

## EDITORIAL

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# Harmonization of Ethics Review Committees

Recently the Thai Medical Council has issued regulations that the conduct of medical research using human participants must always be submitted to the appropriate Ethics Review Committee for approval before the initiation of the study. This important regulations are effective in August 2001 and in consistent with the latest version of the Declaration of Helsinki, year 2000. Undoubtedly these new regulations will have a significant impact on the practice of clinical research in the country.

While the modern clinical trials for health development has sharply increased in number and complexity, the review capacity of various Ethic Review Committees is far lacking behind with several limitations.

A recent survey on structure and function of Ethics Review Committees of medical schools in Thailand has showed great differences in the requirements, criteria and reviewing procedure. These create difficulties for investigators and/or sponsors when submitting research protocols for ethics review, particularly in case of a multicenter trial. Therefore there is an urgent need for elimination of this problem. A national ethics review guideline which is acceptable for all Ethics Review Committees and a harmonized protocol template for submission should be developed.

Thus Forum for Ethics Review Committees in Thailand (FERCIT), a not-for-profit organization consisting of representative members from most of Ethics Review Committees of medical schools in Thailand, has recently established in April 2001. This is a great step forward to establish strong national ethics review capacity system. So far FERCIT has developed a useful module of short course for practical training in ethics review starting at Korn Kaen University, June 2001 and is presently in a process of drafting a harmonized and standardized national guideline for ethics review committees in Thailand and in addition a standardized research protocol template required for submission to ethics committee for consideration. These will be finalized, published and distributed at the end of this year. This project is incidentally sponsored by World Health Organization. The future plan for FERCIT is to cultivate an ethical basis for clinical research in new scientists by developing bioethics course and adding it into the curriculum of medicine, pharmacy and nursing in Thailand.

Finally a Central Ethics Committee Accreditation board to standardise and harmonise the principle Ethics Review Committees in this country will have to be established so that the reality for Thailand as a Center of Excellence in Clomical Trial will be achieved.

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