

Ethics in Reproductive Medical Research

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Ethic principles for practice and research in reproductive medicine have three important aspects:

- a) Respect for person: respect the self determination and choices of autonomous persons, to secure dignity, right, safety and wellbeing of persons concerned.
- b) Beneficence: balance risk and benefit results in the least harm and the most benefit to patients/volunteers.
- c) Justice: distribute benefit and burden fairly to all.

Regarding to biomedical researches involved human participants as well as any human tissues specimens and/ or identifiable data, either in medical teaching institutions or hospitals, private or Governmental, the Thai Medical Council has established regulations recently that all must be approved by the local Ethics Review Committee first.

During the past six years. Ethic Review Committee for Research involved human subjects at the Faculty of Medicine, Chulalongkorn University, has evaluated over 2,000 protocols of research and about 120 protocols were on reproductive medicine. Some protocols were considered to be unethical by latest version of Declaration of Helsinki and International standard guidelines, such as protocols of research of first phase clinical drug trial in pregnant women and on newborn, sexual in young children and unofficial new drug testing at the outpatient department. Concerning these serious problems of physical psychological and social risks to human subjects several measures are suggested:-

- a) The subject of ethics in medical research should be introduced into the medical school curriculum.
- b) Capable and adequate number of Ethic Review Committee members must be trained to cope with rapid

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advancement of science and increasing number of complex clinical trials and genetic study.

- c) Accreditation Board under Medical Council authority should be established to standardize the practice of all Ethics Review Committees in the country.
- d) Adequate financial support for organizing of Ethic Review Committee of institution must also be available.

Forum of Ethic Review Committee in Thailand (FERCIT) which is composed of representatives from various Ethic Review Committee of Research from medical schools and hospitals of this country in on the trail to achieve the excellence in standard of reproductive medical research for Thailand.

FERCIT was established in April 2000 with the objectives:-

1. To advocate and develop protection of dignity right safety and well-being to research participants.
2. To advocate and develop ethical review system for research involved human subject in Thailand.
3. To exchange knowledge and experience among the members of ethical committee.
4. To co-ordinate with other national and international organizations involved with ethical review of research in human subjects.

FERCIT Achievement

1. Published National Guideline of Ethics in research involved human subjects
2. Organizing workshops for training members of Ethic Review Committee of medical institutions and hospitals on eight occasions, training over 700 persons and enrolled over 400 registered members, mostly members of Ethic Review Committee (from 2000-).
3. Translated WHO "Surveying an Evaluating Ethical Review Practices" into Thai language.
4. Printing "News bulletin" for its members every two months.
5. Web site of FERCIT giving information and communication for educations.

Financial support for FERCIT

- a. All major medical schools in Thailand annually

- b. Ministry of Education
- c. Medical Council of Thailand
- d. Pharmapeutical Agency
- e. Membership fee
- f. World Health Organization

Success

- A. Improve standard of ethical review practice in research institution in Thailand
- B. Increase capacity for protection of research participants right and harm
- C. Increase physicians and public awareness of the important of good ethic review practice

- D. Promoting good research practice in Thailand

Conclusion

While medical practice aims at the patient's benefit and well being, research gives its priority on scientific validity, but both procedures have two important principles in common, right and safety of patients/volunteers.

Medical research is indispensable for progress of knowledge and practice. However the value and harm of research depend on qualification of the investigator, adequate protocol assessment and competent monitoring system of the Ethic Review Committee concerned.