

Address by

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Regional Director, WHO South-East Asia***

At the

***Regional Workshop on Capacity-Building for
Ethical Review Committee of
Health Sciences Research***

19-22 October 2009

Bangkok, Thailand

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Professor Pirom Kamolratanakul, President, Chulalongkorn University, Professor Surasak Taneepanichsakul, Dean, College of Public Health Sciences, Professor Prida Tasanapradit, Chairman of the Ethical Review Committee, Chulalongkorn University, distinguished participants, honourable guests, ladies and gentlemen,

On behalf of WHO, I warmly welcome you all to this Regional Workshop. I thank all of you for sparing your valuable time to attend this meeting. I thank Professor Prida, who initiated the idea and requested WHO/SEARO to convene this important workshop jointly with the College of Public Health Sciences. I thank the College of Public Health Sciences for the local arrangements that makes this workshop possible. I thank WHO.

Distinguished participants,

Health services are technology-intensive. Research is indispensable for the development and application of health technology to make such modern health services possible. Strengthening research capacity in Member States is, therefore, an important role of WHO. And in this capacity strengthening, "ethics in research" is one of our overriding

concerns. This is especially the work of “Ethical Review Committees”, that is to ensure, among other things, physical and psychosocial safety of “research participants” or “research subjects”. In the broader context, the work safeguards the “human rights” of those participants or subjects.

Research projects involving human participants demand sound “ethical practice” to ensure such safety, and to safeguard such rights. “Donor agencies” require “ethical clearance” for research involving human subjects before they can make decisions on funding. “Journals” of international standing will not publish the results of research projects involving human subjects, that have not been cleared by credible “Ethical Review Committees”. Not less important, clearance by ERCs certainly provides important “safeguards” for “researchers” themselves. We recognize the “critical role” of ERCs in the research process. This is particularly research in the area of “health sciences”. To ensure high standard of practice in the work of ERCs is a challenging task. WHO has been providing support to improve the performance of ERCs, especially those in developing countries.

To achieve such improvement satisfactorily still requires a lot of efforts and patience. Despite many guidelines and standard operating procedures having been developed for use, and several training workshops having been organized in countries and at regional level, still, in general, there are gaps, lacunae and shortfalls in the work of ERCs in ensuring a high standard of practice in research ethics.

However, we should not, actually we cannot, be discouraged from continuing our efforts to further enhancing the capacity of ERCs. This is to further improve the

performance of these Committees in ensuring “safety” and safeguarding “human rights” of research subjects. And we have to continue enhancing the quality of “ethical practice” of researchers. On the other hand, research “managers” and research “administrators” also need to be always “research-ethics minded”.

Distinguished participants,

There are many issues involved in research ethics. Let me mention a few of them from my experience in dealing with this important area. Among other factors, is the “conflict of interest” involved in the research process and research work makes the situation more complicated for improving research ethics. And this conflict of interest usually leads to difficulty in ensuring “transparency” in management of “research work”. At the institutional level, a clear “policy” on “research ethics” is the “prerequisite” for successful functioning of ERCs. “Administrators” of research institutes need to promote “high standard” of “ethical practice” in their research work. We have to promote “positive attitudes” of researchers towards “ethics in research”; and towards the work of ERCs. Role models need to be developed for researchers to emulate to be good “practitioners” in “research ethics”. “Ethical review” of research projects is delicate work; it needs adequate time and it should not, and cannot be done hurriedly.

At the same time, in certain cases, there is a lot of demands for ethical review of research proposals involving human subjects. Then, the ERCs become too burdened and become “bottlenecks” that delay processing of research projects. This is one of the reasons that turn away researchers from cooperating effectively with ERCs.

For ERCs to be really effective in their work, such bottlenecks must be eliminated. Means and ways have to be found to ensure that ERCs will not be too burdened to compromise the quality of their work.

Another problem area that affects the work of ERCs is the conflict between “researchers” and “ERCs” about “research methodology”. This “research methodology” may significantly affect the safety of research participants in the implementation process.

Often researchers are reluctant to accept recommendations of ERCs, especially recommendations to effect change in research methodology for safeguarding research participants. In this connection, a proper mechanism is needed to help reconcile the difference between researchers and ERCs keeping in view the “overriding consideration” to be given to the safety of research subjects.

Another delicate issue in research ethics is how to obtain consent from research participants in a strictly objective manner. The decision of research participants to cooperate in a study must not be influenced by any kind of incentive. The decision of research participants should be based solely on their valuable contribution to the improvement of people’s health through the concerned research projects, that they are involved. It is customary practice in research involving human participants that certain kind of material incentives are built into proposals. This is to attract the interest of research subjects beyond the ultimate objective of the research projects. How do we ensure that the research subjects correctly understand the research procedures that may potentially be harmful to them? How do we ensure that the decision of the subjects to participate in research will not be affected by any incentive? I hope that the workshop will dwell on this

important issue during the course of its deliberations. This is with the view to improve the situation in regard to obtaining consent from research participants without “prejudice” that is outside the realm of the primary purpose of research projects.

I agree that we need to teach research ethics to the students training in health sciences. This teaching should start as early as possible in their professional training and in their professional career. We need to prepare our researchers in research ethics as early as possible. As part of “hands-on-training”, we may consider involving “students” in the “process” of ethical review but not as “members” of ERCs. This is especially true for “graduate students”. Yes, there are many “ethical issues” involved in “health systems research” and research on “health services delivery systems”. The issues involved are generally in the area of “technology application” for health benefits of people in community. This area involves the development and management of “public health programmes”. This area also touches on “socio cultural” and even “political dimensions” of the community to be served. Certainly, research in this area needs “ethical consideration”; and also consideration of “human rights” aspects in a broader context. It is the area that requires more efforts in the development of effective guidelines for ethical review — the guidelines that may be substantially different from those used for clinical or basic research.

Ladies and gentlemen,

In addition to capacity building, this workshop also aims to create networking of ERCs in countries of the South-East Asia Region. This is commendable indeed. Our practical experiences, especially from our own countries, are most important in the exercise such as this. We should bring up the issues from our practices for discussion and

deliberations during this workshop. Working on our own experiences will ensure “practical solutions” for the problems that we are facing in our countries. We have with us “generic guidelines”, and “training modules” to help improve our performance in research ethics. These guidelines and training modules are for “adaptation” and “application” to help solve our local problems.

Our local problems, in many cases, may relate to our own socio cultural and even political environments at home which need to be taken into account adequately in this exercise. However safeguarding research participants is our “overriding consideration”. And we have to ensure it.

Ladies and gentlemen,

We are talking about “research ethics” or “ethics in research” in reference to the ERCs. In my view, “ethics of researchers” is also very important indeed. If we have researchers who are ethical, most problems that we face in this connection would be solved. Researchers are essentially the key players in research ethics.

I also feel that we should have a separate “ethical code of practice” for researchers. We should deal with “research ethics or ethics in research” in a broader context, encompassing the issues more than safeguarding research subjects. We may already have such a code in place, but if we do not, it is time to consider the same. Ethical issues in research are, more or less, inter-related, and interlinked. To tackle these issues effectively, a holistic approach is needed. Safeguarding research participants, even though extremely important, is only a part of the whole gamut of ethical problems in research.

Distinguished participants,

I am talking from public health perspective. I hope that it would be useful in your deliberations during the course of this workshop. And I hope however that the outcome of this workshop would contribute significantly to capacity building for Ethical Review Committees in health sciences research in our countries.

With these words, ladies and gentlemen, I wish you all a productive meeting. And I wish the meeting all the best and all success.

Thank you very much for your kind attention.