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Editorial

Key Considerations in Biomedical Research Ethics

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INTRODUCTION

Biomedical Research ethics is all about understanding of the nature of conflicts arising from moral imperatives and how to tackle them. In this context a set of principles adopted to assist one's research practices and designs is known as" Research Ethics". Research decision as well as conduct of research must comply with certain code of conduct. Principles to be followed during the conduct of research should underlie, protection of the rights of research participants, enhanced research validity and maintenance of scientific integrity. Indian Council of Medical Research guidelines for Biomedical Research on human participants developed by the ICMR in 2006 has been updated as the "National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017)".[1] Guidelines need updating from time to time because research involving human subjects is expanding in a rapid fashion with the expansion of new research areas and innovative research tools.

CONCEPT: This editorial aims to briefly delineate some key considerations in ethics involving human participants, laboratory animals and in-vitro models.

1. ***Ethics involving human subjects***[2]

- Voluntary participation- study subjects are free to opt in or out of the study at any point in time
- Informed consent - Participants are made aware about the purpose, benefits, risks, and funding behind the study before the consent process
- Anonymity - identities of the participants not known to the researcher
- Confidentiality –Every information/data of the study participant is hidden
- Potential for harm - all types of harm [Physical/ social/ psychological] are kept to a bare minimum
- Results communication – accurate representation of study results with no plagiarism or research misconduct

2. ***Ethics involving Laboratory Animals***[3]

To promote the humane care of animals used in biomedical and behavioral research and

testing, CPCSEA [Committee for the Purpose of Control and Supervision of Experiments on Animals] is constituted by Government of India4. The three Rs (Replace, Reduce, Refine) determine the absolute limits for experiments on animals, even if there are great benefits. Apart from the 3R's other principles guiding animal research are as below.

- Respect for animals' dignity
- Responsibility for considering options (Replace)
- The principle of proportionality: responsibility for balancing suffering and benefit
- Responsibility for considering reducing the number of animals (Reduce)
- Responsibility for minimizing the risk of suffering and improving animal welfare (Refine)
- Responsibility for maintaining biological diversity - use of laboratory animals must not endanger biological diversity
- Responsibility for openness and sharing of data and material - to avoid unnecessary repetition of experiments

3. Ethics involving in-vitro models in clinical research[5]

In-Vitro models hold great promises for various applications in biomedical science and biotechnology. Despite its potential value in bioscience, this technology poses complex ethical challenges that may impede any future benefits for patients and society.

• Source of Stem Cells- fetal or adult tissues, from ESCs [Embryonic Stem Cells] or iPSC [induced Pluripotent Stem Cells]

• Informed Consent of Cell Donors

• Gene Editing - applied to edit genes in ESCs, iPSCs, germ cells, somatic cells or even human embryos

• Creation of Chimeras- Transplantation of human cells in animal models and the subsequent creation of human-animal chimeras for cancer research

CONCLUSION:

Ethics is an integral part of biomedical research. Ultimately every researcher must bear in mind that even if the research idea is valuable to society and scientifically valid, no rationale allows the researcher to inflict harm, violate the human rights or dignity of the study participants.

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