ICMR’s Guidelines for Biomedical Research on Human Participants

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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
1980 ICMR Guidelines

- Ethics Committee
- Informed consent
- Clinical trials
- Research on children, mentally disadvantaged, those with diminished autonomy
- Traditional Medicine
- Publications
Ethical issues in New Biology & Technology
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
The National Ethical Guidelines
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
Differences between 2000 and 2006 Ethical Guidelines of ICMR
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
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
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
- 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
Ethical Review Procedures
Revised ICMR Guidelines - Ethics Committees

Based on WHO Guidelines

Expanded: mostly based on US Guidelines but modified
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
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
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

• Program Evaluation
Human Genetics Research

- General issues
- Pedigree studies
- Privacy/confidentiality
- Genetic screening
- Therapeutic trials including Gene therapy
- Human Genome Project
- DNA and cell line Banking/repository - Excerpt from Draft Guidelines on Biobanking added
- DNA diagnosis
- Pre-natal diagnosis
- Assisted reproductive technologies – removed
- Human Genome Diversity - removed
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
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
Guidelines

Draft Guidelines

- Mental Health
- Dataset protection
- Disaster situations

Ethical Guidelines for Social Science Research (2000)
ICMR’s Ethical Guidelines

ETHICAL GUIDELINES for BIOMEDICAL RESEARCH on HUMAN SUBJECTS

INSTITUTE OF MEDICAL RESEARCH NEW DELHI 2006

THE BIOMEDICAL RESEARCH ON HUMAN PARTICIPATION (PROMOTION AND REGULATION) BILL, 2007

Title different ? 2014
Contents modified
Indirectly mandated

- 2002 - Indian Medical Council Act, amendment

- 2005 - Drugs & Cosmetics Act – Schedule Y

Included in Indian (CDSCO) GCP - 2001
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