Current Status of the Research Ethics Committees in Thailand

Suthee Panichkul MD*, Punkae Mahaisavariya MD**,
Nimit Morakote PhD***, Sumalee Condo PhD****,
Supak Caengow MSc*, Aphronpirom Ketunpanya MD*****

** Office of Research Development, Phramongkutklao College of Medicine and Hospital, Bangkok, Thailand*
*** Department of Dermatology, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand*
**** Faculty of Medicine, Chiang Mai University, Bangkok, Thailand*
***** Faculty of Medicine, Thammasat University, Pathum Thani, Thailand*
****** Forum for Ethical Review Committee in Thailand (FERCIT), Bangkok, Thailand*

Background: *Many research ethics committees (RECs) have been established to review biomedical research involving human subjects in many research institutes. The purpose is "To protect rights and welfare of human research participants". It is necessary to determine how many research ethics committees have been established in Thailand and whether they have a high enough standard to protect the rights and welfare of human research subjects.*
Objective: *To determine the status of research ethics committees in Thailand.*
Material and Method: *One hundred thirty survey questionnaires were distributed by mail to medical schools of universities, public hospitals under the Ministry of Public Health, private hospitals, and research institutes.*
Results: *Seventy-eight questionnaires were returned. Thirty respondents had standard Operating Procedures (SOP). Twenty-two RECs had their own office while 36 had to share the office with other departments or units. Board meeting frequency was once a month. The average number of committee members was 14 and the majority was scientific members. Absence of nonaffiliated members was found in RECs (20.6%). Thirty RECs had never provided training for REC members and investigators, the other 48 provided training at least once a year. Decision are made by consensus in 51 and majority vote in 14 RECs. Twenty-two respondents managed conflicts of interest (COI) by asking those members to leave the meeting before a decision was finalized. Thirty-nine RECs required continuous review after approval of the protocols.*
Conclusion: *Strong support from the organization leader is a key factor to efficiency and high standards of REC operation. Developing a network of RECs will be useful for future development. REC members still need knowledge to better protect the rights, safety, and well-being of research participants.*

Keywords: *Research ethics committees, Current status, Human research subjects*

J Med Assoc Thai 2011; 94 (8): 1013-8
Full text. e-Journal: *http://www.mat.or.th/journal*

Medical and public health research results in improvement of medical care and health promotion for human well-being. It is also necessary to conduct research in human subjects to confirm that the results can be applied to other humans because the body is too biologically complicated to rely on results obtained solely from laboratory or animal studies. Human subjects participating in research must be protected in terms of dignity, rights, safety, and well-being. To do this, investigators must be aware of and follow ethical guidelines in research involving human and institutes must establish research ethics committees (RECs) or institution review boards in order to review research proposal. The question arises as to whether the operation of such RECs or Institutional Review Boards (IRBs) meet international/ national standards for the protection of human participants.

In Thailand, the first research ethics committee was established in 1975[1]. The Human Experimentation Committee or HEC was set by the Medical Department, Chiang Mai University as a result of a research project for algae protein supplement that had serious adverse events. The medical students

Correspondence to:
Panichkul S, Office of Research Development Phramongkutklao College of Medicine and Hopital, 315 Rajwethe Rd, Rajathevi, Bangkok 10400, Thailand.
Phone: 0-2354-7600 ext. 93681, Fax: 0-2354-9084
E-mail: sthpanich@hotmail.com

and some staff protested against the project. The National Research Council of Thailand, with representatives from medical institutes and the secretary of the Medical Council of Thailand held an intensive discussion in May 1975. The outcome of the meeting was "Guidelines for Biomedical Research Involving Human Subjects" with 12 rules, published and sent to the research institutes in Thailand.

Subsequently, many research ethics committees were established to review biomedical research involving human subjects in many research institutes. The purpose was "To protect the rights and welfare of human research participants." It is necessary to determine how many research ethics committees have been established in Thailand and whether they have high enough standards to protect the rights and welfare of human research subjects. In addition, it would be useful to know if institutions had any authority to maintain quality assurance by making a survey of the standards of RECs.

The Forum for Ethical Review Committees in Thailand (FERCIT) is an independent organization. Its members come from medical schools in Thailand or institutes involved in human research. The objective of FERCIT is to protect the rights and well being of research participants and educate researchers and ethics committee members on ethical aspects of human research[2]. The present paper reports the results of a survey of RECs in Thailand in operational terms.

Material and Method

The work team was established in February 2009 and questionnaires were developed. The tool was examined for content validity at a FERCIT administrative team meeting. It was then distributed by mail to medical schools of universities, public hospitals under the Ministry of Public Health, private hospitals, and research institutes, 130 institutes. The questionnaires were sent back by mail between February and April 2009.

Results

Seventy-eight of 130 questionnaires (60%) were returned. Information was incomplete in two and seven indicated no established REC. The other remaining 69 RECs consisted of seven medical schools, 41 public hospitals, one private hospital and 20 institutes.

Data on constitution and operation of RECs were as follows.

Period of operation

The average time since establishment of RECs was six years. Most of them had only one committee except medical schools, which had up to four subcommittees due to many protocols reviewed.

REC operation

Thirty respondents had standard Operating Procedures (SOPs) while 36 did not. Twenty-two RECs had their own office while 36 had to share the office with other departments or units. Only 34 RECs had their own secretariat staff; others had to use staff from other offices. Board meeting frequency was once a month on average.

The average number of committee members was 14, the majority being scientific members. The proportion of scientific and nonscientific members was 6:1. An absence of nonaffiliated members was found in seven (20.6%) RECs. Thirty (43.5%) RECs had never provided training for REC members and investigators; the others provided trainings at least once a year (Table 1).

Protocols submitted for ethical review included behavioral studies 49 (71.0%), post-marketing surveillance 48 (69.6%), and new drug studies 34 (49.3%). There had management of conflicts of interest 59 (85.5%) while 10 (14.5%) did not do so. Decision was by consensus in 51 RECs and majority vote in 14 RECs (Table 2).

Management of conflict of interest (COI)

Twenty-two respondents managed COI by asking those members to leave the meeting before a decision was finalized, but they could provide clarification on some issues before leaving. Fifteen respondents allowed members with conflicting interests to stay in the meeting but refrain from voting. Interestingly, ten respondents did not have COI management (Table 2).

Continuing review

Thirty-nine (56.5%) RECs required continuous review after approval of the protocols by requesting investigators to submit progress reports at 6- or 12-month intervals.

Problems encountered by RECs (Table 3)

Respondents expressed their difficulties or problems encountered in their operation as ranked below in order of frequency.

Table 1. Data on constitution of research ethics committees (RECs)

Data	n = 69	Percentage
Status of research ethics committees		
Medical School	7	10.2
Public Hospital	41	59.4
Private Hospital	1	1.4
Others	20	29.0
Year of establishment (years)	Median (min-max): 6 (1-36)	
Duration of operation RECs (years)	Median (min-max): 2 (1-6)	
Selection of RECs members		
Dean	1	1.7
Director of Hospital	23	39.0
Chair of RECs	17	28.8
Other	18	30.5
Is there REC office space?		
Yes	22	31.9
No	47	68.1
Do the members receive training?		
Yes	38	55.9
No	30	43.1
How often are board meetings held (time/month)	Median (min-max): 1 (1-6)	
Number of RECs	Median (min-max): 14 (5-58)	
Scientific members	Median (min-max): 12 (1-51)	
Non-scientific members	Median (min-max): 2.5 (1-7)	
Are there any standard operating procedures (SOPs)?		
Yes	30	45.5
No	36	54.5

RECs = Research Ethics Committees

- Lack of persons knowledgeable in human research ethics 49.3%
- Members cannot attend the meeting regularly 33.3%
- Lack of resources for operation 27.5%
- Lack of recognition of RECs 21.7%
- Lack of support from higher administrators 18.8%
- Problems with independent status 7.2%
- Other problems 2.9%

Discussion

Now, Thailand has the National Health Act (B.E. 2550 or A.D. 2007). In it, it has article mentioning research in humans. The health personnel that want to do the research in human participants have to get the document informed consent. Beside the Civil and Commercial Code, the Criminal Code is applicable. The Drug Act and Regulations exists as well as the Medical Device Act and Regulations and enforcement follows the Rules of the Medical Council of Thailand, *i.e.*, the Medical Profession Act (B.E. 2544 or A.D. 2001) Section 6., Research and Experiments Conducted on Human Subjects[3].

Saito T et al[4] studied the status of ethics committees of 80 Japanese medical schools and reported an inappropriate composition of the committee in the majority of schools and recommended that more members from outside of the institute, younger members, and female reviewers should be added to the committee. In addition, the review systems in most schools were essentially closed. The review process had not been effectively opened to the public yet, even in the case where subjects had no privacy or volunteer roles appeared in the discussion. Arshad A et al[5], studied the status of health care studies submitted to UK research ethics committees for approval between 2004 and 2005 using a prospective questionnaire-based survey sent out in July 2006 to all 506 principal investigators that submitted research ethics applications to nine Greater Manchester RECs between April 2004 and March 2005. The result was 97% of REC applications were approved, and 87% of studies were in progress or had been completed one to

Table 2. Data on operation of RECs

Data	n = 69	Percentage
Types of research proposal for approval		
Behavioral studies	49	71.0
Drug studies (post-marketing surveillance)	48	69.6
Genetics	16	23.2
New drug studies	34	49.3
Epidemiology	48	69.6
Medical device studies	27	39.1
Intervention	49	71.0
Observation	44	63.8
Individual-based	16	23.2
Document-based	39	56.5
Social survey	47	68.1
Stem cells	8	11.6
Stored biological samples	27	39.1
Other	6	8.7
Management of conflicts of interest		
Yes	59	85.5
No management	10	14.5
The method of decision making of RECs		
Majority vote	14	21.5
Consensus	51	78.5
Are there any continuing review protocols?		
Yes	39	58.2
No	28	41.8
Is there any expedited review?		
Yes	29	45.3
No	35	54.7

RECs = Research Ethics Committees

Table 3. The problems and difficulties that RECs/IRBs encounter

Data	n = 69	Percentage
The problems and difficulties that your REC/IRB encounter		
Lack/insufficient of expertise on ethical review	34	49.3
Insufficiency of resources to operate the REC/IRB	19	27.5
Lacking recognition of the importance of REC/IRB functions	15	21.7
Little or no support to the institute	13	18.8
Inactive/inconsistent participation of members	23	33.3
Not completely independent	5	7.2
Other	2	2.9

RECs =Research Ethics Committees; IRBs = Institutional Review Boards

two years after approval had been granted. Moodley K et al[6] studied Health Research Ethics Committees in South Africa, 12 years into democracy, and surveyed using semi-structured questionnaires that investigated the composition and functions of each REC as well as the operational issues facing committees. The result was health RECs in South Africa have an average of 16 members and REC members are predominantly male and white. Overall, a large discrepancy in findings was reported between under-resourced RECs and well-resourced RECs. The majority of members (56%) are scientists or clinicians who are typically affiliated

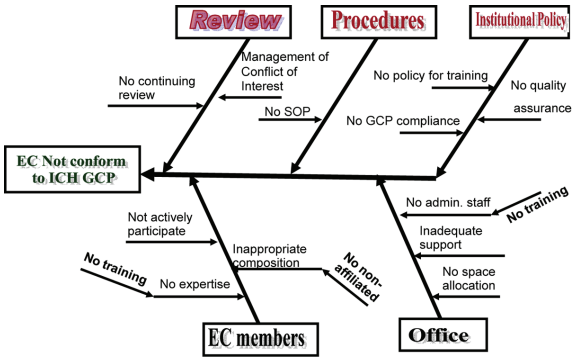

Fig. 1 The factors leading RECs not to conform to ICH GCP standards
RECs = Research Ethics Committees; ICH = International Conference on Harmonisation; GCP = Good Clinical Practice

with the same institution as the health REC. Community representatives accounted for only 8% of memberships. In addition, training needs for health REC members varied widely.

Many RECs have been established in Thailand especially in medical schools and general hospitals. The factors that promote RECs in Thailand might be the enforcement of the Medical Council of Thailand regulations (Medical Profession Act 2001). Medical practitioners who conduct or collaborate in a research or experiment on human subjects shall commence the present study in question only after explicit approval from the relevant ethical committees. The other factors are hospital accreditation and enforcement of research for quality development of the hospital. Factors leading RECs do not conform to ICH GCP included inadequate support such as no space allocation of REC offices, not enough administrator staff, and no training (Fig. 1). An extremely important point is awareness of and strict compliance with guidelines by directors of the institutes that have biomedical research. They should set policy to promote research and support the operation of RECs to protect human research participants, and at the same time, pay attention to independent review. Conforming to ICH GCH standards such as continuing review, setting up standard operation procedures, managing conflicts of interest of investigators, and RECs, and training all stakeholders are also important. The quality assurance of RECs such as risk and benefit ratio of research participants, appropriate composition of EC members, training, independent review process, continuing review of adverse events and management of conflicts of interest is the main duty of the review process.

Conclusion

A strong support from the organization leader is a key factor to efficiency and high standards of REC operation. Developing a network of REC institutes will be useful for further development. FERCIT plays an important role in transferring up-to-date knowledge and maintaining international standards by arranging ongoing training for members who mostly are REC members, so that they will apply knowledge to protect the rights, safety and well-being of research participants.

Acknowledgement

The authors wish to thank all members of the Forum for Ethical Review Committee in Thailand (FERCIT) for all their support. We wish to thank all members of REC members in Thailand who made this study possible.

Potential conflicts of interest

None.

Reference

1. Kulapongs P. The first research ethics committee in Thailand. In: Nawacharoen W, editor. 50th anniversary, Faculty of Medicine, Chiang Mai University. Chiang Mai: Faculty of Medicine, Chiang Mai University; 2009: 227-30. [in Thai]
2. The minutes of the Forum for Ethical Review Committee in Thailand (FERCIT). Bangkok: FERCIT; 2006.
3. Medical Profession Act (B.E. 2544 or A.D. 2001) Section 6. Bangkok: Medical Council of Thailand; 2001.
4. Saito T. Present status of ethics committees of the medical schools in Japan. Tokushima J Exp Med 1991; 38: 103-11.
5. Arshad A, Arkwright PD. Status of healthcare studies submitted to UK research ethics committees for approval in 2004-5. J Med Ethics 2008; 34: 393-5.
6. Moodley K, Myer L. Health Research Ethics Committees in South Africa 12 years into democracy. BMC Med Ethics 2007; 8: 1.

สถานภาพและการดำเนินงานด้านพิจารณาจริยธรรมการวิจัยของคณะกรรมการจริยธรรม การวิจัยในคนในประเทศไทย

สุธี พานิชกุล, พรรณแข มไหศวริยะ, นิมิต มรกต, สุมาลี คอนโด, สุภัค แซ่โง้ว, อาภรณ์ภิรมย์ เกตุปัญญา

ภูมิหลัง: *ปัจจุบันมีการจัดตั้งคณะกรรมการจริยธรรมการวิจัยในคนขึ้นในสถาบันต่าง ๆ เป็นจำนวนมากโดยมีวัตถุประสงค์เพื่อดูแล ปกป้อง คุ้มครองสิทธิ ความเป็นอยู่ที่ดีของอาสาสมัครที่เป็นมนุษย์ที่เข้าร่วมโครงการวิจัยในสถาบันนั้น ๆ จึงเกิดคำถามใหม่ว่าทุกคณะกรรมการที่จัดตั้งขึ้น มีการทำงานที่เป็นมาตรฐานเดียวกัน และได้มาตรฐานสากลหรือไม่*

วัตถุประสงค์: *เพื่อศึกษาถึงจำนวน สถานภาพ และการดำเนินงานด้านพิจารณาจริยธรรมการวิจัยของคณะกรรมการจริยธรรมการวิจัยในคนในประเทศไทยในขณะนี้*

วัสดุและวิธีการ: *โดยส่งแบบสอบถามทางไปรษณีย์ไปยังสถาบันที่น่าจะมีการจัดตั้งคณะกรรมการจริยธรรมการวิจัยในคน ได้แก่ มหาวิทยาลัยที่มีคณะแพทยศาสตร์ และโรงพยาบาลในสังกัดกระทรวงสาธารณสุขระดับโรงพยาบาลศูนย์ โรงพยาบาลทั่วไป โรงพยาบาลในสังกัดหน่วยงานของรัฐอื่น ๆ โรงพยาบาลเอกชนขนาดใหญ่ และสถาบันที่มีการวิจัยด้านวิทยาศาสตร์การแพทย์ จำนวน 130 ฉบับ ทั่วประเทศ*

ผลการศึกษา: *ได้รับแบบสอบถามตอบกลับมาทั้งสิ้นจำนวน 78 ฉบับ คิดเป็นร้อยละ 60 พบว่าคณะกรรมการฯ มีการจัดทำแผนการดำเนินงานมาตรฐาน จำนวน 30 แห่ง มีสำนักงานเป็นเอกเทศแยกต่างหากจากสำนักงานอื่น ๆ จำนวน 22 แห่ง ความถี่ของการประชุมเพื่อพิจารณาโครงการวิจัย โดยเฉลี่ย 1 ครั้งต่อเดือน จำนวนกรรมการในแต่ละคณะโดยเฉลี่ยเท่ากับ 14 คน ส่วนใหญ่เป็นผู้ที่มีคุณวุฒิสายวิทยาศาสตร์ คณะกรรมการฯที่ไม่มีบุคคลภายนอกสถาบันเป็นกรรมการร่วมด้วยมีจำนวน 7 แห่ง คณะกรรมการฯ จำนวน 30 แห่ง ไม่เคยจัดการอบรมด้านหลักจริยธรรมการวิจัยในคนให้กรรมการและนักวิจัยภายในสถาบัน (คิดเป็นร้อยละ 43.5) วิธีการลงมติผลการพิจารณาโครงการวิจัยใช้วิธีเป็นเอกฉันท์ (Consensus) จำนวน 51 แห่ง และวิธีลงมติโดยคะแนนเสียงส่วนใหญ่ (Majority vote) จำนวน 14 แห่ง คณะกรรมการฯจำนวน 22 แห่ง มีการจัดการกับกรรมการผู้มีส่วนได้ส่วนเสียในโครงการวิจัยโดยจะขอให้ออกจากห้องประชุมขณะลงมติ แต่สามารถเข้าร่วมประชุมเพื่อตอบคำถามเกี่ยวกับโครงการวิจัยได้ คณะกรรมการฯที่ทำการติดตามโครงการวิจัยมีจำนวน 39 แห่ง (คิดเป็นร้อยละ 56.5) โดยทบทวนการรายงานความก้าวหน้าของโครงการวิจัยที่ผู้วิจัยส่งมาทุก 6 เดือน หรือ 1 ปี*

สรุป: *ความสนับสนุนจากผู้บริหารองค์กรแก่คณะกรรมการจริยธรรมการวิจัยในคนเป็นปัจจัยสำคัญที่จะทำให้ประสิทธิภาพในการดำเนินงานของคณะกรรมการฯขององค์กรนั้น ๆ มีมาตรฐานเป็นที่ยอมรับความร่วมมือเป็นเครือข่ายกันระหว่างคณะกรรมการฯประจำสถาบันต่าง ๆ จะเป็นประโยชน์ในการเรียนรู้ร่วมกัน*