

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

*Cristina E. Torres, Ph.D.*

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 voluntarily 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* (EMA), 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.

<b>Table 1. SIDCER/FERCAP Strategic Objectives (2000-2010)</b>
<ul style="list-style-type: none"> <li>• To improve communication among ECs/IRBs reviewing health research in the region</li> </ul>
<ul style="list-style-type: none"> <li>• To act as a regional collaborating center for EC/IRB members, investigators, sponsors, regulators, patients, and stakeholders in health research</li> </ul>
<ul style="list-style-type: none"> <li>• To organize international meetings and symposia</li> </ul>
<ul style="list-style-type: none"> <li>• To assist with the adoption and implementation of SOPs for ethical review in the region, taking into consideration the <i>World Health Organization Special Programme for Research and Training in Tropical Diseases (WHO/TDR) Operational Guidelines for Ethics Committees that Review Biomedical Research</i> (2000)</li> </ul>
<ul style="list-style-type: none"> <li>• To facilitate training and education opportunities for health research stakeholders in the region</li> </ul>

- 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."

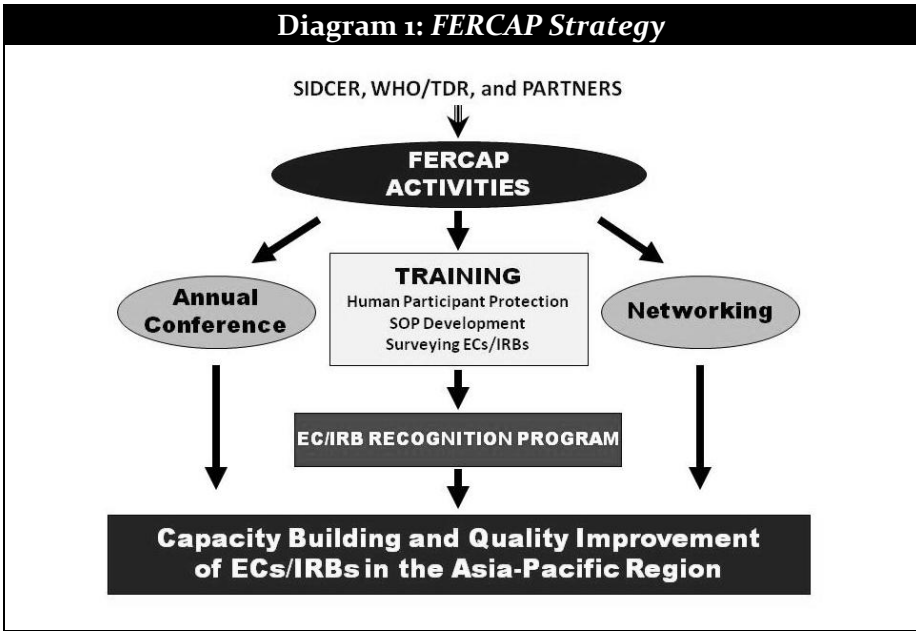
**Table 2. SIDCER/FERCAP Strategic Objectives (2010-2020)**

<ul style="list-style-type: none"> <li>• To foster teamwork and strategic partnerships at the national, regional, and international levels with human research stakeholders sharing common values and common goals</li> </ul>
<ul style="list-style-type: none"> <li>• To promote quality culture in ethical review of health research</li> </ul>
<ul style="list-style-type: none"> <li>• To facilitate training and providing education opportunities for health research stakeholders</li> </ul>
<ul style="list-style-type: none"> <li>• To establish monitoring and evaluation programs for continuous quality improvement of ethical review systems (WHO/TDR, 2009)</li> </ul>

### 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.



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

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

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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