



SIDCER Network and IRB Recognition Programme

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Outline

- Introduction
- Strategic Initiatives for Capacity in Ethical Review (SIDCER)
- Forum for Ethics Review Committee in Asian and Western Pacific (FERCAP)
- SIDCER IRB/IEC Recognition Programme



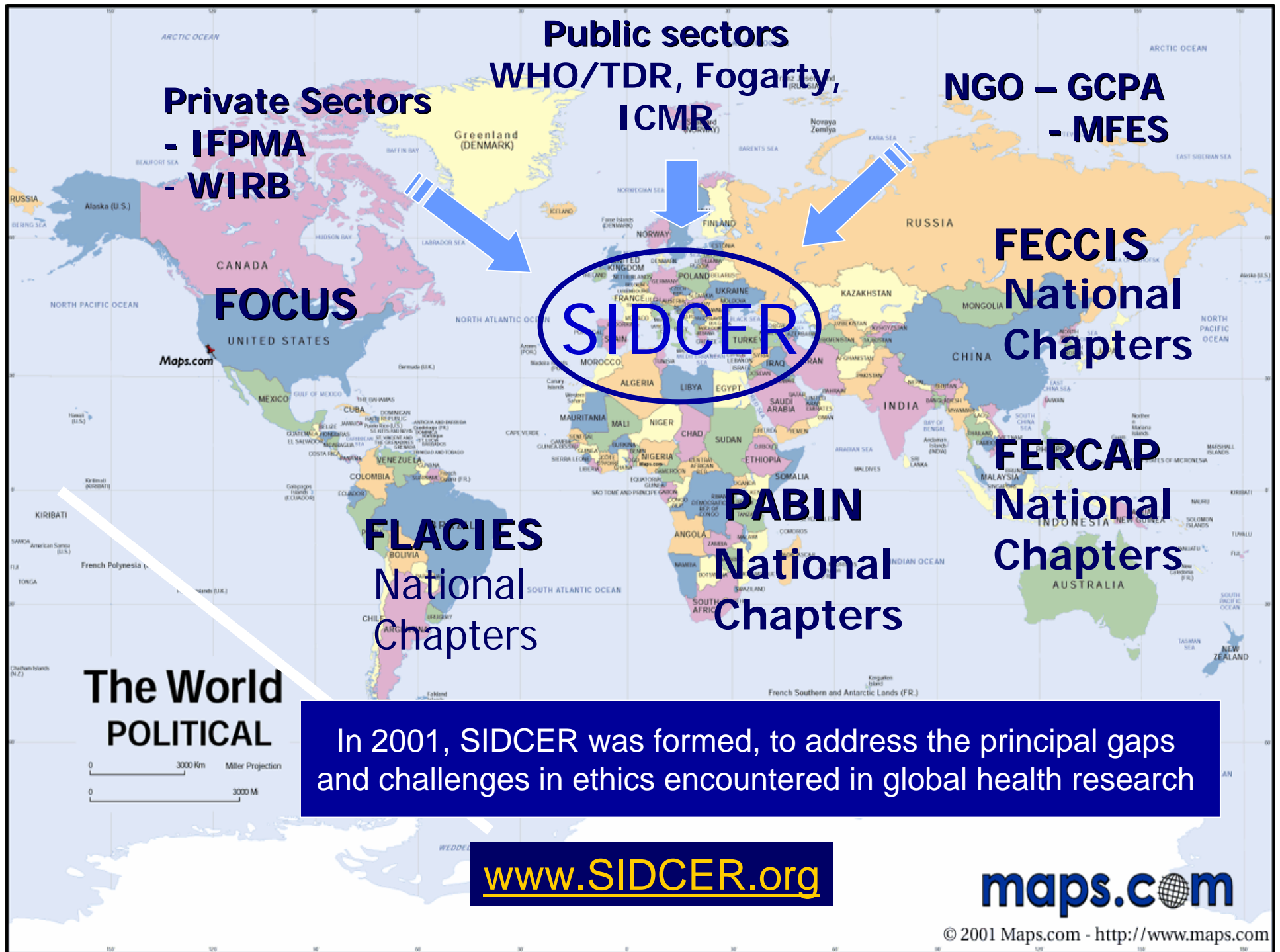
Differences in standards of ethical review

- Inhibited the progress of research,
- raised questions on fairness,
- threatened the protection of the dignity and rights of research participants at local, national, and international levels.



Concerns

- The potential social value, scientific validity, and ethical and social implications of studies
- The ethical evaluation of the risks and benefits of studies to the people most directly affected by the research
- SIDCER was formed in 2001 to address these concerns by promoting responsible decision-making within countries and communities in which people, communities and values may be unfairly exploited



Private Sectors
- IFPMA
- WIRB

Public sectors
WHO/TDR, Fogarty,
ICMR

**NGO - GCPA
- MFES**

FOCUS

SIDCER

**FECCIS
National
Chapters**

**FLACIES
National
Chapters**

**PABIN
National
Chapters**

**FERCAP
National
Chapters**

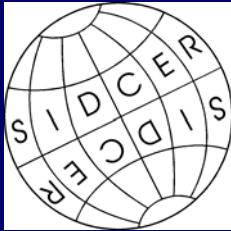
**The World
POLITICAL**

In 2011, SIDCER was formed, to address the principal gaps and challenges in ethics encountered in global health research

www.SIDCER.org

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SIDCER VISION

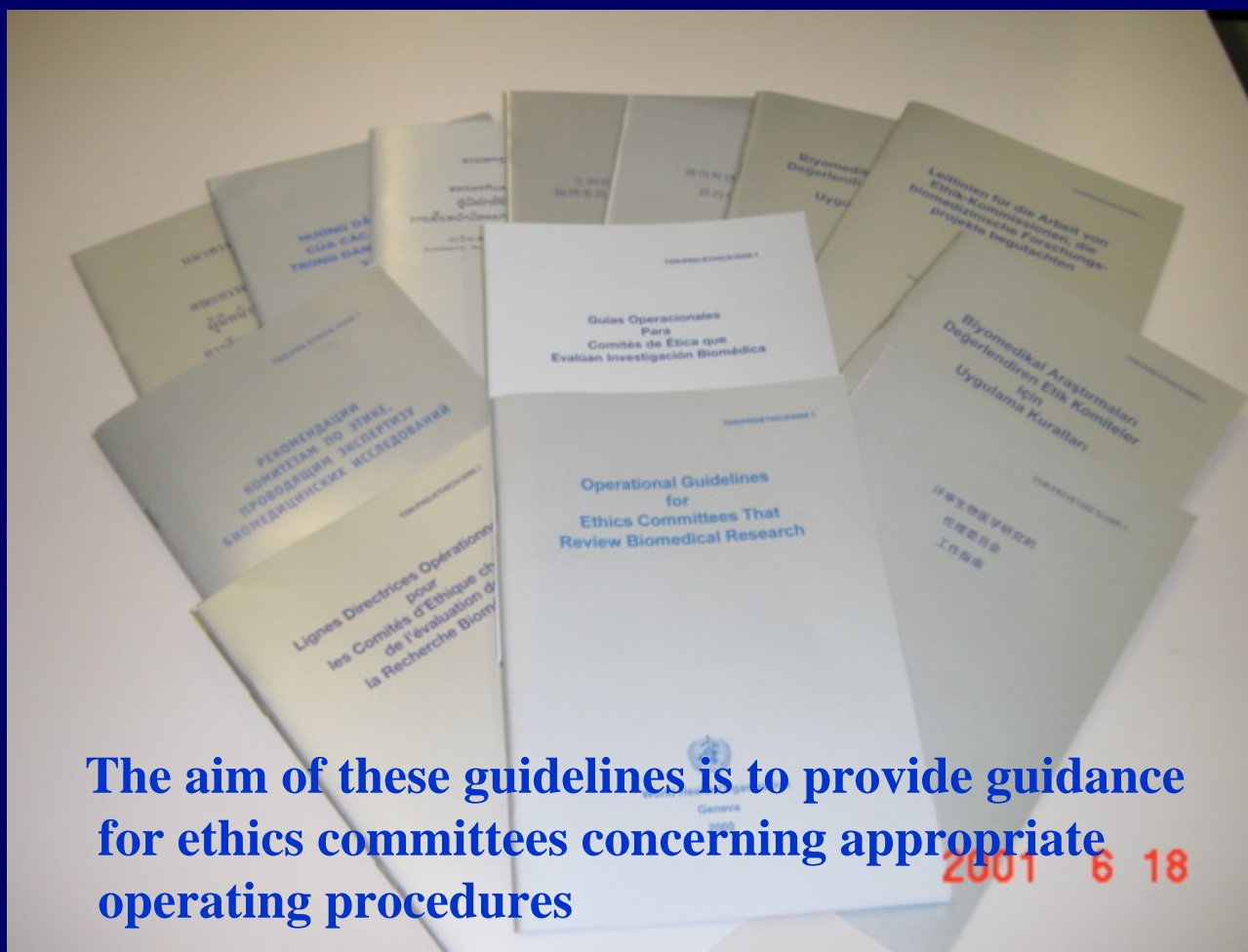
To enhance the protection of human participants in all research endeavors in all countries of the world.

MISSION

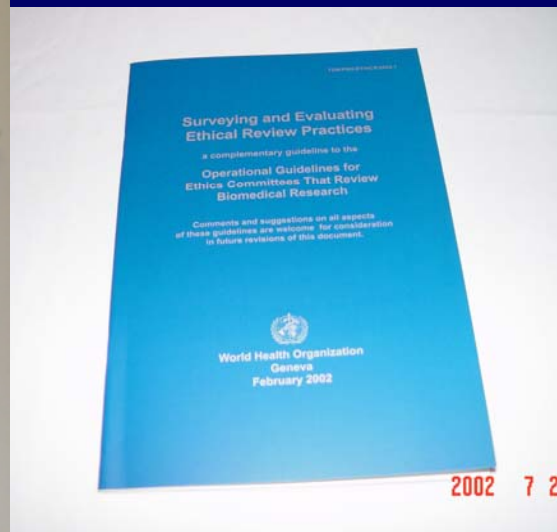
- Promoting the highest ethical and scientific standards for biomedical and behavioral research, and
- Ensuring the quality and effectiveness of ethics review worldwide, with mutual understanding and respect for cultural, regional and national differences.



Operational Guidelines for Ethics Committees That Review Biomedical Research



The aim of these guidelines is to provide guidance for ethics committees concerning appropriate operating procedures



The SIDCER strategy

- Build on ‘grass-roots’ initiatives, fora of ethics committee members committed to improving their own situations
- Build independence and competence through dialogue, exchange, and education
- Invite all parties having a responsibility in health research to engage a long-term sustained involvement in capacity-building for decision-making in ethics



SIDCER activities

- Supporting relevant regional structures and activities, including meetings and workshops to build local capacity for ethical review, strengthening and expanding its international network.
- Promoting sustainable in-country infrastructure for ethical review and provides a systematic approach to surveying and evaluating ethical review practices.



Beneficiaries

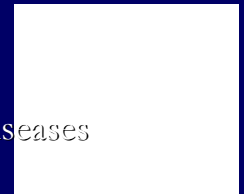
- Research participants, their communities, and the public at large
- The scientific community benefits from a reliable ethical framework for health research
- SIDCER contributes directly to the promotion of responsible governmental and institutional practices in all countries. The development of science and society requires an ethical commitment engaged globally by all stakeholders.





The Forum for Ethical Review Committees in the Asian and Western Pacific Region (FERCAP)

- Established 12 January 2000
- FERCAP is the result of the realization that ethics requires collective wisdom and there is need for a systems approach to address important health research issues in Asia and the Western Pacific
- **Objective:** fostering an improved understanding and better implementation of ethical review of behavioral and biomedical researches in the region.



FERCAP vision and mission

- Vision: To ensure human participant protection in health researches.
- Mission: To foster the development of ethical review committees in member countries toward competency, quality, independence, and effectiveness in reviewing health research

www.FERCAP-SIDCER.org





**FERCAP
ACTIVITIES**

Annual
Conference

TRAINING
Human Subject Protection
SOP Workshop
Surveying ECs

Networking

- 2006 – **Defining the Roles, Responsibilities, and Relations between National Health Authorities and Ethics Committees in Health Research**
- 2007 - **Transparency and Accountability in Health Research :*Towards an Ethics of Responsibility in Human Subjects Protections***
- 2008 – **Empowering Stakeholders in Health Research: *Towards Developing an Ethics of Responsibility***

of Ethics Committees in Asia Pacific



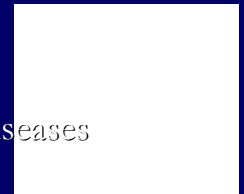
SIDCER Recognition Programme

- **Human Subject Protection Course**
- **IEC/IRB SOPs writing workshop**
- **Self-assessment**
- **Site Survey**

Process of Recognition

ASSESSMENT AND RECOGNITION PROCESS

- ❑ **SELF ASSESSMENT OF ETHICS COMMITTEE**
- ❑ **SURVEY ASSESSMENT**
- ❑ **CORRECTIVE ACTION**
- ❑ **RECOGNITION**



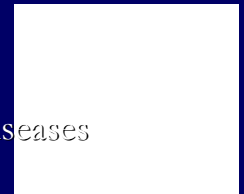


Recognition Certificate

Recognition Certificate

Ethics Committee will be recognized on the quality of the committee based on 5 standards

- 1. STRUCTURE AND COMPOSITION OF EC**
- 2. ADHERENCE TO SPECIFIC POLICIES**
- 3. COMPLETENESS OF ITS REVIEW PROCESS**
- 4. AFTER REVIEW PROCESS**
- 5. DOCUMENTATION AND ARCHIVING**



Methodology of an IEC Survey

Review



Interview



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



SIDCER Recognition



UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases

Aftereffects 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)
- FDA recognize the value of the SIDCER Survey Program
- Changes in regulations and laws in biomedical research requirements and better protection for research subjects



SIDCER Surveyors

FECCIS

- Armenia Michail Aghajanov
- Modova Ina Pgonea
- Russia
 - Marina Guryleva
 - Eugene Rogov
 - Svetlana Vylomova
- Kasakstan Bakhyt Samsarakova
- Uzbekistan Guzal Giyasova

FERCAP

- Suryadi Indonesia
- Thailand
 - Sopit Thammaree
 - Tada Sueblinbong
 - Yupaporn Wattanakool
 - Apornpirom Ketupanya
 - Sankae
 - Sirinart Vasanavathana
 - Preda
- India
 - Roli Mathur
 - Paul Kumaran
 - Vasantha
 - Vijay Kumar
- Taiwan
 - Chih-Shung Wong
 - Benjamin Kuo
 - Hsiang-Ning Luk
 - Chu-Yuan Cheng
 - Hwei-Ling Lee
 - Pey-Wen Jeng
 - Shu-Chiung Chiang
- Laos Supachai Douangchak
- China
 - Heidi Liu
 - Guan
 - Xiuquin
 - Jin Huang
- Korea
 - Young-mo Koo
 - Ockjoo Kim
 - Sang Gyung Kim
 - Hee Yang Shin
 - Im Hee Shin
- Philippines
 - Salome Vios
 - Rosa Gonzales
 - Marita Reyes
 - Vicente
 - Cecilia Thomas
 - Esperanza Espino
 - Cristina Torres
- Sri Lanka Anocha
- Australia
 - Allan Johansen
 - Lisa Hamadian

PABIN

- Ethiopia
 - Dawit ASmamaw
 - Jemal Hussein
 - Yeweyenhareg Feleke
 - Abraham Aseffa
 - Alemnew Fitayehu
 - Martha Zewdie
 - Tesfamariam Mebrahtu
 - Yimtubezinash Woldeamanuel
 - Gnet Mitike
- Nigeria Ogenna Manafa
- Uganda Tom Lutalo

FLACEIS

- Brazil Dirce Guilhem

Recognised ERC/IRB

■ FERCAP = 39

- China
- Korea
- Philippines
- Thailand
- Taiwan

□ FECCIS = 1

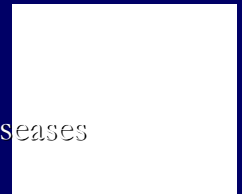
- Russia

■ PABIN = 2

- Ethiopia

Conclusion

- SIDCER builds a framework to address threats to human dignity, human rights, misuses of technological and scientific applications, and economic and commercial exploitation.
- SIDCER contributes to developing shared understandings for protecting research subjects and harmonizing the implementation of national and international ethical standards.
- SIDCER assists local institutions and governments in building their own capacity for ethical review (leading to sustainability) and securing greater international recognition of the quality of ethical review



Thank You for your attention



'.... for ethics committees to have become barriers to ethical research, which could help to improve health care, is certainly immoral'

- Nicholl J. *BMJ* 2000;320:1217

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UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases