Forum for Ethical Review Committees in the Asia and Western Pacific Region

FERCAP NEWSLETTER **December 2006 Edition**

After 2 years of "hibernation", the FERCAP Newletter is back. The "silence" of the newsletter has not been the same with the organization or the FORUM. FERCAP has been and remains a strong voice of advocacy and implementor of pro-active programs towards developing capacity in Asia and the Western Pacific Region, in order to protect the rights and safety of research participants whether individuals or communities.

In this respect the FERCAP will continue to strive and assist the Ethical Review Committees in Asia and Western Pacific to raise the bar of quality of National ERCs in the region in order for them to attain the standards expected of them within the framework of international standards.

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Message from the Chairperson Dr. Vichai Chokevivat

For several years now FERCAP has worked hard to meet the expectations of the members as well as the representative members coming from ethical review committees from the Asia and the Western Pacific Region. Indeed, they came with a new hope from FERCAP; that when the participants in our annual conference come home, they surely got the best practices in order for them to institute changes in the ethical review committees.

In 2004 we focused on Health Research and Access to Medicines in Asia and Western Pacific and in 2005 we dealth with Defining the Roles, Responsibilities and Relation between National Health Authorities and Ethics Committees in Health Research. Now the theme is Transparency and Accountability in Health Research: Towards an Ethics of Responsibility in Human Subject Protection. In all of these fora we build our theme in a logic of coordination and assessment of what is critical and relevant for the protection human participant in research as well as the level of capacity our ERCs need in the Region. Rest assured that we will continue to grow and unite in order to reach our goal of building public trust.

Editorial

Transparency and Accountability Build Public Trust

There is growing interest on the kind of assurance local ethical review committee (ERC) can provide. This has brought out some concern that sometimes move legislation to take action on the way research is reviewed by ethics committees. Some of the important issues that plague us would be the state and evidence of independence of the local ethics review committees and the justification of confidentiality of the process on how decisions are made by the ERCs.

Although we could agree that the local ethics review committees should have a "self regulatory" status, it is also to the protection of the public that statutory mechanisms be put to place. In a more open minded and broader sense, health research should also be directed to ensure that the results of research benefit the people through better health policies and programs, especially the developing countries.

If we are to achieve a higher ground of acceptance and attain public trust, then there is no better time than now that we discuss these issues. This is the theme of this year's international conference of FERCAP.

FERCAP AT A GLANCE

International guidelines and national laws alone cannot guarantee the fullest protections for human subjects in research. Such guidance and regulation ultimately depend upon the integrity of the various stakeholders in research. This integrity can be developed by promoting transparency and accountability throughout the research process. The highest standards in ethics and science can only be upheld and advanced if there is willingness at each stage of the research process to demonstrate commitment and conformity to such standards.

This year's conference examines the existing paradigms defining the roles and responsibilities of the various research stakeholders, including national health authorities, sponsors, investigators, and publishers in their relationship with ethics committees regarding the promotion of transparency and accountability in research.

It is the primary objective of the Conference to describe the place of transparency and accountability within the roles and responsibilities of the research stakeholders, demonstrating the value of responsible behaviour in the performance of their tasks within an overall ethical framework for research focused on the protection of research participants and their communities.

It is also the aim of the conference to achieve the following objectives:

- to describe and compare the roles of and responsibilities of various research stakeholders related to the creation of an ethical infrastructure that supports transparency and accountability in the Asia and Western Pacific region;
- to examine the impact of current international guidelines and local national legislation on promoting research transparency and accountability;

... continue on page 3

EVENTS OF 2004

The 2004 Conference focused on the promotion of the availability of medicines in Asia and the Western Pacific; the development of an ethical framework for research that ensures the best treatment for participants and their communities, during and following research. The following objectives were pursued:
1. The background to decisions on trial designs and medicine availability;
2. The rational use of medicines in reseach as against the medical and ethical requirement to prevent or treat disease;
3. The cost of medicines in research and the investment in healthcare;
4. The responsibilities and limitations of ethics committees in decisions on healthcare and use of medicines in research;
5. The access to medicines by research participants and their communities following research;
6. The compassionate use of medicines following research;
7. The relationship between medicinal development in clinical trials and the availability of medicines in regional and national healthcare;
8. The responsibility of researchers and their organizations for the availability of medicinal products during and after the reseach; and
9. The development of an Asian and the Western Pacific approach to access to medicines in research settings and the daily healt care

EVENTS OF 2005

In 2005, the conference examined the abuses in the conduct of clinical trials that resulted in public indignation. It is also in this thread that regulatory authorities took active role in the regulation of biomedical research. To the extent that statutory initiatives were made because of the decay in the expectation of trust in ERCs, we were equally concerned with how we can narrow the gap and institute changes in the biomedical research system.

The conference also examined the various paradigms that define the roles and responsibilities of national health authorities in health research, particularly their relationship with ethics committees, as well as the range of regulatory involvement of the state.

Specific objectives that were met include:
1. The description and examination of the socio-economic and policy environment of research ethics within especific countries in the Asian and Western Pacific Region;
2. The description and comparison of the rolews of the responsibilities of national
3. The impact of current international

... continue on page 4

FERCAP at a Glance... continued

· to identify and share best practices to address problems and barriers in creating transparent and accountable health research systems that protect human subjects and research participants;
· to consider advancing transparency and accountability in research ethics against a background of
o clear-cut and relevant guidelines and policies related to research ethics;
o value sharing among various research stakeholders;
o synergy among major international, regional, and national health decision makers; and
o effective working relationships among important research stakeholders and ethics committees;
· to examine current developments in Good Clinical Practice regarding transparency and accountability in health research; and
to develop a relevant Asian ethical research infrastructure that encourages transparent and accountable health research policies within the context of diverse Asian cultures alongside pluralistic socio-economic and political systems.

Capacity Building Through Training

There are three major activities in this program, namely:

1. Human Subject/Parcipant Protection Course
2. Development of Standard Operating Procedures for Ethics Committees
3. Surveying and Evaluating Ethics Committees

Through these activities we have improved the national ethical review systems of countries. There were policy changes in the conduct of clinical research in Thailand and Taiwan; Thailand, Nepal, India, Philippines and Taiwan published their national research ethics guidelines; establishments of more ethics review committees; and the publication of the WHO Operating Guidelines, which formally became part of the Japanese regulatory framework. Courses in ethics were formally offered in Thailand (Thammasat University), Japan (Nagasaki University and the Philippines (University of the Philippines). Standard Operating Procedures (SOPs) were developed in India, Thailand and Japan.

Accreditation Program

With intense capacity building and the establishment of Fellowship in the Western Institutional Review Board (WIRB), which started in November 2002, it was time to move on with our thrust help improve the quality of review. This is where the accreditation program to take shape, from the two previous meetings, we have put in place an ERC audit. This involve assembling a team who underwent ERC assessment training and visit ERCs within FERCAP network who are willing to be audited. To date we have audited and recognized 11 ERCs in Thailand, Taiwan and Korea. Before the end of this year the University of the Philippines will be visited by the team; that will be a total of 12 recognitions for the year. Next year two other institutions will formally request for an accreditation visit.

Information Networking

Some ideas have been hatched during the steering committee meeting which will extend FERCAP's activities well beyond ther ERCs. The aim of this initiative is to provide information to all stakeholders including the human participants who are the true focus of protection. This involve developing an information hub for all which can take the form of a radio or tv program which will try to explore the issues of health research and the protection of subjects through the ERCs. It can also take the form of a cyber information hub which could be a termed as research ethics blog wherein subjects can readily throw in their concerns.One favourable effect of this is a mechanism for improved understanding of research bioethics across stakeholders.

Push for a National Forum

Another idea which came up is the activation of the national forum. The aim is to provide a strong network, a single voice, within the country where there is a FERCAP country-specific forum. Since it will not always be possible to reach out to everyone, this a mechanism to strengthen the network harmonization.

Events of 2005... continued

guidelines in ethics on national legislation, guidelines, regulation and research procedures;

4. The identification and share best practices in creating effective health research systems that protect human subjects, research participants and their communities, which can be characterized by (a) clear cut guidlines and policies, (b) values, (c) synergy among major international, regional and national health decision makers, and (d) effective working relationship between National Health Authorities and Ethics Committees;
5. The examination of specific governance issues related to research ethics in various types of biomedical and social science research that are being undertaken in the region;
6. The development of a relevant model of an ethical Asian research infrastructure that integrates health policies with national healthcare programs within the context of diverse Asian cultures, religion, and pluralistic socio-economic and political systems.