

Indian IECs in 2010 and Beyond

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India's Strength

Heterogeneous Population >1.2 billion

- Different Ethnic Groups
- Endogamous tribal population (conserved gene pool)

> 250 Medical Colleges

- Research Institutes
- Universities
- 11,500 hospitals and 14,000 diagnostic laboratories
- 50 R&D labs in the public sector & 200 in Govt. Sector

1.5 lac sub-centres,

- 23,000 primary health centres,
- 4000 community health centres
- 1,600 urban family welfare centres

3 million graduates, 700,000 post-graduates and 1500 PhDs in biosciences and engineering

- Employment for 15,000 scientists exists in Indian Biotech itself.
- 5000 harnessed
- Potential for hiring 50,000 professionals over 5 years in the Contract Research

Ethical Review Framework

Laws & Regulations
Ethical Standards GCP
Study Protocol
Good Science




The Belmont Report

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


- **Autonomy**
- **Beneficence**
- **Justice**





1980 ICMR Guidelines

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



Operational Guidelines & Surveying and Evaluating Ethical Review Practices, WHO

Revised ICMR Guidelines - Ethical Committees



Based on WHO Guidelines



Expanded based on US Guidelines but modified

Challenges

Survey of Institutional Ethics Committees

- In 2001
 - Understand the actual manner in which the Ethics Committees are functioning in different parts of the country
 - Questionnaire - 147 Medical Colleges & ICMR institutes
- Results of 32 responses
 - No Legal expert in most of the committees
 - No appointment procedures / lobbying
 - Decision making by consensus / majority approach
 - No. of proposals variable 2- 60 / meeting
 - Minutes/ record keeping poor
 - No charge for review
 - Independence / Competence ??

Survey of Institutional Ethics Committees (contd.)

- In 2003
 - To develop various training & capacity building through corrective measures & to plan Accreditation of IECs
 - > 1200 questionnaires circulated to public & private institutions
- 223 responses

Survey of Institutional Ethics Committees (contd.)

- Results of 223 responses
 - 137 Institutes had IEC, 43 Institutes had no IEC.
 - Mostly 6-10 members and Chairman from Institute
 - About 54% had meeting as and when required
 - Decision - in meetings (69%), by circulation (8%), by circulation followed by meeting (12.9%)
 - No appointment procedures, quorum, monitoring, record keeping
 - Ethics review part time activity

Institutional vs Independent Ethics Committees

<ul style="list-style-type: none"> • No charge for review • Poorly funded, inadequate administrative structure • Most members untrained • Internal / academic conflicts of Interests • Overburdened without compensation • Offer as service with no business interest • Infrequent meetings • Not Multidisciplinary and Most members senior faculty 	<ul style="list-style-type: none"> • Charge for review • Quality can be demanded & Good pre/post board workup • Members updated/trained • Financial Conflict of interest - risk of not being reappointed • Well compensated • Business interest, competitiveness • Regular Meetings • Multidisciplinary and Multisectorial in nature
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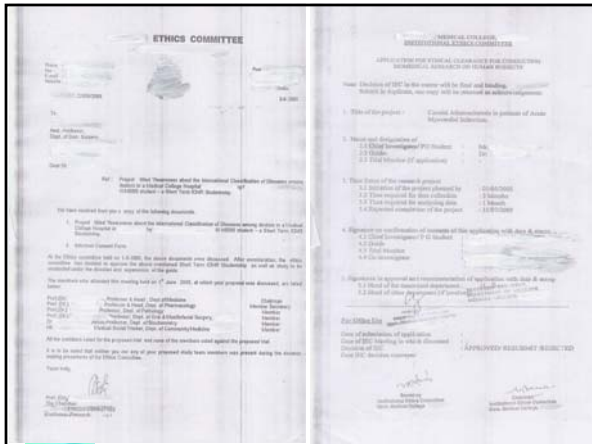
Other Challenges

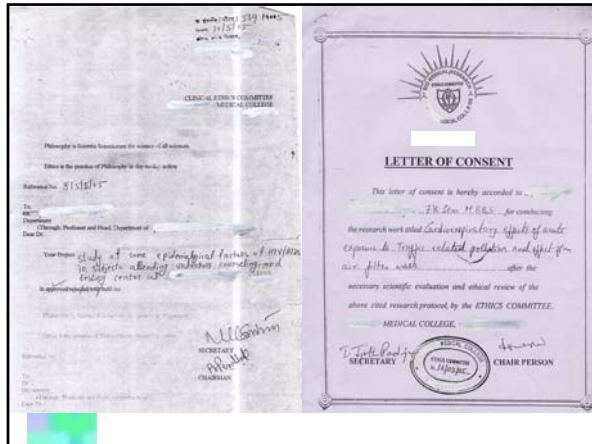
- **Informed Consent**
 - Multiple languages/ illiteracy
 - Lack of time for health professionals to explain
 - Decision making in Joint /Nuclear families
 - Cultural traditions/ religious beliefs
 - Faith, trust and respect for physicians as demi-God
 - Community consultation participation rare
 - Large population disparity in health services to understand implication

Issues facing India



- **Ethical Review**
 - Lack of knowledge regarding functioning and monitoring
 - Non-scientist members often silent during meeting
- **Bioethics education** – Medical Council's recommendations implemented in the curriculum only in few Universities
- **Legislations** – Not specific to regulate human experiments
- **International Collaboration** – multiple clearances earlier, capacity building, transfer of biological material





Ethics Committee power

- Power to withhold approvals / ask for changes in protocol or consent form
- Can ask for 3 monthly/6 monthly/ yearly review depending on risk involvement
- Action taken if misconduct not informed
- Can withdraw permission - Changes in research methods, new information, increased risk
- Premature termination of study- e.g. in case of SAEs
- Arbitration committee – to decide compensation in AE

Quality ethics review and Capacity building

- Establishment of competent IECs
- Providing training and continuing education in ethics through a sustainable communication network of local, regional, national & international expertise
- Effective trustworthy collaboration between various stakeholders
- Creation of awareness about local laws, rules/ guidelines
- Harmonizing the guidelines to maintain uniform ethical standards
- Conflict of interest to be strictly examined

Monitoring of Research

- Once IEC gives a certificate of approval oversight is necessary
- Local Institutional Ethics Committee better geared due to their location
- Actual Site Visits
- Problem - Time, financial constraints, lack of training

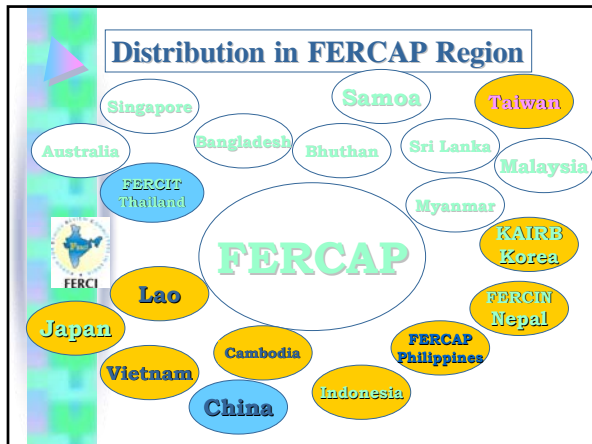
Multicentric Research

- All local ethics committees to approve
 - Decision depends on site specific conditions/ PI/ Community consultations or needs
- Problem of differing time lapse between decisions
- In case of conflicting recommendations on same protocol?
- The National Ethics Committee
 - Central Ethics Committee on Human Research (CECHR) located at ICMR Headquarters

Integration for sustainability of ethical review system

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    graph TD
      A[Training and Opportunities] --- B[Integrated & Sustainable Ethical Review System]
      C[Teamwork & Strategic partnership] --- B
      D[Monitoring & Evaluation] --- B
      E[Quality Culture in ER] --- B
  
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Forum for Ethical Review Committee in India

- Set up the Steering Committee constituted for promoting ethics review in India in 2002.
- National Chapter of FERCAP in India
- Registered and activities started by 2007
- Education & training for EC members mainly

Standard Operating Procedures (SOPs)- All IEC activities

- Constituting IEC
- Selection/Tenure
- Confidentiality agreements
- Training of members
- Consultants
- Submission procedures
- Pre-meeting Assessment
- Initial review
- Expedited Review
- Amendment of protocols
- Continuing Review
- Final Report
- Non Compliance
- Response to subject's request
- Study Termination
- Management of SAEs
- Site Monitoring
- Agenda and Minutes
- Emergency Meetings
- Communications
- Filing & confidentiality
- Audit & Inspections

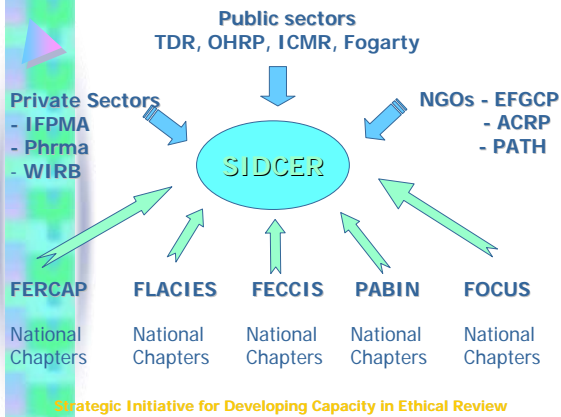
Curriculum for non-scientist members of Ethics Committees



FERCI collaborative program

- What it means to be part of a clinical trial - **Speaking Book** for clinical trial participation for illiterate subjects





▶ Steering Committee



▶ Accreditation of Ethics Committees

▶ Development of accreditation standards

- Standards and policies must be written (e.g., SOPs) and consistent with those in the international and local guidelines and regulations
- Should involve a process in which professionals will accept the standards as part of professional behavior

What should accreditation standards evaluate?

- Structure
 - What the organization has in place
- Process
 - What the organization does
- Outcome
 - What the organization achieves

Outcomes of accreditation

- Improves overall quality of research program through better and more effective processes
- Promotes culture of responsible conduct of research
- Improves protections for research subjects
- Ensures compliance with regulations

Benefits of Accreditation - For sponsors

- Raises overall quality, accountability, and transparency of the research enterprise
- Leads to consistency across organizations
- Produces quality IEC reviews
- Encourages more competent investigators

Other Benefits of Accreditation

- Benefits to government
 - Assists government in discharging its duty in protecting the public
 - Improves acceptance of regulations
- Potential benefits to public
 - Ensures that adequate safeguards are in place to protect well-being of the public when they choose to participate in research

➡ Public trust in research increases

Training Objective

- To improve knowledge and practice of research ethics among various health research stakeholders
 - Research Ethics Committees
 - Investigators
 - Sponsors
 - Regulatory Authorities
 - Participants

SIDCER Recognition Program

Objectives

- To facilitate and support procedures to assist the IRB towards **QUALITY** and **TRANSPARENCY** in ethical review
- To conduct an **independent evaluation** of the IRB and provide feedback on its practices and overall performance
- To ensure its **compliance** to international, national and local standards
- To determine the availability of IRB written Standard Operating Procedures (**SOP**) and its adherence to its procedures

SIDCER Recognition Programme

- Human Subject Protection Course
- IEC/IRB SOPs writing workshop
- Self-assessment
- Site Survey
- Recognition
- Progress report
- Renewal




SIDCER Recognition Program

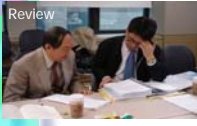
- Self Assessment (ICH GCP)
 - Corrects structural and membership issues
 - SOP revision
 - Address procedural issues (review and post review)
 - Forms and checklist revision
 - Ordering files and archives

Survey Methodology

- Office visit
- Document review
- Review of SOPs
- Interview
- Board observation



Survey Methodology (contd.)



1. Review of EC Self Assessment Form
2. Document review:
SOPs, protocols, agenda and minutes of meetings, SAE reports, membership and staff files



3. Observe an EC full-board meeting



4. Office visit
5. Interview



Recognition Certificate

5 standards for recognition of Quality of Ethics Committee

- 1) Structure (composition, administration etc.)
- 2) Adherence to specific policies for ethical review
- 3) Completeness and quality of its review process
- 4) Monitoring after review
- 5) Communication, documentation and archiving procedures.



FERCAP Achievement

<p>EC Recognition</p> <ul style="list-style-type: none"> • Taiwan – 20 • Korea – 13 • Thailand – 10 • China – 4 • Philippines – 2 • India – 2 • Indonesia – 1 • Sri Lanka – 1 <p>Total - 53</p>	<p>Training SEARO</p> <p>Thailand Indonesia India Nepal Bhutan</p>	<p>Training WPRO</p> <p>China Philippines Korea Cambodia Laos Vietnam Malaysia Japan Mongolia</p>
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Recognised ERC/IRB till 2008

<ul style="list-style-type: none"> • FERCAP = 53 <ul style="list-style-type: none"> – China – Korea – Philippines – Thailand – Indonesia – India – Sri Lanka 	<ul style="list-style-type: none"> • FECCIS = 1 <ul style="list-style-type: none"> • Russia • PABIN = 3 <ul style="list-style-type: none"> • Ethiopia
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After effects of SIDCER Recognition

- Streamlined IRB process
- Institution's support to build up the infrastructure
- Positive chains of surveyor training (training local surveyors) and SIDCER IRB surveys (the local trainees back to institute to prepare the survey)
- Regulators recognize the value of the SIDCER Survey Program (Korea, China, Thailand, Philippines)
- Changes in regulations and laws in biomedical research requirements and better protection for research subjects

Conclusions

- Status of ethics review was wanting earlier
- India gearing up to build capacity in ethics review through trainers
- Networking with Regional Forum FERCAP increasing
- Recognition of 2 ethics committees by SIDCER for first time

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