



A System-Based Framework for Enhancing Human Research Ethics Governance in Higher Education: Evidence from Phetchaburi Rajabhat University, Thailand

Chananut Ngerntong^{1,*}

¹ Institute of Research and Arts & Cultural Promotion, Phetchaburi Rajabhat University,
Phetchaburi 76000, Thailand

Abstract

This study examined the current conditions, management constraints, and development strategies for strengthening human research ethics governance at Phetchaburi Rajabhat University, Thailand. The study employed qualitative documentary research, supported by descriptive analysis of operational statistics from 84 research protocols submitted to the university Research Ethics Committee (REC) during 2022-2024. Primary documents included institutional regulations, standard operating procedures, application forms, REC meeting records, annual reports, and user satisfaction reports. Secondary documents included national and international standards, particularly the National Ethics Committee Accreditation System of Thailand (NECAST), the CIOMS guidelines, ICH-GCP, and World Health Organization guidance. Data were analyzed using content, comparative, and gap analyses, as well as data triangulation. The findings indicated that the university had established a formal research ethics governance system, including institutional regulations, a multidisciplinary REC, standard operating procedures, and an online submission platform. However, seven major limitations were identified: increasing secretariat workload relative to staffing capacity; insufficient lay representation; absence of systematic individual development plans; review timelines that exceed expected benchmarks; a 100% protocol revision rate before approval; incomplete post-approval monitoring; and a partially digitized information system. Based on the findings, the study proposes a System-Based REC Development Framework comprising inputs, NECAST-based processes, outputs, outcomes, and continuous improvement. The framework emphasizes strengthening human resources, policy integration, pre-review support for researchers, electronic post-approval monitoring, and an integrated e-REC system. The proposed framework may be adapted by medium-sized higher education institutions seeking to improve REC efficiency, transparency, accountability, and participant protection in line with national and international research ethics standards.

Keywords: human research ethics, research ethics committee, NECAST, research governance, post-approval monitoring, e-REC system

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1. Introduction

Research involving human participants plays a critical role in generating knowledge and innovation for improving quality of life, health, education, local development, and social well-being. At the same time, such research requires rigorous ethical oversight to ensure respect for human dignity, rights, safety,

privacy, and welfare. Human research ethics governance is therefore not merely an administrative requirement; it is a core institutional mechanism for protecting research participants and strengthening public trust in research.

International ethical frameworks, including the Belmont Report, the CIOMS International Ethical Guidelines for Health-related Research

*Corresponding author; e-mail: chananut.nge@mail.pbru.ac.th

Involving Humans, and the ICH-GCP, highlight the need for independent, competent, transparent, and accountable ethics review systems [1, 2]. These frameworks emphasize risk-benefit assessment, informed consent, privacy protection, scientific validity, fair participant selection, and continuing oversight throughout the research life cycle [3, 4, 5]. In higher education institutions, these principles are operationalized through Research Ethics Committees (RECs), also referred to as Institutional Review Boards (IRBs) or Human Research Ethics Committees.

In Thailand, the quality and standardization of REC operations have been promoted through the National Ethics Committee Accreditation System of Thailand (NECAST) [6, 7]. NECAST provides a structured quality framework covering five domains: (1) committee structure and composition; (2) compliance with institutional policies and specific requirements; (3) protocol review procedures; (4) post-approval procedures; and (5) documentation and archiving. This framework is highly relevant to universities striving to balance an increasing volume of research with limited administrative resources.

Phetchaburi Rajabhat University is a regional higher education institution with missions in teaching, research, community development, and local innovation. Since fiscal year 2021, the number of research projects involving human participants has increased, resulting in a higher workload for the university REC and its secretariat. Although the university has established formal regulations [8], an REC structure [9], standard operating procedures (SOPs) [10, 11], and an online submission system [12], operational constraints persist in review timelines, researcher preparedness, post-approval monitoring, personnel development, and information management.

Previous studies and institutional experiences in Thailand and internationally have reported similar challenges: prolonged review timelines, insufficient administrative support, variation in review practices, limited training, and incomplete electronic systems [13, 14, 15]. However, studies that systematically examine REC management in regional Thai

universities, particularly Rajabhat universities, remain limited [14]. This study addresses that gap by analyzing the human research ethics governance system of Phetchaburi Rajabhat University through a NECAST-based system perspective and proposing a practical development framework for institutional improvement.

2. Objectives

The objectives of this study were threefold: (1) to examine the operational conditions of human research ethics governance at Phetchaburi Rajabhat University; (2) to analyze the problems, obstacles, and management gaps affecting the efficiency of the university REC system; and (3) to propose development strategies for strengthening human research ethics governance in accordance with NECAST and international ethical standards.

3. Materials and methods

3.1 Research design

This study employed a qualitative documentary research design, supported by descriptive analysis of operational statistics. The documentary approach was appropriate because the study aimed to examine institutional governance mechanisms, formal procedures, operational records, and compliance with national and international research ethics standards.

3.2 Data sources and document selection

Data were collected from primary and secondary documents related to the operation of the Phetchaburi Rajabhat University REC during 2022-2024. This period was selected because the university had established a formalized human research ethics system with sufficient operational records available for analysis. Documents were included if they were directly related to human research ethics management, fell within the study period, could be verified for source and accuracy, and reflected the REC's policies, structures, procedures, or operational outcomes.

Primary documents comprised university regulations [8], orders and announcements [9],

SOPs [10, 11], application forms, REC meeting reports, statistical operation reports, annual REC reports [16, 17, 18], satisfaction reports from service users, and reports from training or workshop activities on research ethics. Secondary documents comprised academic literature, national standards, NECAST guidelines [6, 7], the Belmont Report, CIOMS guidelines [1], ICH-GCP [2], WHO guidance [5], and operational manuals or evaluation reports from research ethics committees in Thailand and abroad [13, 14].

3.3 Data analysis

Data were analyzed using content analysis, comparative analysis, and gap analysis. Documentary data were reviewed, coded, categorized, and synthesized according to the five NECAST domains. The university's current practices were then compared with NECAST requirements and relevant international standards to identify strengths, gaps, operational limitations, and development strategies. Quantitative operational data, including the number of protocols submitted, review timelines, revision rates, and satisfaction results, were analyzed using descriptive statistics, including frequencies, percentages, means, and trend comparison across 2022-2024.

Review time was calculated from the date a protocol entered the REC system to the date an ethics approval certificate was issued. The protocol revision rate was calculated by comparing the number of protocols returned to researchers for correction or additional information with the total number of protocols submitted in each fiscal year.

3.4 Trustworthiness

Data credibility was enhanced through triangulation across multiple sources, including university policy documents, SOPs, annual reports, REC meeting records, statistical reports, satisfaction surveys, training reports, and national and international standards. Consistency across these sources was examined before the findings were synthesized.

4. Results

The findings are presented according to the five NECAST domains. Overall, Phetchaburi Rajabhat University had established the foundations of a formal REC system; however, gaps remained in workload management, performance monitoring, post-approval oversight, and digital integration.

4.1 Standard 1: Committee structure and composition

The university had a clear governance structure for human research ethics, supported by the Phetchaburi Rajabhat University Regulation on Human Research (B.E. 2565/2022) [8]. The REC consisted of 24 members, including 10 core members and 14 associate members. Members represented diverse academic disciplines, and external members participated in the committee to strengthen independence and multidisciplinary judgment. The university also allocated a budget for REC meetings, personnel development, and office administration.

Nevertheless, two major gaps were identified. First, the secretariat was staffed by only two support personnel, despite their responsibility for coordination, meeting preparation, document management, communication with researchers, and project follow-up for the entire university. Second, the number of lay persons remained insufficient. Although all committee members had completed training in human research ethics, there was no systematic Individual Development Plan (IDP) for committee members and staff.

4.2 Standard 2: Compliance with specific policies

The university had formal regulations and SOPs covering key REC processes, including protocol submission, initial review, expedited review, exemption review, post-approval monitoring, progress reporting, adverse event reporting, and study closure. The EC-PBRU online submission system was implemented to support ethics submission and project status tracking [12].

However, the study found that REC-related key performance indicators (KPIs) had not yet

been clearly integrated into the institutional strategic plan, quality assurance system, or annual monitoring framework. The information system also did not fully cover all REC processes, particularly post-approval monitoring and integrated reporting.

4.3 Standard 3: Protocol review procedures

The REC applied three types of review according to protocol risk and category: full board review, expedited review, and exemption review. Analysis of 84 research protocols submitted during 2022-2024 found an average review time of 78 days. The minimum review time was 13 days, and the maximum was 186 days when aggregated across the three-year

period. All submitted protocols were returned to researchers for correction or additional information before approval, resulting in a 100% revision rate (Table 1).

The most common reasons for revision were incomplete documents, inconsistencies between the research proposal and supporting documents, incomplete participant information sheets or informed consent forms, insufficient explanation of risks and benefits, and revision requests based on committee recommendations. These findings indicate that review efficiency is linked not only to REC procedures but also to researcher preparedness and the quality of initial submissions.

Table 1. Operational statistics of the Human Research Ethics Committee, 2022-2024.

Fiscal year	No. of protocols	Minimum review time (days)	Maximum review time (days)	Mean review time (days)	Revision rate (%)
2022	26	13	155	75	100
2023	29	31	139	88	100
2024	29	52	186	72	100
Total / Mean	84	13	186	78	100

Note: Review time was calculated from submission to issuance of the ethics approval certificate. Minimum and maximum values in the Total row represent the lowest and highest values across all 84 protocols.

4.4 Standard 4: Post-approval procedures

The university had SOPs for post-approval activities, including protocol amendment review, progress reporting, final report submission, adverse event reporting, complaint management, and premature study termination. These procedures reflect the formal existence of post-approval oversight mechanisms.

In practice, however, post-approval monitoring relied largely on documents and email communication. The EC-PBRU online submission system did not yet provide a complete electronic post-approval monitoring workflow, automatic reminders, or real-time project status tracking [12]. This gap may limit the ability of the REC to monitor continuing

ethical compliance throughout the research life cycle.

4.5 Standard 5: Documentation and archiving

The university had established documentation and record-keeping procedures under its regulations and SOPs. The EC-PBRU online submission system supported electronic submission and partial data storage [12]. However, the overall system remained semi-electronic because paper documents and email communication continued to be used alongside the online platform. A centralized database linking all stages of the project life cycle had not yet been fully developed.

The absence of an integrated database limited systematic retrieval, performance monitoring, audit readiness, and institutional-level reporting. This finding suggests the need for an integrated e-REC system capable of

linking submission, review, approval, post-approval monitoring, reporting, archiving, and traceability (Table 2).

Table 2. NECAST-based gap analysis and development strategies.

NECAST standard	Current status	Gap identified	Development strategy
1. Committee structure and composition	Formal regulation; REC with 24 multidisciplinary members; external members; budget support.	Limited secretariat capacity; insufficient lay representation; no systematic IDP; some reviews need more substantive comments.	Increase secretariat capacity; recruit additional lay persons; develop IDPs; provide continuing training in ethics and research methodology.
2. Compliance with policies	Regulations and SOPs cover major processes; online submission system exists.	REC KPIs are not clearly integrated into strategic planning or institutional quality assurance.	Define REC performance indicators; connect REC governance with strategy, quality assurance, and annual monitoring.
3. Protocol review procedures	Full board, expedited, and exemption reviews are used according to risk.	Average review time was 78 days; 100% of protocols required revision.	Establish pre-review consultation or an ethics clinic; develop researcher checklists; strengthen administrative screening before formal review.
4. Post-approval procedures	SOPs cover progress reports, amendments, adverse events, complaints, and study closure.	Monitoring remains document- and email-based; no automated or real-time tracking.	Develop electronic post-approval monitoring with automated alerts and life-cycle status tracking.
5. Documentation and archiving	Online submission and partial electronic storage are available.	System remains semi-electronic; no integrated database across all processes.	Develop an integrated e-REC system with search, audit trail, reporting, and archival functions.

5. Discussion

The study demonstrates that Phetchaburi Rajabhat University has established important

foundations for human research ethics governance, including regulations, an REC structure, SOPs, and digital submission support. These foundations are consistent with

NECAST expectations and with international guidance requiring ethics review systems to be independent, multidisciplinary, documented, and accountable [1, 2, 5]. Nevertheless, the findings also show that formal structures alone are insufficient to ensure operational efficiency and continuous participant protection. Effective REC governance requires the alignment of people, policies, processes, technology, and continuous improvement mechanisms.

For Standard 1, the existence of a multidisciplinary REC and external members supports independent and balanced ethical judgment. However, limited secretariat staffing and insufficient lay representation may affect workload management, review quality, and community perspectives. International standards emphasize that REC membership should include both scientific and non-scientific perspectives, and that administrative support must be adequate for timely and high-quality review [1, 5]. The findings therefore suggest that human resource planning should be treated as a governance issue rather than a routine administrative matter.

For Standard 2, regulations and SOPs provide a strong compliance base. However, the lack of REC-specific KPIs limits the university's ability to monitor performance, evaluate improvement, and connect REC development with institutional quality assurance. Research governance should include measurable indicators such as average review time, proportion of complete submissions, number of post-approval reports submitted on time, training coverage, user satisfaction, and audit readiness [4]. Integrating these indicators into the university's strategic and quality systems would make research ethics governance more visible and sustainable.

For Standard 3, the average review time of 78 days and the 100% revision rate indicate a need to improve both researcher preparedness and process efficiency. Many delays appear to originate from incomplete or inconsistent submissions. Comparable studies have likewise associated avoidable delays with the timing and completeness of applications [13, 15]. This suggests that REC development should not focus solely on committee review but should

also include upstream support mechanisms, such as pre-review screening, researcher checklists, templates for participant information and consent forms, and an ethics consultation clinic. Such mechanisms can reduce avoidable revisions and improve the quality of protocols before formal review.

For Standard 4, the existence of SOPs for post-approval activities is a strength. However, the lack of an electronic and proactive monitoring system reduces the ability to ensure ongoing compliance after approval. Post-approval monitoring is essential because participant protection does not end at initial approval. Progress reports, amendments, adverse events, complaints, protocol deviations, and study closure should be traceable in a single system. Automated reminders and real-time dashboards would help researchers comply with reporting requirements and help the REC identify overdue or high-risk projects.

For Standard 5, the semi-electronic system reflects a common transition challenge in higher education institutions. While online submission improves accessibility and reduces some paperwork, a fragmented system can still create duplication, data gaps, and weak audit trails. An integrated e-REC system should support the entire research life cycle, from submission and review to approval, post-approval monitoring, reporting, and archiving. Such a system would improve transparency, traceability, institutional reporting, and preparedness for NECAST accreditation.

A key contribution of this study is the proposal of a System-Based REC Development Framework. Unlike a checklist-based compliance assessment, the framework shows the causal relationships among inputs, processes, outputs, and outcomes. For example, limited secretariat capacity and inadequate lay representation affect review timelines, post-approval monitoring, and document management. Conversely, a well-designed e-REC system can simultaneously improve screening, communication, monitoring, reporting, and archiving. REC development should therefore be implemented as an

integrated system rather than as isolated activities.

This study has limitations. As a single-institution documentary case study conducted by researchers familiar with the institution, the findings reflect one regional context and may be subject to insider perspective. Generalization should therefore be treated with caution, and the proposed framework is conceptual and has not yet been empirically validated. These limitations are addressed in the recommendations for future research.

6. Proposed System-Based REC Development Framework

The proposed framework consists of five linked components: inputs, processes, outputs, outcomes, and continuous improvement. Inputs include institutional policy and leadership support, REC members and secretariat personnel, budget, information technology, SOPs, training resources, and facilities. Processes refer to the five NECAST domains: committee structure and composition, policy compliance, protocol review, post-approval procedures, and documentation and archiving. Outputs are an efficient, transparent, accountable, and traceable REC system. Outcomes include improved research quality, stronger participant protection, increased researcher capacity, institutional trust, and alignment with national and international standards (Figure 1).

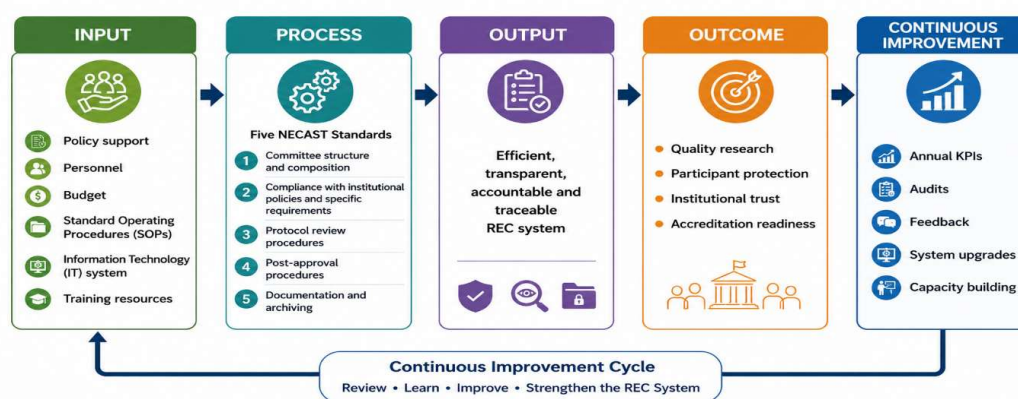


Figure 1. System-Based REC Development Framework aligned with NECAST.

The framework is particularly applicable to medium-sized universities and Rajabhat universities with similar resource constraints. It provides a practical basis for gap analysis, institutional planning, quality assurance integration, and preparation for NECAST accreditation.

7. Conclusions

This study analyzed the human research ethics governance system of Phetchaburi Rajabhat University using the NECAST framework. The findings demonstrate that the university has established a formal governance structure comprising institutional regulations, a multidisciplinary

Research Ethics Committee (REC), standardized operating procedures (SOPs), budget allocation, and an online submission platform. However, several operational limitations remain, including insufficient secretariat capacity, inadequate lay representation, the absence of systematic competency development for REC members and staff, prolonged review timelines, high protocol revision rates, incomplete electronic post-approval monitoring, and semi-electronic documentation. These findings indicate that establishing institutional structures alone is insufficient to ensure an effective research ethics governance system. Sustainable governance also requires continuous organizational development, adequate

institutional support, systematic quality management, and continuous monitoring throughout the research lifecycle.

These findings are consistent with the current direction of research ethics governance development within Thai higher education institutions. Previous studies have reported that many universities have established fundamental governance mechanisms, including institutional regulations, multidisciplinary RECs, ethics review procedures, and ethics training systems. Nevertheless, institutional capacity differs considerably among universities, particularly regional and medium-sized institutions where limitations in personnel, administrative support, and organizational resources remain common challenges. Therefore, strengthening research ethics governance requires not only compliance with national standards such as NECAST but also continuous institutional capacity building and integrated governance mechanisms.

The findings are also consistent with previous research conducted at Rajabhat Universities. Supising et al. [19] developed a system-based management framework for work-integrated education in Rajabhat Universities and demonstrated that successful institutional management depends on integrating policy, information systems, stakeholder collaboration, implementation processes, assessment, and continuous development within a unified governance framework. Although their study focused on work-integrated education rather than research ethics governance, both studies emphasize that effective institutional governance requires integrated policy, standardized operational procedures, stakeholder participation, quality assurance, and continuous improvement rather than isolated administrative activities. This comparison suggests that a system-based governance approach is an appropriate development model for Rajabhat Universities operating under similar institutional contexts and resource constraints.

The present findings are further supported by broader organizational management literature. In their review of ISO

20400 Guidance for Sustainable Procurement, Aroonsrimorakot and Laiphrakpam [20] concluded that successful organizational management depends on integrating institutional policy, strategic planning, stakeholder engagement, personnel development, accountability, performance measurement, and continual improvement into a coherent management system. Likewise, the proposed System-Based REC Development Framework integrates institutional policy, multidisciplinary REC governance, standardized operating procedures, competency development, digital management systems, post-approval monitoring, and quality assurance into a unified governance model. These similarities indicate that research ethics governance should be regarded as an institutional management system rather than merely an administrative review process.

Comparable findings were also reported by Aroonsrimorakot [21], who identified twelve critical success factors for ISO 14001 implementation, including organizational policy, personnel competency, staff participation, management commitment, monitoring and evaluation, and continual improvement. Although ISO 14001 addresses environmental management rather than research ethics governance, both systems share fundamental organizational principles emphasizing leadership commitment, standardized operational procedures, staff competency, monitoring mechanisms, and continuous quality improvement. These common characteristics reinforce the conclusion that the effectiveness of institutional governance depends not only on regulatory compliance but also on systematic organizational management and sustained institutional commitment.

Based on these comparative findings, the proposed System-Based REC Development Framework extends existing governance models by integrating organizational governance, human resource development, digital transformation, quality assurance, and post-approval oversight into a comprehensive research ethics governance system. Unlike conventional REC models that primarily focus

on ethical review prior to project approval, the proposed framework emphasizes governance across the entire research lifecycle, including protocol review, researcher support, post-approval monitoring, quality assurance, institutional learning, and continuous improvement. This lifecycle approach is consistent with internationally recognized principles of integrated governance, accountability, stakeholder participation, and organizational integrity.

Therefore, strengthening research ethics governance in higher education institutions should involve strategic institutional commitment rather than procedural improvements alone. The five strategic directions proposed in this study strengthening committee structure and personnel capacity, integrating REC indicators into institutional strategy and quality assurance, improving review efficiency through researcher support, developing electronic post-approval monitoring, and implementing an integrated e-REC system provide a practical governance model that may be adapted by Rajabhat Universities and other regional higher education institutions facing similar organizational contexts and resource limitations. Consequently, the proposed framework contributes not only to improving operational efficiency but also to enhancing institutional accountability, research quality, and long-term protection of research participants.

8. Recommendations

8.1 Practical recommendations

At the policy level, the university should incorporate human research ethics governance into institutional strategy, annual action plans, and quality assurance indicators. At the operational level, the REC secretariat should develop pre-review screening, researcher checklists, consent-form templates, and an ethics clinic to reduce avoidable revisions. At the human resource level, the university should increase secretariat capacity, strengthen lay representation, and establish Individual Development Plans for REC members and staff. At the technology level, the university

should develop an integrated e-REC system covering submission, review, approval, post-approval monitoring, reporting, archiving, and audit trails. At the network level, Rajabhat universities and medium-sized institutions may adapt this framework to their own contexts and share best practices for REC development.

8.2 Recommendations for future research

Future studies should use mixed methods to incorporate quantitative performance data and stakeholder perspectives from researchers, REC members, and administrators. Comparative studies across Rajabhat universities should be conducted to identify best practices and context-sensitive development models. Future research should design and evaluate an integrated e-REC prototype, measuring effects on review time, workload, cost, compliance, and user satisfaction. Longitudinal studies should assess whether strengthened research ethics governance improves research quality, participant protection, and public trust in institutional research.

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