MINISTRY OF EDUCATION AND TRAINING

MINISTRY OF HEALTH

NATIONAL INSTITUTE OF HYGIENE & EPIDEMIOLOGY

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THE CURRENT STATE OF ORGANIZATION AND OPERATION OF THE INSTITUTIONAL REVIEW BOARD AND THE EFFECTIVENESS OF INTERVENTION

Speciality: Sociological Hygiene and Health Organization

Code: 62.72.01.64

SUMMARY OF PhD THESIS ON MEDICINE

HANOI – 2021

THIS RESEARCH IS COMPLETED AT THE NATIONAL INSTITUTE OF HYGIENE AND EPIDEMIOLOGY

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Counter arguer 2: .....

Counter arguer 3: .....

The doctoral thesis will be defended at the Dissertation Committee of Institutional level at: National Institute of Hygiene & Epidemiology.

At ..., ... 2021.

The doctoral thesis can be found at:

1. The National Library of Vietnam
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THESIS INTRODUCTION

Nowadays, there are more and more studies related to human beings as subjects are conducted. Therefore, protecting the safety, health and rights of research subjects – human beings - have become an international requirement for biomedical studies. According to the regulations, all institutional-level studies of biomedical on human subjects must be evaluated by the Institutional Review Board called IRB. Therefore, we do the research **"The current state of organization and operation of IRB and the effectiveness of the intervention"** with the two following objectives:

1. Describe the organizational status and operational processes of IRBs, 2015.
2. Evaluation of the effectiveness of interventions to improve the quality of operations of some IRBs, 2016–2018.

New points about science and practical value of the topic

1. Description of the current state of organization and operation of IRB in Vietnam in 2015.
2. Assessment of the effectiveness of tools used by IRB in evaluating research proposals in Vietnam till 2015.
3. Recommendations on additional regulations, implementation guidance and control as well as the construction of forms for assessment tools, written notices of decisions to IRBs from 2016 onwards.

The study identified the overall IRBs met the requirement of member number. However, the quality assurance criteria of IRB members are not fully guaranteed. In addition, there is no

consensus in the use of the tool for evaluating the research proposal between different IRBs in Vietnam.

THE STRUCTURE OF THE THESIS

The thesis consists of 129 pages, 31 tables, 7 figures. Introduction: 2 pages. Overview: 35 pages; Research subjects and method: 18 pages; Results: 31 pages; Discussion: 40 pages; Conclusion: 2 pages and Recommendation: 1 page.

Chapter 1
OVERVIEW

1.1. A number of basic concepts related to the topic

1.1.1. The general concept of ethics in biomedical research

Ethics in biomedical research is the principles, ethical norms applied in biomedical studies related to research subjects of human beings. Ethics in research not only matters at the stage of approval of research proposals but also principles, ethical norms need to be complied with in all phases of research from design, conduct, supervision, inspection, processing, analysis and analysis of data.

1.1.2. History of regulations formation on ethics in biomedical studies worldwide

Table 1.1. The coming forth of Laws/ Principles/ Manifesto to control ethics in biomedical studies in the world

No.	Year	The original name of the document
1	1947	The Nuremberg Code
2	1948	Declaration of Geneva

3	1949	World Medical Association Int'l Code of Medical Ethics
4	1953	Wilson Memo
5	1954	WMA Principles for Those in Research & Experimentation
6	1964	Declaration of Helsinki
7	1979	The Belmont Report
8	1996	ICH-GCP
9	2000	Operational Guidelines for Ethics Committees that Review Biomedical Research
10	2009	Research ethics committees: Basic concepts for capacity-building
11	2011	Bioethics Core Curriculum Casebook Series
12	2016	International Ethical Guidelines for Health-related Research Involving Humans

Many countries like Malaysia, the Philippines, India, Australia... have issued national guidelines on ethics in medical research and good clinical practice in both English and native languages to share with other countries.

1.1.3. Basic principles of ethics in biomedical research

International and national guidelines on biomedical research have emphasized that all studies related to human subjects need to be conducted in accordance with three basic ethical principles, namely the respect for humans, inclination to the good, and

equity as mentioned in many of the organisations and international medical association' documents.

1.2. Organization and operating procedure of the Institutional Review Board

Along with the development of ethical regulations in the study of human subjects, the regulations on the Institutional Review Board are increasingly completed. The starting point from the request to have an independent ethics committee to assess periodically studies to protect the research participants based on the three basic principles of research is respect, fairness and inclination to the good. To provide regulations on the number, composition, criteria of the committee, core requirements for the committee on independence, diversity, capacity and transparency with the requirement of the council to set up and comply with its standards.

1.2.1. The concept of the Institutional Review Board

IRB is an independent organization to assess, examine biomedical studies at various levels of the institution, region, country, or region with members specialized in medicine and non-medical, responsible for ensuring the protection of the rights and safety of human subjects in the study according to current regulations.

1.2.2. Functions, tasks of the Institutional Review Board

The Institutional Review Boardhas a role to guarantee with the community in protecting the research human subjects, by evaluating it in order to approve or approve the research conducting on the basis of reviewing the research proposal, research dossier, or revised research proposal; Monitor/check and periodically

review research during implementation, suitability of research products, research instruments, methods and means of obtaining written consents from research participants.

1.2.3. Organization of the Institutional Review Board

The minimum number of council's members is 5 and the number of members has to be large enough to ensure various opinions for discussion.

The ethics council has multidisciplinary and multisectoral members, the composition of the council composed of: male and female members who have expertise and members who have no expertise in the health sector; members do not associate with the donor and funding organizations.

In Vietnam, the ethics council shall be composed of two levels: the national ethics council shall be decided by the minister of health for establishment and the ethics council issued by unit heads.

1.2.4. Operational procedures of the IRB

To ensure the operational quality of research ethics review, the World Health Organization recommends that Ethical Councils in Biomedical Research establish a quality management system with the enactment and implementation of a quality management system. performed according to standard practices. To ensure efficient operation, written regulations, rules and procedures are periodically reviewed on the basis of a regular, step-by-step assessment of performance and results to determine if adjustments are needed. are not. The Board's regulations and procedures should cover the full spectrum of the Board's duties.

1.3. Quality assurance of IRB

1.3.1. IRB's Performance Standard

a) Standard I: Structure and Composition of Ethic Committee

b) Standard II: Adherence to specific policies

c) Standard III: Completeness of its review process

d) Standard IV: After review process

e) Standard V: Documentation and Archiving

1.3.1.2. AAHRPP's Evaluation Standard for IRB

a) Standard 1: The structure and composition of the IRB or EC are appropriate to the amount and nature of the research reviewed and in accordance with requirements of applicable laws, regulations, codes, and guidance.

b) Standard 2: The IRB or EC evaluates each research protocol or plan to ensure the protection of participants.

c) Standard 3: The IRB or EC approves each research protocol or plan according to criteria based on applicable laws, regulations, codes, and guidance.

d) Standard 4: The IRB or EC provides additional protections for individuals who are vulnerable to coercion or undue influence and participate in research.

e) Standard 5: The IRB or EC maintains documentation of its activities.

1.3.2. Quality assessment method of IRB

1.2.4.1. Registration of operation code of IRB

The registration of the operation code of IRB is not a direct performance assessment of the operational quality of IRB, but it is the starting point for the quality assessment operation of IRB on the basis of control of units contain IRB.

1.2.4.2. IRB's self-assessment

According to the previous practice, the application for identification of the number of public recognition, IRB needs to prepare the official evaluation for the recognition of the need for improvement of the performance of the IRB's work and its operation in order to detect the need for improvement in the performance of the IRB's performance and its operation in order to detect rooms for necessary improvement.

Chapter 2

RESEARCH SUBJECT AND METHODS

2.1. Time and place of study

1.1.1. Research time

The study was conducted from January 2015 to December 2018

1.1.2. Research site

The study was conducted at: the offices of the IRB, representatives at the North, South and Central of Vietnam and in the office of the Department of Science, Technology and Training, Ministry of Health.

2.2. Research design

- Cross-sectional descriptive study design with objective 1.
- A statistical study on comparative analysis of the effectiveness of before and after intervention for objective 2.

2.3. Research subjects

- Members, secretariat of IRB.
- Documented IRB data on IRB performance quality management criteria.
- Evidence of IRB activities.

- Regulations, quality management guidelines of the IRB of the management agency.
- Regulations and quality management guidelines of the IRB of the decision-making organization established by term.

2.3. Sample size

Objective 1: Select 30 IRBs to investigate and assess the current situation.

Objective 2: Select 10 IRBs to conduct intervention trials.

2.5. Sample selection criteria

2.5.1. Sampling criteria for objective 1

Sampling by convenience method, using the entire sample with the condition that the IRBs agree to participate in the study.

2.5.2. Sampling criteria for objective 2

A purposeful sampling of IRBs on the basis of the consent of the organization that established the IRB, having enough IRB components in the North, Central and South.

2.6. Research variable

2.6.1. Variables describing the organizational status and operational processes of IRBs in 2015 include: IRB governing body; Status of IRB members; Training status; Quality Assurance Regulations and Operational Tools of the Council.

2.6.2. Variables to evaluate the effectiveness of interventions to improve the quality of operations of some IRBs, 2016-2018, include: Number of IRB members; IRB composition; GCP training certificate; Legal validity of the session; Council secretary; Comply with the SOPs in IRB operations; What the IRB needs to consider; Methods of evaluating records; Research supervision; Finance; Maintain records in IRB operations; Design review/evaluation

sheets; Participate in SOP development training; Develop SOP according to WHO standards; The IRB conducts periodic self-assessments of performance; Inspection by the Regulatory Authority; Forum for Ethical Review Committees in Asia and the Western Pacific (FERCAP).

2.7. The method of data collection

2.7.1. Collect data describing the status of quality management

Use checklists to record general information and directly evaluate IRB's SOPs and quality management forms.

Using semi-structured interview questionnaires to collect opinions from IRB presidents, members, and secretaries on establishing and complying with IRB's quality management regulations.

2.7.2. Collect data to evaluate the results of quality management improvement interventions

- Using a comparison table of newly amended and supplemented contents for IRB quality management in legal documents.

- Use the comment sheet to assess the IRB members' acceptance of the IRB training program.

- Make a tracking sheet to monitor the number of IRBs that have established a quality management system and registered their operation with the Ministry of Health.

2.8. Statistical analysis

Because of the small sample size, only descriptive analysis of the research indicators was used by number (n) and percentage.

2.9. Research ethics

This study does not have interventions on humans, does not use biological samples from humans, but may have psychological and social effects on research participants so that identifying information Research subjects are encrypted to keep the information confidential, do not use information collected in the research for any other purpose other than the research purpose.

This study was appraised and approved by the IRB of the Central Institute of Hygiene and Epidemiology before implementation, code VN1057-06/2015.

Chapter 3
RESULTS

3.1. Actual situation of organization and operation process of IRBs in 2015

3.1.1. Organizational status of IRBs in 2015

Table 3.1. Distribution of IRBs by host in 2015

IRB's governing body	**n (%)**
Universities, institutes	8 (26,7)
Research Institute	7 (23,3)
Central Hospital	8 (26,7)
Provincial Hospital	6 (20,0)
Bioequivalence assessment organization	1 (3,3)
Total	30 (100%)

The survey results of 30 IRBs showed that only 36.7% of IRBs had regulations on the minimum number of members, composition, and criteria for IRB membership. There is no IRB that regulates the ratio between groups of members; Procedures

for appointment, dismissal, replacement, resignation and retraining of IRB members; Minimum number and composition of members for an IRB decision-making meeting. The proportion of IRBs with provisions for initial training, the number of secretaries is very low, 10% and 20% respectively.

3.1.2. The current state of the operation process of IRBs in 2015

According to the survey results, research shows that most IRBs do not have standard administrative procedures. Even 4 standard procedures related to (1) Receipt of appraisal documents; (2) How to deal with the applicant's response to the IRB's comments; (3) Preserve, keep and organize the administrative records, notebooks and forms of the IRB; (4) Maintain confidentiality of research records and IRB documents. But at the time of the survey, no IRB has had these 4 administrative procedures.

3.2. Evaluation of the effectiveness of quality improvement interventions for some IRBs, 2016-2018

3.2.1. Proposing to the Ministry of Health on supplementing and completing regulations and guidelines related to improving the quality of IRB with legal validity

Table 3.19. New criteria for IRB membership are newly added to legal documents to suit Vietnam, 2016-2018

Theme	**New criteria are added, these were non-exist in previous interventions**
IRB's independence	IRB members do not participate in the researches that re appraised by themselves, independent members must have expertise in the health sector.

Theme	**New criteria are added, these were non-exist in previous interventions**
IRB's organization	Specialized sub-committees may be established, may use the seal of the organization that established the IRB.
IRB's members	There must be a Vice President, there must be a clinician.
IRB's membership criteria	Having time to participate, no conflict of interest, commitment to information security, IRB's certificate of training on SOP. Members must have a university degree or higher.
Criteria for President, Vice President of IRB	The deputy head of the organization that establishes the IRB does not participate in serving as the Chairman or Vice-Chairman of the IRB. The person appointed as the Chairman of the IRB shall not exceed 2 terms.
Independent consultant for IRB	Be responsible for sending comments before the meeting to IRB and keeping confidential information and documents related to research.
Training IRB's member	IRB members must have a certificate of continuous training in GCP at least once in 2 years.
IRB's right to research	The right of the IRB to decide on the method of evaluation, to report data related to the study, to recommend to the competent authority to stop the study, to suspend the study, to request amendments and supplements to the protocol. research, the materials provided to the research participants.
IRB's operating principles	Consider the capacity of the principal investigator; Periodic at least once/year appraisal for LLS research.

Theme	**New criteria are added, these were non-exist in previous interventions**
	A certificate of approval with an IRB number is issued. IRB activities must be non-profit.
Document IRB Review	Dossier of acceptance of research results; Written consent from the institution administering the study site to allow the study to be carried out.
IRB's SOPs	There is a list of 34 SOPs related to IRB activities from the application stage to the end of the study.

With specific provisions in Circular 45/2017, from 2017 onwards, IRBs will comply with these criteria to ensure the independence of IRBs when establishing and operating.

3.2.2. Trainging on quality management, developing SOPs to improve the quality of IRB's operations, 2016-2018

Of the 15 training topics on SOPs for IRBs, there are 14 topics corresponding to the training topics of FERCAP for IRBs, with the addition of a second topic Overview of Vietnam's regulations for IRBs to update the training topics. Vietnam's regulations for IRB, especially clarifying the basic differences of IRB compared to the Scientific Council for approval and approval of research protocols, which are very familiar in Vietnam, thereby clarifying difficulties, challenges for IRB to be able to perform its role well, to increase awareness of the role and responsibilities of IRB as well as the significance of establishing and maintaining a standard process system for quality management amount of IRB for all participants in the training.

Out of 10 units that have trained SOPs of IRB, 01 university and 02 hospitals have requested the second training course to improve the capacity of IRB members.

3.2.3. Roles and responsibilities of IRB in establishing and maintaining quality management on the basis of design and development of standard working tools

Table 3.25. Improving the quality of IRB's operations, 2016-2018

Evaluation criteria	No. of IRB	Pre-intervention	Post-intervention
Participate in training on building SOP	10	0	10
Develop 34 SOPs after training according to WHO guidelines	10	0	8/10
Periodic self-assessment IRB reports to the Ministry of Health	10	Seldom	10/10
Number of Regulatory Authority checks with IRBs	10	Very rarely	Very rarely
Number of IRBs registered to participate in regional quality accreditation (FERCAP)	10	No results	No results

Of the 10 IRBs selected for investigation and intervention in this study, after participating in IRB's SOP training, 8 out of 10

IRBs after the training have developed a set of 34 SOPs operating for the Council according to the following criteria. guiding the new regulations of Circular 45/2017, and 2/10 IRB is completing the set of operating SOPs of their units. The annual self-assessment of IRBs' activities to send reports to the Office of the Administration of Science, Technology and Training, Ministry of Health has become a routine matter compared to the pre-intervention period. However, regulatory oversight of IRBs is poor. Up to the end of the study, no IRB had registered to participate in FERCAP's accreditation.

Chapter 4
DISCUSSION

4.1. Discussing the current organizational situation and operational processes of IRB in 2015

In terms of human resources, the number of members of all IRBs is guaranteed to be 5 or more, most IRBs have 7-11 members, but there are also IRBs with 23 members.

Of the 30 surveyed IRBs, 90% of IRBs have unit leaders as president or IRB members, of which there are 8 IRB heads who directly serve as IRB Chairman, this together with the majority of IRB members are Non-independent members seriously affect the objectivity of the IRB's decisions.

IRB independence is an important criterion when assessing the quality of IRB's performance. In order to ensure the objectivity and independence of the IRB, in Decision 111/QD-BYT dated 11/01/2013 of the Minister of Health, it is stipulated that “The head of the unit does not participate as the Chairman of the Council”.

Survey results show that IRB members have received basic training in ethics in biomedical research with human subjects. But there are few IRB members with adequate training in the ethics applied to different types of research, which research in India suggests makes it difficult for the IRB to go beyond a purely scientific assessment.

With its functions and duties, the IRB, in addition to assessing research ethics for biomedical research records before deployment, also has the task of monitoring, examining and supervising research studies. in protocol compliance and ethical compliance in research; evaluate the recording, reporting and handling of adverse events occurring during the research process according to current regulations. However, according to our survey results from 2013 to 2015, there are very few (13/274, accounting for 4.7%) IRB members who are trained in research inspection and supervision skills.

Regarding the status of the IRB SOP, defined by WHO as a general rule "for similar protocols to be treated similarly; when the IRB determines that the approach they have taken to a particular ethical issue in the past is no longer appropriate, they should provide a clear reason for their change of opinion." In other words, the IRB needs to ensure consistency and stability in the evaluation of studies and only be changed when there is a good reason.

According to regulations, the composition of members of the IRB must be diverse (there are members with professional degrees in the health sector related to popular research fields assessed by the IRB, there are non-specialist members in the health sector). health, legal or ethically savvy, members of both

sexes, of various ages) to ensure that a wide range of relevant perspectives are considered in the evaluation and decision-making processes for the studies.

In fact, according to the establishment decision, each Scientific Council to approve the research proposal (Construction Council) and the Scientific Council to accept research results (CSC) only existed for a short period of time and spontaneously. The IRB is dissolved upon completion of its mandate, whereas the IRB has a term of 3 to 5 years with continuity of responsibilities between terms (except in exceptional cases). Thus, to meet the huge workload and ensure consistency in the evaluation of studies, this fact requires IRBs to develop a system of SOPs for their activities.

According to our survey results, 2013-2015, a large proportion of IRBs have not yet issued any SOPs, among the IRBs that have issued SOPs, the number of SOPs issued is still very small compared to the recommendation. WHO report. A survey on the current status of SOPs operating by the Ethics Committee, 2013-2015 shows that a large percentage of IRBs (≥60%) have never issued even a standard procedure (table 3.5). The percentage of IRBs that have not issued any SOPs in the remaining process groups is the group of procedures for IRB establishment and IRB member training 87%, the group of procedures for appraisal methods 80%, the group of administrative procedures is 67%, and the group of procedures for document appraisal is 60%.

In addition, through the investigation of the situation, it was found that many IRB members did not clearly distinguish the

IRB processes from the research management processes of the host organization; There should be 7 units that include the research management SOP in the IRB's SOP.

Regarding the form of the appraisal tool, while most IRBs separate the research proposal comments and the research proposal evaluations into two different votes, still 10% of IRBs combine these two parts into the same sample. votes.

The research results show that only 4/30 (13.3%) IRBs use a comment form stating the problem to be considered and listing the response levels of the protocol for IRB members to choose and Comments, this is the design recommended by the Forum of Ethical Review Boards for Asia and the Western Pacific (FERCAP).

The fact that many comment forms do not arrange the content according to groups of issues with scientific aspects, ethical aspects, researcher capacity and research points, making it difficult to evaluate the proposal.

The contents of assessment of benefits and risks, selection of research population and selection of research participants, protection of privacy and information security of research subjects, and protection of research participants many votes are not mentioned.

Therefore, in order to ensure the quality of research proposal appraisal of IRB members, WHO recommends that IRBs develop a system of SOPs to guide how to use the research protocol evaluation form.

The survey results on the current situation of organization and operational processes of IRBs in the years 2013-2015, show that the quality and quality management of IRBs in Vietnam are still

at a low level, which is difficult to meet. meet regional and international standards.

Moreover, most of IRB's members have been or are members of the Construction Council or the NTSC and are very familiar with the way of working, which is to comply with the current rules and regulations, without SOPs to support in the process. performance of his duties as a member of the Council.

There is also a view of IRB members that there is no need to issue a separate IRB SOP, but the SOP of the National Biomedical Research Ethics Council can be used in IRB activities. Or, the implementation of SOP is only heavy on administrative procedures, does not help the professional appraisal, even affects the time of professional appraisal. Or "some individuals see SOP as a threat that diminishes their importance in the job and is therefore reluctant to share their knowledge and skills".

4.2. Discussion on evaluating the effectiveness of interventions and improving the quality of some IRBs, 2016-2018

Through a descriptive study of the situation from 2013 to 2015, it was found that there are 4 main groups of factors affecting the quality of IRB's performance that need to be considered for intervention, including:

- It is necessary to institutionalize the existing legal regulations relating to quality management of IRB.

- There is a need for training so that IRBs have knowledge on quality management, how to write SOPs, forms for IRB activities according to current WHO guidelines.

- IRB members need to change their perception and see the necessity of maintaining IRB's quality management, understand

the position and role of each IRB member so that IRB can operate independently.

- Strengthen the inspection and supervision of IRB activities by the management agency as well as the organization that established the IRB to improve the quality of operations.

In fact, in order for the inspection and supervision of the quality of IRB's activities to be effective, it is necessary first of all to have specific regulations on quality management of the IRB. At the time of conducting research on the current regulations on the organization, the IRB's activities did not mention IRB's quality management. Therefore, within the framework of this study, we only focus on the first 3 groups of factors, specifically as follows.

(1) Propose to the Ministry of Health to supplement and complete regulations and guidelines related to the establishment and maintenance of quality management of IRBs in legal documents in accordance with regulations applicable country, international guidelines.

(2) Develop programs, documents and organize training and training on quality management of IRBs on the basis of reference to international and national guidelines, together with the establishment of a set of SOPs, forms for IRBs to refer to through training courses.

(3) Increase awareness of the roles and responsibilities of the IRB as well as the significance of establishing and maintaining the IRB's quality system for IRB members and stakeholders through training courses.

Especially, this is the first time a legal document has regulated the IRB's responsibilities in developing and complying with SOPs to perform its functions and duties, as well as its responsibility to publicize. procedures, forms, and periodic review of SOPs at least once a year.

However, there are still some recommendations in the international guidelines that have not been mentioned in Circular No. 45/2017/TT-BYT as it is still acceptable for the deputy head of the organization establishing the IRB to participate in the work. members of the IRB or remove the regulation on the issuance of IRB operational codes.

In our opinion, to ensure feasibility and for regulations to come to life, regulations also need to be consistent with actual conditions and have a suitable roadmap to gradually raise standards.

On the basis of developing, developing programs, documents and organizing training and training courses on quality management of IRBs and aiming at not only IRB members participating in training, but these training courses also extended to members of construction councils. Therefore, it will gradually reduce the perception of the difference between the Construction Council and the IRB, towards IRBs that operate more professionally and fulfill their roles and responsibilities well.

Before 2013, some IRBs or IRB members were trained by international organizations such as US FDA, Family Health International (FHI), PERCAP, ... training on quality management applied to IRBs. . The program and the trainers of these training courses are all foreign, due to the lack of reality in Vietnam, there is no analysis topic in the training program about

the difference between the IRB and the Construction Council, as well as no analysis. workload challenges of IRBs compared with construction activities. This is probably an important reason why, after these trainings, most IRBs have not yet established SOPs for IRB quality management.

With this in mind, we have developed a training program on SOPs for IRBs with 15 topics, of which 14 topics correspond to FERCAP training topics for IRBs, with the addition of a second topic. Overview of Vietnam's regulations for IRB to update Vietnam's regulations for IRB".

In the first set of questions, many IRB members asked to clarify whether the IRB should only evaluate the ethical aspects of the research or should also evaluate the scientific aspects of the research.

In this regard, according to current regulations, both councils are advisory councils, the decision-making power belongs to the person who has the authority to approve the research protocol. There may be cases where the two committees still have different opinions on some specific issues in the research proposal, but they are all for the purpose of helping to perfect the research proposal to ensure scientific and ethical integrity. and feasible, but due to different perspectives, there may be disagreements.

According to GCP, research protocols must be scientifically designed, specific, and detailed, and researchers are responsible for complying with IRB-approved research protocols.

To help avoid missing out on appraisals while saving IRB members time during appraisals, we designed detailed checklists as a support tool. memory aid for appraisers.

In addition to the research proposal review comment form, research report, research proposal review, resubmit or change research proposal form, we have also developed protocol review meeting minutes templates. research, acceptance of research report, certificate of acceptance of research protocol and certificate of acceptance of research.

In order to improve the performance of the IRB, IRB SOPs are needed for activities related to the Commission's mission. Indicates the need to issue a SOP for the operation of the IRB.

4.3. Discuss some limitations in the study of the topic

The selection of only 10 IRBs for this study is a limitation of the study because the sample size is not large, it is not possible to apply statistical math to test the effectiveness of the intervention, but only descriptive statistics can be applied to evaluate the effectiveness of the intervention. The effectiveness of the intervention with the comparison method before and after self-control.

CONCLUSION

1. The actual state of organization and operation process of IRBs in 2015.

1.1. The organizational situation of 30 surveyed IRBs shows that: Research has determined that in 2015 all IRBs met in terms of the number of members, but there was no regulation on the minimum number and composition of members for the meeting to take place. value, as well as the percentage of IRBs that meet the requirements for unit leadership who are not members of the council, the number of non-scientific members is large enough, there are members who are representative of the research subjects, gender balance, and low with rates corresponding to these criteria: 10.0%,

20.0%, 30.0%, 36.7%, respectively. All IRB members are trained in the ethics of biomedical research, but very few members are adequately trained to be able to appraise different types of research.

1.2. The actual status of 30 IRB's research proposal appraisal tool: (1) There is no consensus on both the form of the comment form and the contents to be appraised; (2) There were 10% of IRBs that combined the questionnaires including comments and evaluation of the proposal; (3) The content to be appraised is often not specified, there is a lack of documentation on how to use the outline comment form, only 26.7% of IRBs have a sample form with all 6 main contents that need to be considered in terms of ethics in biomedical research.

2. Effective results of interventions to improve operational quality of some IRBs, 2016 – 2018

- Regarding improvement of relevant legal regulations: Additional specific and detailed regulations and guidelines have been proposed and approved in accordance with international guidelines on organization and operation of the Ethics Council. In the legal document, there are 09 groups of topics related to IRB membership standards, 12 topics related to the independence of the IRB and some additional mandatory provisions that IRB develop SOPs for the operation of the Council.

- Regarding the completion of IRB's appraisal process and tools: It has been developed in a detailed, complete, specific and approved manner for 04 samples of IRB's appraisal tools (Research proposal review form; Research report review form, Evaluation form of dossier submitted again after the meeting; Evaluation form of revised/supplemented protocol after

approval) and 04 written notices of IRB's decision for the research (Minutes of IRB meeting to review research proposal, Research proposal approval certificate, Minutes of IRB meeting to review final report, Research results acceptance certificate).

- Regarding training of IRB members: Developed programs, documents and organized training on standard operating procedures for 10 IRBs. After the intervention, 8 out of 10 IRBs have developed a set of SOPs according to regulations and sent annual activity reports to the Ministry of Health.

RECOMMENDATION

Based on the above research results, we have some recommendations as follows:

1. It is necessary to promulgate standards for assessing the quality of IRB's activities, and to complete regulations on assessing the quality of IRB's activities.

2. Set up an online IRB registration system allowing Councils to register for the first time, register when there are changes, additions, and re-registration.

3. Continue to organize capacity building training courses for IRB members, organizational structure and operation of IRB, support IRBs to develop a set of SOPs to manage the quality of IRBs.

4. New organization of training courses to assess the activities of IRBs, towards the organization of assessment and accreditation of IRB's activities.

5. Supplement in the legal document on strengthening the inspection and supervision activities of the management agency for the operation of IRBs.

LIST OF PUBLISHED ARTICLES THAT RELATED TO THIS THESIS

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