



Shri Shivaji Education Society, Amravati's  
**DR. PANJABRAO DESHMUKH NURSING INSTITUTE**  
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Ref. No. PDNI/ /20

DATE IDAC initiated 20  
Dr. Panjabrao Deshmukh Nursing Institute, Amravati

## **INSTITUTIONAL ETHICAL COMMITTEE**

(Policy and Procedure)

In conformity with the university directions, vide ref. no. MUHS/PG/E-3/352 dated 05/02/2017, the institute has constituted the Institutional Ethical Committee (IEC) dated 21.11.2017. It is a body responsible for reviewing and approving research proposals involving human subjects or potential ethical concerns. Its primary goal is to protect the rights, safety, and well-being of participants. This committee adopted the guidelines of ICMR, New Delhi.

### **1. Aim**

To promote high ethical standards for research activities, and integrating ethical values into practices, policy relationships and organizational activities.

### **2. Objectives**

- To establish research ethical guidelines, principles, and human protection.
- To review research proposals submitted by UG/PG nursing students to ensure the ethical guidelines and principles are adopted.
- To prioritize the safety, rights, and well-being of actual or potential research participants.
- To ensure that participants are fully informed about the research and can voluntarily choose to participate.
- To assess the potential risks and benefits of the research to determine if it is ethically justifiable.
- To monitor ongoing studies to ensure compliance with ethical guidelines and address any concerns that may arise.
- To maintain relevant documents related to IEC.



### 3. Functions of an IEC

- Policy making: The IEC establishes research ethical guidelines, principles and human protection.
- Review and approval: The committee members reviews research proposals submitted by UG/PG nursing students to ensure they adhere to ethical guidelines and principles.
- Protection of human subjects: It prioritizes the safety, well-being, and rights of research participants.
- Informed Consent: The committee ensure that participants are fully informed about the research and can voluntarily choose to participate.
- Risk-benefit analysis: The IEC assess the potential risks and benefits of the research to determine if it is ethically justifiable.
- Monitoring and compliance: The members of committee monitor the ongoing studies to ensure compliance with ethical guidelines and address any concerns that may arise.
- Maintenance of relevant documents related to IEC.
- Holding meetings as per policy.

**4. Committee:** It shall mean “the members of IEC” constituted as per guidelines of ICMR New Delhi. The committee composed of;

- Chairperson: Philosopher - 1
- Member: Basic Medical Scientist - 5
- Member: Clinician: 1
- Member: Clinical pharmacologist: 1
- Member: Legal expert: 1
- Member: Social scientist: 1
- Member: Lay person: 1
- Member: Philosopher/Theologian: 1
- Member: Secretary: 1

**5. Tenure of committee:** The duration of IEC shall be of life-time from the date of its inception.

**6. Meetings:** It shall mean the meeting convened by the chairperson, IEC, Dr. PDNI from time to time.



7. **Chairperson:** It shall mean "the philosopher approved by ICMR New Delhi as a chairperson to hold the IEC meeting.

8. **Secretary:** It shall mean "the head of the institution" of Dr. PDNI Amravati as a secretary to the IEC.

9. **Member:** It shall mean the "members of IEC as per guidelines of ICMR, New Delhi" from different industries to represent the meeting.

10. **Notice of IEC:** Secretary of the committee shall issue the notice or circular of meeting, at least two weeks prior, with date, time and venue.

11. **Quorum:** A minimum of five members is required for a quorum to conduct meeting of IEC, with a mix of medical and non-medical / technical members.

12. **Frequency of meeting:** The committee shall hold meeting once in a year, or whenever required.

### 13. Procedure to hold meeting

Secretary of the committee shall consult the chairperson to fix a date, time & venue to convene meeting. The Secretary shall make necessary arrangement to hold the meeting. Proceedings of the meeting shall be recorded, and the minutes of the meeting shall be circulated to all members of committee.

### 14. ICMR Ethical guidelines for biomedical and health research

The ICMR (Indian Council of Medical Research) has established comprehensive ethical guidelines for biomedical and health research involving human participants, outlined in their 2017 document. These guidelines emphasize the protection of participants' rights, safety, and well-being, and promote ethical conduct in research. Key aspects include the formation and functioning of Ethics Committees (ECs), adherence to ethical principles, and procedures for ethical review.

#### Composition and functioning:

- ECs should be multidisciplinary and multisectoral, ensuring a mix of medical / non-medical, scientific and non-scientific persons, including laypersons.
- A minimum of five members is required for a quorum, with a mix of medical and non-medical/technical members.
- Larger institutions can have multiple ECs, while smaller ones may collaborate with other institutions.

- ECs should be independent, competent, and multidisciplinary in their functions.
- The institutional head appoints the EC and acts as the appellate authority.



#### Ethical Principles:

- All research should adhere to the basic ethical principles: respect for persons (autonomy), beneficence (do good), non-maleficence (do no harm), and distributive justice. These principles are further expanded into 12 general principles in the 2017 guidelines.

#### Review Procedures:

- ECs are responsible for reviewing research proposals before they begin and monitoring them throughout the study.
- ECs ensure that research protocols adhere to ethical guidelines and protect participants' rights and well-being.
- ECs should consider factors like social and cultural norms, emerging ethical issues, and potential biases, particularly in AI-based research.
- ECs may require investigators to present protocols or provide clarifications in meetings.
- Subject experts can be invited to offer their views, but they should not participate in decision-making.

#### Specific Guidelines:

- All biomedical and health research, including systematic reviews, should be submitted to the EC for review or exemption.
- An addendum to the guidelines allows for exemption from ethics review for systematic reviews following standard guidelines and registered prospectively.
- Clinical trials must be registered with the Clinical Trials Registry India (CTRI).
- Informed consent is mandatory for research involving human participants.
- ECs should address issues related to data handling, interpretation, risk minimization, and confidentiality, especially in AI-based research.

Date: 21.11.2017

Place: Amravati

*V.P.*  
21/11/17

(Dr. Veda Vivek)

Principal / Secretary, Institutional Ethical Committee  
Dr. PDNI, Amravati – 444 603