Biomedical Research Ethical Issues In Thailand: Current Status and Future Directions

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Presently, the regulation of biomedical research in Thailand is governed through civil and criminal laws as well as directives from the Medical Council of Thailand. Biomedical research conducted on human must be evaluated and approved by the ethics committees (EC) of relevant institutions such as the medical schools in universities. The limitation of this approach is that although the physicians and nurses involved in such research must adhere to the guidelines and regulations set out by the EC, other individuals involved in the same research, such as pharmacists, medical technologists and scientists are largely unaffected. In addition, the social science aspect of biomedical research is another important consideration because of the potential effect of such research on a subject’s psychosocial status. The EC therefore has many considerations when dealing with human drug testing and clinical trials. The Forum for Ethical Review Committees in Thailand (FERCIT) has thus been created to achieve the following objectives:

- ensure the safety of subjects involved in clinical trials
- look after the welfare of subjects involved in biomedical research in Thailand
- exchange knowledge and share experience
- cooperate with international biomedical research partners and ethical fora

The FERCIT is under the purview of the Forum for Ethical Review Committees in the Asian and Western Pacific Region (FERCAP). The aims of FERCAP are to raise the awareness, enhance the understanding and improve the implementation process of ethical review of biomedical research in the region. The FERCAP is part of the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) which is a network of independently established regional fora created to develop global capacity in ethical review and good research practices. The SIDCER steering committee is composed of representatives of the regional fora and representatives of invited partner organizations. Besides FERCAP, the other regional fora include the Forum for Ethics Committees in the Confederation of Independent States (FECCIS), the Latin American Forum of Ethics Committees in Health Research (FLACEIS), the Forum for Institutional Review Boards/Ethics Review Boards in Canada and the United States (FOCUS), and the Pan African Bioethics Initiative (PABIN).

In Thailand, several medical schools have established ethics committees that adhere to the guidelines and international...
standards as stipulated by organizations such as FERCAP/SIDCER and the Office for Human Research Protections (OHRP). Furthermore, physicians and scientists who are accredited by the OHRP must have their accreditation renewed by the organization every three years.

Currently, the Food and Drug Administration (FDA) of the Department of Health plays a key role in controlling the importation of new drugs from abroad for clinical trials. The FDA is also involved with numerous international collaborations and initiatives which help to ensure product safety. When a pharmaceutical company wishes to conduct a clinical trial in a medical school in Thailand, it must send a proposal to the EC of the medical school for its consideration. After the EC has positively evaluated the proposal, it will forward the proposal and certificate of approval (COA) to the FDA for approval of importation of study drugs. The FDA has already certified the ethics committees of eight medical schools, namely, Chulalongkorn University, Siriraj hospital, Ramathibodi hospital, faculty of tropical medicine at Mahidol University, Phramongkutklao hospital, Chiang Mai University, Khon Kaen University and Songkla University. These institutes can apply for the importation of new drugs for the purpose of conducting clinical trials in Thailand.

The Joint Research Ethics Committees (JREC) is a private organization that was established in 2006 with support from TCELS. This organization aims to be the focal point for multi-center clinical trials and works to ensure that the rights of clinical trial volunteers are protected. The JREC will follow the basic ethical principles for human subject research set out in the Belmont Report Historical Archive of the OHRP, namely, respect for persons, beneficence and justice.

Ethics in biomedical research development in Thailand is moving in the right direction. In the short-term, the various developments as outlined above will culminate in the adoption of international standards for clinical trial activities in Thailand. Furthermore, the industry as a whole (including the relevant agencies) will come to better understand the responsibilities and roles of various players involved in the process from the EC to the physician, nurse, medical technologist, scientist, down to the volunteer in the clinical trial.

Guidelines and Considerations for Biomedical Research

- http://www.cioms.ch
- http://www.gpoaccess.gov/frindex.html
- http://www.hhs.gov/ohrp/belmontArchive.html
- http://www.medic.u.ac.th/fercit
- http://www.fercap-sidcer.org/home.asp