed by the researchers?
- Will deception be used? If yes, why is it necessary?
- What is nature of the deception, and when will the debriefing take place?

About the Material

- How has it been checked for safety?

About Risks

- Any immediate risks to the subjects, including possibly causing them embarrassment, inconvenience, or discomfort?
- Are there any long-range risks to the subjects?
- If there are risks, what is the necessity for them, and how will subjects be compensated for facing such risks?

IRBs are very Concerned about Possible Psychological Harm:

- Eg : a project involving interviewing of women who've been raped.

- Obviously consent must be obtained.
- They're free to withdraw at any time.
- Perhaps have psychological counseling available in case of distress.

Other Ethical Issues

- One should not cheat, falsify data etc.
- One should not plagiarize.

Plagiarism

- Plagiarism is taking another's work and passing it off as your own.
- In a broad sense we are all guilty of plagiarism many times each day.
- We often take ideas from others and don't attribute them to their original source.
- More often than not we don't even know the original source!
- When we talk about the decline and fall of the Roman Empire or say, "To be or not to be, that is the question" in normal conversation, we rarely attribute the words to Gibbon and Shakespeare respectively.

Plagiarism in Research is Usually Quite Different:

- True plagiarism is, quite bluntly, stealing.
- Sometimes a person just copies text word for word from a book or article and pretends that he is the author.
- Or buys an already written paper on the web.
- These are quite deliberate aims to deceive.

How to avoid plagiarism?

One should always provide references for any statistic, graphs, tables and numbers, etc. It's often preferable to take down the substance of an author's idea in your own words, i.e. to paraphrase. The greater part of your paper should be in your own words with appropriate documentation of the ideas of others.

Nowadays, conflicts of interests between the government and medical institutions, between medical institutions and medical personnel, between physicians and patients are getting more and more serious and complex. High technologies not only brought us hopes of cure but have also created a heavy economic burden. The ethical dilemmas of high technology, medicine, brain death, organ transplantation, and concerns about quality of life have become increasingly prominent. A new and more specific code of ethics must be developed to meet the demands of social development and medical service. This new code should integrate the traditional medical ethics with modern principles and values.