

Editorial

Enhancing Ethical Research

Bindu Sharma¹

¹ Central Council for Research in Homoeopathy Ministry of AYUSH, New Delhi, India

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“Many people say that it is the intellect which makes a great scientist. They are wrong. It is character.”Albert Einstein

New medicines, biomedical procedures and ways of altering plants and animals are bringing benefits to millions of people. However, these same innovations also have the potential to bring harms or to raise other kinds of ethical questions about their appropriate use. Human life, dignity of the frail and elderly, bodily integrity and ability to make reasonable decisions, rights to life and health are the fundamental values that are at stake. The study of the *ethical issues* emerging from advances in *biology and medicine is called bioethics*. The word is made up of two parts: ‘bio’ (from the Greek word for ‘life’) and ‘ethics’, so it is the study of ethics as it relates to living things.¹

It looks at ‘what should be done’ when dealing with or taking care of people who cannot speak up for themselves (the severely mentally ill, small children, prisoners) and other living creatures. Bioethics is also concerned with questions about basic human values such as the rights to life and health, and the rightness or wrongness of certain developments in health care institutions, life technology, medicine, the health professions and about society’s responsibility for the life and health of its members.¹ Bioethicists are concerned with the ethical questions that arise in relationships among life sciences, biotechnology, medicine, politics, law and philosophy.²

Quick Facts

Research that involves human subjects raises unique and complex ethical, legal, social and political issues.³ There are three objectives in research ethics:

- To protect human participants
- To conduct research such that it serves the interests of individuals, groups and society
- To examine the research activities for their ethical soundness such as management of risk, confidentiality and informed consent

Bioethics is becoming commonplace among medical schools; since 1990 there has been a 182% increase in bioethics training programmes (2001 statistics; ASBH).¹

Address for correspondence
Bindu Sharma, MD, RZ 101/10B,
Lane No. 5, Mohan Nagar, Pankha
Road, New Delhi 110046, India
(e-mail: drbinduhomoeo@gmail.com).

Why It Is Important to Adhere to Ethical Norms in Research?

Researchers, members of ethics committees and students need to be sensitised about research ethics, essentially in the context of public health research and implementation trials as there may be challenging situations. Research norms

- Promote the aims of research such as knowledge, truth, avoidance of error, prohibition against falsifying.
- Promote the values that are essential for collaborative work such as trust, accountability, mutual respect and fairness.
- Help to ensure that researchers can be held accountable to public.
- Help build public support for research.
- Promote a variety of moral and social values such as social responsibility human rights, animal welfare, compliance with law and public health and safely.⁴

History of Bioethics at a Glance⁵

Some of the most harrowing examples of abuse of human being that continue to drive ethical debate as to how and why these actually happened. In the aftermath of World War II, 23 Nazi physicians and bureaucrats were tried by an American military tribunal for using thousands of concentration camp prisoners as subjects for conducting brutal experiments. What was shocking was that during that period the experiments were performed by reputed investigators, at leading institutions and published in reputable medical journals. Result of the trial was Nuremberg Code in 1948 which was recognised as a landmark document. In 1966, Henry Beecher, Professor of Anaesthesiology, published the landmark article ‘Ethics in Clinical Research’ in *New England Journal of Medicine*. He described 22 studies which violated the basic standards of ethical research involving human beings with an aim to draw attention to the serious ethical problems in the conduct of such research. By the late 1960s medical research involving humans had undergone so many scandals and tragedies that distinguished physicians found it necessary to defend it mainly by invoking utilitarian grounds. In

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the early 1970s, the wholesale violation of human rights in the Tuskegee Syphilis study (1932–1972) was revealed. The study was initiated in Alabama in which more than 400 men, mostly illiterate, were recruited. It was a historical infamy in which 28 men died of syphilis, 100 died of related complications, wives of 40 men were infected and 19 children were born with congenital syphilis. Penicillin was available since 1947, but it was not given to research subjects. The study sparked off a wide-scale public outrage when it became publicly known, and the U.S. government had to close it in 1972. On May 16, 1997, U.S. President Bill Clinton apologised to African American citizens for conducting such a clearly racist study; five of the eight study survivors attended the meeting.

Principles of Bioethics

Early founders of bioethics put forth four principles which form the framework for moral reasoning. These ‘four principles’ have been one of the most widely discussed issues in biomedical ethics with arguments for and against them.

- **Nonmaleficence:** The health care professional should not harm the patient in any way (physical, psychological, social, cultural and financial). All treatment involves some harm, even if minimal, but the harm should not be disproportionate to the benefits of treatment.
- **Justice:** Benefits and risks should be fairly distributed. For each participant, a balance of burdens and benefits should be sought.
- **Beneficence:** The health care professional should act in a way that benefits the patient. Maximise possible benefits and minimise possible harms.
- **Autonomy:** One should recognise the right of individuals to make their own decisions by respecting decision-making capacities of participants—enabling individuals to make reasoned informed choices. Safeguarding the welfare of people with diminished autonomy, their rights, beliefs and customs must be ensured.

Scope of Bioethics

Bioethics is an activity; it is a shared, reflective examination of ethical issues in health care, health science and health policy. It takes place in the media, academy, classrooms, as well as in laboratories, offices and hospital wards.⁶ It involves not just physicians but patients, not just scientists and politicians but the general public.

About 40 years ago, however, it became obvious that we needed a more public, and more critical, debate on ethical standards. Traditional ethical standards have been articulated, reflected on, challenged, and sometimes revised; standards for new issues have been created—then challenged and revised.

New Beginnings

Bioethics also raises new questions about old issues, like the use of placebos and the treatment of pain. Placebo controls become ethically controversial when researchers wish to

introduce new treatment in comparison to no treatment/placebo when there is already a possible successor or competitor to drugs whose use is currently a standard practice.⁷ More controversial still is the use of placebo in surgical trials.

However, a placebo may be used when there is no established effective therapy available. Or withholding an established effective therapy would not expose participants to serious harm but may cause temporary discomfort or delay in relief of symptoms. Or the disease is self-limited. Or the use of an established effective therapy as a comparator would not yield scientifically reliable results and the use of placebo would not add any additional risk of serious or irreversible harm to participants.

In case of a placebo-controlled study, participants must be made to understand that they may be randomised to a placebo group and therefore receive an inert drug, and the protocol must have added safeguards to protect participants from harm such as clear-cut withdrawal criteria, intensive monitoring and rescue medications.

Regulations for Ethical Research

Human research involves significant risks, and it is possible for things to go wrong. Despite the best of intentions and care in planning and practice, sometimes things go awry. Now and then mishaps may arise because of technical errors or an ethical insensitivity, neglect or disregard.⁸

The Nuremberg Code

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 the research must outweigh the risks.

The Declaration of Helsinki

In 1964, the World Medical Association established recommendations guiding medical doctors in biomedical research involving human subjects. The Declaration governs international research ethics and defines rules for ‘research combined with clinical care’ and ‘nontherapeutic research’. The Declaration of Helsinki was revised in 1975, 1983, 1989, 1996, 2000, 2002, 2004 and 2008, and is the basis for good clinical practices used today.

The Belmont Report

The Belmont Report was published in 1979, with attempts to summarise the basic ethical principles identified by the commission in the course of its deliberations. The report is a statement of the basic ethical principles and guidelines that should assist in resolving the ethical problems that surround the conduct of research with human subjects. The three basic ethical principles and their corresponding applications according to the report are: Beneficence, Respect for rights, and Justice.

International Ethical Guidelines for Biomedical Research Involving Human Subjects

The Council for International Organizations of Medical Sciences (CIOMS) published *International Ethical Guidelines for Biomedical Research Involving Human Subjects* in 1982.⁹ These were revised in 1993 and 2002 reflecting the changes, the advances and the controversies that have characterised biomedical research ethics in the past two decades. The guidelines relate mainly to ethical justification and scientific validity of research; ethical review; informed consent; vulnerability of individuals, groups, communities and populations; women as research subjects; equity regarding burdens and benefits; choice of control in clinical trials; confidentiality; compensation for injury; strengthening of national or local capacity for ethical review; and obligations of sponsors to provide health care services.

They are designed to be of use to countries in defining national policies on the ethics of biomedical research involving human subjects, applying ethical standards in local circumstances and establishing or improving ethical review mechanisms. Its core consists of 21 guidelines with commentaries. A prefatory section outlines the historical background and the revision process, and includes an introduction, an account of earlier instruments and guidelines, a statement of ethical principles and a preamble. An appendix lists the items to be included in the research protocol to be submitted for scientific and ethical review and clearance. Appendices also include the World Medical Association's Declaration of Helsinki.⁹

Situation in India

As in the case of many other nations, India too has developed national guidelines for research involving human subjects. In our country the guidelines, which are often cited and followed, are those issued by the Indian Council of Medical Research, New Delhi. The Indian Council of Medical Research brought out the 'Policy Statement on Ethical Considerations Involved in Research on Human Subjects', in 1980, and revised these guidelines in 2000, as the 'Ethical Guidelines for Biomedical Research on Human Subjects'. Since then it has been revised and the latest version has been published in 2006.

Conflict of Interest

None.

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