



Office of the Principal
Heritage Institute Of Medical Sciences, Varanasi

Ref. No. HIMS / PO / 1682 / 2025

Date: 03 / 04 / 2025

NOTIFICATION FOR IEC

- 1) The Ethical Committee of the Institute has been re-constituted. The constitution is as per details given below:-

S. no.	<u>Name</u>	<u>Designation</u>	<u>Role in IEC</u>
1	Dr VM Gupta	Ex Prof IMS-BHU, Varanasi	Chairman
2	Col (Dr) BK Prasad	Professor	Principal cum CMS
3	Dr Neeraj Kumar Singh	Professor, Pathology	Member Secretary
4	Dr Madhu Jain	Prof & HOD Obstetrics & Gynaecology	Member, Medical Scientist
5	Dr SK Gupta	Prof & HOD Pharmacology	Member Medical Scientist
6	Dr Ajmal Singh Bhayal	Prof & HOD Pathology	Member Medical Scientist
7	Dr CP Mishra	Prof & HOD Com Medicine	Member Medical Scientist
8	Mr Manish Singh	LLB (Advocate)	Legal Expert, Non Scientific
9	Dr Suman Tiwari	Social Worker	Non Scientific
10	Dhan Devi	Lay Person	Non Scientific
11	Rekha	Lay Person	Non Scientific

- 2) This notification will be valid for a period of one year from the date of issue or till further orders, whichever is earlier.
- 3) This supersedes all previous notification on the subject.

H B

Col (Dr) BK Prasad
Principal cum CMS
HIMS

Col (Dr) BK Prasad (Retd)
Principal Cum CMS
Heritage Institute of Medical Sciences
NH-2, By Pass Road, Bhadwar, Varanasi

Copy to: Hon'ble Chairman – for info PI

Vice Principal

Medical Superintendent

Director (Operations)

All concerned members

All HODs

Student Sec I/c

Incharge PG Cell

Office Copy (Ethical Committee File) –for records

INSTITUTIONAL ETHICAL COMMITTEE

Institutional Ethics Committee (IEC): It is an independent body responsible for reviewing and approving research proposals involving human participants, ensuring ethical conduct and protecting the rights and well-being of research subjects.

Key functions of IEC

1. Reviewing research proposals: The primary function of an Ethics Committee is to evaluate research proposals to ensure they adhere to ethical principles, scientific validity, and relevant regulations.
2. Protecting human rights: The committee safeguards the rights, safety, and well-being of research participants, including informed consent, confidentiality, and privacy
3. Ensuring ethical conduct: The committee promotes ethical conduct in research and academic activities within the medical college, providing guidance and advice to researchers, faculty, and students.
4. Monitoring research: Ethics Committees may monitor ongoing research projects to ensure adherence to ethical guidelines and protocols.
5. Advising on ethical issues: The committee can provide guidance and advice on ethical issues related to research and clinical practice.
6. Compliance with regulations: Ethics Committees ensure that research activities comply with relevant national and international ethical guidelines and regulations, such as the ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants.
7. Ensuring scientific soundness: While focusing on ethics, the committee also assesses the scientific validity and appropriateness of research methods.
8. Reviewing clinical trial protocols: The committee reviews and approves clinical trial protocols, ensuring they meet ethical and regulatory requirements.

Aim:IEC has been established in Heritage Institute of Medical sciences, Varanasi to formalize and specify the Institution's commitment to promotion of high ethical standards in clinical research, and teaching. This Standard Operating Procedure (SOP) applies to the formation and functioning of the IEC.

Terms of reference:

- To ensure that all proposed research projects conform to standard national and international ethical guidelines and that dignity, right and wellbeing of research participants is protected.
- The committee does not address or interfere in matters of an administrative nature, nor does the committee function as a grievance cell for staff members.

Constitution of IEC:

S. no.	<u>Name</u>	<u>Designation</u>	<u>Role in IEC</u>
1	DrVM Gupta	Ex Prof IMS-BHU, Varanasi	Chairman
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Duration of appointment: Minimum duration for a member would be one year. If a regular member resigns, or ceases to be a member due to any unavoidable reason, a new member will be appointed for the remaining term.

Chairperson: The IEC Chairperson should be from outside the institution, capable of managing the IEC and the matters brought before it with fairness and impartiality. He/she should not be a former faculty member of HIMS Varanasi. The Chairperson will conduct all meetings of the IEC. If the chairperson is not available for reasons beyond control, then his/her designee will act as alternate Chairperson.

Member Secretary: The Member Secretary will be a staff member of institute, responsible for coordinating and managing the activities of the committee including scheduling the meetings, describing the agenda and ensuring that the function of the committee is conducted as per the norms and policies described in this SOP. In absence of Member Secretary of IEC, a HIMS member of IEC may perform the function of the Member Secretary if necessary.

Role of IEC members

- Review and discuss research proposals submitted for evaluation
- Review progress reports and monitor ongoing studies
- Monitor SAEs and recommend appropriate action(s)
- Maintain confidentiality of the documents and deliberations of the IEC meetings
- Declare conflict of interest, if any

- f. To carry out work delegated by Chairperson and Member Secretary
- g. To participate in continuing education activities in biomedical ethics and research
- h. IEC members should become conversant with all national and international ethics Guidelines such as, Indian GCP Guidelines by CDSCO, National Ethical Guideline for Biomedical and Health Research Involving Human Participants and National Ethical Guideline for Biomedical Research Involving Children by ICMR, Standard and Operational Guidance for Ethics Review of Health-Related Research with Human Participants by WHO, ICH-GCP guidelines.
- i. Members are expected to be aware of local, social and cultural norms, as this is the most important social control mechanism

Quorum requirements: For review of each protocol the quorum of IEC shall be at least five members with the following representation:

- 1. Basic medical scientist (preferably one pharmacologist)
- 2. Clinician
- 3. Legal expert
- 4. Social scientist or representative of NGO
- 5. Lay person from community

Guidelines: The IEC seeks to fulfill the requirements for international assurances and is established and functions in accordance with the national law and regulations as cited below:

- 1. Ethical principles expressed in WMA Declaration of Helsinki (Adopted by 18th World Medical Assembly, Helsinki, Finland, June 1964, amended by 64th WMA General Assembly, Fortaleza, Brazil, Oct 2013) and Helsinki Declaration (Oct 2015)
- 2. Nuremburg Code (1945)
- 3. Belmont Report 1979
- 4. International Ethical Guidelines for Biomedical Research Involving Human Subjects (Geneva 1993)
- 5. European Convention on Human Rights and Biomedicine 1997
- 6. Standard and Operational Guidance for Ethics and Review of Health-Related Research with Human Participants (WHO 2011)
- 7. International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use - Good Clinical Practice (ICH-GCP 2016).
- 8. Indian Good Clinical Practice Guidelines (2001) by Central Drugs Standard Control Organization (CDSCO) for clinical trials National Ethical Guideline for Biomedical and Health Research Involving Human Participants by the Indian Council of Medical Research (ICMR 2017)
- 9. National Ethical Guideline for Biomedical Research Involving Children (ICMR 2017), NABH Guidebook to standards for accreditation of Ethical Committees (1st ed. 2015)