

# Promoting Excellence in Ethical Review

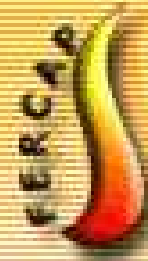
## *Regional Initiatives*



Dr. Vasantha Muthuswamy  
Sr. Deputy Director General  
Indian Council of Medical Research  
New Delhi

[muthuswamyv@icmr.org.in](mailto:muthuswamyv@icmr.org.in)

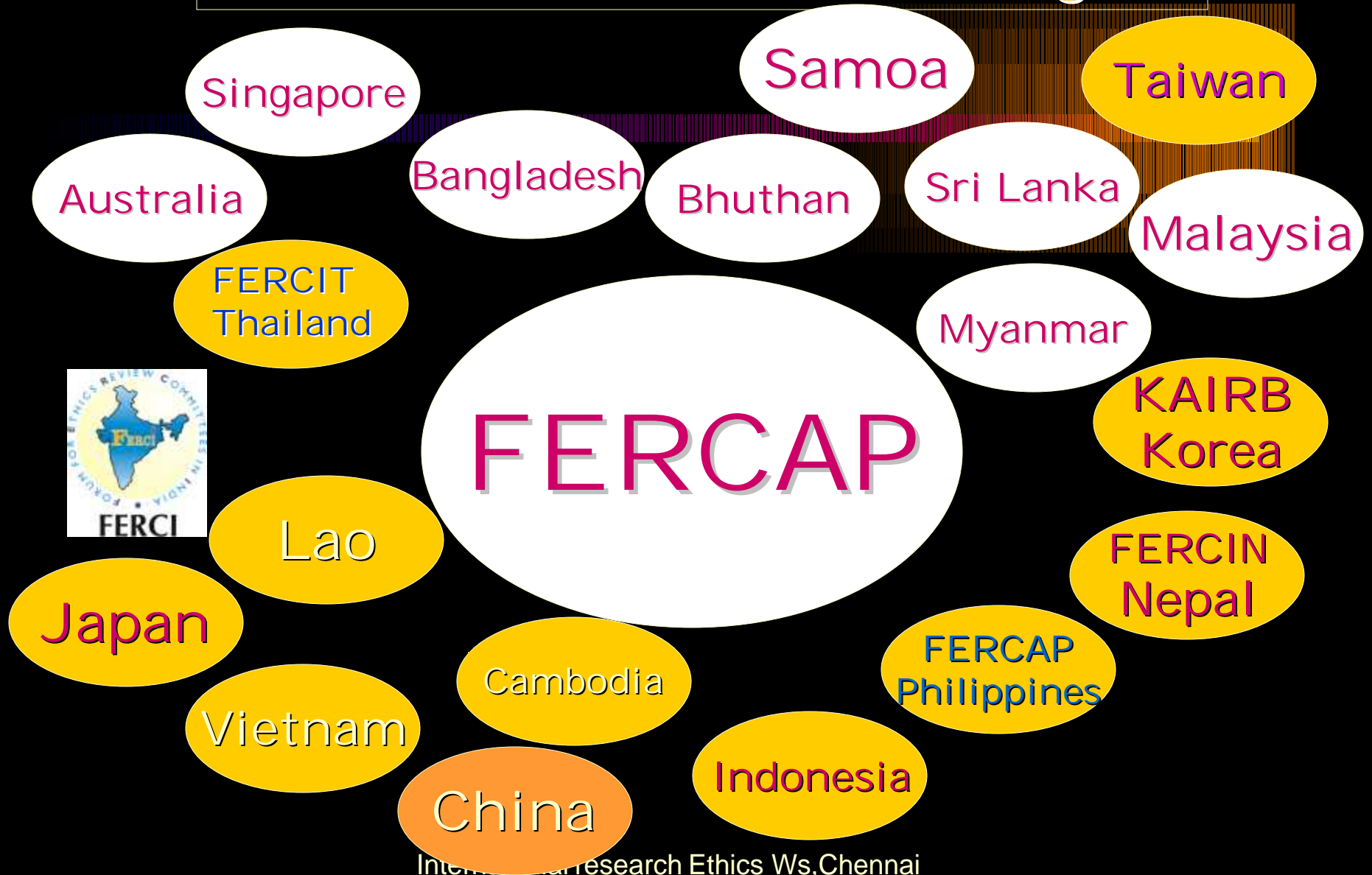
## *FERCAP (Forum for Ethical Review Committee in Asia Pacific)*



Leading light to human rights

- Born on 12th January, 2000 at Bangkok
- SEARO and WPRO countries
- Educate Ethics Committee members
- Networking of member countries & other For a
- Supporting other FORA  
(Latin America, Russia, Africa, Mediterranean,  
Caribbean, US & Canada)
- Translation of operational guidelines of WHO for IECs

# Distribution in FERCAP Region



# *The Aim of the Fora*



To foster the development of ethical review in the regions through

- β workshops and discussions on ethical review
- β promoting regional, national, and local traditions and values in ethical review
- β improving communication & education for ethics committees in the region
- β providing a platform for representation in the international discussion on bioethics

# ACTIVITIES

- establishment of in-country fora for ethical review
- formation of national ethics committees
- development of national guidelines for ethical review
- development of quality assurance guidance
- implementation of international guidance into practices
- development of regionally based training courses
- development of educational materials for members of Ecs
- development of training courses for surveying ethical review
- development of fellowship programmes
- establishment of regional communication formats



# *FERCI* *(Forum for Ethical Review Committee in India)*

- Setting up the FERCI and its Steering Committee constituted for promoting ethics review in India.
- Born in Dec'2002
- National Chapter of FERCAP in India
- Being registered as a trust, the trust deed is prepared
- Lot of interest expressed from industry and Academia
- Can take up accreditation of IECs in India

International research Ethics Ws, Chennai

# *National Chapters*

- FERCI T Thailand
- FERCI N Nepal
- FERCAP Phillipines
- FI RST Taiwan
- FERCI India
- KAI RAB Korea
- JAFI RB Japan
- Indonesia
- Lao PDR
- Cambodia
- Malaysia
- Singapore
- Sri Lanka
- Bangladesh
- Myanmar
- Mongolia
- China

# *The Achievements*

## U **Improved National Ethical Review Systems**

- à changes in policy on conduct of clinical research in *Thailand and Taiwan*
- à published national research ethics guidelines in *Thailand, Nepal, India, Philippines, and Korea*
- à the establishment of National Ethics Committees
- à the establishment of national forums for ethics committee in *Thailand, India, Nepal, Philippines, Korea, Bangladesh, and Taiwan*
- à the establishment of a National Commission on Health Research Ethics in *Indonesia*
- à *WHO Operational Guidelines* introduced as a formal part of the *Japanese* regulatory framework (January 2003).

# *The Achievements*

- u **Strengthened Independence and Competence in Ethical Review through Education & Quality Assessment**
  - à Courses in ethics at Thammasat University (*Thailand*), Nagasaki University, (*Japan*), University of Philippines (*Philippines*).
  - à Development of SOPs for ECs in *India, Thailand, & Japan*
  - à Development of database program (*Thailand*)
  - à The realisation in *India* of six states having been identified by the ICMR as training centers for biomedical research ethics.
  - à Establishment of a programme for surveying Ethics Committees in *Thailand, Korea, India, & Indonesia*
  - à Establishment of a training course for surveyors in *Thailand*
  - à Establishment of Fellowship programme with Western Institutional Review Board (WIRB) (started in November 2002)

**FUTURE PERSPECTIVES  
OF THE SOUTH EAST  
ASIAN COUNTRIES IN THE  
AREA OF ETHICS**

**Outcome of the  
ICMR-WHO Intercountry  
Workshop on Health ethics**

**2002,NewDelhi & 2004,Chennai**

# *FERCAP General Assembly Meeting 2005*

- Place: Prunarai 2 room, A-One Royal Cruise Hotel, Pattaya, Thailand
- Date: December 14, 2005
- Starting time: 8:25 am.
- Adjourned time: 3:45 pm.
- Number of participants: 58 from 19 countries
- Participating FERCAP countries and areas: Australia, Cambodia, Indonesia, India, Japan, Korea, Laos PDR, Nepal, Malaysia, Papua New Guinea, Mongolia, Philippines, Singapore, Sri Lanka, Thailand and Vietnam
- Invited Countries: Belgium, Switzerland, United States

# *Major Developments in the Region*

1. Australian ethical review process is supported by the Ministry of Health

250 IRBs

Guidelines revised every 5 years.

2. National ethics committees

Japan, Indonesia, Malaysia, Philippines, Joint IRB in Taiwan, and on-progress for Joint IRB in Thailand.

3. Challenges

Enforcement of the Korean law on the use of embryonic stem cells, and increasing awareness and involvement of government authorities on protection of human subjects.

## *Major Developments in the Region (contd.)*

- No national ethical review committees
  - Malaysia, Mongolia, Papua New Guinea, Thailand, Vietnam
- Forum for Ethical Review Committees
  - Positive impact & Increased capacity building
- More training needed
- 3 IRBs rewarded certificates of recognition on the quality performances of ethical reviews and management
  - Taiwan, Thailand & China

## *Major Developments in the Region (contd.)*

- Financial support for Conferences by WHO
- Terms of References to be re-looked into
- Next Conference on November 27-29, 2006 at Ngongkhai province, Thailand
- "Transparency and Accountability in Health Research: Towards an Ethics Responsibilities on Human Subject Protection"

# ***SIDCER***

*Strategic Initiative for Developing Capacity  
in Ethical Review*

## ***VISION***

To ensure protection for all human participants in  
health research globally

## ***MISSION***

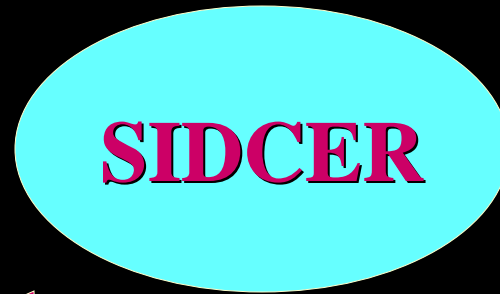
- **to build competent, independent, in-country decision making for promoting responsible conduct of human research through its international network of Fora**
- **to monitor the quality and effectiveness of ethics review worldwide, with mutual understanding and respect for cultural, regional and national differences.**

**Public sectors**  
**TDR, OHRP, ICMR**

**Private Sectors**

- IFPMA
- Phrma
- WIRB

**NGOs - EFGCP**  
**- IOWH**



**FERCAP**

National  
Chapters

**FLACIES**

National  
Chapters

**FECCIS**

National  
Chapters

**PABIN**

National  
Chapters

**FOCUS**

National  
Chapters

# *Activities - Good Clinical Practice*

## Researchers

- u Training in Good Clinical Practice
- u Training in Ethics in Clinical Research
- u Training in Regulatory Requirements

## Clinical Monitors

- u Training in Good Clinical Practice
- u Training in Ethics in Clinical Research
- u Training in Regulatory Requirements
- u Training on how to monitor under GCP Framework

## Ethics Committees

# *Coordination and Networking*

- Facilitate the regional Fora to establish forum at National level
  - Development of Tools: Guidelines, SOPs
  - Bioethics Courses: Universities
  - Training course for Surveyors: FERCAP
  - Fellowship Program : WIRB, 6- 12 month fellowship
  - SOPs:training - FERCAP
  - Database for Ethics Committees: FORA
  - Annual Conference: US DHHS/OHRP
  - Workshops for Training for Ethics Committee Members, Development of SOP, Survey and Evaluation of Ethics Committees- China, India, Mongolia, Taiwan, SriLanka
- International research Ethics Ws,Chennai

# *Challenges for SIDCER*

- Building a system/ infrastructure for ethics review that is responsive and sustainable
  - Time and resources for ethics review
  - System and infrastructure for accreditation
- Lessons from other regions, including developed countries, e.g. multicenter studies
- Build on existing educational programs and materials to make them more robust and culturally appropriate
- Registry of resources and database of IEC/IRBs in countries
- Monitoring and evaluation: developing indicators for effectiveness of capacity building efforts and of ethical review systems

## *Conclusion*

- Clinical Research is a vital step to increase knowledge regarding human health
- The role of disease endemic countries is essential to the solution of health problems
- Increase in research capacity in these countries is important and that Ethical Review Capacity is crucial

***•Ethics should focus on capacity-building for local decision-making and the ability to exercise those decisions independently***

## *Conclusion*

SIDCER provides the international community with not only a means to build in-country human subjects protection programs, But...also a way to measure and provide accountability regarding the quality and effectiveness of ethical review worldwide, taking into account internationally accepted standards alongside the need for mutual understanding and respect for cultural, regional and national differences.

# THANK YOU



International Business Ethics Ws, Chennai