



**Short Term Training on Bioethics**  
**Institutional Ethics Committee, IIT Madras, Chennai**  
**21-23 June 2023**



# **Ethical Principles and Guidelines**

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# Outline

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- Research Ethics
- What makes health research ethical? – guiding principles
- National ethical guidelines for biomedical and health research involving human participants

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# Research Ethics

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Code of conduct – of right and wrong – while conducting research on human participants

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Nuremberg Code 1947

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Declaration of Helsinki 1964

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Belmont Report 1979

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ICH-GCP 1996

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CIOMS 2002

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Nuffield Council of Bioethics 2002

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UNESCO Universal Declaration on Bioethics and Human Rights 2005

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What makes health research ethical?

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## Collaborative Partnership

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- Community engagement – who is community representative?
- Respect for community values, circumstances, culture, social practices
- Benefit sharing

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# Social Value of Research

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- Who benefit from conducting the research?
- What is the potential benefit for each beneficiary?
- How will social value be enhanced?
- How will adverse impacts be minimized?

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# Scientific Validity

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- Study design
- Sampling, sample size, representativeness
- Good science is essential for ethical research

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# Fair participant selection

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- Research participant choice limits harms
- Research participant choice enhances social value
- Vulnerability



# Favorable risk-benefit ratio

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- Risks – physical, psychological, social, economic
- Probability of risks and magnitude of risks
- Probability and magnitude of benefit
- Benefits must outweigh risks



# Independent Ethical Review

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- Institutional Ethics Committee
- Independent and Competent
- Transparent review process

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# Informed Consent

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- Understandable, simple information provided to participants
- Plans in place to obtain consent from legally authorized representative if participant is incapable
- Symbolizing consent
- Right to refuse to participate
- Culturally competent

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# Respect for Participants

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- Minimize harms
- Privacy
- Confidentiality
- Follow up care after completion of research

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National ethical guidelines for  
biomedical and health research  
involving human participants ICMR,  
2017

**Table 1: General Principles**

1. Principle of Essentiality	7. Principle of Professional Competence
2. Principle of Voluntariness	8. Principle of Maximization of Benefit
3. Principle of Non-exploitation	9. Principle of Institutional Arrangements
4. Principle of Social Responsibility	10. Principle of Transparency & Accountability
5. Principle of Ensuring Privacy & Confidentiality	11. Principle of Totality of Responsibility
6. Principle of Risk Minimization	12. Principle of Environmental Protection

**Table 2: General Ethical Issues**

Benefit–risk assessment	Informed consent process	Privacy and confidentiality
Distributive justice	Payment for participation	Compensation for research related harm
Ancillary care	Conflict of interest	Selection of vulnerable and special groups as research participants
Community engagement	Post-research access and benefit sharing	

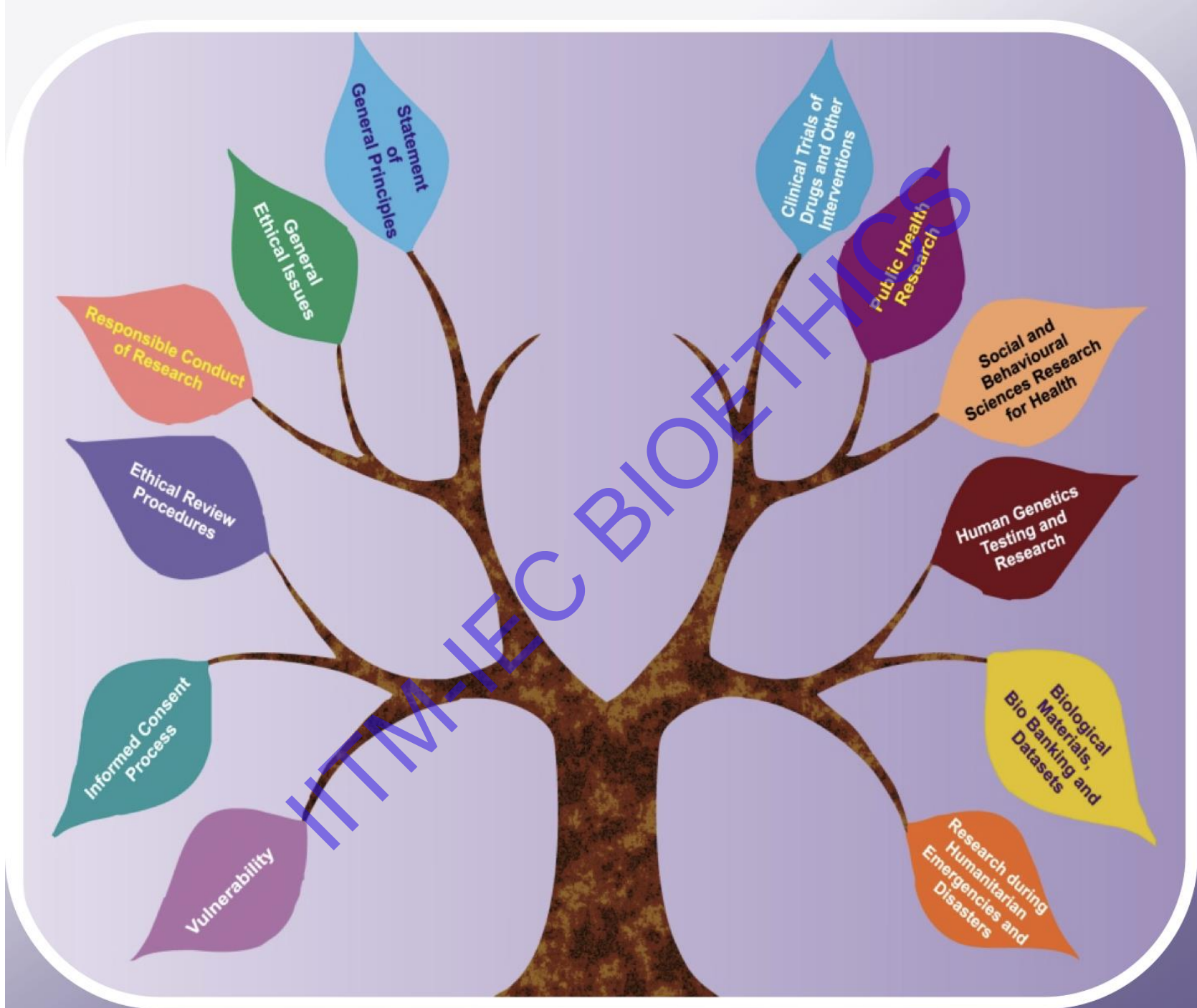
# Types of research covered by the ICMR guidelines

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- Clinical trials of drugs and other interventions
- Public Health Research and Social and Behavioral Sciences research for health
- Human genetic testing and research
- Biological materials, biobanking and datasets
- Research during humanitarian emergencies and disasters

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Thank you

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