An Education Program for Thai IRB Staffs: "Modern IRB Officers"

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Presentation at the 1st Asia Pacific Research Ethics Conference (APREC 2010)
16th-18th September 2010, Orchard Hotel, Singapore.

ABSTRACT

Objective: Standard operating procedures and education for Institutional Review Board (IRB) staff are important issues and will contribute to their competency and effectiveness in working. An educational program for Thai IRB staff, taught by Siriaj IRB staff, was developed.

Methods: A one-day course was organized with two objectives: to know the framework of Strategic Initiative for Developing Capacity for Ethics Review (SIDCER) and Forum for Ethical Review Comittees in Asia and Western Pacific Region (FERCAP) survey, and to learn to conduct the day-to-day activities of IRB effectively. The course included lectures, IRB office visit and a researcher's input. Each Siriraj IRB staff was assigned one IRB member to provide guidance, comment and assistance. The program began with rationale and objectives, followed by the framework of SIDCER's recognition program, Standard Operating Procedures (SOPs), review process, data management and archive. Staffs showed their documents, time table and tips to improve the work. An invited clinical researcher presented his expectation and perception of IRB services. Lastly, participants visited the office to observe the staffs' daily activities, the IT system, website, and archiving of documents. Sharing experience and knowledge was encouraged. A questionnaire and open discussion were used to evaluate the program.

Results: Thirty-two participants of 15 institutes varied in experience. They shared their experience and knowledge with questions, answers and feedback. Participants indicated positive satisfaction and gained more knowledge after the course, whereas Siriraj IRB staff had better understanding of their roles. A future educational course may be twice a year as recommended.

Conclusion: The program could educate and reinforce IRB staff about their roles and responsibilities. Such education could also increase their understanding about SIDCER/FERCAP surveys.

Keywords: Siriraj Institutional Review Board, IRB staff, Education, Research ethics.

Siriraj Med J 2012;64:98-100

E-journal: http://www.sirirajmedj.com

INTRODUCTION

The mission of the Institutional Review Board (IRB) is to protect the rights, safety and welfare of human research subjects in a consistent manner throughout the institute.[1-7] In these regards, IRB staffs' general responsibilities are to advocate and maintain knowledge of local/national/international acts, laws, regulations, procedures, and ethical standards. They also assist in administration of the IRB, process incoming applications to the committee in a timely manner and ensure that all required documents have been submitted. Disappointingly, the majority of the Thai IRB staff lack specific education and training programs that can effectively ensure that they understand ethical issues for research.[8] Their skills are achieved mainly by on-the-job process. Having inadequate knowledge, they are unable to implement regulations and carry out their responsibilities effectively. Thus, regular training for IRB staff is important to ensure their consistency and competence.[1-4] In Thailand, not to mention about the staff education, it is difficult even to recruit staff.

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Received 17 March 2012
Revised 12 June 2012
Accepted 13 June 2012

It is proposed all over the world that IRB staffs, particularly the new ones, must be oriented, educated and trained.[1-10] At minimum, such orientation and education should provide IRB staff with knowledge and skills to uphold acts, laws, regulations, institute / university policy, procedures and ethical standards on the protection of human research subjects.[1-8] We at the Siriraj IRB believe that education for IRB staff is a fundamental issue for IRB staff and will contribute to better research conduct in Thailand.[1-11] In addition, we would like to share our experience with other IRB staff to improve the quality and effectiveness of IRB administration.[7-8,10-11] Subsequently, an educational program for IRB staff was developed.

Objective

The purpose of this paper is to describe an education program for Thai IRB staff, taught by IRB staff of the Faculty of Medicine Siriraj Hospital in 2010. A one-day course, "Modern IRB Officers", was developed and organized with the following objectives for the trainees:

1. to know the framework of good IRB function according to the Strategic Initiative for Developing Capacity for Ethics Review (SIDCER) and Forum for Ethical Review Committees in Asia and the Western Pacific Region (FERCAP) survey
2. to learn to conduct day-to-day activities of IRB effectively
3. to learn about the requirements and potential obstacles to set up and/or uphold an IRB committee and to exchange the experience.

MATERIALS AND METHODS

Methods

A brainstorm among the Siriraj IRB chairperson, committee members and staffs was conducted to design the course. Initially by informal questioning of what the staffs thought would be the needed knowledge, educational activities and team building exercises were planned. Finally, it was decided to have a one-day course, 7 lecture sessions by IRB staffs, a visit to the Siriraj IRB office and listen to feedback from one of our core customers (a clinical researcher). The process of training and delegating work assignments were discussed. There were 7 topics presented by 7 Siriraj IRB staffs. Each IRB staff was assigned one Siriraj IRB committee as her mentor who would provide guidance and comment on the IRB staffs' PowerPoint presentation in addition to assist in answering questions after each session.

The program began with an introduction to the rationale and objectives of the program. These were followed by learning about the framework of SIDCER/FERCAP's recognition program, presentation of the guidelines for setting up an IRB, the Siriraj Standard Operating Procedures, initial review process, continuing review process, adverse event report, protocol amendment, data management and archiving of documents. Siriraj IRB staffs demonstrated their documents and explicated their ideas about time table and tips to improve the work. There was one session that included a clinical researcher to present his expectation and perception of the IRB services. Lastly, participants were divided into 8 subgroups to visit the Siriraj IRB office. Each subgroup had a chance to observe each working station of the office closely. By rotating to each site, the participants would learn the ways of conducting day-to-day activities of the Siriraj IRB, the IT system, the Siriraj website, and archiving documents step by step. Practical time was scheduled for demonstration of archiving documents by using a computerized system and for accessing the Siriraj website.

An open discussion was facilitated. Everyone was encouraged to share one's own experience and knowledge to the group with ample questions and answers.

In order to evaluate the effectiveness of the course, a 9-item questionnaire was conducted. The participants rated the appropriateness of the content, quality of the presentation, the appropriateness of time spent in each session, the hand-out, the knowledge both before and after training, and applicable of achieved knowledge, based on a 4-rating scale (1= the least / worst, though 4 = the best / most). The comment and recommendation were also documented.

RESULTS

The course was organized on 29 June 2010. Participants were 27 IRB staff and 5 IRB members from 15 institutes all over Thailand. More specifically, the level of participants' experiences in Institutional Review Board varied from more than 5 years (44%), less than 1 year (31%), and had no experience (25%).

After the course, their assessment and feedback were collected. Evaluation of satisfaction level showed positive feedback with 44.8% and 55.2% of rating scale at the level of 3 and 4, respectively. Participants indicated that they gained more knowledge after the course with 3.1% and 59.4% of pre-training and post-training knowledge, respectively. Basically, they were concerned about the SIDCER/FERCAP assessment and dilemmas faced such as documentation, initial and continuing protocol reviewing processes. Time and additional guidelines related to IRB office procedures, tricks to endorse procedures, regulation, and ethical standards related to human subject protection were discussed. Frequently asked questions related to ethics which IRB staff might encounter were also discussed. Other shared questions and comments were related to basic information on the roles of IRB staff and discussion of research ethics issues. Staff's burden and workload were also brought up. Participants agreed that training of the IRB staff should be conducted periodically, similar to continuing education seminars. In addition, they requested that this course should be organized again twice a year so that more IRB staff could join.

DISCUSSION

We intended to create and implement an educational program that would motivate and educate IRB staff. Furthermore, such a program would also effectively train our IRB staff and IRB committee members (here were mentors). They should be able to communicate with research team members (the clinical researcher) who conducts human subjects research. It is recommended that orientation and education procedures should be appropriate for the type of audience (e.g., IRB staff, IRB administrator, IRB members).[1-10] As we aimed to educate IRB staff, we involved them in selecting topics for the course. As a result, we are convinced that by communicating with IRB staff to identify the need for education and including them in training activities were the key points of the success of this education program.

Our staff at Siriraj IRB were instrumental in preparing the IRB committee to be recognized by the SIDCER/

FERCAP in 2009. For the participants, the ability to demonstrate understanding of processes and procedures were very important. All should utilize the course and assembly as educational opportunities.

Participants shared their experience and asked questions. Topics of discussion included their weak capacity, lack of social/behavioral research experiences, right to access medical records, consent process, vulnerable subjects, conflicts of interest, review protocol, and monitoring process. They revealed that a shortage of IRB staff members and committees were their momentous burden, topping up their responsibilities in checking and overseeing the completeness of the human subject research protocols. Generally the lack of sufficient resource is one of the common problems affecting IRB quality. Consequently, requiring enough staff, space, infrastructure and IT support to run IRB as well as receiving training were implied to be the minimum acceptable for their needs.

The success of the training program was revealed. Evaluation of satisfaction showed a very positive feedback with a mean score more than 4 out of 5 rating scale. Participants indicated that their knowledge and understanding of IRB staff's job, procedures and ethical standards on the protection of human research subjects were greater than before. By teaching others, the Siriraj IRB staffs had better understanding and gained more insight of their roles.

With changing acts, laws, regulations and guidelines, it is important to maintain up-to-date knowledge of procedures and the protection of human subjects and policies. These aspects were not included explicitly in this program as it is an important issue that needed extra session(s) to learn. Similarly institute/university policy was not incorporated in this training as each institute's/university's policy and function varies from one to another. Each IRB mission and vision should be aligned with the institute/university policy in spite of IRB independence. Other appropriate skills and experience that should be considered are experience in human subject research, computer and database skills, good communication skills and best service behaviors.

By organizing this course and involving IRB staffs in training activities, we found that this is a good way to increase Siriraj IRB staff's knowledge. At the same time, the program opened opportunities for participants to discuss their problems and pitfalls in running their own IRBs. The Siriraj IRB staff and participants have the abilities and commitment to be appropriately trained, although human research regulation experience is relative rare among applicants.

In the future, we hope that new IRB staff shall complete training upon initial appointment to be IRB staff. More specifically, they shall complete a role-specific competency and assessment tool within a suitable timeline of their start date in the IRB. Furthermore, they shall complete a basic course for biomedical and social/behavioral research within their orientation period. Attending annual /routine IRB member training is also expected. Special issues may be added to staff training on as needed basis. Finally, all IRB staff attendance and participation in training courses shall be documented and such documentation shall be maintained by the IRB office.

Implement

Future training of IRB staff programs with a 2-day course twice a year may be performed on as needed basis with workshop for specific topics. Continuing education encompasses many activities such as certification, educational workshops, regular staff meetings and others. Since we implemented our program, we received many comments and praises that the course was very useful and unique.

ACKNOWLEDGMENTS

The authors thank Siriraj IRB staffs and committee for their contribution. We also appreciate travel grant support from the Faculty of Medicine Siriraj Hospital, Mahidol University for presenting this work at the 1st Asia Pacific Research Ethics Conference (APREC 2010) during 16th-18th September 2010, Orchard Hotel, Singapore.

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