

Ethical Principles of Biomedical Research



ICMR Bioethics Unit

Biomedical research in India is governed by the 'ICMR-National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017'. These guidelines apply to all biomedical, social, & behavioral science research for health conducted in India involving human participants, material, or data. This infographic provides a checklist of questions to help ethics committees and individual researchers ensure that their research is ethical and compliant.



1. Essentiality

- Is human participation/samples/data essential for the proposed research?
- Are there any alternative experimental models available?



3. Non-exploitation

- Are the study's benefits and burdens distributed fairly without arbitrariness/discrimination?
- Are vulnerable populations a part of your study and how are their rights being protected?



5. Privacy & Confidentiality

How are you protecting participants' privacy and confidential information?

Will the participant data be identifiable or anonymized; if anonymized then reversibly or irreversibly?



research?
Is the study planned, conducted, evaluated, and monitored by competent professionals?

experienced to undertake the proposed



9. Institutional Arrangements

- Does your institution have adequate funds, manpower, training, and infrastructure for the research and to handle adverse events?
- Does it have policies for research governance and the infrastructure to support your research?

11. Totality of Responsibility

- How will you ensure that the stakeholders involved in your study are responsible for their actions and compliant with guidelines?
- Are their roles and professional, social, and moral responsibilities clearly defined?



2. Voluntariness

- Do the participants have the freedom to choose whether or not to participate in the study without any influence, bias, fear, or undue incentives?
- Are they informed about the study's purpose, time commitment, risks, benefits, alternatives, and their right to withdraw?



4. Social responsibility

- Does your research create or worsen social and historical divisions?
 - Could it disrupt community harmony by increasing social divides?



- What are the potential risks of your research, and how have you ensured care and compensation for participants?
- Can the risks and discomforts be further reduced?



8. Maximisation of Benefit

- What are the benefits of your study and do they outweigh the risks?
- How can you further maximize the direct and indirect benefits to the participants and society at large?

10. Transparency & Accountability

- How will you ensure transparency and communicate/ publish the research outcomes while safeguarding privacy and confidentiality?
- How will you conduct your research fairly, responsibly, transparently, and free of conflicts of interest?





12. Environmental Protection

 What steps have you taken to conserve resources and protect the environment at all stages of the study?





For more information refer "ICMR-National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017"

