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Exploration of the Collaborative Review Mechanism for Regional Ethics Centers in University-Affiliated Hospitals

Shuzhen Ye

Department of Science and Technology, Wenzhou Medical University, Wenzhou, China
Email: ysz@wmu.edu.cn

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Abstract

With the surge in multicenter clinical studies, the traditional decentralized ethical review model is facing severe challenges due to its inefficiency and inconsistent standards. In China, regional ethics committees established in university-affiliated hospitals are regarded as a key approach to addressing this dilemma. This paper systematically elaborates on the current exploration status of regional ethics centers in collaborative review and ethical mutual recognition by university-affiliated hospitals in China, constructs a theoretical model for collaborative review, analyzes its operational mechanisms, practical obstacles, and legal regulatory dilemmas, and discusses its future development direction from the interdisciplinary perspective of "ethics and government." The effective operation of regional ethical collaborative review not only relies on the professional capabilities of ethics committees themselves but also requires clear government support in improving legal frameworks, enhancing administrative supervision coordination, and establishing mechanisms for sharing responsibility and risks. In the future, a diversified ethical governance system characterized by "government guidance, institutional autonomy, and regional collaboration" should be established.

Keywords

Regional Ethics Committee, Collaborative Review, Ethical Mutual Recognition, University-Affiliated Hospitals, Multicenter Clinical Study, Ethical Governance, Ethics and Government

1. Introduction

With the rapid advancement of translational medicine and precision medicine,

multicenter clinical studies have become the gold standard for validating the efficacy and safety of novel drugs and therapies. However, in multicenter studies, each participating institution must conduct independent ethical reviews of the same research protocol, which leads to significant resource waste and efficiency bottlenecks. As multicenter, cross-disciplinary collaborative medical research continues to grow, establishing a high-quality, efficient, ethical collaborative review and mutual recognition system has become an inevitable requirement for multi-institutional studies [1]-[3].

In recent years, the Chinese government has successively introduced policies to encourage the exploration of regional ethics committee construction. The Regulations on Ethical Review of Life Science and Medical Research involving Human Beings (2023) clearly stipulate that institutions should establish an ethical review collaboration mechanism to support mutual recognition of ethical reviews for multicenter studies [4]. As core carriers of high-quality medical resources and scientific research innovation in China, university-affiliated hospitals have taken the lead in piloting collaborative reviews by regional ethics centers, which are specialized ethics review entities serving multiple medical or research institutions within a geographic region, providing centralized or coordinated ethical review services for multicenter studies. However, these explorations face practical challenges at the government level, such as ambiguous legal status, unclear administrative oversight, and undefined liability boundaries, as well as the ethical tension of balancing efficiency with subject protection [5] [6].

This paper adopts an interdisciplinary perspective from "Ethics and Government" to systematically examine the regional ethical collaboration review model led by university-affiliated hospitals, analyze its operational logic and challenges within the current legal and regulatory framework, and provide references for establishing an efficient and compliant ethical governance system.

2. Institutional Background and Driving Forces of Regional Ethical Collaboration Review in China

2.1. Methodology for Policy and Case Selection

This study employs qualitative policy analysis and comparative case study methodologies. Through systematic searches of government official websites, we selected the most relevant policies and regulations. Regional case selections were based on their representation of different governance models identified in the literature, as well as varying degrees of policy maturity. As no primary empirical data were collected, the analysis is descriptive and analytical in nature rather than an empirical evaluation.

2.2. Policy Evolution and Driving Forces

The emergence of regional ethics collaborative review is not merely a spontaneous academic initiative, but is strongly driven by governmental regulation. Since 2016, a series of policies and regulations have been successively introduced at the na-

tional level, providing institutional foundations for the establishment of regional ethics committees (Table 1).

Table 1. Main policies and regulations for the construction of regional ethics committees in China.

Year	Policy/Regulation Name	Core Content
2016	Measures for Ethical Review of Biomedical Research Involving Human Subjects	The direction of the construction of the ethics committee was put forward for the first time
2020	Good Clinical Practice for Medicinal Products	Clarify the ethical review requirements of multicenter clinical trials
2023	Measures for Ethical Review of Life Science and Medical Research Involving Human Subjects	Explicitly require the establishment of a collaborative mechanism for ethical review and mutual recognition of results
2023	Measures for the Review of Scientific and Technological Ethics (Trial)	Propose standardized requirements for the establishment and operation of regional ethics committees
2025	Consensus on Ethical Collaborative Review for Multicenter Clinical Research in Medical Institutions in the Yangtze River Delta Region	Promoting the Institutionalization and Standardization of Regional Ethical Collaborative Review
2025	Regulations on Clinical Research and Clinical Translation Application of New Biomedical Technologies	Propose comprehensive requirements for the ethical regulation of cutting-edge technologies

Xu Weiwei *et al.* pointed out that the establishment of an efficient, standardized, and mutually recognized ethical review collaboration mechanism is a crucial support for the construction of a scientific and technological innovation community [7]. Through a comprehensive analysis of the current status of regional ethics committees in China, Wu Bian *et al.* found that there are currently various organizational models such as "government leading + industry participation" and "alliance co-construction" [8]. Jiang Haihong *et al.* emphasized that establishing regional ethics committees is an important aspect and means to improve the ethics committee mechanism. To this end, the relationship between regional ethics committees and institutional ethics committees should be clarified, so as to promote the efficiency of ethical reviews, enhance unified coordination services, and facilitate mutual recognition of ethical review results [9].

Ethics committees in university-affiliated hospitals typically possess high academic standards and serve as teaching demonstration institutions for medical schools. This dual role grants them both the academic authority to lead the establishment of unified standards for regional ethics centers and exposure to regulatory pressures from university administrations, hospital management, and government health authorities. Through comparative analysis of institutional ethics committees and regional ethics committees, Wen Zhuming *et al.* found that institutional ethics committees can provide timely and comprehensive insights into

project implementation details, but face challenges such as low review efficiency and inconsistent evaluation criteria. In contrast, regional ethics committees demonstrate advantages including higher review efficiency, consistent evaluation standards, and relatively superior review quality, though they struggle to obtain a real-time, thorough understanding of project execution [10]. Both models should leverage their respective strengths to complement each other and achieve synergistic development.

3. Main Models and Mechanisms of Collaborative Review

Through a review of typical pilot experiences in Beijing, Shanghai, Guangdong, Jiangsu, Sichuan, and other regions, the current regional ethical collaboration review models in university-affiliated hospitals primarily manifest in the following three patterns (Table 2).

Table 2. Comparison of three typical models for regional ethical review collaboration in university-affiliated hospitals.

Characteristic	Mode 1: Alliance-Based Model	Mode 2: Government-Authorized Model	Mode 3: Host-Institution Model
Dominant Force	Spontaneous alliance of university-affiliated hospitals	Designated by the local health commission/drug administration	Led by a single-core hospital
Legal Basis	Inter-agency cooperation agreement	Administrative authorization or government document	Relying on the constitution of the institution
Review Method	Rotating presiding or independent presiding	Centralized presiding, approved by the member units	The leading unit has full power to review
Legal Liability	Shared responsibility as per the agreement	Administrative coordination, risk sharing	The leading unit shall bear the main responsibility
Applicable Scene	Member unit research within the alliance	All eligible institutions within the region	Collaborative group of multicenter studies
Representative Cases	Beijing medical ethics review mutual recognition alliance	Guangdong provincial regional ethics review committee	Sichuan regional ethics review committee for traditional Chinese medicine

3.1. Alliance-Based Model

This model is based on contractual agreements among multiple university-affiliated hospitals to establish a mutual recognition framework. Typically, a "primary review" system is employed, where the ethics committee of the lead institution conducts the primary review, and participating institutions apply expedited review provided no substantial objections are raised. While flexible, this model has weak enforcement. In the event of subject harm, liability disputes can arise.

3.2. Government Authorized Model

The regional ethics committee is formally established through official documents issued by the local health administrative department, granting the center jurisdic-

tion over ethical review for certain studies within the region (typically multicenter studies). This model possesses the strongest administrative authority and legal safeguards, but it may face management cost issues due to overlapping responsibilities with the original ethics committees of medical institutions.

3.3. Host-Institution Model

This model centers on a single, academically preeminent university-affiliated hospital. Its ethics committee functions as a regional ethics center, providing review services for smaller institutions or research projects lacking independent ethics review capacity, with mutual recognition of outcomes governed by contractual agreements.

3.4. Constructing a Theoretical Model for Collaborative Review

The alliance-based model (Model 1) emphasizes coordination but lacks robust accountability mechanisms. The government-authorized model (Model 2) strengthens standardization and accountability through administrative mandates, while the host-institution model (Model 3) relies heavily on coordination but faces risks of conflicting interests. All three models exhibit inherent limitations. This study synthesizes the strengths of these approaches to develop a tripartite collaborative review model (**Figure 1**), which comprises three core components, three primary stakeholder categories, and a hierarchical decision-making framework.

Three core components: 1) Standardization Layer: unified review criteria, templates, and procedural rules jointly established by the Regional Ethics Center and participating institutions. 2) Coordination Layer: the presiding institution responsible for case diversion, adjudication assignment, and dispute resolution. 3) Accountability Layer: predefined responsibility allocation, quality audit mechanisms, and appeal procedures.

Three primary stakeholders: 1) Regional Ethics Committees– serving as the central hub, they conduct principal reviews of multicenter studies and issue binding opinions. 2) Participating institutions: retain responsibility for local feasibility assessments and post-approval monitoring, but delegate ethical judgments to the Regional ethics committees. 3) Government regulators: provide legal authority, oversee quality, and intervene in cases of severe non-compliance or subject harm.

A hierarchical decision-making logic: 1) Low-risk studies: automatic mutual recognition requiring only notification. 2) Medium-risk studies: collaborative review supplemented by rapid local validation. 3) High-risk studies: substantive review by participating institutions, with the REC's preliminary assessment serving as a binding reference to minimize redundant inquiries.

4. Operational Process of Regional Ethical Collaboration Review

4.1. Detailed Workflow Phases

This section transforms the tripartite collaborative review model into executable

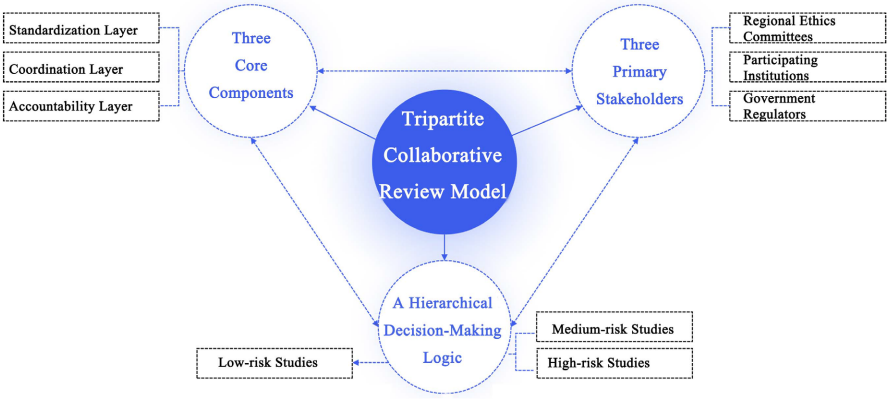

Figure 1. The tripartite collaborative review model.

operational workflows. The efficient operation of the regional ethics collaborative review relies on standardized process design. Based on a comprehensive analysis of existing policy requirements and practical experiences from various regions, a complete collaborative review process typically includes the following core components (Figure 2).

The following five phases correspond to steps 1 - 5 in Figure 2, with each phase explicitly indicating its affiliation to the tripartite collaborative review model.

Phase 1: Case Entry and Triage (Standardization Layer). The multicenter study protocol is submitted to the regional ethics committee. If it meets the criteria, the protocol proceeds to the principal investigator assignment phase.

Phase 2: The Regional Ethics Committee Review (Standardization Layer). The regional ethics committee designates lead reviewers based on the rotation roster or professional field, and records and communicates the results within the specified working days according to the project risk level.

Phase 3: Ethical Mutual Recognition (Coordination Layer). An ethical opinion letter shall be issued, and the study will proceed if no objections are raised.

Phase 4: Dispute Resolution (Coordination Layer). The regional ethics committee follows a step-by-step resolution protocol: 1) Written clarification by the lead reviewer; 2) Teleconference between the lead reviewer and the objection institution; 3) Ad hoc panel including external ethicists; 4) Submission to the government regulatory authority for binding arbitration.

Phase 5: Follow-up Review and Supervision (Accountability Layer). After approval, the regional ethics committee is responsible for coordinating annual continuous reviews and adverse event monitoring. Government regulatory authorities conduct unannounced inspections and data verification, with each center submitting follow-up review reports to the regional ethics committee for record-keeping. Participating institutions are responsible for local adverse event reporting and protocol deviation documentation. The regional ethics committee releases comprehensive annual reports to all participating institutions and government regulatory agencies.

In this process, the Regional Ethics Committee serves as the core hub and mutual recognition platform, functioning not only as a communication bridge among participating institutions but also undertaking critical responsibilities such as standardizing review criteria, coordinating dispute resolution, and facilitating mutual recognition implementation. Government regulatory authorities oversee and regulate the collaborative review system through methods like unannounced inspections and quality assessments, ensuring the quality of ethical reviews and the protection of participants' rights.

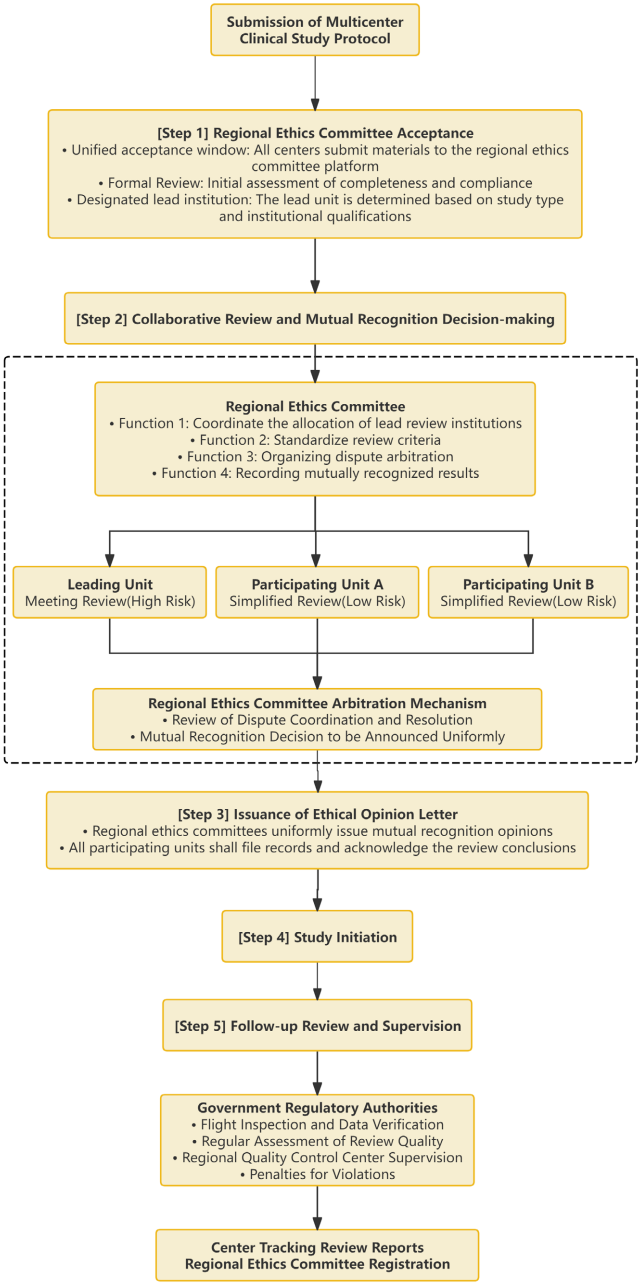

Figure 2. Standardized workflow diagram for collaborative review centered on the regional ethics committee.

4.2. Collaborative Review Responsibility Matrix

The responsibility matrix (Table 3) is designed to clarify how responsibilities are divided among the regional ethics committee, lead institution, participating institutions, sponsors, and regulators at the review, approval, monitoring, and adverse-event stages.

Table 3. Collaborative review responsibility matrix.

	Review Stage	Approval Stage	Monitoring Stage	Adverse-Event Stage
Regional Ethics Committee	Presiding judge, Convening the joint meeting	Release final approval or conditional approval	Coordinate annual continuous reviews; maintain the central registry	Receive reports of serious adverse events; coordinate investigations
Lead Institution	Designate the lead reviewer (if authorized by the regional ethics committee)	Inform the subjects; implement the approved protocol	Report local deviations to the regional ethics committee	Report serious adverse events to the regional ethics committee within 24 hours; provide preliminary causal assessment
Participating Institution	Raise objections within the stipulated time	Obtain administrative approval from local authorities	Monitor local compliance; Report local deviations	Report serious adverse events to the regional ethics committee and the principal investigator; implement corrective measures
Sponsor	Provide a complete protocol and investigator's manual	Ensure all approvals are in place before the study begins	Submit the data security oversight committee report	Funding compensation and subject compensation
Regulator	Conduct unannounced quality audits	Registration and approval in the national database	Review of the regional ethics committee annual report	Investigate systemic failures; implement sanctions

5. Discussion: Tension and Adjustment between Ethics and Government Regulation

While collaborative review has proven highly effective in boosting efficiency, critical challenges persist when viewed through the dual lens of "Ethics and Government".

5.1. The "Gray Zone" of Legal Liability

In the collaborative review model, how should liability be determined when subject harm occurs? Should the primary reviewing institution, participating institutions, or the regional ethics committee itself bear responsibility? Current government regulations have not yet clarified the legal status of regional ethics committees. From the legal perspective, the lack of independent legal status for ethics

committees constitutes a key factor contributing to numerous practical challenges [11] [12]. Granting ethics committees independent legal status has become an urgent priority.

Consider a hypothetical but possible scenario: a participant from a participating institution experiences a serious adverse event due to a protocol deviation that was not disclosed to the regional ethics committee. The participant simultaneously sues both the participating institution and the regional ethics committee. According to the current Chinese tort law, the regional ethics committee, lacking independent legal person status, cannot be listed as a defendant. The liability may entirely fall on the participating institution, even if the review process of the regional ethics committee may have overlooked warning signals. This "gray area" inhibits institutional participation in collaborative reviews and leaves participants facing uncertain avenues for relief.

5.2. The Paradox of Homogenization in Review Criteria

The prerequisite for regional mutual recognition lies in "standard consistency." However, there exist discrepancies in understanding ethical principles among university-affiliated hospitals and even within different departments of the same institution. Forced implementation of a "one-size-fits-all" approach to mutual recognition may overlook the unique vulnerabilities of specific study populations within particular organizations. In order to ensure homogeneity and high efficiency in ethical collaborative review and mutual recognition, government agencies should lead the establishment of ethical review alliances with clearly defined responsibilities and rights [1]. We should give priority to the system according to actual needs, communicate effectively, and jointly promote ethical collaborative review and mutual recognition of results [13]. Balancing the efficiency-oriented logic of government governance with the ethics imperative to protect individual dignity is central to effective system design.

5.3. Insufficient Support from Information Platforms

Effective collaborative review depends on integrated information platforms. Currently, most university-affiliated hospitals use independent ethics review systems, leading to severe data silos. The establishment forms of China's regional ethics committees vary, with no consensus on their functional scope and inconsistent definitions of "regions," primarily established at provincial or municipal administrative levels. The incomplete legal framework for regional ethics committee construction at the national level has constrained their progress [14]. The lack of a government-led, unified regional ethics mutual recognition information platform results in inefficient circulation of review opinions, and the real "paperless" rapid mutual recognition cannot be realized.

5.4. Dual Role Dilemma of University-Affiliated Hospitals

University-affiliated hospitals play a dual role as both "athletes" and "referees" in

regional ethics collaboration reviews. On one hand, they are direct participants in clinical research, serving as the primary entities responsible for subject recruitment and project implementation. On the other hand, their ethics committees must undertake coordination and review functions for regional ethics centers. Such overlapping roles may lead to conflicts of interest—when a university-affiliated hospital acts as the lead reviewing institution for its own research projects, how can fairness toward other participating units be ensured? Through case analysis of the Sichuan Provincial Regional Ethics Committee for Traditional Chinese Medicine, Ma Xitao *et al.* found that while the institutional model demonstrates higher operational efficiency, it requires the establishment of more robust mechanisms to mitigate conflicts of interest [15]. This dilemma highlights the need for further institutional improvements to enhance the independence and impartiality of regional ethics committees.

To ensure the operability of conflict of interest control, the following safeguard measures are recommended: 1) Recusal rule: Any ethics committee member with financial or professional interests in the study under review must abstain from the review and voting processes. 2) External independent members: At least 20% of voting members of the regional ethics committee should come from outside participating institutions (e.g., community representatives, legal experts, or ethicists from non-affiliated universities). 3) Independent appeal channels: Participating institutions or sponsors may appeal the regional ethics committee decision to a government-appointed appellate body. 4) Separation of coordination and review roles: The regional ethics committee Secretariat (responsible for case triage and administrative affairs) should be structurally separated from the review panel. Secretariat staff shall not participate in approval voting to prevent administrative convenience from overriding ethical judgment.

5.5. International Comparison: Single-IRB (Institutional Review Board) and Mutual-Recognition Frameworks

The regional ethical collaboration review model of China is not unique. Internationally, several jurisdictions have adopted similar or alternative mechanisms to address the inefficiency of redundant reviews.

- United States: Evolution of Single IRB Mandatory Order

The single institutional review board (sIRB) policy in the United States mandates that all NIH-funded non-exempt multicenter studies undergo sIRB review. However, practical implementation still faces numerous challenges: some institutions lack the capacity to function as sIRBs and are forced to rely on external central IRBs; compliance costs shift from the review process to inter-institutional agreement management. In 2024, Morain *et al.* published a scoping review systematically analyzing core challenges in sIRB implementation, particularly local context considerations—how sIRBs ensure adequate understanding and respect for regional ethical context differences across geographically diverse studies remains a focal point in academic and policy discussions [16]. Notably, recent de-

bates have begun questioning the assumption that "a single IRB equals efficiency." The 2026 Institute for Progress policy analysis indicates that restricting academic researchers to using only their institution's IRB may undermine sIRB's efficiency advantages; granting researchers the right to select external IRBs could more effectively introduce competition and enhance review quality [17].

- EU: From the CTR Framework to FAST-EU Fast Track

The European Union does not have a mandatory single review mechanism. The Clinical Trial Regulation (CTR) 536/2014, which came into full force on January 31, 2022, established a unified Clinical Trial Application System (CTIS), but ethical review remains the autonomous responsibility of individual Member States. Significant structural differences exist among national ethics committees, with inconsistent review timelines, resulting in multi-track reviews for multinational trials [18]. On November 27, 2025, the EU officially launched the FAST-EU (Facilitating and Accelerating Strategic Trials) fast-track pilot initiative, marking the most substantial progress to date in coordinating multi-country ethical reviews [19]. This initiative aims to reduce the total cycle time for multinational clinical trials from submission to regulatory decision to 70 calendar days, while integrating opinions from ethics committees across all participating Member States into a parallel workflow. A key innovation lies in FAST-EU's explicit requirement to "fully integrate opinions from ethics committees of participating Member States" rather than mutual recognition or coordination [20]. Beyond FAST-EU, the EU has established the MedEthicsEU network to enhance collaboration and procedural coordination among ethics committees across Member States. Additionally, Member States have adopted diverse approaches to ethical review reforms. For instance, Norway established the nationally authorized REK KULMU Ethics Committee, specifically responsible for research ethics evaluation of clinical trial applications [21].

- Comparison and Uniqueness

The model of university-affiliated hospitals in China differs in three key aspects: 1) Institutional anchoring—Regional ethics committee is embedded in academic medical centers both physically and administratively, leveraging their expertise, but this also creates the dual-role dilemma discussed in Section 5.4; 2) Government-driven regionalization—Unlike the U.S. sIRB model (for specific studies) or the EU model (based on member states), China's model is explicitly regional (provincial or municipal), aligning with administrative boundaries; 3) Progressive legalization—China lacks a federal single review mandate and instead conducts trials through regional pilots and soft law (consensus documents), whereas U.S. mandates carry legal binding force. This comparative perspective suggests that China's model may be better suited to local conditions but faces greater risks of legal uncertainty and inconsistent implementation. Notably, the U.S. academic community points out that if academic researchers are restricted to using only their institution's IRB, the efficiency advantages of sIRB may be difficult to achieve; granting researchers the right to choose external IRBs might be more effective [17], a notion that shares interesting similarities with China's model and warrants attention in future comparative studies.

6. Future Outlook and Policy Recommendations

To promote the sustainable development of regional ethical collaboration review in university-affiliated hospitals, the following recommendations are proposed.

6.1. Clarify Legal Positioning (Government Dimension)

It is recommended that legislative bodies or the health administrative authorities enact specific regulations to clarify the legal status and responsibility-sharing mechanisms of regional ethics committees in collaborative reviews. Exploration should be conducted to establish risk-sharing models, such as "review liability insurance" or "government guarantee", to alleviate concerns among ethics review committee members.

6.2. Establish a Tiered Mutual Recognition Mechanism (Ethics Dimension)

Unconditional mutual recognition should not be pursued for all projects. Hierarchical mutual recognition should be implemented based on the risk level of research: low-risk studies (e.g., retrospective medical record analysis) shall adopt a rapid filing system; medium-risk studies shall utilize a collaborative review model; high-risk studies (e.g., gene therapy, first-in-human trials) still require substantive review by individual centers, but evaluation opinions should be shared to minimize redundant efforts.

6.3. Develop a Digital Regulatory Network (Governance Dimension)

Establish a unified and interconnected regional ethics review information platform funded or guided by the government. Achieve full-process digitization from application, review, approval, to follow-up review, and utilize blockchain technology to ensure the immutability and traceability of the review process.

6.4. Strengthen the Exemplary Role of University-Affiliated Hospitals (Institutional Dimension)

By leveraging the professional expertise and educational resources of university-affiliated hospitals, a regional ethics training center should be established with unified training and assessment standards. This initiative will enhance the ethical review capabilities of primary healthcare institutions within the region and improve the professional uniformity of ethics committee members. Concurrently, it is essential to refine the conflict of interest management system for ethics committees in university-affiliated hospitals to ensure their impartiality and independence in fulfilling their roles at the regional ethics center.

7. Conclusion

The collaborative review mechanism of regional ethics centers in university-affiliated hospitals represents a significant innovation in multi-center clinical research ethics governance. It is not only a technical means to enhance research efficiency

but also a profound redefinition of the boundaries between government oversight and ethical autonomy. Current explorations have achieved preliminary results, but finding the optimal balance between "efficiency" and "safety" requires strong government support in legal system provision, administrative supervision coordination, and information infrastructure development. In the future, a regional ethics collaboration network with clear responsibilities, unified standards, and efficient operations will provide solid ethical safeguards for the healthy development of biomedical research in China.

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Conflicts of Interest

The author declares no conflicts of interest regarding the publication of this paper.

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