



# Institutional Ethics Committee (IEC)



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# Learning Objectives

- ⌘ What is Ethics ?
- ⌘ What is Institutional Ethics Committee (IEC) ?
- ⌘ What is the objective of IEC ?
- ⌘ Composition of Institutional Ethics Committee
- ⌘ Role of Institutional Ethics Committee
- ⌘ Role of IEC members

# What is ethics?

A branch of philosophy which is the systematic study of reflective choice (decision problems), of the standards of right and wrong (moral principles) by which it is to be guided, and of the good or bad (consequences) toward which it may ultimately be directed

**An ethical problem occurs when a person make a choice among alternative actions & the right choice is not absolutely clear**

**Often that choice affects the well-being of other persons**

# Ethics in Clinical Practice

- ⌘ Ethics is the **code of conduct** which distinguishes between acceptable and unacceptable behaviors in the society
- ⌘ All people recognize some common ethical norms but different individuals interpret, apply, and express ethics in different ways in light of their own values and real life experiences



⌘ Ethics may be defined as a method, procedure, or perspective for deciding how to act and for analyzing complex problems and issues


⌘ **While a medical practitioner will evaluate ethics on the basis of health, disease, survival, etc, an economist will examine the cost and benefits, a social worker will evaluate ethics in respect to impact on the society and principles at stake**

# Ethics



# Values, Morals, Ethics

- ⌘ **Values** signify what is important and worthwhile. They serve as a basis for moral codes and ethical reflection
- ⌘ **Morals** are codes of conduct governing behavior. They are values put into practice as actions
- ⌘ **Ethics** provide a systematic, rational way to work through dilemmas and to determine the best course of action in the face of conflicting choices



**Bioethics** is a way of understanding and examining what is “right” and what is “wrong” in biomedical research and practice



# Institutional Ethics Committee (IEC)

- ⌘ Institutional Ethics Committee (IEC) is a committee comprising of experts to lay person, formed by law
- ⌘ It is mandatory by “Law”,(ICMR Ethical Guidelines for Biomedical Research On Human Participants) that all proposals on biomedical research involving human participants should be cleared by an appropriate “**Institutional Ethics Committee (IEC)**”

# **Institutional Ethics Committee (IEC)**

- ⌘ **Safeguard the welfare and the rights of the participants is the main objective of IEC**

# Institutional Ethics Committee (IEC)

- ✧ The mandate of the IECs will be to review all research projects involving human subjects to be conducted at the Institute, irrespective of the funding agency
- ✧ **The role of IEC can be modified according to the requirement of each Institute**

# **Institutional Ethics Committee (IEC)**

- Members should be a mix of medical / non-medical, scientific and non-scientific persons including legal person, lay public to reflect the differed viewpoints

# **Institutional Ethics Committee (IEC)**

- ❧ The IEC is entrusted not only with the initial review of the proposed research protocols prior to initiation of the projects but also have a continuing responsibility of regular monitoring of the approved programmes to foresee the compliance of the ethics during the period of the project.

# Institutional Ethics Committee (IEC)

- ⌘ IECs should be multidisciplinary and multisectorial in composition
- ⌘ It is a committee comprising of experts, non experts
- ⌘ Independence and competence are the two hallmarks of an IEC
- ⌘ **Safeguard the welfare and the rights of the participants is the main objective of IEC**

# Objectives of IEC

- ✧ The objective of Institutional Ethics Committee (IEC) is to **ensure quality and consistent ethical review mechanism for health and biomedical research**
- ✧ **Following standard guidelines**

# Role of IEC

- ❧ IEC will review and approve all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and well being of all **actual and potential research participants.**
- ❧ **The goals of research, however important, should never be permitted to override the health and well being of the research subjects.**





**✧ The IEC will ensure principles of research ethics -**

**✧ Autonomy**

**✧ Beneficence**

**✧ Non maleficence**

**✧ Justice**

## **IEC will ensure-**

- ⌘ Planning, conduct and reporting of the proposed / ongoing research
- ⌘ Informed consent process
- ⌘ Risk benefit ratio
- ⌘ Distribution of burden and benefit
- ⌘ Provisions for appropriate compensations

# **IEC will ensure-**

- ⌘ Review of proposals before start of the study as well as monitor the research throughout the study until and after completion of the study through appropriate well documented procedures.
- ⌘ The committee will also examine compliance with all regulatory requirements, applicable guidelines and laws.

# Composition of IEC

The composition may be as follows-

- ✎ 1. Chairperson
- ✎ 2. 2 Basic medical scientists
- ✎ 3. 2 Clinicians from various Institutes
- ✎ 4. One legal expert or retired judge
- ✎ 5. One social scientist / representative of nongovernmental voluntary agency
- ✎ 6. One philosopher / ethicist / theologian
- ✎ 7. One lay person from the community
- ✎ 8. Member Secretary



**❧ IEC should be constituted in the following pattern :**

**❧ i) A Chairperson**

**❧ ii) A Deputy Chairman if required**

**❧ iii) A Member Secretary**

**❧ iv) 5-15 members from different Departments / Specialties / Disciplines or areas**

# IEC

- ⌘ The number of persons in an ethics committee should be kept **fairly small** (7-9 members)
- ⌘ **No specific recommendation for acceptable maximum number**
- ⌘ **12-15 is the maximum number**
- ⌘ **Minimum of five persons is required to compose a quorum**

# IEC

- ❧ The **Chairperson** should preferably be from **outside the Institution** and **not head of the same Institution**
- ❧ The **Member Secretary** should be from the **same Institution, should conduct the business of the Committee**
- ❧ Other members should be a mix of medical / non-medical, scientific and non-scientific persons including lay public to reflect the differed viewpoints

# IEC

- ⌘ **Authority under which IEC is constituted - The Institutional Head constitutes the IEC**
- ⌘ The **duration of appointment** is initially for a period of **2-3 years**, at the end of 2-3 years, the committee is **reconstituted**
- ⌘ **50% of the members will be replaced by a defined procedure**
- ⌘ A member can be replaced in the event of **death or long term nonavailability or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member**



# IEC

- ⌘ A member can tender resignation from the committee with proper reasons to do so
- ⌘ All members should maintain absolute confidentiality of all discussions during the meeting and sign a confidentiality form
- ⌘ Conflict of interest should be declared by members of the IEC

# IEC

- ⌘ IEC may call upon **subject experts** as independent consultants who may provide special review of selected research protocols, if needed
- ⌘ These experts may be specialists in ethical or legal aspects, specific diseases or methodologies, or represent specific communities, patient groups or special interest groups e.g. Cancer patients, HIV/AIDS positive persons or ethnic minorities
- ⌘ They are required to give their **specialized views** but do not take part in the decision making process which will be made by the members of the IEC

# IEC

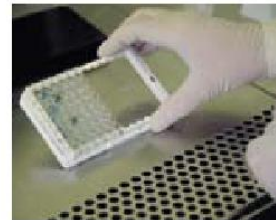
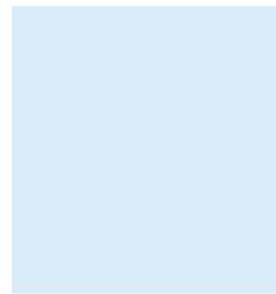
- ☞ The meeting of the IEC should be held on scheduled intervals as prescribed and additional meetings may be held as and when the proposals are received for review
- ☞ **Decisions will be taken by consensus after discussions, and whenever needed voting will be done**

# IEC

- ⌘ The decisions will be minuted and **Chairperson's approval taken in writing**
- ⌘ **All relevant new guidelines should be brought to the attention of the members**
- ⌘ Members should be encouraged to attend **national and international training programs** in research ethics for maintaining quality in ethical review and be aware of the latest developments in this area

# Ethical considerations in biomedical HIV prevention trials

UNAIDS/WHO guidance document



# Rationality & Ethics



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# Thank you

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☞ **Wish you a Happy learning !!!**