

Research Ethics Training Needs in Thailand and Vietnam

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Abstract

Background To describe the types of research being conducted and the availability of research ethics training and research ethics review in Thailand and Vietnam.

Methods An English survey with four major domains, Research Area, Societal Conditions, Research Ethics, and Basic Information was translated into Thai and Vietnamese by native training partners from the NIH Fogarty Research Ethics Training Program. **Setting/Participants** The survey was administered in two modes - an online survey distributed via an email link in Thailand, and an onsite paper survey in Vietnam. Participants were Thai and Vietnamese trainees and investigators from prestigious universities.

Results In Thailand, there were 363 respondents (9.3% online response rate); in Vietnam there were 117 survey participants. Among those who conduct research, 81% in Thailand and 92% percent in Vietnam reported that their research involves human subjects. Among human subject researchers, 83% in Thailand reported having ethics training, and among these, only 44% reported having formal training. In Vietnam, 66% reported having research ethics training; among them, 72% had formal training. Human subject research reported include clinical observations (26% from Thailand and 26% from Vietnam) and clinical interventions (29% from Thailand and 26% from Vietnam). Significant proportion of respondents reported that their institutions have guidelines (97% in Thailand; 89% from Vietnam) and have established Institutional Review Boards (92% in Thailand; 77% in Vietnam). 76% and 79% of respondents in Thailand and Vietnam respectively reported no experience in teaching research ethics. Lack of trained research ethics teachers (38% in Thailand and 59% in Vietnam), training materials (34% in Thailand; 43% in Vietnam), and an adequate curricular “delivery platform” (58% in Thailand; 49% in Vietnam) are most pressing issues.

Conclusions We identified gaps in research ethics training in these two South East Asian countries undergoing rapid socioeconomic transition and identified future curricular focus opportunities.

Background

The quest to find cures and treatments for diseases has propelled the research enterprise globally; much of the progress was made possible due to animal and human experiments, and there is a need to train researchers to conduct research ethically. In the words of Claude Bernard—“The principle of medical and surgical mortality consists in never performing on man an experiment which might be harmful to him in any extent even though the result might be highly advantageous to science i.e. to health of others”¹. The Nuremberg Code was introduced in 1947, after World War II, where gruesome experimentations were performed on captives and prisoners of war.² Since then, many policy recommendations on protection of human subjects research have been introduced, among them the Declaration of Helsinki (DoH)³, the Belmont Report (USA) and the Common Rule (CFR 45,46)^{4,5}. These policy recommendations have been revised over time to address new and controversial issues in research. Many developing countries have

established laws and regulations on ethics in research and some have established ethics boards;⁶ however, inadequacy of training and lack of resources have been impediments to the proper supervision of human subjects research⁷.

Thailand and Vietnam are two countries undergoing rapid economic transition, making them attractive locations for foreign investment and healthcare developments.^{8,9,10} A report from The Association of Southeast Asian Nations (ASEAN) Economic Community (AEC) showed that Southeast (SE) Asian countries are competing for influence as medical hubs for billions of dollars of foreign direct investment (FDI). Between 2016 and 2017, the net FDI inflows increased from 2.81 bn to \$8 bn for Thailand, and from \$11.8 bn to 14.1bn for Vietnam, according to The World Bank Report Year 2018¹¹ this has been rapidly rising in recent years, according to ASEAN Investment Report Year 2018 and Bloomberg News.^{12, 13} To maintain their reputations as auspicious potential healthcare partners, Thailand and Vietnam have aggressively invested in public and private healthcare infrastructure and workforce development, as seen in their increasing health expenditures as a total percentage of GDP from 1995 to 2014, where Thailand increased from 3.5% to 4.1% and Vietnam from 5.2% to 7.1%.^{14,15,16} Pharmaceutical and medical device developments in major and provincial locations in the two countries validate market potential for burgeoning returns and positive impacts on health care accessibility and affordability.^{17,18} If foreign partners align their expected outcomes with Thailand and Vietnam's social and economic goals and comply with government regulations, there are opportunities for mutual economic, healthcare, and quality of life advancements.¹⁹

In Thailand, the National Research Council of Thailand was established in 1975. A 12-rule "Guidelines for Biomedical Research Involving Human Subjects" was distributed to research institutions throughout the country.²⁰ In addition, the Medical Council of Thailand, created by the Medical Profession Act, issued rules on "the observance of the medical ethics", acting as an additional oversight to medical ethics review at individual institutions in Thailand.²¹ A survey conducted in 2009 by the Forum for Ethical Review Committees in Thailand (FERCIT) found that among 78 medical schools, public hospitals, private hospitals and research institutes, 7 denied having a research ethics committee (REC), only 30 institutions had Standard Operating Procedures; among the 69 institutions that were included in the study, 43.5% never provided training for REC members and investigators and 44.5% of RECs did not require continuous review.²⁰ In Vietnam, there is a national ethics committee called the Ethical Evaluation Committee in Biomedical Research, as well as the Council of Ethics in Biomedical Research at

Grass-Root Level (CEBRGL), a group of multiple institutional ethics committees working at the grassroots level. Investigators at institutions without a CEBRGL are required to seek approval from an ethical or scientific council with a portion of its members certified by the Vietnam Ministry of Health.^{22,23,24}

Today, ethics in research is a discipline of its own that requires rigorous training. The World Federation of Medical Education requires that ethical values and behavior should be among the core competencies in the medical education curriculum. In the United States, any person who is involved in human subjects

research has to receive certified training. We received funding from the NIH Fogarty Center to train scholars in Thailand and Vietnam in research ethics, adapting to their country-specific contexts. As part of this program, we conducted surveys to investigate 1) what kinds of research area and topic meet societal concerns and are being conducted; 2) what types of research ethics training are available in Thailand and Vietnam for researchers and how rigorous they are, and 3) identify the gaps and needs in training and ethics review in these two South East Asian countries.

Methods

Survey design and content

The survey was created in English and then translated into Thai and Vietnamese by country-specific training partners from the NIH Fogarty Research Ethics Training Program. (See Appendix/supplementary material for complete survey). The survey had four major domains: 1) Research Area; 2) Societal Conditions; 3) Research Ethics, and 4) Basic Information.

In research area, participants were asked to respond to several questions regarding their area of research. Participants could select multiple responses. For example, for the question: “What has been your main research area for the past five years?” There were seven large categories to choose from: non-communicable disease, genetics, infectious diseases, maternal and child health, non-clinical fields, nutrition and metabolism, public and environmental health, and other. Each of these categories had specific subcategories, and an option to write an open response to provide additional explanations. The second domain, “Societal Conditions”, focused on the perceived societal concerns, with the aim to understand each culture and tradition in the context of the research conducted. For example: In your opinion, “What are the main societal, health-related concerns in your country? Please select all applicable answers.” The third domain, “Research Ethics”, delved into the specifics about the availability of established ethical guidelines for research, and research ethics training. We ask broad questions such as: “In your opinion, which resource is currently most lacking for research ethics training?” and specifically, “Does your institution have an Institutional Review Board”? Finally, in domain four, “Basic Information”, we asked respondent’s background information such as: “In which country are you currently working?”; “What is your age?”, etc. (see Appendix for details)

Survey administration

After receiving feedback from country-specific training partners from Thailand (Mahidol University; Naresuan University; Burapha University, and Silpakorn University), and Vietnam (Hanoi Medical University; University of Medicine and Pharmacy of Ho Chi Minh City, and Hue University of Medicine and Pharmacy), it was determined that two modes of the survey administration were needed to fit societal survey practices. The online survey sent via email was created for Thailand based on the recommendation of our training partners, and an onsite paper survey was found to be the preferred mode for Vietnam.

In Thailand, at the recommendation of Mahidol University information technology department, an URL link to an online survey was emailed by co-investors at Mahidol University to faculty members (academia only, not including support staff) at Mahidol University, Burapha University (Chonburi Province) and Naresuan University (Phitsanulok Province), using an email list provided by those universities. The online survey was completed between October and December 2016.

In Vietnam, surveys were administered through convenience sampling in October 2016. The onsite paper surveys were distributed prior to ethics training seminars that were open to faculty and staff involved in research in the health professions (e.g. physician, nursing, public health, social work, etc.) at two of our collaborating institutions: Hanoi Medical University in Hanoi and the University of Medicine and Pharmacy of Ho Chi Minh City. The purpose of the survey was explained in full detail, and respondents were explained of the voluntary and de-identified nature of their participation in this study.

The Institutional Review Board at Stanford University (Protocol 29189), Mahidol University (Thailand) and University of Medicine and Pharmacy of Ho Chi Minh City (Vietnam) approved the study. Other local universities i.e. Hanoi Medical University (Vietnam), Burapha University (Thailand) and Naresuan University (Thailand) gave permission to administer the anonymous survey instrument.

Analysis

Descriptive analyses were performed using Microsoft Excel 2010 and STATA (StataCorp. 2015. *Stata Statistical Software: Release 14*. College Station, TX: StataCorp LP)

Results

In Thailand, the online survey was distributed to 3,909 faculty members. There were 363 respondents, yielding a 9.3% response rate in Thailand. The convenience sample in Vietnam yielded a total of 117 survey participants, with 81 from the Hanoi Medical University seminar and 36 from the seminar at the University of Pharmacy and Medicine of Ho Chi Minh City.

Among the respondents, 23% were male and 75% were female from Thailand; 41% were male and 57% were females from Vietnam (*Table 1*). The proportion of respondents who had a PhD/Doctoral degree from Thailand was 47% compared to 10% from Vietnam. The majority of the respondents from both countries (>95%) work in their home country; 81% (Thailand) and 53% (Vietnam) of the respondents work in academic institutions.

Among those who conduct research, 81% in Thailand and 92% in Vietnam reported that their research involves human subjects (*Table 2*). Among these, 26% each from Thailand and Vietnam reported working on “clinical observations” (imaging, EKG, exams [physical exams and lab tests], study of nature of the disease); 29% from Thailand and 26% from Vietnam reported that their work involves “clinical interventions” (drugs, devices, biopsies, imaging with contrast).

In terms of [general] research ethics training received in these countries, 34% of the respondents in Thailand and 45% of the respondents in Vietnam had received formal education through their degree programs (i.e. medical doctor, nursing, social work, etc.). In addition, 50% and 27% of respondents received ethics training on-the-job in Thailand and Vietnam respectively.

We examined the number of respondents who work on human subjects research and had prior training in ethics (not shown in tables). Among the respondents who reported conducting research involving human subjects from Thailand, 84% reported having ethics training; however, only 44% reported they had formal training, i.e. from their health professional degree programs. Among respondents from Vietnam who reported conducting human subjects' research, 66% reported having ethics training. Among those who received training, 72% reported they had formal training (from their health professional degree programs).

With regard to institutional review (see *Table 3*), 97% of respondents in Thailand reported that their institution has established ethical guidelines for research, compared to 89% in Vietnam. Furthermore, 92% of the respondents in Thailand reported having an Institutional Review Board (IRB) at their institution, compared to 77% of Vietnam respondents. Among the Vietnam respondents 5% did not respond to this question of IRB, while 18% of them reported that their institutions do not have an IRB

In terms of experience in teaching research ethics, 76% and 79% of respondents in Thailand and Vietnam respectively reported no experience. Furthermore, respondents indicated that currently the resource most lacking in research ethics training in their country is the availability of teachers (39% of respondents in Thailand and 59% in Vietnam), materials (34% in Thailand and 43% in Vietnam), and an adequate curricular "delivery platform" (58% in Thailand and 49% in Vietnam).

Discussion

Our needs assessment survey fielded in Thailand and Vietnam has allowed us to gain an insight of the current landscape in research ethics training and research ethics review in these two SE Asian countries. By identifying the training gaps at the major training centers of these two countries, we can begin to identify opportunities to address research ethics needs in these two countries. Furthermore, it provides a unique opportunity to expand research ethics-training programs in SE Asia that are tailored to each country's needs and unique cultural context.

According Accreditation of Human Research Protection Programs 2018 report, 94% of institutions have their own IRB, only 6% do not have their own IRB. Most research institutions, universities, and health-care facilities have at least one IRB, and the majority has more than one²⁵, in addition, there are a number of independent or commercial IRBs.²⁶ Our finding that 97% of Thai survey respondents reported having established ethical guidelines for research is reassuring and higher than previous estimates of 88%²⁰ however, we found that 6% reported not having an institutional review board in their institutions, a potential problem for research ethics reviews. Similarly, in Vietnam, even though 89% reported having established ethical guidelines in their institutions, 18% reported they do not have an institutional IRB (5%

did not respond to this question). This may be because the IRB was established recently, and/or participants might not have been aware of it because they had not initiated new studies at the time of the survey. There remains a large gap for research ethics review in Vietnam given that its national regulations require approval for research from a CEBRGL or a certified ethical council.^{22,23, 24} Due to the limited information obtained from our survey, it is not clear whether those respondents in Vietnam without institutional IRB were still conducting research with oversight from an outside institution. In the United States, despite IRB approval being necessary to conduct research, institutions are not required to have their own IRB as there are external IRBs that can also conduct the reviews.²⁷

Our study showed that the majority of respondents in Thailand (84%) and Vietnam (72%) had received general research ethics training through either formal education (from their health professional degree programs) or on-the-job training. These results are similar to what we have seen in dozens of countries where the Collaborative Institutional Training Initiative (CITI) program in human subjects protection and responsible conduct of research²⁸ are pre-employment requirements²⁹, and a requisite of completion for many health-related degrees. However, the specifics of the research ethics training were not available in this survey.

We also found a considerable gap in resources in research ethics training, including lack of teachers, materials and delivery platform. Our program, the Asia Collaborative for Medical Education (ACME) Fogarty Research Ethics Training Program, funded by the US NIH Fogarty International Center, aimed to increase the capacity for research ethics training by applying the “train the trainer” model, using tele-education and in-person training sessions.³⁰ Prior studies have shown that “train the trainer” programs are very effective in building capacity in regions where there is a lack of local resources of experts of a field.^{31,32} Our training program has trained more than 20 scholars in Vietnam, Thailand and Taiwan from 2014 to 2017; seven of the scholars have taken leadership positions in their Institutional Review Boards and ethics training programs.

Our study has several limitations. First, the surveys were conducted at major training institutions in Thailand and Vietnam at one point in time, i.e., Mahidol University, Burapha University (Chonburi Province), and Naresuan University (Phitsanulok Province) in Thailand; Hanoi Medical University in Hanoi, and the University of Medicine and Pharmacy of Ho Chi Minh City in Vietnam. In Thailand, there are over 100 universities and in Vietnam there are over 50 universities. Therefore, the results of from this study may not be fully representative of the research community of either of these countries. However, the participants in the study are from the best educational institutions of each of these two countries. Therefore, the gaps we highlighted on the issues relating to ethics training, resource availability and research ethics oversight in these universities may not be representative of the whole country. Our results may have over-estimated the training and ethics review capacity in these countries. Second, different survey modes were used in Thailand and Vietnam (online survey in Thailand vs onsite paper survey in Vietnam.); this could prevent accurate comparisons between the two countries in research capacity. Moreover, the paper survey in Vietnam used a convenience sample of those who attended a research

ethics seminar; this may have biased towards those who are interested in the topic. Third, our response rate for the emailed online survey was low in Thailand (~10%) and this may have introduced a bias in the results, because the respondents may be more knowledgeable in research ethics issues. Finally, we did not have details on the content of the research ethics training respondents received. Nevertheless, our survey can serve as a starting point for identifying opportunities, gaps, and focus in research ethics training for these countries undergoing rapid economic transition with expanding research portfolios.

Conclusions

Thailand and Vietnam are undergoing rapid socioeconomic transition, including health-related research; our needs assessment survey identified areas for future curricular development and training in research ethics.

Abbreviations

ACME Asia Collaborative for Medical Education

AEC Asian Economic Community

ASEAN Association of Southeast Asian Nations

CEBRGL Council of Ethics in Biomedical Research at Grass-Root Level

CFR Code of Federal Regulations

CITI Collaborative Institutional Training Initiative

DoH Declaration of Helsinki

EKG Electrocardiogram

FDI Foreign Direct Investment

FERCIT Forum for Ethical Review Committees in Thailand

GDP Gross Domestic Product

IRB Institutional Review Board

NIH National Institutes of Health

REC Research Ethics Committee

Declarations

Ethics and Consent to Participate

We obtained a Waiver of Documentation of Consent from Stanford IRB, as this study involved an anonymous survey of health professionals, no identifying information (including IP addresses) was requested or recorded. Stanford IRB # 29189.

Consent for Publication

Not Applicable

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing Interests

The authors declare that they have no competing interests.

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Authors' Contributions

CW, AH and MC conceptualized and designed the study and critically reviewed the manuscript.

PM administered the surveys in Thailand, translated the English version to Thai and provided help with study design input and data coding.

PW reviewed the survey instrument and conducted training and administered the survey in Vietnam, and critically reviewed the manuscript.

TH conducted training and helped administer the survey and critically reviewed the manuscript.

YH, OT, NL, NV and PA organized and administered the surveys in Vietnam and translated the English version to Vietnamese, and critically reviewed the manuscript.

UP, DW, MU, and CW analyzed the data and drafted the initial manuscript.

All authors read and approved the final manuscript.

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Tables

Table 1: Respondent Characteristics

Country	Thailand		Vietnam	
	N	%	N	%
Surveys N (%)	363	100	117	100
Age	363	100	117	100
<30	24	7	34	29
30-40	142	39	52	44
41-50	92	25	26	22
>50	99	27	2	2
No answer	6	2	3	3
Gender	363	100	117	100
Male	82	23	48	41
Female	272	75	67	57
No answer	9	2	2	2
Highest Level of Education	363	100	117	100
High school	0	0	2	2
Bachelor's degree	50	14	36	31
Master's degree	129	36	54	46
Ph.D./Doctoral degree	169	47	12	10
Other	7	2	13	11
No answer	8	2	1	1
Country of Work	363	100	117	100
Thailand	356	98	1	1
Vietnam	1	0	113	97
No answer	6	2	3	2
Profession*	363	100	117	100
Medical doctor	72	20	54	46
Nurse	76	21	9	8
Pharmacist	4	1	2	2
Dentist	8	2	3	3
Public health professional	21	5	14	12
Social worker	2	1	4	3
Trainee for my profession	6	2	20	17
Other	165	46	42	18
No answer	20	4	1	1
Abroad Training	363	100	117	100
No	231	64	87	74
Yes	126	35	28	24
No answer	6	2	2	2
Years of Research Experience	363	100	117	100
<3	88	24	46	39
3 to 6	92	25	39	33
7 to 10	66	18	16	14

>10	111	31	15	13
No answer	6	2	1	1
Type of Institution Employed by*	363	100	117	100
Government institution	78	21	24	21
Academic institution (e.g. university)	295	81	62	53
Non-profit organization	7	2	3	3
For-profit organization	5	1	5	4
Other	1	0	22	19
No answer	5	1	5	4

*Respondents were able to choose multiple choices

Table 2: Research Type

Country	Thailand		Vietnam	
	N	%	N	%
Surveys N (%)	363	100	117	100
What has been your main study type for the past five years?*	363	100	117	100
Basic science research	123	34	37	32
Clinical research	163	45	49	42
Health services/Health policy research	106	29	21	18
Epidemiological research	50	14	28	24
Meta-analysis/Review	42	12	5	4
Other	44	12	2	2
No Answer	5	1	1	1
What have been your sources of data for the past five years? Please select all applicable answers.*	363	100	117	100
Human subjects	295	81	108	92
Animals	34	9	3	3
Human biological material/Biobank	71	20	11	9
Medical records	111	31	49	42
Other	16	4	3	20
No Answer	7		0	
If you conduct research on human subjects, which of these activities do you participate in, if any? Please select all applicable answers. *	363	100	117	100
Clinical observation (imaging, EKG, exams, natural history studies)	96	26	30	26
Clinical intervention (drugs, devices, biopsies, imaging w/ contrast)	105	29	31	26
Behavioral/psychological intervention	94	26	22	19
Behavioral/psychological observations (surveys, interviews)	140	39	64	55
Analysis of existing samples/data	163	45	40	34
Other	14	4	2	2
No Answer	20	5	3	2

*Respondents were able to choose multiple choices

Table 3: Research Ethics Training and Ethics Review

Country	Thailand		Vietnam	
	N	%	N	%
Surveys N (%)	363	100	117	100
Does your institution have established ethical guidelines for research?	363	100	117	100
Yes	352	97	104	89
No	8	2	8	7
No Answer	3	1	5	4
Does your institution have an Institutional Review Board (IRB)?	363	100	117	100
Yes	335	92	90	77
No	23	6	21	18
No Answer	5	2	6	5
Have you received research ethics training?	363	100	117	100
Yes	290	80	75	64
No	68	19	33	28
No Answer	5	1	8	7
Through which of the following means did you receive research ethics training? Please select all applicable answers.	363	100	117	100
Formal education (i.e. degree programs for medical doctor, nursing, social work, etc.)	123	34	53	45
On-the-job training	183	50	32	27
Personal study/Self-education	109	30	19	16
Other	32	9	6	5
No answer	77	21	36	31
Do you have experience teaching research ethics?	363	100	117	100
Yes	81	22	19	16
< 1 year	12	3	4	3
1-3 years	29	8	3	2
4+ years	40	11	4	3
No	278	76	92	79
No answer	4	1	4	3
In your opinion, which resource is currently most lacking for research ethics training?	363	100	117	100
Teachers	141	39	69	59
Materials	122	34	50	43
Delivery platform	210	58	57	49
Other	19	5	2	2
No Answer	66	18	8	7

*Respondents were able to choose multiple choices

Strengths And Limitations Of This Study

- The study described current research ethics training landscape in Thailand and Vietnam.
- The survey was designed with considerable input from our local training partners in Thailand and Vietnam and the translation was done by native Thai and Vietnamese research scholars taking into consideration the language, social and cultural differences between the east and the west.
- Survey questions were specifically designed to probe the unmet needs in research ethics training from the survey participants.
- Because the online email survey in Thailand and a paper survey using convenience sample in Vietnam were conducted from leading universities, our findings may under-estimate the current gaps in research ethics training across the overall landscape.
- Two different survey modes were used based on local conditions, which may limit our ability to directly compare the results between Thailand and Vietnam.