FERCAP @10

IN COMMEMORATION OF A DECADE OF CAPACITY BUILDING IN ETHICAL HEALTH RESEARCH IN THE ASIA-PACIFIC REGION

WITH CONTRIBUTIONS FROM

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Forum for Ethical Review Committees in the Asian & Western Pacific Region

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Forum for Ethical Review Committees in the Asian and Western Pacific Region (FERCAP)
& Daegu Catholic University Medical Center Institutional Review Board (DCUMC IRB)
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Atoy M. Navarro & Cristina E. Torres

The *Forum for Ethical Review Committees in the Asian & Western Pacific Region* (FERCAP) is now ten years old. FERCAP was formally established by a group of bioethicists, ethics committee (EC)/institutional review board (IRB) members, health researchers, and medical practitioners in Bangkok, Thailand on January 12, 2000 as a result of the realization that ethical health research in the Asia-Pacific region requires collective wisdom and cooperation among various stakeholders (FERCAP, 2000). Since its founding, FERCAP has worked for capacity building in ethical health research in the region. Towards this goal, FERCAP spearheads major programs that include the following:

- *Annual International Conference*
- *Training Programs*
  - *Human Participant Protection Course* (HPPC)
  - *Standard Operating Procedure* (SOP) *Development Course*
  - *Surveying and Evaluating Ethical Review Practices Course*
  - *Various trainings in good clinical practice* (GCP)*, health research ethics, and strategic quality management* (SQM)
- *Networking*
  - *Strategic Initiative for Developing Capacity in Ethical Review* (SIDCER)
  - *World Health Organization* (WHO)/*Special Programme for Research and Training in Tropical Diseases* (TDR)

- *WHO South-East Asia Regional Office* (SEARO)
- *WHO Western Pacific Regional Office* (WPRO)
- *WHO-TDR Clinical Coordination and Training Center* (CCTC)
- *Various national, regional, and international institutions and organizations*

Together with its partners, FERCAP is also very much involved in the *SIDCER Recognition Program*, a global program that promotes good ethical review practices in health research among ECs/IRBs by implementing international criteria for surveying and evaluating ethical review practices (SIDCER, 2005; WHO/TDR, 2005).

In commemoration of a decade of capacity building in ethical health research in the region, FERCAP has put together this compilation of articles that highlight the forum's networking and partnership experiences during the last ten years. Vichai Chokevivat's contribution on "The FERCAP Story: A Decade of Fruitful Collaboration with Partners in Ethical Health Research" presents a brief history of FERCAP and an overview of the forum's main activities. In her essay "SIDCER @ 10," Juntra Karbwang-Laothavorn contextualizes the forum within the *Strategic Initiative for Developing Capacity in Ethical Review* (SIDCER), an independent public-private partnership initiative. Lisa Hamadian and Allan K. Johansen discuss the *SIDCER Recognition Program* in their paper "Reviewing Ethical Reviewers: The SIDCER/FERCAP Experience" while Atoy M. Navarro and Kesara Na-Bangchang narrate about the forum's engagements with its current home in their paper "At Home @ Thammasat University: The Case of FERCAP and WHO-TDR CCTC." Suggesting that the FERCAP network is not *just* an exchange of information and experience but a forum that incorporates a dimension of reciprocity unusual in contemporary organizations, Rachel Douglas-Jones imparts her reading of the forum in her contribution on "Fostering Common Goals and Sharing Values: Revisiting FERCAP's Regional Alliances." Cristina E. Torres' "Reflections on the FERCAP Experience: Moving Forward with Partnerships and Networks" provides a view of FERCAP from the EC/IRB grassroots and from within the forum. And finally,

Kenji Hirayama gives his thoughts on FERCAP's prospects for the future in his article "FERCAP Beyond 10."

All these commemorative essays showcase some of FERCAP's most important networking and partnerships forged during the last decade. By looking back at these productive networking and partnerships, the forum also looks forward to more years of capacity building in ethical health research in the Asia-Pacific region.

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THE FERCAP STORY: A DECADE OF FRUITFUL COLLABORATION WITH PARTNERS IN ETHICAL HEALTH RESEARCH*

Vichai Chokevivat, M.D., M.P.H.

As we celebrate the 10th year anniversary of the *Forum for Ethical Review Committees in the Asian & Western Pacific Region* (FERCAP), it is but apt that we look back to our beginnings and look towards our future as a regional forum. Having served as FERCAP's Founding Chair and being one of the "older" members of the forum, I would like share with you the FERCAP story of fruitful collaboration with partners in ethical health research.

In this short article, I will present a brief history of FERCAP as well as provide you with an overview of the forum's main activities during the last decade. I will also share some of my thoughts regarding the forum's future.

Brief History of FERCAP

FERCAP was first conceived during a *World Health Organization* (WHO)-sponsored *Seminar on the Ethical Review of Clinical Research in Asian and Western Pacific Countries* held at Chiangmai, Thailand on August 2-4, 1999. In that seminar coordinated by Dr. Juntra Karbwang-Laothavorn, it was observed that although the concern for human subject protection in health research began quite a

* Revised version of the paper presented during the *10th FERCAP International Conference: Networking and Alliance Building for Ethical Health Research*, Equatorial Shanghai Hotel, Shanghai, China, November 23, 2010.

long time ago as proven by the history of international ethical guidelines, there were obvious weaknesses in human subject protection in developing countries. It was noted that there were no ethics committees (ECs)/institutional review boards (IRBs) in some developing countries while there were few ECs/IRBs in most developing countries. It was also observed that there were no standard operating procedures (SOPs) for ECs/IRBs in most Asia-Pacific countries. Most ECs/IRBs in the region focused on initial review of research protocols without proactive continuous review. Based on these observations, we concluded that we need to develop capacity in human subject protection in our region as soon as possible. But the question is how?

In our discussions during the seminar, we noted that working with government will be very difficult and very slow because of too much red tape. So instead of working with government, we chose to start from scratch and create our own organization starting with the participants of the seminar. We planned to meet again in Bangkok, Thailand five months later. During the waiting period, Francis Crawley prepared the terms of reference (TOR) for FERCAP and drafted the *Operational Guidelines for Ethics Committees that Review Biomedical Research* (WHO/TDR, 2000) which became our *Silver Book*.

The TOR was agreed upon by the founding members of FERCAP at its *First General Assembly,* following the *Meeting on Guidelines and Standard Operating Procedures for Ethical Review* organized by the WHO/*Special Programme for Research and Training in Tropical Diseases* (TDR) and *Thammasat University* (TU) in Bangkok, Thailand on January 10-12, 2000. The approval of the TOR on January 12, 2000 marked the official founding of FERCAP. The first Steering Committee was elected and composed of myself as Chairperson, Dr. Leonardo de Castro of the Philippines as Vice-Chairperson, Dr. Vasantha Muthuswamy of India as Secretary, Dr. Kesara Na-Bangchang of Thailand as Treasurer, Dr. Gemiliano Aligue of the Philippines as Education Officer, Peter Sy of the Philippines as Communication Officer, and Dr. Cheng Ping of China, Dr. Suriadi Guwanan of Indonesia, Dr. Kenji Hirayama of Japan, and Dr. Mahani Mansor Clyde of Malaysia as Member Representatives (FERCAP, 2000).

Main Activities of FERCAP

FERCAP's main activities revolved around efforts in support of the establishment of national ECs/IRBs in the Asia-Pacific region. In relation to this, we organized annual conferences as well as training courses for EC/IRB members. We assisted ECs/IRBs in preparing their SOPs. We also encouraged the translation of the *Silver Book* into several Asian languages. For continuous EC/IRB improvement, we helped develop the handbook *Surveying and Evaluating Ethical Review Practices* (WHO/TDR, 2002), the companion for the *Silver Book* which became our *Blue Book*.

FERCAP also expanded its activities beyond the Asia-Pacific region. We assisted in the formation of the *Strategic Initiative for Developing Capacity in Ethical Review* (SIDCER), a global network of independently established regional fora for ECs/IRBs with a common interest in the development of ethical review. We also worked with other regional fora such as the *Pan-African Bioethics Initiative* (PABIN), *Forum for Ethics Committees in the Confederation of Independent States* (FECCIS), *Foro Latino Americano de Comites de Etica en Investigacion en Salud [Latin American Forum of Ethics Committees in Health Research]* (FLACEIS), and the *Forum for Institutional Review Boards [IRBs]/Ethics Review Boards [ERBs] in Canada and the United States* (FOCUS).

In collaboration with SIDCER, we spearheaded the *SIDCER Recognition Program*, a global program that promotes good ethical review practices in health research among ECs/IRBs by implementing international criteria for surveying and evaluating ethical review practices (SIDCER, 2005; WHO/TDR, 2005). In the Asian region, 73 ECs/IRBs have already been recognized (FERCAP, 2010). To facilitate our collaboration with these recognized ECs/IRBs, we formed the *Network of Asian Recognized Ethics Committees* (NAREC) as a subcommittee within FERCAP composed of ECs/IRBs from Bhutan, China, India, Indonesia, Philippines, South Korea, Sri Lanka, Taiwan, and Thailand.

All these successful collaboration with partners in ethical health research would not have been possible without the hardworking efforts of some key FERCAP members. Foremost among these key members

are Dr. Juntra, the "mastermind" behind the establishment of FERCAP and Francis, the "philosopher" who drafted the forum's foundational documents. Through the years, we are also lucky to have among our ranks Dr. Vasantha, Dr. Suriadi, Dr. Kenji, Dr. Mary Ann Lansang and Dr. Cristina Torres of the Philippines, Dr. Anoja Fernando of Sri Lanka, Dr. Benjamin Kou of Taiwan, and Dr. Kesara who provided us with strong leadership. Dr. Heidi Liu of China and Atoy Navarro of the Philippines also provided the forum with a strong Secretariat under the leadership of Dr. Cristina.

Looking back, choosing the right persons who provide FERCAP with strong leadership and management is one of our keys to success. Having the cooperation and support from our members is also an important key for our fruitful collaboration with partners in ethical health research. We all work in effective, efficient, and transparent manner to provide the right activities that adhere to the right principles and practices for ethical health research. The right people, the right activities, and the right principles and practices -- these are our keys to success.

The Future of FERCAP

Although a lot has improved, the capacity for ethical review in the Asia-Pacific region still needs continuous and further development especially in the face global challenges in ethical health research. We in FERCAP must remain strong to continue to play our important role in the capacity building and quality improvement of ECs/IRBs in our region.

To keep FERCAP strong and make us even stronger, we need the strongest commitment from our members in every country to adhere to our principles and practices, maintain our main activities, support our Steering Committee and Secretariat, and encourage more and more participation from our present and future members.

With the strongest commitment from our members in every country, I see more and more decades of fruitful collaboration with partners in ethical health research.

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SIDCER @ 10

Juntra Karbwang-Laothavorn, M.D., Ph.D.

The *Strategic Initiative for Developing Capacity in Ethical Review* (SIDCER) is an independent public-private partnership initiative. SIDCER promotes responsible decision-making within countries and institutions so that research participants and their communities experience a real value from ethical review and its contribution to health research. SIDCER provides the international community with not only a means to build in-country human subject protection programs, but also a way to measure and provide accountability regarding the quality and effectiveness of ethical review worldwide. This is the approach SIDCER set out from the start, and it is the approach SIDCER will remain true to over the next 10 years.

The Beginning

In 2001, SIDCER was launched under the aegis of the UNICEF/UNDP/World Bank/World Health Organization *Special Programme for Research and Training in Tropical Diseases* (WHO/TDR) as a public-private partnership project. SIDCER is designed to address the principal gaps and challenges in ethics encountered in global health research.

Based on the experience of SIDCER over the past 10 years, it was found that differences in the standards and practices of ethical review in different institutions have contributed to inhibiting progress in health research. This is not acceptable, especially from an ethical perspective. Research is needed to prevent or alleviate suffering brought about by disease. Ethics committees do function differently in

different countries and different institutions. No one model that will work for all ethics committees around the world. Nevertheless, ethics committees have an obligation to raise their standards and improve their practices by working more closely with one another and those who carry out the research.

The initiative's network of regional fora creates unique opportunities for professional development and learning, while fostering innovative approaches to cross-cultural, cross-national, and cross-regional understanding and mutual support. These fora span the world, and include **FERCAP** (*Forum for Ethical Review Committees in Asia and Western Pacific Region*) in Asia and Western Pacific, **FLACEIS** (*Fora Latino Americano de Comites de Etica en Investigación en Salud*) in Latin America, **PABIN** (*Pan-African Bioethics Initiative*) in Africa, **FECCIS** (*Forum for Ethics Committees in the Confederation of Independent States*) in Eastern Europe (the former Soviet Union), and **FOCUS** (*Forum for Ethical Review Boards/Institutional Review Boards in Canada and the United States) in North America*).

The Aim

The aim of SIDCER is to ensure global protection for all people participating in health research through partnerships that cross cultures, societies, sectors, and organizations. This vision is expressed in its organizational structure as well as in the activities and guidance it develops and promotes.

The Organization

The organization comprises a steering committee, advisory board, and secretariat. The steering committee is responsible for the program development and funding. Members include representatives from the regional fora and from invited partner organizations.

The initiative's advisory board is composed of representatives of organizations involved in international health research and ethics. Its function is to advise the steering committee on the objectives and development of SIDCER and its projects.

The secretariat provides overall coordination of the activities of SIDCER and helps to promote international and multi-sectoral cooperation with the initiative.

The Mission

SIDCER's overall mission is to foster competent and independent in-country decision-making to promote the responsible conduct of human research through its network of fora and to monitor the quality and effectiveness of ethical review worldwide. Mutual understanding and respect for cultural, regional, and national differences plays a vital part in this process, along with education at all levels, both formal and non-formal.

The Activities

SIDCER supports relevant regional structures and activities, including meetings and workshops to build local capacity for ethical review, strengthening and expanding its international network. The training curriculum on human subject protection and the standards operating procedures (SOP) training workshop for ethics committees have been performed within the regional fora.

To develop ethics in health research within the context of local values, SIDCER takes into account international standards like the WHO/TDR *Operational Guidelines for Ethics Committees that Review Biomedical Research* (2000), as well as national and international ethical and regulatory frameworks linked to ethical review. SIDCER promotes the development of quality assurance and processes for improvement in health research ethics, focusing primarily on ethical review practices in its publication of *Surveying and Evaluating Ethical Review Practices* (2002*)*. SIDCER also promotes sustainable in-country infrastructure for ethical review and provides a systematic approach to surveying and evaluating ethical review practices.

In 2003, SIDCER worked together with the *Western Institutional Review Board* (WIRB) in the establishment of the post-graduate fellowship program on bioethics and ethical review. The aim

of the program is to better understand ethics in different settings and to enhance the capacity of individuals from different countries to develop and apply ethical principles and practices when reviewing health research. The goal has been from the start to develop an enabling environment that promotes shared values and a common understanding of best practices for protecting research subjects. In the past 7 years, the program has trained 62 scientists from the regional fora countries. Most of these fellows now play a pivotal role in promoting ethical health research in their own countries and in shaping the growth of the regional fora.

In 2005, SIDCER launched the *SIDCER Recognition Program* to assess and evaluate the ethical review practices of ethics committees. The five SIDCER standards were established based on the WHO/TDR *Operational Guidelines for Ethics Committees that Review Biomedical Research* (2000) and the *International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Harmonized Tripartite Guideline-Guideline for Good Clinical Practice (GCP)* (1997). The SOPs for the recognition program and the SIDCER surveyors' training curriculum were developed, and the SIDCER surveyors were trained. The three ethics committees that were surveyed during the first year of the program were the *Joint Institutional Review Board* (JIRB) in Taipei, the *Changhua Christian Hospital Institutional Review Board* in Changhua, and the *Royal Thai Army* Medical Department Institutional Review Board in Bangkok. The *SIDCER Recognition Program* SOPs and the surveyors' training curriculum have been revised, taken into account the experiences from the first year surveys. The external evaluation of the recognition programme has been performed after 5 years of its implementation to further improve and maintain the quality of the surveyors' training, surveyors, and the operation of the recognition program.

In 2010, the human subject protection training curriculum was harmonized and the core presentations for the course have been developed.

The Progress

After 10 years of its existence, SIDCER managed to establish local training and capacity strengthening program, competent ethics committees, and ethical review system in 12 countries/areas (Bhutan, China, India, Indonesia, Philippines, Sri Lanka, South Korea, Taiwan, Thailand, Ethiopia, Russia, and Uganda), a total of 76 ethics committees have been recognized as compliance with international standards. These ethics committees have served as national and international benchmarks that define the performance of ethics committees in Asia and Africa. They continue to influence the national research environment towards more defined ethical regulations and infrastructures towards more accountability in the conduct of health research. The process of establishing systems and infrastructure for the ethics committee accreditation is on going in two countries, *i.e.,* Thailand and the Philippines.

The Challenge

Creating sustainable ethical review system in research is a daunting task but it is imperative for quality research. The research stakeholder network is vital for the development and maintaining the quality of the system. In addition, "political will" needs to be fostered not only at the international levels but also nationally, so that health research and human subject protection are placed at the top of the political agenda.

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REVIEWING THE ETHICAL REVIEWERS: THE SIDCER/FERCAP EXPERIENCE*

Lisa Hamadian, M.D. & Allan K. Johansen, D.V.M.

Despite playing a key role in a clinical trial, the ethics committee (EC) is an entity over which sponsor auditors have no jurisdiction. Auditors may gain an insight into the ECs' processes by indirectly examining and reviewing their documentation in the trial master file, including membership details, approval letters, correspondence pertaining to the study and sometimes their standard operating procedures (SOPs). They may also schedule an interview with the Chairman or any member of an EC to discuss and exchange better practices. With this limitation to the audit, what is beyond the documentation (and a short interview during an investigator audit), is a complete unknown for the sponsor and their auditors.

Ethical Review Evaluations

There is growing national and international interest in ensuring that ethical review processes achieve the highest standards with regard to protecting individuals and communities. The assurance of research subject protection requires that ethical review standards are established and these along with the performance of the EC, are evaluated.

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* Revised and updated version of the paper published in *GCPj (Good Clinical Practice Journal)*, Informa UK Ltd, May 2008, 8-10. The authors wish to thank Prof. Dr. Juntra Karbwang-Laothavorn of WHO/TDR for the permission given to write this article as well as quote parts of the WHO Guidelines. They would also like to thank Prof. Dr. Cristina Torres of FERCAP for the information relating to areas of improvement and recommendations for ECs.

With this in mind, the *Special Programme for Research and Training in Tropical Diseases* (TDR) of the *World Health Organization* (WHO) published two guidelines. The first was the *Operational Guidelines for Ethics Committees that Review Biomedical Research* (WHO/TDR, 2000), which aimed to facilitate, support, and ensure that the quality of the ethical review of biomedical research is maintained worldwide. This was followed by *Surveying and Evaluating Ethical Review Practices* (WHO/TDR, 2002), which contributed to an international framework for surveying and evaluating ethical review practices. This guideline suggests a cooperative and educative model and is less concerned with the "enforcement" of standards and more with "learning" from the review of EC practices.

Under the WHO, the *Strategic Initiative for Developing Capacity in Ethical Review* (SIDCER) was formulated as a network of independently established regional fora for ECs, in five regions of the world (WHO/TDR, 2005). These are:

- *Forum for Ethics Committees in the Confederation of Independent States* (FECCIS)
- *Foro Latino Americano de Comites de Etica en Investigacion en Salud [Latin American Forum of Ethics Committees in Health Research]* (FLACEIS)
- *Pan-African Bioethics Initiative* (PABIN)
- *Forum for Institutional Review Boards [IRBs]/Ethics Review Boards [ERBs] in Canada and the United States* (FOCUS)
- *Forum for Ethical Review Committees in the Asian and Western Pacific Region* (FERCAP)

SIDCER has established a framework for surveying and evaluating ethical review practices through a recognition (or accreditation) program. Since 2004, SIDCER/FERCAP has conducted a series of training seminars in Asia for potential surveyors (who are mostly EC members in their respective countries) to carry out the recognition survey, as well as training for EC members in general. Surveys, the methods of which are similar to an industry audit, have been carried out since 2005 with those interested in the *SIDCER Recognition Program*.

The SIDCER Survey

The objectives of the survey are to facilitate and assist ECs toward achieving quality and transparency in ethical review, and to provide feedback on the practices and performances of the EC based on the SIDCER standards in the following areas:

- Structure and composition of the EC
- Adherence to policies and regulations
- Completeness of its review procedures
- Adoption of post-review procedures
- Documentation and archiving

There are numerous benefits to participating in the survey program (Box 1). Before starting this process, an EC requesting a survey must fill-in a self-assessment checklist to assess whether they will later be evaluated. For every survey, a survey team is identified. This team consists of two trained and qualified independent surveyors not originating from the country being surveyed, one local surveyor, and several in-country trainee-surveyors who also act as translators, if required. The survey team members are bound by a confidentiality agreement, signed prior to the survey. They must also declare any conflict of interest (COI) and agree to follow the SIDCER SOPs for surveying and evaluating ethical review practices.

Box 1: *Benefits of Participating in a SIDCER Survey*

- Assurance to the public that the EC protects research subjects from harm and exploitation and preserves their rights
- Validation of compliance with established international standards (for example, WHO, ICH-GCP) which require the ethical and scientific review of research
- An objective evaluation of good practices by independent external surveyors
- The opportunity to learn from the experiences of other countries
- Upgrading the quality of ethical review globally
- The recognition of respectable ECs for the protection of human subjects

Program Activities

A survey plan is presented at the opening meeting. This comprises a three-day activity program, which includes a tour of the EC office, interviews with members and staff, a review of documents and files, and the observation of a full EC board meeting. A final meeting is held at the end to summarize and discuss the survey's findings.

The review of documents and procedures is a tedious and time-consuming exercise. Completing this task in the allotted timeframe is challenging, largely due to the volume of documents to review and the cross-referencing and consistency checks required. A review and evaluation are performed on the following:

- Applicable national laws and regulations for the EC
- All EC SOPs
- Membership files (for example, an individual's *curriculum vitae*, terms of reference, letter of appointment, initial and continuous training records –- including evidence of GCP training)
- Protocol files (a representative sample of protocols reviewed by the EC in the past three years)
- EC documents for reviewing serious adverse event (SAE) reports
- Board meeting agendas and minutes
- Communication records with, for example, applicants, regulatory authorities or the authority under which the EC is established

Observation of a full board meeting, where protocols are addressed and discussed, is carried out to evaluate group dynamics, the management of COI, and the actual adherence to written SOPs –- Are the EC's decision-making procedures in line with their SOPs? Do they follow the "write what you do and do what you write" approach? The surveyors are also required to observe the effectiveness and quality of the review process. Stemming from these surveys, common problems have been identified and consequently recommendations were made (Box 2).

After implementing acceptable corrective action, recognition will be granted to an EC for a maximum period of three years. A recognized EC will be required to produce annual reports for review and monitoring by the SIDCER committee. This should include all relevant activities of the EC in the past year, any amendments to the SOPs and guidelines, and/or new SOPs introduced. Up until the end of 2010, 73 ECs in Asia, including Bhutan, China, India, Indonesia, Philippines, South Korea, Sri Lanka, Taiwan, and Thailand had been surveyed and recognition awarded (FERCAP, 2010) (Box 3).

Box 2: *Common Recommendations to Ethics Committess Following a SIDCER Survey*

EC Structure and Composition

- Improve gender representation (research has impact on the health of both men and women)
- Initiate early and on-going training
- Empower lay persons to raise relevant issues
- Train medical members to assess risks and vulnerability
- Address COI in board membership

EC SOPs

- Address gaps between SOPs and practice
- Improve consistency and completeness of SOPs
- Availability of forms and checklists
- Completeness of review process
- Improve risk assessment processes
- Provide better protection to vulnerable subjects
- Improve the evaluation of investigator team qualifications
- Provide complete patient information sheets
- Check that informed consent form contents reflect the relevant patient information

Board Meetings

- Meet quorum and COI requirements
- Produce complete meeting agendas and minutes, and standardize these
- Organize comments and the flow of discussion
- Summarize issues for board decision
- Consider both scientific and ethical issues
- Improve member preparation for board discussion

Post-Review

- Identify investigator post-review responsibilities in an approval letter
- Suggest appropriate action for SAE reports
- Define investigator responsibilities following study termination
- Submit and follow-up both progress reports and end-of-study reports
- Use a database to monitor approved protocols
- Take appropriate action to address patient queries and complaints

EC Office and Archiving

- Ensure privacy and confidentiality protection
- Provide appropriate facilities for EC functions
- Compile complete protocol files that trace its history
- Ensure availability and completeness of files
- Check separation of active and completed protocols with proper coding and recording

Box 3: *Asian Recognized Ethics Committees*

Bhutan

- Research Ethics Board of Health (REBH), Ministry of Health (MOH) - Bhutan [Thimphu | 2010]

China

- Shanghai Changhai Hospital Ethics Committee, Second Military Medical University (SMMU) [Shanghai | 2007, 2010]
- Affiliated Hospital of Nanjing University of Traditional Chinese Medicine Institutional Review Board [Nanjing, Jiangsu | 2007, 2010]
- Huashan Hospital Institutional Review Board (HIRB), Fudan University [Shanghai | 2008]
- Ethics Committee of the First Affiliated Hospital, Nanjing Medical University, Jiangsu Province Hospital [Nanjing, Juangsu | 2009]
- Southwest Hospital Institutional Review Board [Chongqing | 2010]
- Ethics Committee of Xi Yuan Hospital of China Academy of Chinese Medical Sciences [Beijing | 2010]
- Ethics Committee of Guangdong Provincial Hospital of Traditional Chinese Medicine [Guangzhou | 2010]

- Beijing Tiantan Hospital Institutional Review Board, Capital Medical University [Beijing | 2010]
- Ethics Committee of the Second Affiliated Hospital of Tianjin University of Traditional Chinese Medicine [Tianjin | 2010]
- Shanghai Cancer Center Institutional Review Board (SCCIRB), Fudan University [Shanghai | 2010]

India

- Tata Memorial Centre Human Ethics Committee (TMC-HEC) [Mumbai | 2009]
- Ethics Committee for Research on Human Subjects (ECRHS) of SETH G.S. Medical College and King Edward Memorial (KEM) Hospital Institutional Review Board [Mumbai | 2009]

Indonesia

- National Institutes of Health Research and Development (NIHRD) Ethics Committee [Jakarta | 2009]

Philippines

- University of the Philippines Manila (UPM) National Institutes of Health (NIH) Ethics Review Board [Manila | 2007, 2010]
- Research Institute for Tropical Medicine (RITM) Institutional Review Board, Department of Health (DOH) - Philippines [Muntinlupa, Metro Manila | 2007, 2010]
- University of the Philippines Manila (UPM) College of Medicine (CM) Research Implementation and Development Office (RIDO) Ethics Review Board [Manila | 2007, 2010]
- University of the Philippines Manila (UPM) Philippine General Hospital (PGH) Ethics Review Board [Manila | 2010]

South Korea

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- Inje University Busan Paik Hospital (IJUBPH) Institutional Review Board [Busan | 2007, 2010]
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- Ajou University Hospital Institutional Review Board [Gyeonggi-do | 2008]
- Inha University Hospital Institutional Review Board [Seoul | 2009]
- Kangbuk Samsung Hospital Institutional Review Board [Seoul | 2009]
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- Keimyung University Dongsan Hospital Institutional Review Board [Daegu | 2010]
- Kyungpook National University Hospital Institutional Review Board [Daegu | 2010]
- Yeungnam University Medical Center Institutional Review Board [Daegu | 2010]
- Kangdong Sacred Heart Hospital Institutional Review Board [Seoul | 2010]
- National Cancer Center Hospital Institutional Review Board [Seoul | 2010]
- CHA Bundang Medical Center Institutional Review Board, CHA University [Gyeonggi-do | 2010]
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Sri Lanka

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Taiwan

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Conclusion

When conducted in an open and honest manner, the recognition survey can identify an EC's strengths and areas requiring improvement. Independent external surveyors provide an objective evaluation of good practice and validate their compliance with international guidelines. The survey has the ability to recognize a competent EC, which can adequately protect human subjects, and it improves the perceived quality of ethical review globally.

The *SIDCER Recognition Program* started in Asia through FERCAP has provided recognition to 73 ECs in the region, with growing interest from others both in Asia and worldwide. This accreditation provides sponsors with the confidence that ethical review of research proposals is carried out according to established guidelines and practices and performance of the EC meet international standards.

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AT HOME @ THAMMASAT UNIVERSITY: THE CASE OF FERCAP & WHO-TDR CCTC PARTNERSHIP

Atoy M. Navarro & Kesara Na-Bangchang, Ph.D.

The terms of reference (TOR) of the *Forum for Ethical Review Committees in the Asian & Western Pacific Region* (FERCAP) was agreed upon by its founding members during its *First General Assembly,* following the *Meeting on Guidelines and Standard Operating Procedures for Ethical Review* organized by the *World Health Organization* (WHO)/*Special Programme for Research and Training in Tropical Diseases* (TDR) and *Thammasat University* (TU) in Bangkok, Thailand on January 10-12, 2000. The approval of the TOR on January 12, 2000 marked the official founding of FERCAP (FERCAP, 2000). This historical information clearly points out that right from the very start, FERCAP has been working with TU in a joint effort to contribute towards ethical review capacity.

From 2000 up to 2008, the FERCAP office was housed at the *Ministry of Public Health* (MOPH) of Thailand through the offices of the *Thai Food and Drug Administration* (FDA) from 2000 to 2004, *Department for the Development of Traditional and Alternative Medicine* (DTAM) from 2004 to 2007, and *Institute for Development of Human Research Protection* (IHRP) from 2007 to 2008. During these years, FERCAP and TU continued to work together especially in offering the annual *International Course on Research Ethics* organized with the University of Bergen (UB) - Norway (TU, FERCAP & UB, 2003). Through the *Graduate Program in Biomedical Sciences* (GPBMS) of the *Faculty of Allied Health Sciences* (FAHS), TU also helps out in the annual *FERCAP International Conference*. From 2008, TU began housing FERCAP in its Rangsit Campus. The FERCAP office was

initially located at GPBMS, FAHS, TU from 2008 to early 2009 before it moved to its present location. In early 2009, FERCAP found its new home at the *WHO-TDR Clinical Coordination and Training Center* (CCTC) at TU.

But the FERCAP and WHO-TDR CCTC partnership at TU is not limited to sharing office space. FERCAP and WHO-TDR CTTC have since worked together for the development of ethical and quality health research (Navarro, 2009). In this short article, we will present the shared vision and mission of FERCAP and WHO-TDR CCTC as well as examples of their successful collaborations from 2009 to 2010.

Shared Vision and Mission of FERCAP and WHO-TDR CCTC

WHO-TDR CCTC is a joint initiative between WHO/TDR and TU (TU & WHO/TDR, 2008; WHO/TDR, 2008). WHO/TDR Scientist and FERCAP Founding Member Prof. Dr. Juntra Karbwang-Laothavorn, TU FAHS Dean Prof. Dr. Vithoon Viyanant, and TU GPBMS Director and FERCAP Treasurer Prof. Dr. Kesara Na-Bangchang were the focal persons who facilitated the formation of the center with Prof. Dr. Kesara serving as its Founding Director (Navarro, 2009). In mid-2009, WHO-TDR CCTC declared its vision as "a leading service provider and catalyst for the development of quality and ethical health research." The center's mission is "dedicated to training and quality management of health research by promoting and evaluating models of integrated systems and facilitating the formation and maintenance of sustainable networks globally" (WHO-TDR CCTC, 2009b).

Not long after WHO-TDR CCTC's declaration of its vision and mission, SIDCER-FERCAP updated its vision as "a leading global network that fosters an integrated and sustainable ethical review system towards quality culture in health research" and its mission as "dedicated to developing capacity for sustainable models of integrated quality ethical review systems through strategic alliances with health research stakeholders" (FERCAP, 2009).

From their vision-mission statements, FERCAP and WHO-TDR CCTC share similar goals geared toward the development of ethical and quality systems in health research through strategic and sustainable

alliances and networks. This shared vision and mission are reflected in the successful programs and projects that were collaborated on by FERCAP and WHO-TDR CCTC.

Successful FERCAP and WHO-TDR Collaborations

WHO-TDR CCTC conducts and facilitates trainings in health research ethics, good clinical practice (GCP), good clinical laboratory practice (GCLP), and clinical data management (CDM). FERCAP Coordinator Prof. Dr. Cristina Torres and FERCAP Research Fellow Mr. Atoy Navarro have been actively involved in various collaborative programs and projects with WHO-TDR CCTC (Navarro, 2009). On February 9-17, 2009, FERCAP participated in the *Workshop on the Harmonization of WHO/TDR Short Training Courses* where various training modules including health research ethics modules were standardized (WHO/TDR, 2009a). Prof. Dr. Juntra presented about the ethical and quality requirements in developing vaccine during the *WHO/TDR Short Course on Immunology and Vaccinology* held on May 4-8 (WHO/TDR, 2009b). Dr. Glenn Laverack and Dr. Pascal Launois of the *WHO/TDR Empowerment Unit* visited the center on May 29-30 to discuss further the partnership with the various programs of WHO-TDR CCTC (WHO-TDR CCTC, 2009a). On June 4-8, the strategic plan of WHO-TDR CCTC was developed during the *Total Quality Management (TQM) Training Workshop* (WHO/TDR, 2009c; WHO-TDR CCTC, 2009b).

FERCAP also took part in the *Good Clinical Practice (GCP) Short Courses* held on July 20-31 (WHO/TDR & WHO-TDR CCTC, 2009). On August 3-7, WHO/TDR, SIDCER/FERCAP, and WHO-TDR CCTC organized the *SIDCER-FERCAP Strategic Quality Management (SQM) Training Workshop* where SIDCER/FERCAP's strategic plan was updated (WHO/TDR, 2009d). FERCAP together with TU, UB, and the *Thailand Center of Excellence for Life Sciences* (TCELS) held the annual *International Course on Research Ethics* at WHO-TDR CCTC on October 5-7 (TU, FERCAP & UB, 2009). WHO-TDR CCTC also gave assistance during the *FERCAP International Conference on Developing Leadership in Ethical Health Research Towards Good Practices and Integrated Systems* held at Chiang Mai, Thailand on November 22-26 (FERCAP, 2009).

Collaborative programs and projects for 2010 started with FERCAP's participation in the *WHO/TDR and WHO-TDR CCTC Strategic Project Management Training Workshop* held on Febraury 8-12 where FERCAP's project charter, project plan, and quality plan were formulated (WHO/TDR & WHO-TDR CCTC, 2010). FERCAP also consolidated the curriculum borne out of the *WHO/TDR and WHO-TDR CCTC Short Course Development Meeting on Ethical, Legal, and Social Issues (ELSI) in Biomedical Product Research and Development (R&D) in Asia* held on March 5-6 (WHO-TDR CCTC, WHO/TDR & FERCAP, 2010). FERCAP also helped out in the *Good Clinical Practice (GCP) Short Courses* held on July 20-31 (WHO/TDR & WHO-TDR CCTC, 2010). And finally, FERCAP together with TU, and the *Forum for Ethical Review Committees in Thailand* (FERCIT) held the annual *International Course on Research Ethics* at WHO-TDR CCTC on September 27-30 (TU & FERCAP, 2010).

The Future of FERCAP and WHO-TDR CCTC Partnership @ TU

FERCAP's partnership with TU dates back to the forum's foundation year. But recently, this cooperation was strengthened with the housing of FERCAP at TU and the establishment of WHO-TDR CCTC. FERCAP and WHO-TDR CCTC have a shared vision and mission and they worked together successfully on various programs and projects during the last two years.

In the years to come, it is expected that FERCAP and WHO-TDR will continue to collaborate especially with the offering of training courses as the main focus of their cooperation. Foremost of these training courses are the ongoing annual *International Course on Research Ethics* and the soon to be offered *Short Course on Ethical, Legal, and Social Issues (ELSI) in Biomedical Product Research and Development (R&D) in Asia*.

With this continuing partnership, FERCAP and WHO-TDR CCTC are indeed at home @ TU.

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FOSTERING COMMON GOALS & SHARING VALUES: REVISITING FERCAP'S REGIONAL ALLIANCES*

Rachel Douglas-Jones, M.A.

Why might an anthropologist find the work of the *Forum for Ethical Review Committees in the Asian & Western Pacific Region* (FERCAP) interesting? Anthropologists study all aspects of human life, paying close attention to what people do and say. In my doctoral research, I focus on notions of capacity building and governance and have attempted to understand what gives FERCAP its distinctive organizational culture. As part of a *United Kingdom* (UK) *Economic and Social Council* (ESRC) project on *International Science and Bioethics Collaborations*, the work is a contribution to studies of biomedical science in action and the consideration of the place of ethics in practice (UK ESRC, 2007-2010). The methods employed for this research were primarily qualitative, involving semi-structured interviews and participant observation, as well as the analysis of documents and photographs. In interviews, I asked members of FERCAP why they were involved in ethical review, I talked to them about some of the challenges and difficulties but also about rewards and positive experiences. I was able to meet and talk with trainers and surveyors in five countries. As I have got to know members of the international medical community, I am certain that many of you who I have interviewed have been to twice as many countries in the same period, for conferences, events, teaching lectures, and trainings. FERCAP both represents and is a community distributed across the region. Findings presented here will be a familiar commentary to those

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who are a part of FERCAP, as they reflect experiences shared with one another and with me as I attended surveys, trainings, conferences, and meetings. In this paper, I reflect on to the kinds of exchanges that go on in the events that are organized. I then turn to some of your comments and metaphors to look at how common goals and values are generated and sustained, and finally, consider how these contribute to growing the network you run.

Exchange is a well established theme in anthropological literature. One of the classic texts in Anthropology is *Argonauts of the Western Pacific* (1922), in which Bronislaw Malinowski writes about his experiences in the Trobriand Islands. These are a small group of islands off the eastern coast of Papua New Guinea, where Malinowski lived for many years during the Second World War. Today anthropologists continue to study the social relations of the people with whom they live. When Malinowski studied the Trobriand Islanders, he became fascinated by a network of exchange of valuable items that stretched across the islands. Through observations and by joining them on their canoe voyages, he found a pattern to the journeys, the gifts, and the ceremonies. The beautiful and valuable amshells they passed on were part of a rotating system of exchange that flowed anticlockwise, and necklaces were part of a rotating system of exchange that flowed clockwise. This system was called Kula.

As members of FERCAP will know, people are nowadays incredibly mobile, and their social networks are massively dispersed. Members of FERCAP clearly don't exchange shells, but they do exchange a different sort of "valuable." One is as physical, as tangible as the shells and necklaces -- files and paperwork. The other is far more intangible: experiences of ethical review practices. In focusing on what passes between members, I have noticed that in doing this work, another sort of valuable is created: the relationships between members which support and run a network of volunteer surveyors and trainers. Trainings and surveys are sometimes described in the language of exchange -- the exchange of information. We all experience exchanges in daily life; we are familiar with the market. Where there are things that can be passed between parties, they are commensurable. But this is quite impersonal language. Usually in economic or market exchanges we do not see the person we transacted with again. There isn't much point in earning their respect or their friendship, sharing

useful advice. That is why I am suggesting that what is going on in the FERCAP network is not *just* an exchange of information and experience, but it incorporates a dimension of reciprocity unusual in contemporary organizations.

Trainings, Paperwork, and Information

Let us first reflect on why members of FERCAP exchange files, experiences, paperwork, and processes. As each of FERCAP's annual conferences show, the massive growth of the clinical trials industry is the cause of much of FERCAP's activities and concerns. FERCAP wants to develop regional capacity in ethical review and contribute to good research practices. Many members with whom I spoke stated that the primary goal is to contribute to human subject protection globally through better ethical review practices. However, with many different research environments, institutional and legislative contexts, it might be difficult to coordinate the effort. FERCAP hopes to ensure that the challenges faced across the region can be made into something that can be tackled through a common approach. This common approach involves the regular exchange of stories, advice, processes, and experiences.

Observations during the research have found that FERCAP trainers regularly incorporate the knowledge and stories they gain from surveys and meetings around the region into training sessions. Thus FERCAP trainings serve multiple purposes. As well as the primary activity of imparting information to participants, they provide the opportunity for people to ask questions, and aim to generate an environment that is conducive to learning. Trainings are also an opportunity for making a sense of community, as is evident in one statement I heard: "we form a group of ethics committees and act together to ensure we act ethically and ensure ethics is being carried out in each institution." In this description, the members of ethics committees form under common goals. But trainees don't necessarily start out having common goals. One trainer commented that

> At the beginning they don't care. Then they start to listen. It's… transformative. At the beginning they don't care, then they hear… You see them change, from

> the baseline to the end; they see different things; this one is not about the knowledge, more about motivating them.

While the purpose of much research ethics training around the world is based on the imparting of information, we can see that the goal of FERCAP trainers is also to produce a competent subject, someone who is not just aware of ethics but also capable of performing ethics related tasks and reflecting on them. As one trainee said: "I think the idea is that we police ourselves not that the regulators tell us what's wrong with us." Bringing people together in training sessions, then, is not done solely to educate then, but also to inspire and offer encouragement. An important part of what has been called the "FERCAP model," is that the goals and values are intertwined, made, and reinforced through these interactions. In achieving a goal of training committee members, the training sessions also communicate values including cooperation and friendship. While the effectiveness of training is tested by measuring individuals, an aim that is impossible to quantify -- and one which is therefore not captured -- is the friendships and relationships that develop during these sessions. These relationships also have effects that are difficult to capture.

Surveys, Friendships, and Metaphors

Bob Layton (1997, 101), a social anthropologist has noted that "reciprocal exchanges differ from market exchanges because they are used to create or maintain ongoing social relationships between the participants." One of the events that I both participated in and observed in detail was the process of conducting a survey. A survey *could* operate like this: the date is arranged, the surveyors come. They do their work, they deliver their verdict, and they leave. But as one of the surveyors put it, simply coming to do a survey *is not exchange for getting recognition*. The end of the survey is not the end of the relations. The parties -- both surveyed and surveyors -- part with obligations and responsibilities. The surveyors will prepare a report, the surveyed committee will act on it, and their response will be assessed. This is still not the end. It leads to another event, one that takes place at the conference, where delegates of recognized committees receive their plaques of recognition in the company of

colleagues. This could also be the end, but it is not. As part of a commitment to ongoing improvement and quality control, the committee will be resurveyed in three years. Trainees at the survey may go on to survey other committees, the surveyed become the surveyors, and so the connections continue.

Metaphors used by members of FERCAP offer a distinctive imagery through which to consider what the organization is trying to achieve. Linked with the ongoing connections of the survey, one of the most striking metaphors links the network to the idea of a family. The FERCAP conference is one of the best opportunities to see this metaphor in action, as people travel from across the region to meet up with one another. At the conference in 2009, one attendee commented that at the conference, "you have a lot of family members, everyone can see you, everyone can do something for you." It is a place to go for support and also for friendship. Many conferences in ethics are about "updating one's knowledge," and of course this is important. But the FERCAP conference is also about seeing people and consolidating relationships. As one member commented last year, "If you are just here to talk about yourself, that is not the way, that is not the attitude, we are family in the region."

Another way in which members of FERCAP have tried to explain their feelings and motivations about the network is through the images of houses. "We may have a really nice house," commented a conference attendee "but the house might not be in a nice environment. We have to think about that, have to have some shared values." I asked her to elaborate:

> If you have your house and it is nice, you cannot just be happy with that. You need to think about what is around it. That is our values. You cannot just care about your house; you need to care about it all!

This comment shows how members of FERCAP think across borders, and think regionally when they consider the work of their network. Of course, the region covered by FERCAP includes nations with very different experiences of and priorities in hosting and conducting research. Ethics review committees are differently institutionalized, supported, and tested. Despite this, FERCAP

members regularly demonstrate both sensitivity to and accommodation for the differences. Another metaphor shows that this accommodation isn't always easy:

> FERCAP lives in a big house, but sometimes they don't know the other culture is in the house. Even though the house is big and has everything, in other culture you need to change and change your regulations, depending on people's culture. Can't just say everything you're right and other is wrong.

In this quote, at the same time as acknowledging the necessity for attention to flexibility, by the house as a metaphor, the speaker illustrates how his thought returns to imagining the challenges as a common problem by situating everyone in the same house.

Models, Measurement, and Networks

Conventional thinking dictates that when we design a model, we take it and implement it across a variety of settings. To a large extent, this is what *International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use* (ICH, 1997) and the *World Health Organization* (WHO/TDR, 2000) guidelines on ethics review committees are. Or as many of you have put it to me, they are a recipe. But, as with cooking, it matters when we put ingredients in. One of the ways in which FERCAP excels is that it appraises and tailors its recommendations to the committee in question, commenting on its resources, the kind of institutional support it has, the experience of its staff and its members. Surveys include an interview with members of the committee to take their views into account, and during the final report meeting, members are encouraged to be present so that they can ask questions, query particular recommendations. This has also been described in terms of cooking! As one member said to me,

> FERCAP is a bottom up organization. We don't want people to have a meal, we say let's cook together. It's not "you will eat now and this is what you will eat and this is what you will cook."

This doctoral research has not been designed to produce statistics upon which recommendations for improving capacity building can be based. It has been about listening to the narratives, metaphors, and stories FERCAP tells about itself. In feeding back analyses of findings to you, it is in the hope that you will find them interesting, and perhaps even useful in some way, whether that is in arranging further activities, implementing them, or simply reflecting on what it is you are engaged in at this 10 year juncture. I would offer only one comment of caution on the proliferation of measurements. Measurements are extremely useful: we can use them to tell how well we are doing, where we can do better, and to some extent, how we can improve actions and processes. However, when everyone is focused on striving for improvement and committed to quality work, there is a tendency towards the measurement of all things. But as I think the metaphors I have highlighted here illustrate, there are qualities in your network and actions that cannot be quantified. Not all the qualities of people, or their relationships, are measurable. As the people of your network and the relationships they form between one another are one of your strongest resources, there may be ways other than measurement -- such as personal profiles, commentaries, peer-to-peer networking, life experience reflections, and newsletter articles -- that could celebrate this.

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REFLECTIONS ON THE FERCAP EXPERIENCE: MOVING FORWARD WITH PARTNERSHIPS AND NETWORKS*

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Reflecting on the *Forum for Ethical Review Committees in the Asian & Western Pacific Region* (FERCAP) experience for the past decade, my position as FERCAP Coordinator since 2004 affords me a unique vantage point to assess its contribution as an organization. I consider my personal involvement as both an advantage and a disadvantage since I could be subjective in making this assessment. But I think that a firsthand experience is very valuable in providing insights on FERCAP's early years and I consider it a great honor and special privilege to have contributed to its direction and growth during its early years. It has made research ethics an important part of my career as a social scientist and I am proud of my personal contribution to this important field.

First, I would like to reflect on how my work in FERCAP contributed to my professional growth. I became involved in research ethics committees (RECs) in the late 1990s as a social scientist who voiced out community concerns in a biomedical committee at the *University of the Philippines* (UP) *College of Medicine*. There was no model to follow and we devised our own means to review clinical trials submitted to the committee. In 2003, I was sent for a fellowship at the *Western Institutional Review Board* (WIRB) with funding from the *World Health Organization* (WHO) and the *Fogarty Grant* of UP. My local academic experience was enriched by the fellowship and when I

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was appointed as FERCAP Coordinator in 2004, I was ready to work at the Asian regional level. As Coordinator, my job was to plan, implement, and coordinate FERCAP activities related to capacity building of RECs. My work has enabled me to understand FERCAP's potential and eventual role in improving the environment for human subject protection in the Asia-Pacific region. Visiting our partner countries made me realize the urgency of the work to build an ethical review infrastructure that we could promote. I soon realized that FERCAP's unique role was to develop and advocate for a systems approach in ethical review. We worked on developing a template for standard operating procedures (SOPs) that we encouraged our member partners/countries to adopt. We were interested in developing country models of ethics committees (ECs)/institutional review boards (IRBs) that could be replicated at the national and regional levels. My work and FERCAP experience were largely influenced by my social science perspectives and background in social history and my participation in health governance. I was convinced that ECs/IRBs were vital to good institutional and national health research governance that should take into consideration the local culture and traditions.

In support of the ethical review system that we were promoting, we were able to develop the curriculum for human subject protection to enable members of ECs/IRBs and investigators to understand the rationale, the principles, and their application to preparing and analyzing health research protocols. Together with the SOP training, we were able to operationalize the various ethical principles to enable ECs/IRBs to perform their tasks and regulatory mandate. The *Strategic Initiative for Developing Capacity in Ethical Review* (SIDCER) *Recognition Program* was soon implemented as a means to voluntary assess RECs related to their compliance with international ethics guidelines and local regulatory requirements. The *SIDCER Recognition Program* was successful in reinforcing our advocacy for a systems approach to ethical review. The approach was to recognize the contribution of individual ECs/IRBs to human subject protection and to publicly acknowledge their contribution during the annual FERCAP Assembly. Soon, we were training and surveying ECs/IRBs in developed economies like Taiwan and South Korea and emerging economies like Thailand and the Philippines. Other stakeholders took notice and we were invited to present our program at international conferences of the *European Medicines Agency* (EMEA), the *Drug*

Information Association (DIA), WHO, and national conferences and meetings in Asia, Europe, Africa, and North America.

In analyzing the organization, I will focus on what I believe are the FERCAP's essential factors for success: a) worthy cause, b) organizational focus, and c) shared values.

Worthy Cause

An organization's work is judged based on its worthy objectives and its ability to achieve its objectives. When FERCAP was founded in 2000 to serve as a regional forum of ECs/IRBs in Asia, its strategic objectives were clearly defined. They served as important organizational milestones that defined FERCAP's achievement. The strategic objectives (Table 1) were based on a clear understanding of the bioethics environment in Asia in 2000 when ECs/IRBs were weak and did not understand their roles and functions. After all, the *International Conference on the Harmonization of Good Clinical Practice* (ICH-GCP) that institutionalized ECs/IRBs was only promulgated in 1997.

Table 1. SIDCER/FERCAP Strategic Objectives (2000-2010)
• To improve communication among ECs/IRBs reviewing health research in the region
• To act as a regional collaborating center for EC/IRB members, investigators, sponsors, regulators, patients, and stakeholders in health research
• To organize international meetings and symposia
• To assist with the adoption and implementation of SOPs for ethical review in the region, taking into consideration the *World Health Organization Special Programme for Research and Training in Tropical Diseases (WHO/TDR) Operational Guidelines for Ethics Committees that Review Biomedical Research* (2000)
• To facilitate training and education opportunities for health research stakeholders in the region

- To coordinate regional communication about ethical review of research with WHO and other international organizations involved in ethical review (FERCAP, 2000)

FERCAP's worthy cause was strengthened by its operational framework that advanced a duty-based ethics. It was clear that FERCAP's audience were members of the scientific community, rather than patients and participants in research. Strategically, it made sense to emphasize beneficence and the duty of the scientific community to protect research participants. The duty-based approach in research ethics was also clearly understood in the East Asian setting that is clearly steeped in the Confucian tradition of beneficent governance and grounded in the Buddhist principle of selflessness. Consequently, it became important to promote transparency and accountability for health research stakeholders (sponsors, investigators, institutions, ECs/IRBs) to prevent harm to participants in the course of research.

FERCAP's operational framework also aims to institutionalize a check and balance system in health research governance and set up an external quality assurance system. These are modern concepts in organizational governance that further strengthened the focus on the traditional "duty to protect." The operational framework defined the strategic approach to implement FERCAP's objective "towards capacity building of stakeholders and quality improvement of ECs/IRBs in the Asia-Pacific region." By 2010, it is safe to claim that FERCAP's strategic objectives were achieved with the training held in almost all countries in Asia and 73 recognized ECs/IRBs in 9 countries/areas and changes in guidelines and regulations in FERCAP areas being implemented.

For its second decade, the SIDCER-FERCAP strategic objectives have been redefined and upgraded based on its achievements during the previous period (Table 2). In 2009, during the *SIDCER-FERCAP Strategic Quality Management (SQM) Training Workshop* in Bangkok, the strategic plan was updated with the vision of becoming "a leading global network that fosters an integrated and sustainable ethical review system towards quality culture in health research" and with a mission "dedicated to developing capacity for sustainable models of integrated quality ethical review systems through strategic alliances with health research stakeholders."

Table 2. SIDCER/FERCAP Strategic Objectives (2010-2020)
• To foster teamwork and strategic partnerships at the national, regional, and international levels with human research stakeholders sharing common values and common goals
• To promote quality culture in ethical review of health research
• To facilitate training and providing education opportunities for health research stakeholders
• To establish monitoring and evaluation programs for continuous quality improvement of ethical review systems (WHO/TDR, 2009)

Organizational Focus

Lest FERCAP be lost with its multiple objectives, the forum makes sure that it is well grounded and has organizational focus. Diagram 1 summarizes the activities to achieve the strategic objectives. The FERCAP Secretariat is busy all year round doing training with strategic in-country partners and surveying individual ECs/IRBs to assess their practices in compliance with international and national guidelines and regulations. It has formed strategic alliances with academic and public sector partners to promote its advocacy in various countries.

FERCAP has established its niche in the field of bioethics with its focus on developing and sharing its modules to organize an ethical review system that is able to apply the ethical principles found in international guidelines to the review of protocols submitted to the RECs (Table 3). It emphasizes compliance with the following international guidelines: a. *Declaration of Helsinki* (WMA, 2008), b. *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (CIOMS, 2002, 2009), c. *ICH Harmonized Tripartite Guideline-Guideline for GCP* (ICH, 1997), and d. *Operational Guidelines for Ethics Committees that Review Biomedical Research* (WHO/TDR, 2000). At the same time, its various country partners emphasize compliance to local regulations and guidelines for ethical research.

Diagram 1: *FERCAP Strategy*

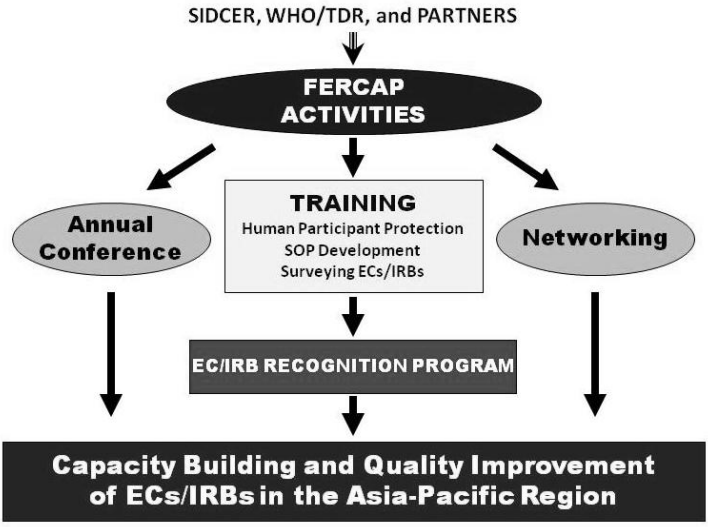

Table 3. *FERCAP Initiatives in Support of Ethical Review Systems*

Ethical review system goals	FERCAP initiatives
Protection for research participants	*Human Participant Protection Course* (HPPC)
Consistency and cooperation	*Standard Operating Procedure* (SOP) *Development Course*
Highest attainable quality in science and ethics	*SIDCER Recognition Program*

In the review of clinical trials, the emphasis is on compliance with ICH-GCP to enable credible data reviewed by compliant ECs/IRBs from Asian sites to be accepted by regulatory authorities of sponsor countries in the United States and Europe. Through training and voluntary assessment of ECs/IRBs, GCP violations and deviations in Asian sites could be minimized. FERCAP highlights best practices from its member country partners and institutions. Some of these practices include assigning a role for non-medical/non-scientific members like lawyers and community representatives, emphasis on risk assessment of clinical interventions by physician members, use of primary reviewers and joint ECs/IRBs, etc. The annual international conference

serves as a forum to present new ideas and highlight best practices from various stakeholders. The objective is to gather together regulators, EC/IRB members, sponsors, scientists, academics, and community representatives to dialogue with one another in the pursuit of feasible means to promote ethical research.

The approach has made it possible to operationalize the basic ethics principles of autonomy, beneficence, and justice in the review of health research and translate them into tools, such as checklists and assessment forms to assist the EC/IRB members in reviewing protocols, consent forms, and related documents. Such tools assist the member reviewers to make a vulnerability assessment, identify and minimize risks of clinical or behavioral interventions, maximize benefits to the individual, community, and/or science. The review of the informed consent process and document ensures focus on full disclosure, comprehension, and voluntariness, at the same time that confidentiality is assured.

FERCAP also emphasizes the importance of documentation of EC/IRB procedures in compliance with GCP. EC/IRB forms have been standardized to ensure that the EC/IRB is provided adequate information to assess and approve protocol related documents. EC/IRB template forms like a standard application form, reviewer assessment form, conflict of interest declaration, minutes template, approval letter form, informed consent template, and continuing review form have been developed to assist ECs/IRBs to efficiently perform their tasks. Orderly documentation makes possible an orderly filing system that facilitates audit and inspection of EC/IRB operation. Furthermore, good documentation provides a good baseline for continuous quality improvement that ECs/IRBs begin to commit to.

While FERCAP focuses on the format of good review systems, it encourages and ensures good quality of ethics review. During the FERCAP survey of an EC/IRB, real time observation of EC/IRB board meetings is done and feedback to the EC/IRB is provided about completeness of its review process in terms of the discussion of technical and scientific issues as well as ethical issues to protect participants in research, decision-making process, and efficiency and effectiveness.

Shared Values

Aside from our worthy cause and organizational focus, another factor for success is FERCAP's shared values with its partners and members.

In terms of organizational linkages, FERCAP is a project of the WHO/*Special Programme for Research and Training in Tropical Diseases* (TDR) and maintains active partnership with the two WHO regional offices, the *Southeast Asia Regional Office* (SEARO) and the *Western Pacific Regional Office* (WPRO). FERCAP has linkages with government organizations and academic institutions as well as national ethics forum and organizations. It develops good relationships with regulatory agencies to promote the principles of human subject protection.

In working towards organizational sustainability, FERCAP subscribes to the values of equity, efficiency, and effectiveness. Equity is shown in our being accessible to both developed and developing countries and in our socialized costing of programs. While members from developed economies pay for training and surveys and participation in annual meetings, members from developing countries are subsidized to provide them access to FERCAP programs. Efficiency is demonstrated in our cost-effective programs that emphasize minimum cost and maximum coverage. Volunteer trainors and surveyors reduce the cost of conducting FERCAP programs in various countries at the same time that it affords the volunteers opportunities to learn from each other and contribute to a common cause. Effectiveness is shown in FERCAP's focus on the application of ethics principles rather than theories. ECs/IRBs that have been surveyed manifested a better appreciation and application of ethical principles in the review of health research protocols.

In terms of organizational adaptability, FERCAP promotes the grassroots approach through the use of local partners and resources. Our forum is respectful of local regulations, guidelines, and cultures and we do not involve ourselves in political issues between countries but rather we focus on the welfare of human research participant, a cross-cutting concern in health research governance. FERCAP

emphasizes an inclusive approach among stakeholders that focuses on duty-based ethics rather than a conflict-based model.

Over and above our shared values related to organizational linkages, organizational sustainability, and organizational adaptability, is the personal commitment and dedication of our FERCAP members and officers to scientific integrity and ethics in research that move our forum forward. These personal commitment and dedication are strengthened by the friendships and mutual respect which are the underlying norms in FERCAP relationships. In FERCAP, there's always mutual trust and cooperation.

Concluding Remarks

To conclude these reflections on the FERCAP experience, I would like to summarize our forum's achievements, share some lessons learned, and pose some challenges.

Since our founding year in 2000, FERCAP has organized annual international conferences in Thailand, the Philippines, and China. Our forum has done various trainings in WHO SEARO countries like Bangladesh, Bhutan, India, Indonesia, Nepal, Sri Lanka, and Thailand and WHO WPRO countries such as Cambodia, China, Japan, Laos, Malaysia, Mongolia, Philippines, South Korea, and Vietnam. As of 2010, FERCAP has 73 recognized Asian ECs/IRBs from Bhutan (1), China (10), India (2), Indonesia (1), Philippines (4), South Korea (21), Sri Lanka (1), Taiwan (22), and Thailand (11). Our forum also assisted in the recognition of ECs/IRBs from Ethiopia (2), Russia (1), and Uganda (1).

The *SIDCER Recognition Program* has definitely succeeded in making its mark on the Asian environment. 1) It has streamlined the EC/IRB process by developing good models of ethics review that have been adopted by 73 recognized ECs/IRBs in 9 countries/areas. 2) It has improved institutional support for ECs/IRBs in terms of better research infrastructures and governance that institutionalized the role of the EC/IRB. 3) It has created a committed group of surveyors who visit each other's countries and ECs/IRBs to learn from one another and replicate good practices in their own settings. 4) Regulators have recognized the contribution of ECs/IRBs towards good governance and

have adopted better guidelines and regulations that formalized the regulatory framework for better human subject protection. The improvement of guidelines and regulations are evident in Taiwan, China, South Korea, the Philippines, and Thailand.

From our FERCAP perspective, some lessons have been learned and reinforced such as: 1) Quality review is neither an economic nor a technology issue. Quality review may be harmonized across developed and developing country settings. What is more important is the commitment to the protection of human participants and material incentives become minor concerns. EC/IRB members need to be convinced about the importance of their task for them to exert their utmost effort. 2) Voluntary participation, relevance, and local support are required for sustainability. The work of FERCAP is to motivate people to volunteer and to contribute their efforts to accomplish the task of developing the capacity of ECs/IRBs. Volunteers need to feel good about what they are doing and they should feel that their efforts are capable of "making a difference." They need to be convinced that they are creating a better world and a better environment. 3) Respect for cultural and socio-political differences is important. Members involved in the work focus on the common task, rather than on their political and cultural differences. They begin to see each other as friends and co-workers despite their divergent political and cultural background. Asia is a land of contrast and diversity but the FERCAP experience is about a common goal.

After 10 years of its existence, FERCAP faces important challenges in the next decade. Some of these challenges are the following: 1) There is need to sustain the interest of FERCAP stakeholders by continuing to be relevant to the needs of its country, institutional and individual partners. 2) There is a need for fresh ideas to be creative and innovative and in each step of the way. 3) Mutual trust and respect should be maintained among the members of the FERCAP network. 4) There is need to convince FERCAP's critics about the value of its contribution. 5) The future is about developing FERCAP's competitive advantage in the field of research ethics.

While moving forward with our partnerships and networks, we are reminded that FERCAP is about taking responsibility for one

another. Our forum is about a friend helping a friend. This is the fuel that pushes us to move forward.

So while the dogs bark, our FERCAP train moves on.

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FERCAP BEYOND 10

Kenji Hirayama, M.D., Ph.D.

After 10 years of the fruitful adventure of the *Forum for Ethical Review Committees in the Asian & Western Pacific Region* (FERCAP), the only concern for the members of the previously and newly formed Steering Committee is the new Chair because he is the only active member of FERCAP from Japan so far. However, I am very much optimistic because that is our only concern.

As all of us have noticed, the world is getting smaller because of the development of transportation and communication devices. Actually, internet communities like Facebook provoked the democratic movements of several countries to change their governments. I appreciate such modern technologies in making positive ways of change but at the same time I am pretty much confident that virtual is virtual and that we really need more face to face contacts to make real communication. Of course 10 years from now, more fantastic technologies will overtake such virtual situation.

In terms of close communication, FERCAP has been promoting an ideal community in the region. More and more ethics committees (ECs)/institutional review boards (IRBs) are getting involved in our activities and their quality of review improved quite dramatically. Based on such an achievements, I would like to proceed with three major agenda as Chair: continuous quality improvement of EC/IRB review practices, stronger support for the establishment if national accreditation systems, and promotion of ethical product research and development for public health.

Continuous Quality Improvement of EC/IRB Review Practices

We are now entering the second phase of quality management of ECs/IRBs in the region. In this phase, an increase in the number of second generation FERCAP surveyors is necessary to maintain our survey and evaluating system. The FERCAP education and training program will be much more empowered by using all possible technologies and mechanisms.

Stronger Support for the Establishment of National Accreditation Systems

Related to continuous quality improvement of EC/IRB ethical practices, we are strongly proposing that each country establish a national accreditation system to improve its quality that their society can rely on. We will support such efforts to establish national accreditation systems.

Promotion of Ethical Product Research and Development for Public Health

We have been working together for 10 years dreaming of our final products that will benefit our own societies and communities. To make this dream come true, EC/IRB quality is essential and at the same time we will need more human resources in the region to push the activities of product research and development to meet regional public health needs. Along this line, six universities namely, Nagasaki University, Tokyo University, Thammasat University, Chulalongkorn University, Shanghai Second Military Medical University, Universidad de Antioquia, Colombia, made an alliance through a *Diploma Course on Product Research and Development to Meet Public Health Needs* six years ago. The fifth course was held in Nagasaki last October 10 to November 1, 2011. This course will finally be connected to a Ph.D. course in each university. FERCAP will continue to help in providing the ethical component for these Diploma and Ph.D. programs.

Beyond Expectation

I like the word synergy. Synergistic effect will be produced by our passion. I hope that FERCAP will advance further not only along the proposed agenda but ***beyond expectation***.

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COMPLIMENTS FROM FERCAP PARTNERS

COMPLIMENTS FROM DCUMC IRB

The Daegu Catholic University Medical Center
Institutional Review Board
(Since 1998)

The institutional official who has authority over the ***Daegu Catholic University Medical Center Institutional Review Board*** (DCUMC IRB) is **Ho Gak Kim M.D., Ph.D.** Within DCUMC IRB are two IRBs: IRB for drug and all biomedical research that has **Oh Dae Kwon M.D., Ph.D.** as chairman with two panels and IRB for medical device that has Ho Gak Kim M.D., Ph.D. as chairman with one panel.

The DCUMC IRBs are responsible for protecting the rights and welfare of human subjects in research projects conducted by the faculty and staff of the institution. The DCUMC IRBs review all human subject research projects done by the faculty and staff of Daegu Catholic University Medical Center. The DCUMC IRBs try to comply with the agreements underlying human safety assurances by satisfying institutional policy as well as national policy [***Korean Good Clinical Practice*** (KGCP)] and international policies and regulations including the ***Declaration of Helsinki***.

The DCUMC IRBs were registered at the ***United States*** (U.S.) ***Office for Human Research Protections*** (OHRP)/***Federalwide Assurance*** (FWA) in 2006 which was followed by the recognition from the ***Strategic Initiative for Developing Capacity in Ethical Review*** (SIDCER)/***Forum for Ethical Review Committees in the Asian and Western Pacific Region*** (FERCAP) in November 2008. The DCUMC IRBs are scheduled to receive re-recognition in November 2011. Two members of the DCUMC IRBs (**Im Hee Shin Ph.D.** and **Sang Gyung Kim M.D., Ph.D**.) have been devoted in promoting quality ethical review in the region by working as SIDCER/FERCAP surveyors. The DCUMC IRBs have good collaborations with SIDCER/FERCAP as well as with the ***Korean Association of Institutional Review Boards*** (KAIRB) and the ***Western Institutional Review Board*** (WIRB).

This November 20-23, 2011, DCUMC IRBs have the exciting challenge of hosting the ***11th FERCAP Annual International Conference*** and ***FERCAP General Assembly*** in Daegu, South Korea.

COMPLIMENTS FROM DCUMC IRB

Panel 1 (Drug & Biomedical Research)	Panel 2 (Drug & Biomedical Research)	Panel 3 (Medical Device)
Oh Dae Kwon M.D., Ph.D. *Chairman*	Oh Dae Kwon M.D., Ph.D. *Chairman*	Ho Gak Kim M.D., Ph.D. *Chairman*
Im Hee Shin Ph.D. *Expert Secretary*	Jung Kyu Kim M.D., Ph.D. *Secretary-General*	Im Hee Shin Ph.D. *Expert Secretary*
Bo Kyung Moon *Expert Secretary*	Duck Yoon Kim M.D.,Ph.D. *Expert Secretary*	Sang Gyung Kim M.D.,Ph.D. *Expert Secretary*
Joong Gu Kwon M.D.,Ph.D. *Member*	Sang Gyung Kim M.D.,Ph.D. *Expert Secretary*	Jae Gueon Ryu M.D.,Ph.D. *Expert Secretary*
Hoon Kyu Oh M.D.,Ph.D. *Member*	Jong Yeon Kim M.D.,Ph.D. *Expert Secretary*	Jeong Kyu Kim M.D.,Ph.D. *Expert Secretary*
Sung Hwa Bae M.D.,Ph.D. *Member*	Jin Kyung Kim M.D.,Ph.D. *Member*	Dong Seok Sohn M.D.,Ph.D. *Member*
Seung Hoon Baek M.D. *Member*	Ki Cheul Sohn M.D. *Member*	Dae Hyun Kim M.D.,Ph.D. *Member*
Jin Bae Lee M.D. *Member*	Seong Kyu Kim M.D.,Ph.D. *Member*	Jong Ki Kim Ph.D. *Member*
Tea Young Choi M.D. *Member*	Mi Jung Eun *Member*	Jin Tae Jung M.D.,Ph.D. *Member*
Hyun Dong Chae M.D. *Member*	Myung Sook Yu Ph.D. *Member*	Bo Kyung Moon *Member*
Jong Sock Park Ph.D. *Member*	Seung Deok Gang *Member*	Jong In Youn Ph.D. *Member*
Kyu Suk Kim *Member*	Kyu Suk Kim *Member*	Hyun Dong Chae M.D. *Member*
Tae Sik Lim *Member*	Su Ho Lee *Member*	Sung Won Youn M.D., Ph.D. *Member*
		Ki Cheul Sohn M.D. *Member*
		Jong Seok Park Ph.D. *Member*
		Su Ho Lee *Member*
Myung Hyun Lee *Staff*	Myung Hyun Lee *Staff*	Hae Oak Yoo *Staff*
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COMPLIMENTS FROM NEKKEN

The tropics, the most ecologically diverse region on Earth, present an ongoing complexity of tropical diseases and other health problems. In view of the remarkable advances made in the field of international exchange in recent years, it is imperative that these problems be addressed from a global perspective. Based on this understanding, the ***Institute of Tropical Medicine, Nagasaki University*** (NEKKEN), aims to overcome tropical diseases, particularly infectious diseases, and the various health problems associated with them, in cooperation with related institutions and organizations, to strive for excellence in the following:

- Spearheading research in tropical medicine and international health
- Making global contribution through disease control and health promotion in the tropics by applying the fruits of research
- Cultivating researchers and specialists in tropical medicine and international health

It is in view of these goals that NEKKEN supports the capacity building initiatives for ethical health research of the ***Strategic Initiative for Developing Capacity in Ethical Review*** (SIDCER)/***Forum for Ethical Review Committees in the Asian & Western Pacific Region*** (FERCAP). The last 10 years saw NEKKEN and SIDCER/FERCAP working together in programs such as the *International Course on Research Ethics* and the *Diploma Course on Product Research and Development to Meet Public Health Needs* of Nagasaki University. **Kenji Hirayama, M.D., Ph.D.** of NEKKEN is currently FERCAP Chair. In the years to come, NEKKEN and SIDCER/FERCAP will continue to work for ethical research in tropical medicine and international health especially in the Asia-Pacific region.

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COMPLIMENTS FROM WFCMS-ERC

The ***World Federation of Chinese Medicine Societies*** (WFCMS) is an international academic organization with its headquarters in Beijing, China. Currently there are 201 member institutions covering 58 areas/countries registered with this organization. WFCMS is devoted to promoting understanding and cooperation among academic groups of Chinese Medicine all over the world, strengthening international academic exchange, improving their qualifications for Chinese Medicine, protecting and developing Chinese medicine, working to have Chinese Medicine gain access to the mainstream of medical system in various countries, promoting exchange and cooperation among Chinese Medicine and other medicines in the world and, therefore, making greater contributions to the health of mankind.

Under the approval of the Ministry of Civil Affairs last September 2010, the ***Ethics Review Committee of the World Federation of Chinese Medicine Societies*** (WFCMS-ERC) was formally established during the ***Inaugural and the First Annual Academic Conference of Ethics Review Committee of the World Federation of Chinese Medicine Societies*** (WFCMS-ERC 2011) held in Nanjing, China on November 19-20 2011. WFCMS-ERC is constituted by volunteers worldwide who are interested in ethical review of Chinese Medicine clinical research. It mainly consists of personnel who work on Chinese Medicine clinical research, biomedical research, or Traditional Medicine clinical research, and ethical review of research. The goals of WFCMS-ERC are to standardize and improve the capacity of ethical review of Chinese Medicine clinical research through academic study, cooperation and communication, quality assessment and criteria developing; to study and discuss characteristics of clinical research of Traditional Medicine and its impact on ethical review; and finally, to contribute to promoting respect and protection of subjects' rights and safety. For more information, please refer to http://www.wfcms.org/

COMPLIMENTS FROM THE DAEGU HOST AND SUPPORTERS

11th FERCAP International Conference
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