

**The ICMR Ethical Guidelines – Putting India on the Global Bioethics Map**

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**Ethics in Traditional Medicine**

- Prime concern- safety and best interest of patients
- Liberal outlook
- Cost effective Rx to the poor
- No drastic/costly measure for the incurable
- Maintain confidentiality
- Avoid institutional entanglements that would compromise independent judgment
- Refrain from unsavory financial deals
- Refrain from advertising
- Professionalism with patients and colleagues



*Caraka Samhita*

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**Ethics & Islamic Perspective**

- Egyptian papyri (16th century BC)
  - As long as the doctor followed the rules, they were held to be non- culpable, should the patient die.
  - If the doctor transgressed the rules and the patient dies, the doctor paid with his life.
- Hammurabi set fees according to the social status of the patient. Codes were laid down for physicians and surgeons.
- *Kamilussana*, a 10th century Unani manuscript and other literature being studied by ICMR trainees

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**Ali al-Ruhawi (1200AD) - 'Adab el-Tibb' -  
Medical Ethics**

- "The physician must better his relationship to and endure the distress of the patient.
- Must pay attention to any statement heard from them.
- *No matter what the circumstances, he must acquire information from anywhere or anything, which may prove beneficial to the recovery of the patient.*
- Must not discourage any complaints of the patient or display of his distress since these symptoms, which occur, may be important in the diagnosis of the illness.
- Must show mercy; this is not possible except by the fear of God. If the physician has these traits, then he speaks only the truth and does good for all the people"

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**OLDER CODES OF MEDICAL  
ETHICS**

- 10<sup>th</sup> Century BC – 200 AD : *Caraka Samhita* (written code)
- 4<sup>th</sup> Century BC : Hippocratic Oath




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**First Do No Harm**

***“Primum non nocere”***  
***(first do no harm)***

***“Pradhama na nash”***

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## The Belmont Report

Ethical Principles and Guidelines  
for the Protection of Human Subjects of Research



The National Commission for the Protection of Human  
Subjects of Biomedical and Behavioral Research  
April 18, 1979

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Principle	Application
<b>Respect for persons</b> > Individuals should be treated as autonomous agents > Persons with diminished autonomy are entitled to protection.	<b>Informed consent</b> > Subjects, to the degree that they are capable, must be given the opportunity to choose what shall or shall not happen to them > The consent process must include three elements: <input type="checkbox"/> Information, <input type="checkbox"/> Comprehension, and <input type="checkbox"/> Voluntariness.
<b>Beneficence</b> > Human subjects should not be harmed > Research should maximize possible benefits and minimize possible harms.	<b>Assessment of risks and benefits</b> The nature and scope of risks and benefits must be assessed in a systematic manner
<b>Justice</b> > The benefits and risks of research must be distributed fairly.	<b>Selection of subjects</b> > There must be fair procedures and outcomes in the selection of research subjects

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## 1980 ICMR Guidelines

- Ethics Committee
- Informed consent
- Clinical trials
- Research on children, mentally disadvantaged, those with diminished autonomy
- Traditional Medicine
- Publications




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**Major areas identified by the Central Ethics committee on Human Research (1996)**

- Clinical evaluation of drug/ devices/ diagnostics/ vaccines/ herbal remedies
- Epidemiological research
- Human Genetic Research
- Transplantation research including fetal tissue transplantation
- Assisted Reproductive technologies

**Released in 2000**

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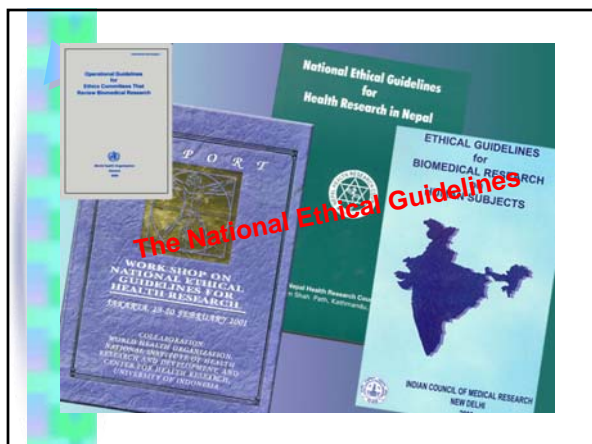
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**FWA : US - Compliance with the following procedural standards:**

- 45 CFR 46 and all of its subparts (A,B,C,D)
- 45 CFR 46, subpart A (Common Rule)
- 21 CFR 50 and 21 CFR 56
- CIOMS International Ethical Guidelines
- ICH-GCP-E6 Sections 1 through 4
- Canadian Tri-Council Policy
- Indian Council of Medical Research
- Other (please submit copy to OHRP with this Assurance)

OHRP website – Compilation of documents related to Human Protection

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**Differences between 2000 and 2006 Ethical Guidelines of ICMR**

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**Difference – General Principles**

- Essentiality
- Voluntariness, informed consent and community agreement (ECs shall decide about waiver)
- Non-exploitation
- Privacy and confidentiality
- Precaution and risk minimisation
- Professional competence
- Accountability and transparency
- Maximisation of the public interest
- Institutional arrangements
- Public domain
- Totality of responsibility
- Compliance

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## Difference - Ethical Review Mechanism

Basic responsibilities of Ecs – **Special situations**

Composition – No. changed with specification for drug trial as per Schedule Y of Drugs & Cosmetics Act

Terms of Reference

Training

Regulation

Review Procedures – Exemption from review, expedited review, full review

Submission of Application

Decision Making Process

Review Process

Periodic Review

Continuing Review

Interim Review

Monitoring

Record Keeping

Administration and Management

Special Considerations

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## General Issues

- Informed consent of subject – **Fresh /re-consent**
- **Waiver of consent**
- Obligations of investigators
- Essential information for prospective research **participants**
- Compensation of participation
- **Conflict of interest**
- Selection of special group of research **participants**
- Selection of special groups as research **participants**
- Essential information on confidentiality for prospective research **participants**
- Compensation from accidental injury
- Post – trial access
- International Collaborative Research/**Assistance in Biomedical/ Health Research**
- Researcher's relations with the media and publication practices

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## Specific Principles

- Clinical Trials of Drugs, Devices, Vaccines, Diagnostic agents, Herbal Drugs
- Epidemiological Studies
- Human Genetics Research
- Transplantation Research including Fetal tissue and Xeno- transplantation
- Assisted Reproductive Technologies

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## Issues in Clinical trials

- DRUG TRIALS – special considerations increased
  - Phases of clinical trials – Combined Phase I & II & special studies
  - Multicentric trials - special concerns increased
  - Contraceptive trials
  - Monitoring ADRs / Aes – text changed
- Vaccine trials including r-DNA and combination vaccines - special concerns increased
- Devices/ Surgical procedures – text changed
- Herbal remedies – text changed

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## Epidemiological Studies

- Definition/Types of studies
- General Principles
- Specific Principles - Informed consent – individuals & communities, inducements, risks, benefits, ethical review procedures, conflict of interest – community participation
- Privacy/ Confidentiality
- Programme Evaluation

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## Human Genetics Research

<ul style="list-style-type: none"> <li>• General issues</li> <li>• Pedigree studies</li> <li>• Privacy/confidentiality</li> <li>• Genetic screening</li> <li>• Therapeutic trials including Gene therapy</li> <li>• Human Genome Project</li> </ul>	<ul style="list-style-type: none"> <li>• DNA and cell line Banking/ repository - Excerpt from Draft Guidelines on Biobanking added</li> <li>• DNA diagnosis</li> <li>• Pre- natal diagnosis</li> <li>• Assisted reproductive technologies – removed</li> <li>• Human Genome Diversity - removed</li> </ul>
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## Organ Transplantation

- Definitions
- Live donor transplants
- Cadaver donor transplants
- Research on recipients
- Fetal tissue transplantation
- Xeno-transplantation
- Transplantation for cosmetic purposes
- **Stem cell research & therapy - Excerpt from National Guidelines added**




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## Assisted Reproductive Technologies

- Definitions
- Informed consent
- Privacy/confidentiality
- Selection of donor
- Legitimacy of the child
- Surrogate motherhood
- Research on embryos/spare embryos



Excerpt from National Guidelines added

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## Guidelines










**Draft Guidelines**

- Mental Health
- Dataset protection
- Disaster situations

Ethical Guidelines for Social Science Research (2000)

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## Ethical Guidelines for Biomedical Research

The image shows three book covers. The first is 'ETHICAL GUIDELINES for BIOMEDICAL RESEARCH on HUMAN SUBJECTS' by the Indian Council of Medical Research, New Delhi, 2002. The second is 'ETHICAL GUIDELINES for BIOMEDICAL RESEARCH on VULNERABLE PARTICIPANTS' by the Indian Council of Medical Research, New Delhi, 2008. The third is 'The Bill' titled 'THE BIOMEDICAL RESEARCH ON HUMAN PARTICIPANTS (PROMOTION & REGULATION) BILL, 2007'.

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## Indirectly mandated

- Indian Medical Council Act, amendment 2002
- Drugs & Cosmetics Act – Schedule Y

The image is a screenshot of the Clinical Trial Registry of India website, showing a search interface and a list of clinical trials.

Clinical Trial Registry of India  
[www.ctri.in](http://www.ctri.in)

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## Role among developing countries

- Referred by many developing countries before own national guidelines were prepared
- Accepted by US as equally protective to human participants
- Indian guidelines more stringent due to over-precaution
- Guidelines for research using traditional medicine accepted by WHO for phase II trials in humans if traditionally used for traditional indication – adopted in China
- Draft Research ethics guidelines for disaster situations prepared by regional working group included in ICMR guidelines

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