

Country Report from ABN Representatives
***Emerging Ethical Challenges of
Healthcare Digitalisation***

India

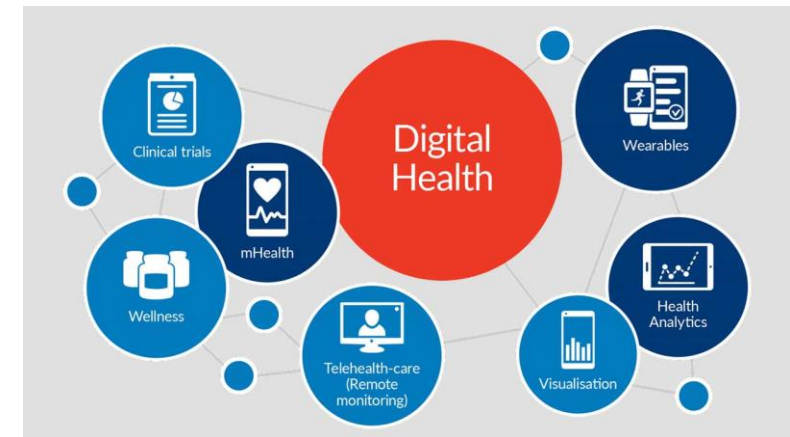
ABN Meeting, 4 September 2023

Outline

1. Summary of **Country's** State of Healthcare Digitalisation and Emerging Technologies
2. Summary of Ethical Challenges Faced by India
3. Existing Initiatives in India and/or Plans and Recommendations to Address the Ethical Challenges
4. Other Major Achievements or Ongoing/Upcoming Bioethics Initiatives in **Country**

1. Summary of India's State of Healthcare Digitalisation and Emerging Technologies

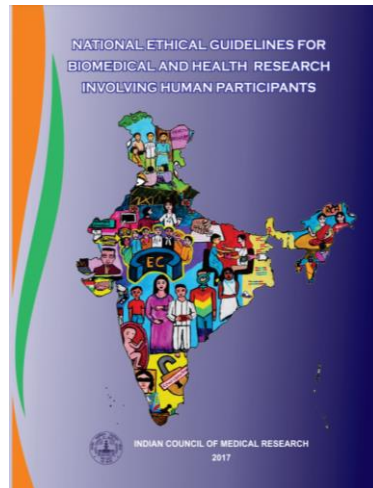
- **Healthcare Digitalization in India:**
 - Digital Health Mission- National Digital Health Mission (NDHM)
 - Telemedicine
 - Health Apps and Wearables
- **Emerging Technologies in Healthcare:**
 - Artificial Intelligence (AI)
 - Big Data Analytics
 - Genomics and Precision Medicine
 - IoT in Healthcare-The Internet of Things (IoT)
 - Blockchain Technology in Healthcare



2. Summary of Ethical Challenges Faced by India

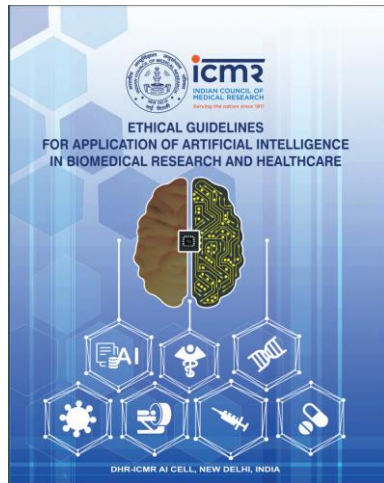
| S/N | Ethical challenge(s) arising from healthcare digitalisation/emerging technologies |
|-----|---|
| 1 | Data Privacy and Security Ownership and Control of Data-Defining ownership rights of health data, especially in cases of data generated through wearables and IoT devices. |
| 2 | Informed Consent-Addressing the digital literacy gap among patients and healthcare providers to ensure effective utilization of digital tools |
| 3 | Accuracy and Reliability <ul style="list-style-type: none">Establishing standards for interoperability between various digital health platforms to enable seamless data sharing.Spread of incorrect medical information through digital platforms. |
| 4 | Equity and Accessibility |
| 5 | Regulation, Monitoring and Oversight |
| 6 | Transparency and Accountability-algorithmic transparency, bias mitigation |

3. Existing Initiatives in India and/or Plans and Recommendations to Address the Ethical Challenges



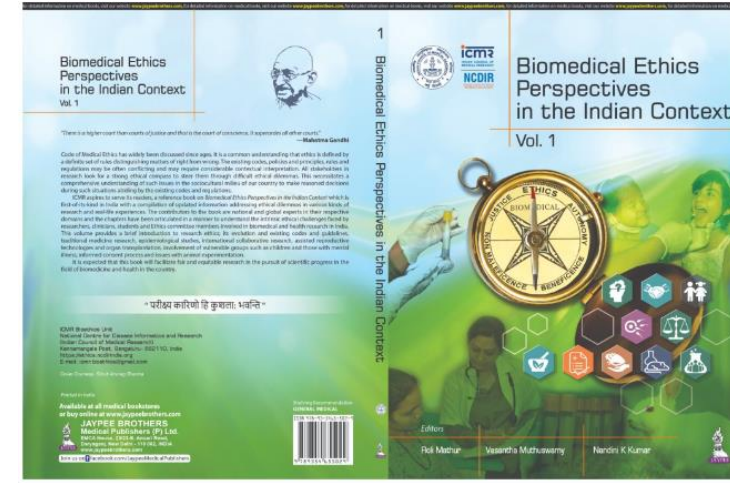
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National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017



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ICMR Bioethics Reference Book on Biomedical Ethics Perspectives in the Indian Context, 2022

Ethical Guidelines for Application of Artificial Intelligence in Biomedical Research and Healthcare

4. Other Major Achievements or Ongoing/Upcoming Bioethics Initiatives in India

ICMR's National Ethical Guidelines address a range of discussions often raised in public forums around biomedical research



New Areas:

- Public health research
- Social and behavioural sciences research for health
- Responsible conduct of research
- Research during humanitarian emergencies and disasters



National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017

FREQUENTLY ASKED QUESTIONS



General Ethical Issues

- Benefit: risk assessments
- Privacy and confidentiality
- Informed consent process
- Distributive justice
- Payment for participation
- Compensation for research related injury or harm
- Ancillary care
- Conflict of interest
- Community engagement
- Selection of vulnerable persons
- Post study access and benefits sharing

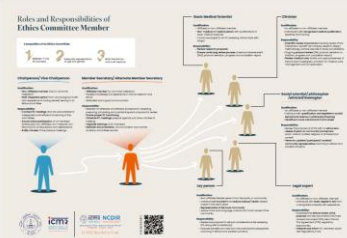


ETHICS AND GOVERNANCE OF ARTIFICIAL INTELLIGENCE FOR HEALTH

WHO GUIDANCE



Roles and Responsibilities of Ethics Committee Member



Home > Public Consultation:

ICMR Consensus Policy Statement for the Ethical Conduct of Controlled Human Infection Studies (CHIS) in India 2023 (Last Date: August 16, 2023)

Public Consultation
ICMR Consensus Policy Statement For The Ethical Conduct Of Controlled Human Infection Studies (CHIS) In India 2023

ICMR Bioethics Unit has formulated a consensus policy statement to address the ethical concerns related to the conduct of Controlled Human Infection Studies in India. The statement has been developed through a process of rigorous engagement with experts in the last few months. These studies may play a crucial role in advancing the scientific understanding of infectious diseases and thereby accelerating the development of treatment strategies. However, being a very specialized type of research involving deliberately infecting healthy volunteers with a specific pathogen under controlled conditions, these may have a lot of ethical challenges and an attempt has been made to address these issues in this document.

The document is being posted on ICMR Bioethics Unit website for Public Consultation for a period of ONE month. All those who are interested may provide their comments/ suggestions/ feedback by 16th August, 2023. The document can be downloaded from [here](#). Comments may be provided in the attached format as available [here](#).

Please send comments/ feedback /suggestions by email to:

Dr. Roli Mathur,
Scientist F and Head,
ICMR Bioethics Unit;
Email: icmrbioethicsunit@gmail.com.

The last date for receiving the comments is 16th August 2023.

Please visit [ICMR website](#)

ICMR Bioethics Unit

Guidelines for ICMR Network of Institutions

Joint Ethics Review of Multicentre Research



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FOR ETHICS COMMITTEES

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ICMR DHR Outreach Program for Ethics Committees