

Practice and Exploration of Refined Management of Scientific Research Project Ethical Review in a Public Tertiary Hospital

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Abstract: With the high-quality development of public hospitals, clinical research has grown rapidly and become increasingly diversified. The traditional extensive research ethics management model, characterized by superficial review, low efficiency, and inadequate process supervision, can hardly satisfy the standardized governance requirements of modern hospital scientific research. To solve the prevalent problems of formalized ethical review, loose process management, and weak risk prevention, and to comply with national regulations on scientific and technological ethics governance, medical institutions are actively constructing refined research ethics management systems. This study takes a tertiary-A public hospital as the research object, investigates the current state of its research ethics management, summarizes the characteristics of refined ethical management, and analyzes existing practical deficiencies. Following the research logic of status investigation, characteristic summary, problem analysis, and countermeasure optimization, this study constructs a practical and replicable refined management system suitable for tertiary-A hospitals. By adopting standardized, regular, and targeted management strategies, the system effectively improves research ethics management efficiency, standardizes clinical research behavior, and fully protects the legitimate rights and interests of research subjects. The findings can provide practical references for medical institutions to optimize research ethics systems and promote refined management reforms.

1. Introduction

Clinical research is a critical pillar for the advancement of clinical medical technology and the high-quality development of public hospitals. The ethical management of scientific research serves as the foundation for regulating medical research conduct, safeguarding the rights and interests of research subjects, and preventing compliance risks [1]. In recent years, China has introduced multiple policies on the governance of science and technology ethics, explicitly requiring medical

institutions to move away from the traditional "form-focused, substance-neglecting" review model. This shift drives the evolution of research ethics from procedural checks to substantive risk prevention, and from experience-based extensive management to refined and standardized governance [2].

As regional core platforms for clinical research, public tertiary-A hospitals face a large volume and wide variety of research projects with significant risk variations, which demand greater professionalism, precision, and whole-process oversight in ethical review. Traditional ethics management, which often focuses on preliminary formality reviews, suffers from inadequate process supervision and insufficient whole-process control, which makes it difficult to adapt to the rapid development of clinical research. To address these challenges, this paper introduces the concept of refined management.

Based on the ethical management practices of a public tertiary-A hospital, this study analyzes the current status and shortcomings, summarizes management characteristics, and proposes a pathway to optimize ethical governance, thereby providing a practical reference for other medical institutions.

2. Challenges in Research Ethics Management and the Necessity of Refined Management

Currently, public tertiary-A hospitals have fully implemented a comprehensive review system for medical research ethics. A working model centered on the ethics committee and coordinated with research management departments has been established, enabling the routine completion of tasks such as project approval, process supervision, and final acceptance [3]. However, the rapid growth in the number of research projects and the expansion of study types—from traditional retrospective analyses to high-risk areas like clinical trials, interventional studies, biospecimen research, and real-world studies—have made the risk landscape more complex.

In practice, the existing ethical management system at our hospital only meets basic compliance needs and remains largely extensive and experience-based. Management efforts are concentrated on formality checks at the initial approval stage, while oversight is weak for project amendments, interim quality control, and final archiving. Heavy reliance on manual offline operations results in insufficient digital management. Furthermore, there is a lack of differentiated management rules for projects with varying risks and from different disciplines. This is compounded by the diverse composition and high mobility of research staff, leading to significant variations in ethical competence, with a general preference for research outputs over ethical compliance. These issues result in high rates of revision requests, improper research implementation, and missing documentation, posing notable ethical compliance risks.

In this context, implementing refined management is of significant practical importance. This model, through standardized processes, differentiated risk control, full-cycle supervision, and targeted training, overcomes the shortcomings of the traditional extensive approach, such as vague standards, lax control, and fragmented management. It ensures the ethical safety of high-risk projects while enhancing the approval efficiency for ordinary projects. It optimizes the allocation of ethical resources, improves the ethical literacy of personnel, and the capacity for information-based management, and ultimately drives the transition from formal compliance to substantive risk prevention, solidifying the governance foundation for high-quality and compliant hospital research.

3. Analysis of Refined Management Practices in Research Ethics

3.1. Characteristics of Refined Management

3.1.1. Comprehensive Institutional Frameworks

Compared to the experience-based and highly subjective nature of extensive management, standardization and process orientation are prominent features of refined research ethics management [4]. Refined management relies on a comprehensive institutional framework to standardize ethical review criteria, risk assessment, data verification, and rectification verification standards, thereby minimizing biases due to subjective human judgment. It also details the entire workflow, from submission intake, review, and interim review to final archiving. By defining the standards, timelines, and responsibilities for each position, it establishes a system of clear accountability and closed-loop operations, ensuring every aspect of ethics management is guided by rules and evidence, thus achieving standardized ethical governance.

3.1.2. Tiered Risk Control

Precise classification and differentiated control are distinctive features of refined ethics management and key differentiators from traditional extensive management [5]. This model avoids a "one-size-fits-all" review approach. Instead, it establishes a tiered risk control mechanism based on the level of intervention, risk level, subject characteristics, and discipline type. For low-risk observational studies, the approval process is streamlined to enhance efficiency. Conversely, for high-risk interventional studies and research involving vulnerable populations, the review and oversight are intensified. This rational allocation of resources allows for precise risk identification and management, effectively balancing ethical safety with project efficiency.

3.1.3. Whole-Process Oversight

Closed-loop control across the full lifecycle is a crucial feature of refined ethical management [6]. Traditional management often focuses only on the initial review, leaving gaps and vulnerabilities in the subsequent oversight. Refined management transforms this fragmented approach by extending risk prevention across the entire project lifecycle, including initiation, implementation, amendments, adverse event management, mid-term review, and final archiving. Through routine supervision, dynamic monitoring, and ledger management, it establishes a working chain of preventive evaluation, in-process control, and post-hoc review, eliminating blind spots and fostering a long-term stable pattern of ethical compliance.

3.2. Shortcomings in Refined Management

3.2.1. Lack of Specificity in the Institutional Framework

Although our hospital has established a foundational framework for refined research ethics management, there are still gaps in the supporting systems. Existing regulations are mostly general principles, lacking specific implementation rules for different disciplines, risk levels, and study types. Operational standards are vague and poorly aligned with actual clinical research. Furthermore, the mechanism for updating regulations is deficient, failing to keep pace with national policy changes. Some management initiatives remain only at a framework level, with ambiguous enforcement standards and responsibilities, limiting their effectiveness and hindering the overall quality of ethics management [7, 8].

3.2.2. Lack of a Differentiated Personnel Training Mechanism

Professional competence is crucial for the effective implementation of refined management. However, our hospital's current ethics training system is insufficient to meet the needs of refined management. Training often takes a "one-size-fits-all" format, failing to differentiate instruction for various roles and levels of researchers, which makes it difficult to cater to the learning needs of clinicians, core researchers, and students [9, 10]. The training also tends to emphasize theory and policies, lacking practical content such as operational guidance, risk assessment, and case studies. This results in a poor understanding of regulatory standards among researchers, leading to frequent compliance issues during project application and implementation stages, thereby preventing the full realization of refined management requirements.

3.2.3. Lagging Digitalization of Ethics Management

Information technology is a crucial vehicle for improving the efficiency and quality of refined management. However, the digitalization of our hospital's ethics management is lagging and cannot support high-precision routine control. A significant portion of the work still relies on manual operations. Functions such as dynamic project monitoring, risk warning, data statistics, and traceability are underdeveloped, making precise supervision of numerous projects difficult. The incomplete electronic filing system leads to scattered data and untimely ledger updates, hindering troubleshooting and quality analysis. The manual model is labor-intensive, error-prone, and severely undermines the effectiveness of refined management [11].

4. Optimization Strategies and Practical Insights for Refined Research Ethics Management

4.1. Refining the Ethics Management System to Consolidate the Institutional Foundation

To address issues such as insufficient system specificity, poor practical applicability, and limited effectiveness, our hospital revised the research ethics management system according to the principles of continuous improvement and dynamic optimization. We constructed a three-tier institutional framework of "General Guidelines – Specific Rules – Job Standards" to achieve full-scope whole-process risk coverage.

First, we rigorously revised the general management rules to align with the latest national policies, such as the Measures for the Ethical Review of Science and Technology (Trial) and the Measures for Ethical Review of Life Sciences and Medical Research Involving Human Subjects. This revision clarified the objectives, principles, rights, responsibilities, and control standards for refined management, consolidating the institutional foundation [12, 13].

Subsequently, based on the types, risk profiles, and disciplinary differences of research projects, we refined supporting management regulations. We issued specific rules for tiered risk review, clinical trial management, retrospective study review, project amendment management, and subject rights protection. These documents define the review criteria, procedures, and verification requirements for different studies, addressing the poor adaptability of general regulations. Simultaneously, we clarified the roles, responsibilities, and operational procedures for ethics administrators, committee members, and principal investigators, integrating refined control requirements into every position and operational process, thereby ensuring clear accountability for all actions.

4.2. Implementing Tiered Risk Management to Enhance Risk Prevention Specificity

To leverage the advantages of differentiated control in refined management, our hospital

established a tiered risk management system based on research contexts. Projects are categorized into high-, medium-, and low-risk categories based on intervention type, subject characteristics, risk-benefit ratio, and research scenario. This enables tiered review, classified oversight, optimized resource allocation, and more targeted ethical control.

For low-risk projects such as retrospective case reviews, routine data mining, and non-invasive observational studies, our hospital established a fast-track review channel. These projects undergo a simplified approval model of "initial review by a primary reviewer and confirmation by the chair," significantly reducing approval times while maintaining compliance [14].

For medium-risk projects, such as conventional clinical studies, we employ a standard full ethics committee review coupled with a quarterly monitoring model. The focus of oversight is on the standardization of protocol implementation, the completeness of informed consent, and the effectiveness of basic risk prevention.

For high-risk projects, including clinical trials of new drugs and devices, human interventional studies, and biospecimen research, as well as projects involving vulnerable groups like children, pregnant women, the elderly, and critically ill patients, stringent control standards are implemented. These projects are all reviewed by the full ethics committee at convened meetings, with a thorough review of the study's scientific validity, the completeness of risk prevention plans, and the comprehensiveness of subject protection [15]. Additionally, a special verification ledger for high-risk projects was established, incorporating monthly random checks, whole-process dynamic monitoring, mandatory immediate reporting of adverse events, and a closed-loop rectification mechanism to comprehensively safeguard the ethical safety of high-risk projects.

4.3. Connecting Whole-Process Oversight to Achieve Closed-Loop Ethical Quality Control

Adopting a whole-process control philosophy, our hospital has transformed the fragmented oversight model. We established a full-lifecycle closed-loop supervision system covering project initiation, implementation, amendments, mid-term quality control, and final acceptance, enabling comprehensive and traceable management of ethical risks and thereby addressing the shortcomings in process supervision.

At the initiation stage, we implement a dual-review mechanism of "Formal Preliminary Review and Substantive Re-Evaluation." Administrative staff verify the completeness, conformity, and logic of application documents, correcting issues in advance. The ethics committee members focus on evaluating scientific validity, risk-benefit, informed consent, and privacy protection, preventing risks at the source [16, 17].

During the implementation stage, differentiated supervision is conducted according to the risk level, focusing on protocol adherence, subject enrollment, informed consent, and privacy protection, thereby identifying compliance risks promptly.

For project amendments, we enforce the core principle of "Approval First, Implementation Second," detailing review standards for any changes to study design, sample size, personnel, or timeline. Any unauthorized changes or non-compliant research conduct is strictly prohibited.

At the final acceptance stage, we comprehensively review the project's ethics file, verification records, and rectification materials. Projects with incomplete documentation or unresolved issues are not permitted to close, ensuring closed-loop ethical quality control throughout the lifecycle.

4.4. Implementing Differentiated Ethics Training to Bridge Personnel Competency Gaps

To address the uneven ethical competence among researchers and the limited effectiveness of uniform training, our hospital established a differentiated ethics education system. Training content is tailored to different needs, solidifying the personnel foundation for refined management.

Routine training is provided for all medical and research staff quarterly, covering the latest ethical policies, application procedures, common compliance issues, and basic risk control standards. This training is designed to continuously correct the cognitive bias towards research outputs over ethical compliance and enhance the basic ethical literacy of all staff.

Specialized training is offered to core clinical researchers and high-risk research teams, focusing on review criteria, risk assessment skills, protocol optimization, and adverse event management for clinical trials and interventional studies. Using real case studies from the hospital, this training aims to improve the practical skills and risk management capabilities of core research teams.

Mandatory pre-entry training is provided for new researchers, such as resident physicians and graduate students. This training systematically covers the entire ethical compliance process for initiating research, providing practical instruction on details such as documentation, informed consent drafting, record-keeping, and final archiving, thereby helping these individuals quickly establish a compliance mindset [18]. Simultaneously, ethics committee members and administrators are regularly engaged in external academic exchanges, policy workshops, and case discussions to harmonize review standards and enhance the professional competence of the ethics management team.

4.5. Utilizing Digital Tools to Enhance Ethical Management Efficiency

To address problems of low efficiency, high error rates, and difficulty in traceability associated with manual management, our hospital, in line with the development of smart hospitals, established an intelligent research ethics management platform. This platform facilitates the transition from experience-based to digitally driven management, integrating modules for application review, risk alerts, process verification, and statistical archiving to cover the entire ethics management process.

At the application front-end, the platform features an intelligent validation function. It automatically generates a checklist of required documents based on a project's risk level, alerts users to missing documents, format errors, or non-compliant content, significantly reducing the rate of application returns.

In the mid-stream monitoring phase, the system tracks project progress in real-time, automatically flagging overdue milestones, expired projects, and high-risk projects. This replaces manual ledger tracking, enabling dynamic and precise oversight. Administrators can perform document verification, issue follow-up, rectification tracking, and ledger updates online, substantially improving management efficiency.

At the back-end review stage, the platform comprehensively stores the whole-process records of refined management, including review opinions, verification records, rectification actions, and approval documents, all in electronic form. This establishes a standardized electronic archive that provides comprehensive data support for research quality reviews, refined quality control assessments, and external audits. Digital tools have effectively resolved many drawbacks of manual management, enhancing intelligent governance for our hospital's research ethics [19, 20].

4.6. Refining the Assessment and Accountability Mechanism to Sustain Management Effectiveness

To ensure the routine implementation and long-term sustainability of all refined management measures, and to prevent procedures from becoming mere formalities, our hospital established a linkage mechanism between ethics quality control and assessment. Compliance with ethical requirements is incorporated into the departmental research quality assessment and the individual research integrity evaluation system, forming a long-term management model of "daily supervision, quarterly assessment, and annual review," and continuously reinforcing the effectiveness of refined

management.

During routine operations, dedicated ethics administrators use the intelligent platform for online dynamic monitoring, supplemented by on-site random checks, to comprehensively identify ethical compliance risks during project implementation. All identified issues are uniformly documented, categorized, and tracked, with responsible parties required to complete rectification within a deadline. Issues are considered closed only after re-verification confirms that rectifications are adequate, enabling dynamic problem control and whole-process closed-loop governance.

Concurrently, our hospital conducts a quarterly hospital-wide special inspection for ethical quality control. The inspection compares departmental research compliance against refined control standards, identifies common and specific problems, and publishes a hospital-wide quality control report with required corrective actions. An annual work review is conducted to summarize performance, identify remaining shortcomings, and set priorities for the following year. This establishes a positive cycle of "implementation — inspection — assessment — review — optimization," continuously improving the quality of refined ethical governance in research.

5. Conclusion

This study systematically examines the practice and optimization pathways of refined management in research ethics review at a public tertiary-A hospital. Through a structured analysis of current challenges—including insufficient institutional specificity, the absence of differentiated personnel training, and lagging digital infrastructure—we have identified critical barriers that hinder the transition from traditional extensive ethics management to a more robust, risk-proportionate governance model.

In response, our hospital has implemented a comprehensive refined management framework centered on five interconnected strategies: refining the institutional system with a three-tier regulatory architecture, adopting tiered risk-based review mechanisms, establishing whole-process closed-loop oversight, delivering differentiated ethics training tailored to diverse researcher profiles, and deploying an intelligent digital platform to automate and streamline ethical oversight. These interventions have collectively enhanced review efficiency, strengthened substantive risk prevention, and improved compliance traceability across the project lifecycle.

The practical experience demonstrates that refined management, when systematically operationalized, effectively resolves the longstanding deficiencies of formality-focused and fragmented ethics oversight. It not only safeguards the rights and interests of research subjects but also fosters a culture of ethical accountability among investigators, thereby reinforcing the scientific integrity and institutional credibility of hospital-based clinical research.

While the findings are context-specific to a single tertiary-A hospital, the proposed framework offers transferable insights and practical tools for other medical institutions seeking to modernize their ethics governance in alignment with national regulatory mandates. Future research should focus on validating the long-term effectiveness of this model through multi-center comparative studies, further integrating artificial intelligence for predictive risk analytics, and refining outcome-based metrics to evaluate the sustained impact of refined ethics management on research quality and patient safety.

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