

Putting Ethics First in Biomedical Sciences, Engineering and Technological Research – Minimizes Harm and Increases Benefits

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Introduction

Biomedical sciences, engineering and technology are relatively new entrants compared to the traditional disciplines like Mathematics, Physics, Chemistry, Botany, Zoology to name a few in the academia. But these are the new fields of academia in which experienced as well as semi-experienced players carry out research. Hence these fields of research have moved from inter-disciplinary to multi-disciplinary in a short span of time and soon will reach as a TRANSDISCIPLINARY academic study and research. Biomedical sciences are a set of sciences applying essential features of natural sciences, physical sciences, and philosophy to develop knowledge, interventions, or technology that are of use in healthcare and public health developed on sound ethical principles. Biomedical engineering and technology deals on the advances in the field of engineering and technology to improve human health and health care at all levels of human development and is the application of the principles and problem-solving techniques of engineering and technology to biological sciences, physical sciences and medical sciences of human development based on sound ethical principles.

Basic biomedical science research addresses mechanisms that underlie the formation and function of living organisms, ranging from the study of single molecules to complex integrated functions of humans, contributes profoundly to our knowledge of how disease, trauma, or genetic defects alter normal physiological and behavioural processes based on sound ethical principles.

Biomedical engineering and technology research is multidisciplinary, bringing together expertise in engineering, physics, materials science, computation, biology and medicine to increase our understanding of diseases, improve diagnosis, and develop treatments that benefit human health. Researchers are enlarging the boundaries of science and engineering technology, developing new tools and techniques to help solve some of the most challenging problems in medicine and public healthcare. It's a wide subject area that includes the development of Artificial Intelligence to enhance healthcare, the development of microscopic technology and development of bionics and prosthetics. Biomedical Engineering covers everything from nanomedicine to macro and micro-medicine. It remains a thought provoking question why this new field of discipline has yet to come out with concrete ETHICAL PRINCIPLES which can develop this field of study and research be more objective and focussed. Even now we tend to borrow from medical ethics and nursing ethics without incorporating innovative basic ethical principles of research in this new evolving field of research. In this editorial the author throws some light on what can be included as new but not exhaustive in the field of biomedical research.

It will be the duty of the experts to work on this as a concept note and evolve new policies and guidelines for this research field which deals with the lives of animals and the human beings. Let us start with the basic axioms of medical ethics namely Autonomy, Justice, Beneficence, non-Maleficence and Human dignity. The following text is one

of the best guidelines for those involved in biomedical research in human populations. The goal of biomedical clinical research is to develop generalizable knowledge that improves human health or increases understanding of human biology. People who participate in clinical research make it possible to secure that knowledge. The path to finding out if a new drug or treatment is safe or effective, for example, is to test it on patient volunteers. But by placing some people at risk of harm for the good of others, clinical research has the potential to exploit patient volunteers. The purpose of ethical guidelines is both to protect patient volunteers and to preserve the integrity of the science.

The ethical guidelines in place today were primarily a response to past abuses, the most notorious of which in America was an experiment in Tuskegee, Alabama, in which treatment was withheld from 400 African American men with syphilis so that scientists could study the course of the disease. Various ethical guidelines were developed in the 20th century in response to such studies.

Some of the influential codes of ethics and regulations that guide ethical clinical research include:

- Nuremberg Code (1947)
- Declaration of Helsinki (2000)
- Belmont Report (1979)
- CIOMS (2002)
- U.S. Common Rule (1991)

Using these sources of guidance and others, seven main principles have been described as guiding the conduct of ethical research:

- Social and clinical value
- Scientific validity
- Fair subject selection
- Favourable risk-benefit ratio
- Independent review
- Informed consent
- Respect for potential and enrolled subjects

Social and Clinical Value

Every research study is designed to answer a specific question. Answering certain questions will have significant value for society or for present or future patients with a particular illness. An answer to the research question should be important or valuable enough to justify asking people to accept some risk or inconvenience for others. In other words, answers to the research question should contribute to scientific understanding of health or improve our ways of preventing, treating, or caring for people with a given disease. Only if society will gain useful knowledge — which requires sharing results, both nega-

tive and positive — can exposing human subjects to the risk and burden of research be justified.

Scientific Validity

A study should be designed in a way that will get an understandable answer to the valuable research question. This includes considering whether the question researchers are asking is answerable, whether the research methods are valid and feasible, and whether the study is designed with a clear scientific objective and using accepted principles, methods, and reliable practices. It is also important that statistical plans be of sufficient power to definitively test the objective, for example, and for data analysis. Invalid research is unethical because it is a waste of resources and exposes people to risk for no purpose.

Fair Subject Selection

Who does the study need to include, to answer the question it is asking? The primary basis for recruiting and enrolling groups and individuals should be the scientific goals of the study — not vulnerability, privilege, or other factors unrelated to the purposes of the study. Consistent with the scientific purpose, people should be chosen in a way that minimizes risks and enhances benefits to individuals and society. Groups and individuals who accept the risks and burdens of research should be in a position to enjoy its benefits, and those who may benefit should share some of the risks and burdens. Specific groups or individuals (for example, women or children) should not be excluded from the opportunity to participate in research without a good scientific reason or a particular susceptibility to risk [1-3].

Favourable Risk-Benefit Ratio

Uncertainty about the degree of risks and benefits associated with a drug, device, or procedure being tested is inherent in clinical research — otherwise there would be little point to doing the research. And by definition, there is more uncertainty about risks and benefits in early-phase research than in later research. Depending on the particulars of a study, research risks might be trivial or serious, might cause transient discomfort or long-term changes. Risks can be physical (death, disability, infection), psychological (depression, anxiety), economic (job loss), or social (for example, discrimination or stigma from participating in a certain trial). Has everything been done to minimize the risks and inconvenience to research subjects, to maximize the potential benefits, and to determine that the potential benefits to individuals and society are proportionate to, or outweigh, the risks? Research volunteers often receive some health services and benefits in the course of participating, yet the purpose of clinical research is not to provide health services.

Independent Review

To minimize potential conflicts of interest and make sure a study is ethically acceptable before it even starts, an independent review

panel with no vested interest in the particular study should review the proposal and ask important questions, including: Are those conducting the trial sufficiently free of bias? Is the study doing all it can to protect research volunteers? Has the trial been ethically designed and is the risk–benefit ratio favourable? In the United States, independent evaluation of research projects is done through granting agencies, local institutional review boards (IRBs), and data and safety monitoring boards. These groups also monitor a study while it is ongoing.

Informed Consent

For research to be ethical, most agree that individuals should make their own decision about whether they want to participate or continue participating in research. This is done through a process of informed consent in which individuals

- (1) Are accurately informed of the purpose, methods, risks, benefits, and alternatives to the research,
- (2) Understand this information and how it relates to their own clinical situation or interests,
- and
- (3) Make a voluntary decision about whether to participate.

There are exceptions to the need for informed consent from the individual — for example, in the case of a child, of an adult with severe Alzheimer's, of an adult unconscious by head trauma, or of someone with limited mental capacity. Ensuring that the individual's research participation is consistent with his or her values and interests usually entails empowering a proxy decision maker to decide about participation, usually based on what research decision the subject would have made, if doing so were possible.

Respect for Potential and Enrolled Subjects

Individuals should be treated with respect from the time they are approached for possible participation—even if they refuse enrolment in a study—throughout their participation and after their participation ends. This includes:

1. Respecting their privacy and keeping their private information confidential.
2. Respecting their right to change their mind, to decide that the research does not match their interests, and to withdraw without penalty.
3. Informing them of new information that might emerge in the course of research, which might change their assessment of the risks and benefits of participating.

4. Monitoring their welfare and, if they experience adverse reactions, untoward events, or changes in clinical status, ensuring appropriate treatment and, when necessary, removal from the study.

5. Informing them about what was learned from the research. Most researchers do a good job of monitoring the volunteers' welfare and making sure they are okay. They are not always so good about distributing the study results. If they don't tell you, ask.

Ethics in the development of new instruments in biomedical research is another major aspect to be highlighted in the forthcoming issues.

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