Bismillahir Rahmanir Rahim

Dr. Md. Aminul Haque Khan

MBBS, MCPS, FCGP

FCPS, MD [BSMMU]

Professor & Head

Department of Biochemistry

Enam Medical College,Savar,Dhaka

Dr. Rukhsana Parvin

Associate Professor

Department of Medicine

Enam Medical College, Savar, Dhaka

Medical Journals
and
Ethics of Research


Right
Wrong
Ethics

The purpose of research is to advance human knowledge and research has mainly been diverted to experiments, including both human and the nonhuman biological experimentations. The process of research and innovation involving human beings and animals requires certain medical ethics.

Ethics may simply be defined as certain norms for conduct that distinguish between acceptable and unacceptable behavior. Most people learn ethical norms at home, in religious settings such as mosque, church, at school, or in other social settings. The ethical norms develop throughout life.

Ethical norms govern conduct in medicine, law, engineering, business and other disciplines also. Ethical norms also serve the aims and goals of scientific and biomedical research.

Research and experimentations are categorized into three main types — basic, applied and toxicology which are interlinked and overlapping as well.

Basic research

In basic research experiments are conducted with a view to advancing knowledge. This type of research helps us in better understanding the way organisms behave, develop and function biologically. Largest number and greatest varieties of laboratory animals are used in this type of research.

Applied research

Applied research incorporates problem-solving behavior and seeks to achieve the best possible solutions of medical problems. This type of research is aimed at solving specific and practical problems, often relating to the treatment or cure of disease and disorder in humans and animals.

Toxicology or Safety testing

This refers to the process in which commercial products are tested on animals to measure potential adverse biological reactions to the ingredients. Since 1960, all drugs to be introduced in clinical practice have to undergo animal testing to establish pharmacological standard, including the toxic effects of that particular drugs.

Drug testing in its final stage enters into clinical trials involving human participants. A clinical trial is a controlled prospective study that involves human participants or subjects and is designed to determine the efficacy of a therapeutic intervention, preventive measure, diagnostic procedure or medical or surgical device. Key features of clinical trials are —

Phase I: **Designed to provide information about pharmacokinetics and pharmacodynamics; this is useful in determining minimal and maximal dosages.**

Phase II: **Focused on drug efficacy and safety and determining appropriate range of drug doses.**

Phase III: **Large population sample; a comparison of new therapeutic intervention with standard treatment or placebo.**

Phase IV: **Large scale, long-term postmarketing studies; focused on identifying morbidity, mortality and adverse events.**

There are various issues related to clinical trials — most importantly, to what extent the patients or volunteers clearly understand the clinical trial process, thereby having an opportunity to make an educated and informed decision about participating in a clinical trial.

Ethics of research

Clinical research has a potential risk of harm. So, sound ethical standard must be maintained. Respect for human dignity, informed consent, privacy, lack of harm, justice, maximum benefit are to be considered at all levels during the process of research.

The 1981 Geneva Declaration of the World Medical Association and the International Code of Medical Ethics declare that a physician shall act only in the interest of his patient. Freedom of scientific research shall not subject a man to subjugation, definite or probable harm exploiting his material needs and shall not entail cruelty to animals also.

Human research

Participation in a research program should not be held under duress, social and other pressures and financial need should not be exploited. Excessive or inappropriate financial or other inducement for participation in research is unethical.

Guidelines in the Declaration of Helsinki should be observed. In 2002, "International 21 Guidelines for Biomedical Research involving Human Subjects" were formulated (mentioned later). All research activities are to be conducted under the supervision of institutional Ethical Review Committees.

Animal experimentation

Rights of animals must also be ensured during experimentation with animals. Uses of animals must be done within ethical boundaries. It should be remembered that every creature has a right of protection and preservation. Sanctity of life regardless of whether it is animal or human should be considered.

It is mandatory for the researchers to treat the animals with as much as compassion and sympathy as possible. However, alternatives to animals should be searched for.

While using animals for research, one should adhere to the basic principles of Reduction, Replacement and Refinement.

Reduction refers to methods that enable researchers to obtain comparable levels of information from fewer animals, or to obtain more information from the same number of animals.

Replacement refers to the preferred use of non-animal methods over animal methods whenever it is possible to achieve the same scientific aim. Refinement refers to methods that alleviate or minimize potential pain, suffering or distress, and promote welfare for the animals used.

Ethical issues in religious perspective

Muslim scholars, after examining all aspects of research, have deduced the principles that freedom of scientific research shall not entail the subjugation of man, harming him or subjecting him to definite or probable harm, defrauding him or exploiting his material needs or denying his therapeutic needs; and that it shall not entail cruelty to animals or torturing them.

In Buddhism and possibly also in other religions indiscriminate slaughtering of animals is highly discouraged.

Relationship with the pharmaceutical industries

Pharmaceutical industry places a vital role in biomedical research. The interdependence and relationship across the different groups of specialties requires certain ethical obligations.

Authorship

A person should be listed as the author of a paper only if that person made a direct and substantial intellectual contribution to the design of the research, the interpretation of the data, or the drafting of the paper.

It is not ethical to enlist or to be enlisted as coauthors in a research article without having substantial contribution in the research work. Those who just helped with the experiments, commented on the protocol or manuscript or helped in collection of data etc can be acknowledged.

Who gets credit for authorship?

The best way to avoid disagreements about who should get credit and in what order is to talk about these issues at the beginning of a working relationship, even though many people often feel uncomfortable about such topics.

Publication credit should accurately reflect the relative contributions. Mere possession of an institutional position, such as department chair, does not justify authorship credit. Minor contribution to the research or to the writing for publications can be acknowledged appropriately.

Research misconduct

Research misconduct means: Fabrication, Falsification, or Plagiarism (FFP) in proposing, performing, or reviewing research, or in reporting research results.

(a) Fabrication is making up data or results and recording or reporting them.

(b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

(c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

(d) Research misconduct does not include honest error or differences of opinion.

Other types of ethical violations

- **Duplicate publication/submission of research findings; failure to inform the editor of related papers that the author has under consideration or “in press”**
- **Unrevealed conflicts of interest that could affect the interpretation of the findings**
- **Misrepresentation of research findings — use of selective or fraudulent data to support a hypothesis or claim**

International 21 Guidelines for Biomedical Research involving Human Subjects (prepared by the Council for International Organizations of Medical Sciences [CIOMS] in collaboration with the WHO in 2002) —

Guideline 1

Ethical justification and scientific validity of biomedical research involving human beings

Guideline 2

Ethical review committees

Guideline 3

Ethical review of externally sponsored research

Guideline 4

Individual informed consent

Guideline 5

Obtaining informed consent: Essential information for prospective research subjects

Guideline 6

Obtaining informed consent: Obligation of sponsors and investigators

Guideline 7

Inducement to participate in research

Guideline 8

Benefits and risks of study participation

Guideline 9

Special limitations on risk when research involves individuals who are not capable of giving informed consent

Guideline 10

Research in populations and communities with limited resources

Guideline 11

Choice of control in clinical trials

Guideline 12

Equitable distribution of burdens and benefits in the selection of groups of subjects in research

Guideline 13

Research involving vulnerable persons

Guideline 14

Research involving children

Guideline 15

Research involving individuals who by reason of mental or behavioral disorders are not capable of giving adequately informed consent

Guideline 16

Woman as research subjects

Guideline 17

Pregnant woman as research subjects

Guideline 18

Safeguarding confidentiality

Guideline 19

Right of injured subjects to treatment and compensation

Guideline 20

Strengthening capacity for ethical and scientific review and biomedical research

Guideline 21

Ethical obligation of external sponsors to provide health-care services

Can a terminally sick person who is dying because of his/her ailment be used for research of interrogation?

With the consent of the individual, or his next of kin, scientific research within the margins of safety can be allowed. However, during such research, the basic human rights of hydration, nutrition, nursing, and pain relief must be ensured.

Conclusion

- **Strict regulations and ethical bindings are required for approving research proposals.**
- **Biomedical research involving human beings must be conducted only by scientifically qualified persons, and under the supervision of a clinically competent medical person.**

Every biomedical research project involving human subjects must be started after having assessed the predictable risks, in comparison with foreseeable benefits, to the subjects or to others. Individual concern must always supersede the interests of science and society.

All those participating in the research must be adequately informed of the aims, methods, anticipated benefits, potential hazards of the study, and the discomfort it may cause. They must be informed that they have free choice to withdraw, or abstain from participation in the study, even they give their consent. While taking informed consent to participate in the research project, the researchers must not influence the patient to participate.

- **When legal incompetence exists, informed consent must be obtained from the legal guardians in accordance with the existing national legislation.**

- **All research protocols must be approved by the institutional Ethical Review Committee.**

- **It would be unethical to hide any fact from the patient or other participants of clinical trials. A participant should never be misguided or betrayed.**

- **Before inventing a new wheel, researchers must take into consideration previously existing diagnostic and the therapeutic procedures.**

- **Researcher must know what their ethical obligations are.**
- **Your subjects won’t care how much you know, but they will know how much you care.**

- **Finally, we would like to encourage the leaders of academic research groups to inform their students and research associates about the ethical responsibilities of authors of scientific publications and to insure that, when they are given the responsibility for submitting a paper, they are fully aware of ethical guidelines. Research Ethics is an integral part of research.**

Further reading

- Helsinki Declaration adopted by the **World Medical Association** in 1964, amended in 1975, 1983, 1989, revised in 2000 and again amended in 2004. Available at:

- The National Institute of Health (NIH) offers an online tutorial, “Human Participants Protections Education for Research Teams”. Available at: http://cme.nci.nih.gov

- NIH Bioethics Resources. Website: http://www.nih.gov/sigs/bioehics/index.html

- The Department of Health and Human Services' (DHHS) Office of Research integrity. Website: www.ori.hhs.gov

- Association for the Accreditation of Human Research Protection Programs. Website: www.aahrpp.org

Thanks