Bioethics of medical and biological experiments and clinical research.

A powerful researcher always have more to gain than a single research participant

Science is not the highest value to which all other orders of values should be subordinated

REASERCH ETHICS

Research ethics is based on the premise that it is ethical to experiment on human in carefully controlled conditions.

Experiment on human are as-

✓ **Understanding of pathogenesis of diseases**

✓ **to test new drugs, biological products, procedures, methods and instruments**

✓ **preventing or treating their diseases or postponing their untimely death**

The ethical requirements in the research on human are-

- obtaining informed consent from the potential subject,

- the need for the subject to derive a health benefit from the experiment and

and at the same time

keeping the risk to the subject as small as possible.

Evolution Of Research Ethics

After the world war II the power and potential of medical science expanded greatly.

Key elements of this radical alternation include the

- **development of antibiotics,**
- **the introduction of birth control pill,**
- **the discovery of powerful psychotropic drugs,**

new resuscitative and life supportive techniques

- **artificial respiration and dialysis**
- **organ transplantation**
- **manipulation of the human genome.**

Emergence of research ethics

- **advancement of technological devices in**

- **New conceptions of social justice**

Importance Of Bioethics In Health Research

Bioethics serves as an important instrument of change in

- **medicine,**
- **law and**
- **social attitudes.**

Ethical justification & scientific validity of research

The primary purpose of medical research involving human subjects is to improve prophylactic, diagnostic and therapeutic procedures and the understanding of the aetiology and pathogenesis of disease.

Ethical review

The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol. This protocol should be submitted ethical review committee,

Ethical review of externally sponsored research

- in the country of the sponsoring organization.

- and the research carried out in that country.

Inducement to participate

Subjects may be reimbursed for lost earnings, travel costs and other expenses incurred in taking part in a study; they may also receive free medical services.

Benefits and risks of study participation

Medical research involving human subjects should be conducted only by

- scientifically qualified persons

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

- These groups should not be included in research unless the research is necessary to promote the health of the population represented.

Research in populations and communities with limited resources

- The research is responsive to the health needs and the priorities of the population or community in which it is to be carried out; and

- Any intervention or product developed, or knowledge generated, will be made reasonably available for the benefit of that population or community.

Choice of control in clinical trials

research subjects in the control group of a trial should receive an established effective intervention. In some circumstances it may be ethically acceptable to use an alternative comparator, such as placebo or “no treatment”.

Continued

Placebo may be used:

- When there is no established effective intervention;
- When withholding an established effective intervention would expose subjects to, at most, temporary discomfort or delay in relief of symptoms.
- When use of an established effective intervention as comparator would not yield scientifically reliable results and use of placebo would not add any risk of serious or irreversible harm to the subjects.

Research involving children

- The research might not equally well be carried out with adults;

- The purpose of the research is to obtain knowledge relevant to the health needs of children;

Women as research subjects

- Investigators, sponsors or ethical review committees should not exclude women of reproductive age from biomedical research.

Pregnant women as research participants.

✓Investigators and ethical review committees should ensure that prospective subjects who are pregnant are adequately informed about the risks and benefits to themselves, their pregnancies, the fetus and their subsequent offspring, and to their fertility.

✓Research in this population should be performed only if it is relevant to the particular health needs of a pregnant woman or her fetus.

Safeguarding confidentiality

The investigator must establish secure safeguards of the confidentiality of subjects; research data.

Right of injured subjects to treatment and compensation

Investigators should ensure that research subjects who suffer injury as a result of their participation are entitled to free medical treatment.

In the case of death as a result of their participation, their dependants are entitled to compensation. Subjects must not be asked to waive the right to compensation.

Strengthening capacity for ethical and scientific review and biomedical research

- ✓ Many countries lack the capacity to assess or ensure the scientific quality or ethical acceptability of biomedical research proposed or carried out in their jurisdictions.

- ✓ In externally sponsored collaborative research, sponsors and investigators have an ethical obligation to ensure that biomedical research projects for which they are responsible in such countries contribute effectively.

Ethical obligation of external sponsors to provide health-care services

- **Health-care services that are essential to the safe conduct of the research;**

- **Treatment for subjects who suffer injury as a consequence of research interventions; and,**

- **Services that are a necessary part of the commitment of a sponsor to make a beneficial intervention or product developed as a result of the research reasonably available to the population or community concerned.**

If a definitive attempt is made during the planning stages of an experiment on human beings, to keep the ethical as well as scientific criteria in mind, it is possible often to perform the necessary research to yield the desired information.

Thank you