Capacity building in research ethics in India:
Some priorities and actions for global partnerships

K. Satyanarayana
Sr Deputy Director-General
Indian Council of Medical Research
New Delhi 110029
India
E mail: kanikaram_s@yahoo.com
Indian Council of Medical Research

- Founded in 1911 as Indian Research Fund Association
- Renamed as ICMR in 1949
- Apex organization to formulate, conduct, coordinate and promote biomedical research
- Autonomous organization funded by Ministry of Health & Family Welfare
The Mandate

To undertake and support basic, epidemiological, applied and operational research in the areas of national public health importance using tools including those of modern biology.

Better Health......

.......through research

Ethics, Research and Globalization, Brussels, 14-15 May 2007
Scope of talk

- Status of research ethics in India
- Guidelines available
  - Ethical guidelines for animal experimentation
  - Ethics for Human experimentation
  - Publication ethics
- Some specific areas of concern
  - Clinical trials
  - Globalization
  - IPR issues
  - New technologies viz., Biotechnology, Nanotechnology *etc.*
- Way forward toward positive ‘global partnerships’
Ethics in Biomedical Research in India

- National Guidelines available in India
  - Animal Experimentation
  - Research on Human subjects
  - Guidelines for Assisted Reproduction Technologies
  - Guidelines for Stem Cell Research
  - Publication/Authorship
  - IPR and Tech Transfer Policies
Use of Animals in Bio-Medical Research

- CPCSEA Guidelines for Laboratory Animal Facility
- Indian National Science Academy (INSA) Guidelines for Care and Use of Animals in Scientific Research.
- ICMR Guidelines for use of Laboratory Animals in Medical Colleges.
Use of Animals in Bio-Medical Research

Acts and Rules

Ethical Guidelines for Biomedical Research

Guidance Document
On
Humane Care and Use of Laboratory Animals

Indian Council of Medical Research
New Delhi
2006

Ethics, Research and Globalization, Brussels, 14-15 May 2007
Some Indian Human Ethics Regulations

- 1956: Code of Medical Ethics, MCI
- 1980: Policy Statement on Ethical Considerations involved in research on Human Subjects
- 1986: EPA Act for r-DNA products
- 2000: Revised ICMR Ethical guidelines
- 2001: Indian GCP Guidelines
- 2002: Amendment to Drugs and Cosmetics Act
- 2007: Revised ICMR Guidelines
Ethical Guidelines for Research on Human Subjects

- Revised ICMR Guidelines in February, 1980
- Statement of General Principles
- Statement on Specific Principles
- Guidelines have been converted into law which is pending before the Indian Parliament

Ethics, Research and Globalization, Brussels, 14-15 May 2007
Ethical Guidelines for Biomedical Research (2007)

- National consultation over
- Finalized for release
Guidelines for Accreditation, Supervision and Regulation of ART Clinics

Provides guidelines for

- ethical practice of acceptable ART methods
- taking measures for setting up of an independent body through legislation for accreditation, regulation and supervision of infertility clinics in India.
Publication ethics - current status

- Still a matter of serious concern
- Unethical practices surfacing from major laboratories and well known scientists
- To be addressed at various levels:
  - Young researchers
  - Established scientists
  - Reviewers
  - Journal editors
Publication ethics

What is being done?
- ICMR
  - Capacity building
  - Policy Guidelines
- Indian National Science Academy, New Delhi
- Council of Scientific & Industrial Research, New Delhi
- Society for Scientific Values, New Delhi
Publication ethics - Case studies

- J Biological Chemistry (2006)
The Genetic Heritage of the Earliest Settlers Persists Both in Indian Tribal and Caste Populations

- 18 Authors, 7 Institutions
- 6 countries – Esotonia, UK, Germany, Russia, Kuwait and USA
- Funding – NIH, USA, EU Commission, Esotonia Research Council
- “After informed consent was obtained, 180 blood samples were collected from health and maternally unrelated volunteers belonging to *Chenchu* and *Koya* tribes from Andhra Pradesh …”
The Kundu Episode

- Two papers in *Journal of Biological Chemistry* from a prestigious laboratory in Pune in 2005
- Group leader a Bhatnagar Awardee
- Whistle blower – some data in the second paper same as in the first one
- Investigation done. Committee absolves the author. Blames the junior scientist
- Society for Scientific Values take up the investigation
- Investigator found guilty (May 2007)
- Action still awaited
Publication ethics

- What needs to be done
- National policy on ethics and authorship
- Need for institutional mechanisms for investigation
- No national nodal agency/authority
- International collaboration
Clinical Trails in India

- Huge emerging problem
- Global Market over US$ 30 billion
- Conducting of clinical trials in developing countries on the rise
- India becoming a global hub for clinical trials
- Market expected to grow **15% per year to** from the current US$ 150 million US$ 1.5 billion by 2010
- Cost factor – saving of 40-60 % as compared to the US
- Translates to over US$150-200 million!
Clinical Trials in India

- Currently more than 150 clinical trials being conducted in India in major Hospitals – No records
- Several unethical trials reported in the media - conducted by the Big pharma
- Unreported??
- 100,000 patients to be enrolled
- 3000 sites
Clinical Trials - Concerns

- Little concern for patients/subjects
- Institutional Ethics Committees?
- Independent Ethics Committee?
- Registration of Clinical Trials
What needs to be done

- Rigorous monitoring
- Guidelines required on
  - New emerging Technologies
  - Data and material sharing
- Capacity building
- Harmonization of Ethical Guidelines
- Partnership with global agencies- WHO/WTO
As a condition for registering pharmaceutical products, countries normally require applicants to submit (disclose) data relating to quality, safety and efficacy (so called "test data"), as well as all other relevant information on the physical, chemical characteristics and composition of the product for marketing approval.
The issue that is currently being debated in India relates to whether such data protection should be introduced in India and whether the drug regulatory authority (the Drug Controller-General of India) can rely on these test data submitted by the applicant company (patent holder) for market authorization for the product of third party.

- Article 39.3 of the TRIPS Agreement on Data Protection
- Adverse impact on the introduction on generics, and on public health system - access to drugs
Concerns of globalization

- Geographical imbalance in representation in International/UN bodies
- Unresolved issues of WTO/TRIPS
- Gene piracy
- Denial of environmental-friendly technologies
Unresolved issues on TRIPS

- Article 27.3 (b)
- Doha issues on public health
- Patentability of Microorganisms
- Gene Piracy
- Technology Transfer issues
- Harmonization of global IPR systems
The Way Ahead

- Focused North-South Partnerships
- Facilitated South-South dialogue
- Studies on Ethics and IPR, especially on emerging technologies
- More attention to publication/Research Ethics
Thank you