Original Article

Unmet Research Ethics Committee Requirement Components and Review Outcomes of Medical Trainees' Research Protocols in a Thai Medical School

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Objective: To assess unmet research ethics committee (REC) requirement components and review outcomes of the trainees' research protocols submitted to the REC.

Materials and Methods: We conducted a retrospective study of protocols which trainees were principle investigators of and were submitted to Human Ethics Committee of Thammasat University during 2014 to 2016. Unmet REC requirement components and review outcomes of the trainees' protocols were compared with the faculty's protocols of which review type and review period were matched.

Results: 86 trainees' protocols and 86 faculty's matched protocols were included. The most common unmet REC requirement component for the trainees' protocols were inadequate description of methodology (71%). Significantly higher proportion of the trainees' protocols had inadequate literature review, incorrect sample size calculation, and inadequate privacy and confidential management compared to the faculty's protocols. Protocol approval rate were not different between the trainees' and faculty's protocols (98% vs. 95%). However, the median time from initial protocol submission to approval was significantly longer among the trainees' protocols (71 vs. 53 days; $p = 0.005$).

Conclusion: Feedbacks and focused education on these unmet REC requirement components are necessary for the trainees to improve their knowledge on research ethics and efficiency in research protocol submission to the REC.

Keywords: Medical trainees, Research protocol, Research ethics committee, Unmet requirement, Review outcomes

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Medical research protocols require review and approval by a research ethics committee (REC) to ensure feasible study design, execution, and analysis along with protection of privacy, confidentiality, and informed provision of benefits versus risks for participation. The majority of submitted protocols (71 to 96%) reportedly yield final approval[1-3]. Significant delays in protocol reviews and approval are due to the investigator's lack of familiarity with the REC standard operating procedures along with limited knowledge of research protocol preparedness plans and knowledge about REC requirements for approval[4]. Additional factors reported to influence the review process include insufficient training of the review committee members, lack of national ethics guidelines and accreditation, non-reconciliation of reviewer comments, workload burden, and lack of efficiency in protocol review[1,5-8]. A study on REC review and approval in Canada revealed that research protocols with more than minimal risk, submission of research protocol in the earlier years, and research protocols funded by for-profit sponsors were associated with longer approval time[9].

In Thailand, principal investigators generally submit research protocols to the designated REC of their institutions. The REC reviews the submitted protocol, information sheets (IS), informed consent form (ICF), case record forms, and other relevant documents according to national and international guidelines[10-13], after which the committee determines if the research can be done, requires revision before approval, or does not meet ethical standards to conduct. If approved, the REC will conduct continuing review of research protocol amendments, serious adverse events, protocol deviations, protocol violations, progress reports, and final reports until the research projects are completed and closed. Members of the REC are required to have training in research ethics that usually includes human research subject protection, good clinical practice (GCP), and standard operating procedures; investigators are required

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to be trained in human research subject protection and/or GCP before conducting the research. These training sessions are usually arranged by the REC of the institution or the national authorities for research ethics several times per year. The National Ethics Committee Accreditation System in Thailand and the Forum of Ethical Review Committees in the Asian and Western Pacific Region provide accreditation of the research protocol reviews in Thailand.

Conducting medical research has been encouraged among Thai medical students and is a requirement for postgraduate training in Thailand. However, these trainees have encountered challenges, presumably associated with limited training in clinical trial design, protocol development, and research ethics within standard educational curriculums. Knowledge about research ethics and REC review process seem inherently necessary to facilitate research protocol submissions for REC approval. To date, there are a paucity of studies that have assessed the research protocol submissions of trainees. The objectives of this study were to describe characteristics, unmet REC requirement components, and review outcomes of protocol submissions by trainees compared to faculty.

Materials and Methods

Study design and setting

A retrospective matched control study was conducted of research protocols and relevant documents submitted to the REC of Thammasat University Medical School (REC-TU), Pathumthani, between 1 November 2014 and 30 November 2016. The school enrolls approximately 200 medical students, 50 residents, and 20 fellows each year; the REC-TU reviews approximately 250 biomedical and biosocial research protocols annually, submitted by faculty, physicians in training, medical students, health science students of the medical school, and research affiliates of the medical school's healthcare facilities. The trainee protocol preparation and submissions are generally supervised by the trainee research advisors. The REC-TU arranges a training session annually about REC requirements for protocol submission for investigators and provides learning materials downloadable from the REC-TU's website. This study was approved by REC-TU. Inclusion criteria were 1) all research protocols and relevant documents for which trainees were the principal investigators, and 2) matched protocols and relevant documents of the faculty (ratio 1: 1) by type of REC review (full board or expedited) and calendar year. Research protocols with incomplete data or unavailable outcomes of interest were excluded.

Data collection and outcome measurement

The investigator (TK) identified the eligible research protocols from the database of REC-TU. These eligible research protocols and relevant documents were reviewed and assessed for criteria recommended in national and international guidelines[10-13] and in the REC-TU learning materials. The investigator (TK) determined whether the submitted protocols and their relevant documents met or failed to meet REC requirement components. For research protocols, collected data included type of study, type of REC review, departments of the principal investigators, sources of the research budget, and unmet REC requirement components based on the resolutions of REC-TU meeting in regards to 14 specific criteria created by REC-TU: review type, research title, background, literature review, cited references, research objectives, study methodology, sample size calculation, outcome measurement, statistical analysis, conflict of interest declaration, management of privacy and confidential issues, recruitment, and consent process. For the IS and ICF, unmet REC requirement components were based on the resolution achieved at the REC-TU meeting in regards to 12 specific criteria created by REC-TU: research team contact information, reasons for invitation to participate in the study, information about study duration number of study participants, research procedure, risks of study participation, benefits from study participation, travel compensation, expenses the participants are responsible for, alternatives if the participants choose not to participate in the study, privacy and confidential management, investigator responsibility when adverse reactions occur, and the quality of language. Revised documents of the principal investigators following the recommendations of REC-TU were reviewed. Review outcomes included the initial review outcome, the number of unmet REC requirement components, the time required for the approval process, and the proportion of protocols approved at 6 months. The unmet REC requirement components and review outcomes were compared as trainee versus faculty protocols.

Statistical analysis

All analyses were performed using SPSS, version 15.0 (SPSS, Chicago, Illinois). Descriptive data were presented in percentage and median. Categorical variables were compared using the Pearson's χ^2 or Fisher's exact test, as appropriate. Continuous variables were compared using Mann Whitney U test. The *p*-values less than 0.05 were considered statistically significant.

Results

Characteristics of the research protocols submitted to the REC-TU

Of the 182 eligible research protocol, 10 were excluded due to incomplete data or uncertain outcomes of interest (5 faculty protocols and 5 trainee protocols). A total of 172 remaining research protocols were included for analysis. There were 86 faculty protocols matched to 86 trainee protocols submitted by residents (n = 57, 66%), fellows (n = 21, 24%), and medical students (n = 8, 9%). Forty-three trainee protocols (50%) were full-board reviews and 43 (50%) were expedited reviews (Table 1). Most of the trainee protocols were for research within the Internal Medicine Department (45%), with grants from the Faculty

of Medicine (51%). Compared to the faculty protocols, a higher proportion of the trainee protocols were retrospective studies (43% vs. 19%) and without a funding source (37% vs. 13%) (Table 1).

Unmet REC requirement components for the research protocols

The five most common incomplete REC requirements within submissions from medical trainees were categorized as description of methods (71%), research title (i.e. the title did not correlate with research methodology or objectives) (55%), literature review (38%), information about consent process (36%), and sample size calculation (27%). For faculty submissions, the five most common incomplete research submissions were categorized as description of methods (59%), information about consent process (51%), research title (38%), sample size calculation (33%), and exclusion criteria (23%) (Table 2). Compared to the faculty protocols (Table 2), a significantly higher proportion of trainee protocols had inappropriate research title (55% vs. 38%), unclear or inadequate literature review (38% vs. 19%), incorrect sample size calculation (15% vs. 6%), no conflict of interest declaration (26% vs. 11%), and no description for management of privacy and confidential issues (21% vs. 7%).

Unmet REC requirement components for the information sheets and informed consent forms

The five most common incomplete trainee REC requirement components for the IS and ICF were categorized as information on how to contact the research team (46%), the research procedure (39%), study duration (35%), compensation (35%), and risks of study participation (26%). In comparison, the faculty's top five incomplete REC requirement components for the IS and ICF were categorized as the research procedure (37%), compensation (31%), how to contact research team (28%), study duration (28%), and number of study participants (25%) (Table 3). In the comparison of IS and ICF requirements, missing information about the risks of study participation was noted for trainees (26%) versus faculty (9%); there were no significant

Table 1. Characteristic of 172 research protocols submitted for Research Ethics Committee review and approval

Characteristic	All (n = 172) No. (%)	Trainees' protocols (n = 86) No. (%)	Faculty's protocols (n = 86) No. (%)	*p*-value[a]
Review type				1.00
Full board	86 (50)	43 (50)	43 (50)	
Expedited	86 (50)	43 (50)	43 (50)	
Study type				0.001
Retrospective	53 (31)	37 (43)	16 (19)	
Prospective	52 (30)	18 (21)	34 (40)	
Randomized controlled	35 (20)	21 (24)	14 (16)	
Cross-sectional	27 (16)	9 (11)	18 (21)	
Descriptive	5 (3)	1 (1)	4 (5)	
Department of the principal investigators				<0.001
Internal medicine	63 (37)	39 (45)	24 (28)	
Pediatrics	19 (11)	7 (8)	12 (14)	
Pre-clinical sciences	14 (8)	1 (1)	13 (15)	
ENT/Ophthalmology	14 (8)	2 (2)	12 (14)	
Surgery	10 (6)	6 (7)	4 (5)	
Orthopaedics	10 (6)	4 (5)	6 (7)	
Obstetrics and Gynecology	10 (6)	8 (9)	2 (2)	
Emergency department	9 (5)	8 (9)	1 (1)	
Radiology	7 (4)	7 (8)	0 (0)	
Community medicine	4 (2)	0 (0)	4 (5)	
Thai traditional medicine	4 (2)	3 (4)	1 (1)	
Psychology	4 (2)	0 (0)	4 (5)	
Anesthesiology	2 (1)	0 (0)	2 (2)	
Epidemiology	1 (1)	0 (0)	0 (0)	
Rehabilitation medicine	1 (1)	0 (0)	1 (1)	
Budget				<0.001
Internal source	91 (53)	44 (51)	47 (55)	
None	43 (25)	32 (37)	11 (13)	
External source	38 (22)	10 (12)	28 (33)	

[a] = Comparison between trainees' protocols and faculty's protocols

Table 2. Comparison of unmet research ethics committee requirement components between trainees' and faculty's research protocols

Unmet component	Trainees' protocols (n = 86) No. (%)	Faculty's protocols (N = 86) No. (%)	*p*-value[a]
Inappropriate self-evaluation of review type			
Misevaluating full board to expedited review	15 (17)	14 (16)	0.84
Misevaluating expedited to exempt review	2 (2)	7 (8)	0.17
Inappropriate research title	47 (55)	33 (38)	0.03
Unclear or inadequate background	17 (20)	9 (11)	0.09
Literature review			
Unclear/inadequate	33 (38)	16 (19)	0.004
Incorrect	2 (2)	2 (2)	1.00
References			
No citation	2 (2)	7 (8)	0.17
Incorrect	3 (4)	0 (0)	0.25
Unclear objective	9 (11)	5 (6)	0.27
Incorrect study type	8 (9)	4 (5)	0.37
Sample size			
No sample size calculation	23 (27)	28 (33)	0.40
Incorrect sample size calculation	13 (15)	5 (6)	0.04
No information about study duration	3 (4)	0 (0)	0.25
Inclusion criteria			
Unclear	20 (23)	19 (22)	0.86
Inappropriate	11 (13)	8 (9)	0.47
Exclusion criteria			
Unclear	19 (22)	20 (23)	0.86
Inappropriate	14 (16)	10 (12)	0.38
Methodology			
Inadequate information	61 (71)	51 (59)	0.11
Inappropriate to test hypothesis	3 (4)	1 (1)	0.62
Unethical	2 (2)	3 (4)	1.00
Inappropriate outcome measurement	2 (2)	0 (0)	0.50
Statistical analysis			
Inadequate	10 (12)	15 (17)	0.28
Inappropriate	2 (2)	3 (4)	1.00
No conflict of interest declaration	22 (26)	9 (11)	0.01
Management of privacy and confidential issues			
No description	18 (21)	6 (7)	0.008
Inadequate	2 (2)	11 (13)	0.02
No information about recruitment process	16 (19)	16 (19)	1.00
Consent process			
No information	31 (36)	44 (51)	0.04
Inappropriate	2 (2)	0 (0)	0.50

[a] = Comparison between trainees' protocols and faculty's protocols

differences in other REC requirement components (Table 3).

Outcomes of the research protocol review

After the initial review, 91% of the 172 research protocols submitted by trainees and faculty required revision for approval (Table 4). These initial review results were not significantly different in regards to type of protocol review or submission by trainees versus faculty. Compared to the faculty protocols (Table 4), the trainee protocols had significantly more unmet REC requirements (median number of 5 vs. 4) for all protocols and for protocols requiring full board review ($p<0.05$). For expedited review protocols, the time from REC sending review results to PIs to the REC receipt of protocol revisions, the time from REC sending review results to PIs to protocol approval, and the time from initial protocol submission to protocol approval were significantly longer for trainee protocols than for faculty protocols (27 vs. 12 days, 63 vs. 30 days and 78 vs. 54 days, respectively). There were no significant time differences for full board review of trainee and faculty protocols and the proportion of research protocols approved within 6 months after initial submission were comparable between the trainee and faculty protocols (98% vs. 95%) (Table 4).

Table 3. Comparison of unmet research ethics committee requirement components between trainees' and faculty's protocol information sheets (IS) and informed consent forms (ICF)

Unmet component	Trainees' IS and ICF (n = 46) No. (%)	Faculty's IS and ICF (n = 69) No. (%)	*p*-value[a]
Research team contact information			
No information	21 (46)	19 (28)	0.06
Inadequate	2 (4)	0 (0)	0.16
Reasons for invitation to participate in the study			
No information	6 (13)	4 (6)	0.31
Inappropriate	2 (4)	1 (2)	0.57
No information about study duration	16 (35)	19 (28)	0.47
No information about the number of study participants	11 (24)	17 (25)	0.86
No information about research procedure	18 (39)	25 (37)	0.85
No information about risks of study participation	12 (26)	6 (9)	0.01
Benefits from study participation			
No information	1 (2)	6 (9)	0.24
Inappropriate	5 (11)	7 (10)	0.94
Travel compensation			
No information	16 (35)	21 (31)	0.70
Inappropriate	4 (9)	1 (2)	0.16
No information about expenses the participants are responsible for	7 (15)	10 (15)	0.97
No information about alternatives if the participants choose not to participate in the study	6 (13)	3 (5)	0.16
No information about privacy and confidential management	2 (4)	3 (5)	1.00
Investigator responsibility when adverse reactions occur			
No information	8 (17)	9 (13)	0.56
Inappropriate	3 (7)	1 (2)	0.30
Language used is difficult to understand	10 (22)	15 (22)	0.94
Space for signature not provided in the informed consent form	2 (4)	2 (3)	1.00

[a] = Comparison between trainees' and faculty's IS and ICF

Discussion

The major finding of this study was that the trainee protocol submissions were more frequently incomplete or inadequate for REC approval relative to the faculty protocol submissions. In prior reported assessments, the common protocol submissions gaps were in informed consent, justification of recruitment, assurance of subject anonymity, scientific validity, research methodology, sample size calculation, eligibility criteria, statistics and funding[2,3,14,15]. There were significant gaps in information for the research methods, consent process, conflict of interest declaration, management of privacy and confidential issues, literature review, sample size calculation, contact information, research procedures, participant compensation, and risks of study participation. These protocol submission gaps for trainee protocol submissions were especially evident for the full board review protocols. These findings suggest there is an educational opportunity to improve the protocol preparedness for the research design, execution, analysis, and ethical requirement components. The trainee's assigned research advisor can provide critical appraisal and contributions to the REC submission, in addition to notable contributions to scientific communication and data dissemination[1,16]. In addition, the existing REC-TU annual training session on REC requirements for protocol submission should be continued and incorporated into the interventions to improve efficiency of research protocol submission by the trainees.

The proportion of final approvals for the trainee protocols (98%) was higher than previously reported (71%) in the literature[1]. In our study, the trainees were listed as the principal investigators while in the prior study the submissions were not first authored by trainees. Additionally, there may be differences in characteristics of submitted protocols, mentor engagement, and the REC review processes. The rates of REC approval within 6 months were not significantly different between the trainees' and the faculty's research protocols. However, the trainee protocols took significantly longer time than the faculty protocols from initial submission to protocol approval and from the REC sending review results to principal investigators to receipt of revised protocols. These findings suggest that revision process by the trainees was likely problematic and may be due to their lack of knowledge on research ethics and lack of understanding of the ethical points raised by the reviewers. It should be noted that revision of protocols meeting expedited

Table 4. Comparison of protocol review outcomes between trainees' and faculty's protocols

Outcomes	All review protocols (n = 172)			Full-board-reviewed protocols (n = 86)			Expedited-reviewed protocols (n = 86)		
	Trainee (n = 86)	Faculty (n = 86)	*p*-value	Trainee (n = 43)	Faculty (n = 43)	*p*-value	Trainee (n = 43)	Faculty (n = 43)	*p*-value
Initial review result (%)			0.77			0.71			1.00
Approved	4 (5)	4 (5)		0 (0)	0 (0)		4 (9)	4 (9)	
Revision for approval	79 (92)	77 (90)		40 (93)	38 (88)		39 (91)	39 (91)	
Revision for resubmission	3 (4)	5 (6)		3 (7)	5 (12)		0 (0)	0 (0)	
Median number of unmet REC requirement components in research protocols (IQR)	5 (4 to 6)	4 (3 to 6)	0.02	5 (4 to 7)	4 (3 to 5)	0.002	4 (3 to 6)	4 (3 to 6)	0.90
Median number of unmet REC requirement components in information sheets and informed consent forms (IQR)	4 (2 to 5)	3 (2 to 4)	0.08	4 (2 to 5)	3 (2 to 4)	0.16	4 (3 to 7)	3 (2 to 5)	0.19
Time from REC sending review results to principal investigators to receipt of revised protocols (days, median, IQR)	21 (8 to 55)	13 (8 to 25)	0.02	20 (7 to 49)	14 (9 to 31)	0.46	27 (10 to 67)	12 (7 to 21)	0.009
Time from REC sending review results to principal investigators to protocol approval (days, median, IQR)	48 (31 to 89)	30 (20 to 52)	0.001	41 (26 to 64)	29 (19 to 65)	0.16	63 (33 to 121)	30 (22 to 51)	<0.001
Time from initial protocol submission to protocol approval (days, median, IQR)	71 (47 to 113)	53 (38 to 78)	0.005	68 (50 to 82)	53 (40 to 84)	0.16	78 (44 to 130)	54 (37 to 73)	0.01
Protocols not approved due to no revision ever sent back (%)	2 (2)	4 (5)	0.68	1 (2)	2 (5)	1.00	1 (2)	2 (5)	1.00

[a] = Comparison between trainees' and faculty's protocols
IQR = Interquartile range, REC = Research ethics committee

review for trainees was longer than revisions of protocols meeting full board review when compared to the faculty review timelines. This may be explained by the less pressure to initiate the studies at a specific time given that most of the expedited-reviewed protocols were retrospective studies.

From the study findings, we propose three interventions that may improve the efficiency of research protocol submission by the trainees and the faculty. First, feedback and educational interventions should focus on specific gaps identified by the institution's REC. Second, protocol submission templates that have all sections prefilled with essential ethical statements, have questions explicitly asking about ethical components or have reminders on REC requirement components of the protocol, IS, and ICF, should be created and required for submissions. Lastly, a recommendation specific for the trainees would be for the research advisors to review and provide sign-off of protocol submissions.

In one prior study, elective rotations of trainees with a REC and assignment to review samples of research protocols were shown to improve their knowledge on research ethics, informed consent, and risks and benefits of study participation[17]. Further investigation is required to determine appropriate interventions to improve the quality of research protocols submitted by the trainees. The interventions may include focused education on research ethics and how to efficiently submit research protocols to the REC, the use of protocol templates, IS, and ICF, along with determination of time permitted for protocol re-submission. After implementation of these interventions, the number and content of unmet REC requirement components and time used from initial submission to protocol approval should be re-evaluated.

As inherent to retrospective study design, there are notable limitations to acknowledge. First, characteristics of the trainee and faculty protocols may not be all matched. However, the types of REC review (full board and expedited) and the calendar year of submission that were chosen as matched characteristics were considered the important factors affecting the review process. Second, the retrospective design of the study may not allow for detecting other factors affecting the review outcomes, such as daily workload of the trainees and the faculty. Third, in our institution, the work on REC-TU submission was generally done by PIs (faculty or trainees). However, in some situations, other trainees or research assistants might help the faculty in the submission process of the protocols. Thus, the outcomes of interest for the faculty protocols may not completely represent the work done by the faculty.

Conclusion

The trainee protocols submitted to the REC had more unmet REC requirement components and required more time to protocol approval compared to the faculty protocols. These may indicate the trainees' lack of knowledge about research ethics, REC review process and adequate mentoring process in such topics. Stakeholders including REC and authorities responsible for trainee education should recognize these deficiencies and provide appropriate interventions to improve the content of trainee protocol submissions. Such interventions need to be tailored according to the findings from locally-conducted studies.

What is already known on this topic?

Medical students, residents and fellows (trainees) have encountered challenges in submission of research protocols for Research Ethics Committee (REC) approval. These are presumably associated with limited training in clinical trial design, protocol development, and research ethics within standard educational curriculums. However, limited data exists on deficiencies in REC requirement components of research protocols and relevant documents submitted by the trainees.

What this study adds?

The trainee protocols submitted to the REC had more unmet REC requirement components and required more time to protocol approval compared to the faculty protocols. Feedbacks and focused education on these unmet REC requirement components and research mentoring are necessary for the trainees to improve their knowledge on research ethics and efficiency in research protocol submission to the REC.

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Potential conflicts of interest

The authors declare no conflicts of interest.

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ประเด็นที่ไม่สอดคล้องกับข้อกำหนดและผลการพิจารณาโครงร่างการวิจัยของนักศึกษาแพทย์และแพทย์ประจำบ้านในโรงเรียนแพทย์แห่งหนึ่งในประเทศไทย

ธนา ขอเจริญพร, สุมาลี คอนโด, ทิพาพร ธาระวานิช

วัตถุประสงค์: เพื่อประเมินสิ่งที่ต้องปรับปรุงแก้ไขและผลการพิจารณาทางจริยธรรมการวิจัยในคนของโครงร่างการวิจัยของนักศึกษาแพทย์และแพทย์ประจำบ้าน

วัสดุและวิธีการ: การศึกษาโดยการทบทวนโครงร่างการวิจัย ซึ่งนักศึกษาแพทย์และแพทย์ประจำบ้านเป็นผู้วิจัยหลักและส่งมาให้คณะอนุกรรมการจริยธรรมการวิจัยในคนชุดที่ 1 (คณะแพทยศาสตร์) มหาวิทยาลัยธรรมศาสตร์พิจารณาในช่วงปี พ.ศ. 2557 ถึงปี พ.ศ. 2559 สิ่งที่ต้องปรับปรุงแก้ไขและผลการพิจารณาถูกเปรียบเทียบกันระหว่างโครงร่างการวิจัยของนักศึกษาแพทย์และแพทย์ประจำบ้าน กับโครงร่างการวิจัยของอาจารย์แพทย์ที่มีลักษณะการพิจารณาและช่วงเวลาที่ได้รับการพิจารณาเหมือนกัน

ผลการศึกษา: มีโครงร่างการวิจัยของนักศึกษาแพทย์และแพทย์ประจำบ้าน 86 โครงร่าง และของอาจารย์แพทย์ 86 โครงร่างที่นำมาศึกษา สิ่งที่ควรปรับปรุงที่พบบ่อยที่สุดสำหรับโครงร่างการวิจัยของนักศึกษาแพทย์และแพทย์ประจำบ้าน คือ การอธิบายเกี่ยวกับกระบวนการวิจัยที่ไม่เพียงพอ (ร้อยละ 71) เมื่อเทียบกับโครงร่างการวิจัยของอาจารย์แพทย์ โครงร่างการวิจัยของนักศึกษาแพทย์และแพทย์ประจำบ้านมีสัดส่วนของโครงร่างที่มีการทบทวนวรรณกรรมไม่ครบถ้วนเพียงพอ มีการคำนวนขนาดตัวอย่างที่ไม่ถูกต้อง และมีการจัดการกับการรักษาความเป็นส่วนตัวและความลับของอาสาสมัครไม่เพียงพอมากกว่า อัตราการอนุมัติโครงร่างการวิจัยของนักศึกษาแพทย์และแพทย์ประจำบ้านเทียบกับของอาจารย์แพทย์ไม่แตกต่างกันอย่างมีนัยสำคัญ (ร้อยละ 98 เทียบกับ ร้อยละ 95) อย่างไรก็ตามค่ากลางของระยะเวลาที่ใช้ตั้งแต่ยื่นโครงร่างการวิจัยเพื่อพิจารณาจนถึงได้รับอนุมัตินั้นมากกว่าสำหรับโครงร่างการวิจัยของนักศึกษาแพทย์และแพทย์ประจำบ้านอย่างมีนัยสำคัญ (71 วัน เทียบกับ 53 วัน, $p = 0.005$)

สรุป: การแจ้งผลการประเมินแบบป้อนกลับ และการให้การศึกษาที่มุ่งเน้นในสิ่งที่ควรปรับปรุงแก้ไขของโครงร่างการวิจัยเป็นสิ่งจำเป็นสำหรับนักศึกษาแพทย์และแพทย์ประจำบ้านเพื่อพัฒนาความรู้เกี่ยวกับจริยธรรมในการวิจัยและเพิ่มประสิทธิภาพในการเตรียมและส่งโครงร่างการวิจัยเพื่อให้คณะอนุกรรมการจริยธรรมการวิจัยในคนพิจารณา