

# Unit-III

# Medical Research

Criticism of Orthodox medical ethics

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- Ethics in medical research deals with number of confusing situations in real time.
- Guidelines have been proposed for standardized ethical practice throughout the globe.
- The four fundamental principles of ethics which are being underscored are autonomy, non-maleficence, beneficence, and justice.

- Some special ethical issues have particular relevance to a specific research (Ex:Psychiatric research) is arising primarily from the specific vulnerabilities.
  - Ex: In Psychiatric research, vulnerable population like mental illness, pregnant ladies or children are the challenges faced by some research methodologies.
- Accordingly, sensitivity is required in the design of psychiatric research.

- An issue, mainly for the developing countries, has been the extent to which ethical principles are considered universal or as culturally relative.
- The challenge to international research ethics is to apply **universal ethical principles** to biomedical research in a **multicultural world** with a **multiplicity of health-care systems** and considerable **variation in standards** of health care.

***“In spite of having Good Ethical Framework, there is always some degree of Malpractice in Medical Research”***

# Certain Principles which are prone for violation

## **PRINCIPLES OF ESSENTIALITY**

- Refers to whether the research is considered to be absolutely essential after a due consideration of the existing scientific knowledge in the proposed area of research.

## **PRINCIPLES OF VOLUNTARINESS, INFORMED CONSENT, AND COMMUNITY AGREEMENT**

- Research participants should be fully apprised of the research and the associated risks and benefits.
- The participants should be informed of the right to abstain from the research or withdraw consent at any time.
- Where research entails treating any community, the principles of voluntariness and informed consent apply to the community as a whole and to each individual member.

# PRINCIPLES OF NON-EXPLOITATION

- The participants should be fully apprised of all the possible dangers that may arise during the research so that they can appreciate all the physical and psychological risks.
- Each research should include an in-built procedure for compensation for the human participants either through **insurance cover** or by any other appropriate means to cover foreseeable /unforeseeable risks

# PRINCIPLES OF PRIVACY AND CONFIDENTIALITY

- The identity and records of the participants are as far as possible kept confidential (except when required for legal reasons).
- This is to avoid any form of discrimination or stigmatization as a consequence of having participated in the research.



## **PRINCIPLES OF ACCOUNTABILITY AND TRANSPARENCY**

- The research or experiment should be conducted in a fair, honest, impartial, and transparent manner after full disclosure is made by those associated with the research or experiment

# PRINCIPLES OF PUBLIC DOMAIN

- The research findings should be brought into the public domain so that its results are generally made known through scientific and other publications.

# PRINCIPLES OF TOTALITY OF RESPONSIBILITY

- Professional and moral responsibility should be observed, for the due observance of all the principles, guidelines, or prescriptions of those directly or indirectly connected with the medical research.
- This extends to the institutes where this research is carried out, as well as the sponsors of the research.

**“In-spite of all these Principles,  
Many occasions there will be violation of at least  
one or more Principles of Medical Ethics”**

- Though a number of ethical guidelines have been formulated for clinical research, malpractice is still widely acknowledged.
- It could be understood by the fact that ethical guidelines in many countries like India are just the recommendations and not a law.
- For proper enforcement, guidelines should be made a part of the law like Developed countries.

**THANK YOU**