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OPTIMIZING THE FUNCTIONING OF LOCAL BIOETHICS COMMITTEES IN KAZAKHSTAN: A REVIEW OF INTERNATIONAL PRACTICES AND PROSPECTS FOR DEVELOPMENT. LITERATURE REVIEW.

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Abstract

Introduction. Local Bioethics Committees (LBCs) are an integral part of the system for protecting the rights and safety of participants in biomedical research. Their activities must align with international ethical standards while being adapted to the specific national context. In Kazakhstan, as in many countries with an emerging research infrastructure, the operation of LBCs faces several organizational and procedural challenges.

Objective. This review aims to systematize international experience in the organization and functioning of Local Bioethics Committees and to explore the potential for its application in the context of the Republic of Kazakhstan.

Search strategy. A systematic literature review was conducted using the PICO model. The main question addressed was, does the implementation of international practices (e.g., GCP training, process standardization, digitalization, and KPI monitoring) improve the performance of LBCs in countries with developing research systems, such as Kazakhstan, compared to existing approaches? Searches were performed in PubMed, Scopus, Web of Science, and eLibrary databases for the period 2020–2024. The analysis was guided by Donabedian’s quality assessment model (structure – process – outcome).

Results. The review found that developed countries emphasize the standardization of application submission and review processes, digitalization of interactions, mandatory GCP (Good Clinical Practice) training for LBC members, and implementation of performance monitoring systems (KPIs). These approaches ensure a high level of transparency, timeliness of ethical review, and trust from the research community.

Conclusions. The analysis of international experience demonstrates that practices such as process standardization, digitalization, mandatory GCP training for committee members, and systematic KPI monitoring significantly enhance the transparency, timeliness, and credibility of ethical review. These approaches can be successfully adapted to the Kazakhstani context, considering the national setting and existing research infrastructure. The use of Donabedian’s model enables a systematic evaluation and optimization of LBCs in terms of structure, processes, and expected outcomes. Adopting international practices may become a crucial step toward strengthening bioethical oversight in Kazakhstan and ensuring the proper protection of research participants’ rights.

Keywords: Local Bioethics Committees, bioethics, GCP, Kazakhstan, ethical review, efficiency, international experience.

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Резюме

ОПТИМИЗАЦИЯ ДЕЯТЕЛЬНОСТИ ЛОКАЛЬНЫХ КОМИТЕТОВ ПО БИОЭТИКЕ В КАЗАХСТАНЕ: ОБЗОР МЕЖДУНАРОДНОГО ОПЫТА И ПЕРСПЕКТИВЫ РАЗВИТИЯ. ОБЗОР ЛИТЕРАТУРЫ

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Введение. Локальные комитеты по биоэтике (далее- ЛКБ) являются неотъемлемым элементом системы защиты прав и безопасности участников биомедицинских исследований. Их деятельность должна соответствовать международным этическим стандартам и адаптироваться к контексту конкретной страны. В Казахстане, как и в ряде стран с формирующейся исследовательской инфраструктурой, работа ЛКБ сопровождается рядом организационных и процедурных вызовов.

Цель. Целью настоящего обзора является систематизация международного опыта в области организации и функционирования локальных этических комитетов, а также определение возможностей его применения в условиях Республики Казахстан.

Стратегия поиска. Использован систематический подход к отбору литературы с применением модели PICO. Улучшает ли внедрение международных практик (например, обучение GCP, стандартизация процессов, цифровизация и KPI) работу локальных этических комитетов в странах с развивающейся исследовательской системой, таких как Казахстан, по сравнению с существующими подходами?

Поиск проводился в базах данных PubMed, Scopus, Web of Science и eLibrary за период 2020–2024 гг. Анализ осуществлялся с опорой на модель оценки качества Донабедиана (структура – процесс – результат).

Результаты. Обзор выявил, что в развитых странах с особое внимание уделяется стандартизации процессов подачи и рассмотрения заявок, цифровизации взаимодействия, обязательному обучению членов ЛКБ принципам надлежащей клинической практики (good clinical practice-GCP), а также внедрению системы мониторинга показателей эффективности (KPI). Эти подходы обеспечивают высокую степень прозрачности, своевременность этической экспертизы и доверие со стороны исследователей.

Выводы. Анализ международного опыта показал, что внедрение таких практик, как стандартизация процедур, цифровизация процессов, обязательное обучение членов ЛКБ принципам надлежащей клинической практики (GCP), а также систематический мониторинг показателей эффективности (KPI), способствует значительному повышению прозрачности, своевременности и доверия к этической экспертизе. Эти подходы могут быть успешно адаптированы в условиях Казахстана с учётом национального контекста и существующей исследовательской инфраструктуры. Опора на модель Донабедиана позволяет системно оценить и оптимизировать работу ЛКБ по параметрам структуры, процессов и ожидаемых результатов. Внедрение международных практик может стать важным шагом к повышению качества биоэтического надзора в Казахстане и обеспечению соблюдения прав участников исследований на должном уровне.

Ключевые слова: локальные комитеты по биоэтике, биоэтика, GCP, Казахстан, этическая экспертиза, эффективность, международный опыт

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Түйіндеме

ҚАЗАҚСТАНДАҒЫ ЖЕРГІЛІКТІ БИОЭТИКА КОМИТЕТТЕРДІҢ ҚЫЗМЕТІН ОҒТАЙЛАНДЫРУ: ХАЛЫҚАРАЛЫҚ ТӘЖІРИБЕГЕ ШОЛУ ЖӘНЕ ДАМУ ПЕРСПЕКТИВАЛАРЫ. ӘДЕБИЕТТІК ШОЛУ.

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Кіріспе. Жергілікті биоэтика комитеттер(ЖБК) биомедициналық зерттеулерге қатысушылардың құқықтары мен қауіпсіздігін қорғау жүйесінің ажырамас бөлігі болып табылады. Олардың қызметі халықаралық этикалық стандарттарға сай келуімен қатар, ұлттық ерекшеліктерге бейімделуі тиіс. Қазақстанда, басқа да зерттеу инфрақұрылымы дамып келе жатқан елдер сияқты, ЖБК жұмысы бірқатар ұйымдастырушылық және рәсімдік қиындықтарға тап болуда.

Мақсаты. Бұл шолу жергілікті этикалық комитеттерді ұйымдастыру мен олардың жұмыс істеуіне байланысты халықаралық тәжірибені жүйелеуге және оны Қазақстан Республикасының жағдайында қолдану мүмкіндігін зерделеуге бағытталған.

Іздеу стратегиясы. PICO моделін пайдалана отырып жүйелі әдеби шолу жүргізілді. Негізгі зерттеу сұрағы: халықаралық тәжірибелерді (мысалы, GCP бойынша оқыту, процестерді стандарттау, цифрландыру және тиімділік көрсеткіштерін (KPI) бақылау) енгізу, Қазақстан сияқты дамып келе жатқан зерттеу жүйесі бар елдердегі ЖБК қызметінің қазіргі тәсілдермен салыстырғанда жақсаруына ықпал ете ме?

Іздеу PubMed, Scopus, Web of Science және eLibrary дерекқорларында 2020–2024 жылдар аралығында жүргізілді. Талдау Донабедианның сапаны бағалау моделі (құрылым – үдеріс – нәтиже) негізінде жүргізілді.

Нәтижелер. Дамыған елдерде өтінімдерді беру мен қарау үдерістерін стандарттауға, өзара әрекеттестікті цифрландыруға, ЖБК мүшелеріне арналған GCP оқытуын міндетті етуге және тиімділік көрсеткіштерін (KPI) қадағалау жүйелерін енгізуге баса назар аударылады. Бұл тәсілдер этикалық сараптаманың ашықтығын, жеделдігін және ғылыми қауымдастық тарапынан сенімділікті қамтамасыз етеді.

Қорытындылар. Халықаралық тәжірибені талдау үдерістерді стандарттау, цифрландыру, комитет мүшелеріне GCP бойынша міндетті оқыту және KPI жүйелі түрде бақылау сияқты тәжірибелердің этикалық сараптаманың ашықтығын, жеделдігін және сенімділігін айтарлықтай арттыратынын көрсетеді. Бұл тәсілдерді Қазақстан жағдайына бейімдеу, ұлттық ерекшеліктер мен қазіргі зерттеу инфрақұрылымын ескере отырып, сәтті іске асыруға болады. Донабедиан моделі құрылым, үдерістер және күтілетін нәтижелер тұрғысынан ЖБК-ті жүйелі түрде бағалауға және оңтайландыруға мүмкіндік береді. Халықаралық тәжірибені енгізу Қазақстандағы биоэтикалық бақылауды күшейту және зерттеу қатысушыларының құқықтарын тиісті деңгейде қорғау жолындағы маңызды қадам болмақ.

Түйінді сөздер: жергілікті биоэтика комитеттер, биоэтика, GCP, Қазақстан, этикалық сараптама, тиімділік, халықаралық тәжірибе.

Дәйексөз үшін:

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Introduction

Local Bioethics Committees (LBCs) serve as a key mechanism for protecting the rights, freedoms, and interests of participants in clinical and biomedical research. Their primary function is to ensure the ethical legitimacy of scientific projects based on the principles of respect for persons, justice, beneficence, and non-maleficence. LBC activities are regulated by international guidelines (GCP, CIOMS, the Declaration of Helsinki) as well as national regulations. In the Republic of Kazakhstan, LBCs operate in accordance with orders from the Ministry of Health and are overseen by the Central Bioethics Commission.

According to several studies, countries with developing research infrastructure (including Kazakhstan) face significant challenges: delays in application review, a formalistic approach to protocol assessment, the absence of unified digital systems for application submission and monitoring, and a shortage of qualified committee members [10].

In international practice, researchers frequently encounter difficulties in preparing documentation for ethical review. One of the main challenges is the lack of standardized templates and clear requirements, leading to inconsistent practices across institutions. This not only increases the administrative burden but can also undermine the quality of the research itself. For example, in Australia and China, researchers report difficulties adapting to varying ethics committee requirements, which delays approvals and may affect project timelines [9].

Moreover, the issue of conflicts of interest is a major factor affecting the objectivity of ethics committee decisions, especially in smaller research institutions. In such organizations, researchers and LBC members may have informal relationships that hinder independent decision-making. International recommendations emphasize the need for strict conflict of interest management, including mandatory disclosure and the development of mitigation strategies. For example, Canada and the United Kingdom have well-established procedures for identifying and

managing such conflicts, thereby increasing trust in the ethics review system [16].

Given these international practices, Kazakhstan should prioritize the development and implementation of standard operating procedures for LBCs, as well as create mechanisms to manage conflicts of interest. This would enhance the transparency and effectiveness of ethical review in the country and help align national standards with international requirements.

Objective of the review: To systematize the best international approaches to the organization and functioning of LBCs and to determine the feasibility of their adaptation to the context of Kazakhstan.

Methodology

A systematic approach to literature selection was employed for this review, based on the principles of evidence-based analysis and the PICO model (Population, Intervention, Comparison, Outcome). The search strategy was designed to capture a comprehensive range of relevant information on the functioning of Local Bioethics Committees (LBCs) in different countries and to generalize their experience in terms of applicability to the Kazakhstani context.

The literature search was conducted in the databases PubMed, Scopus, Web of Science, and eLibrary (to include domestic and Russian-language sources).

The search was limited to publications from January 1, 2020, to March 2024 and included both English and Russian languages. PICO question “Does the implementation of international practices (e.g., GCP training, process standardization, digitalization, and KPI monitoring) improve the performance of LBCs in countries with developing research systems, such as Kazakhstan, compared to existing approaches?”

Inclusion criteria:

- Publications in peer-reviewed scientific journals;
- Articles analyzing the work of ethics committees;
- Studies focused on the structure, processes, or outcomes of LBC activities;

• Regulatory and methodological documents with practical applicability.

To structure the analysis, the **Donabedian quality model**, originally proposed in 1966 and adapted for healthcare and research infrastructure evaluation, was used. The model includes three levels (Fig. 1):

• **Structure** (staff composition, regulatory documents, infrastructure);

• **Process** (procedures, workflows, digital platforms, interaction with applicants);

• **Outcome** (review timelines, rejection rates, stakeholder satisfaction).

This methodology enabled a systematic evaluation of LBC activities and the identification of the most successful and replicable practices.

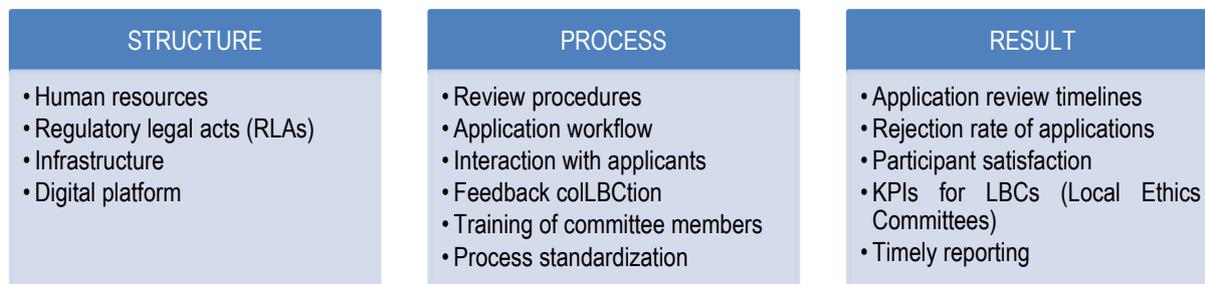


Fig. 1. Quality model for optimizing the work of LBCs (Local Bioethics Committees).

Structure of Local Bioethics Committees (LBCs)

The structure of Local Bioethics Committees determines their ability to effectively and impartially evaluate research protocols. In international practice, the commonly accepted model includes representatives from various professional fields: healthcare professionals, lawyers, community representatives, biostatisticians, and bioethics specialists. Such multidisciplinary composition is recognized as essential for forming objective and balanced decisions [3].

In the United States, Institutional Review Boards (IRBs) are required to have at least five members, including at least one scientist, one practitioner, and one community representative. Additionally, significant attention is given to preventing conflicts of interest: IRB members must not participate in the review of projects with which they may have direct or indirect connections [8].

In Kazakhstan, the structure of LBCs varies across institutions. In most cases, committees are established at universities or research centers and typically consist of faculty members and/or researchers from the same institution. The lack of clear requirements regarding independence, qualifications, number of members, and internal evaluation mechanisms makes the operation of some LBCs unstable and susceptible to bias risks.

Process of Work of Local Bioethics Committees

The work of Local Bioethics Committees (LBCs) is based on the principles of independence, objectivity, and adherence to international norms for the protection of research participants' rights. The main functions of LBCs include evaluating research protocols for scientific validity and compliance with ethical standards and ensuring participant safety.

In international practice (e.g., in the United Kingdom, Canada, and South Korea), the structure of LBC work is standardized and regulated by relevant guidelines. According to the UK Health Research Authority (HRA) guidance, each protocol undergoes at least three stages: administrative validation, ethical review, and issuance of an expert opinion with recommendations [15].

The process of submitting, reviewing, and approving research protocols is a central element of LBC functioning. It determines how promptly and thoroughly ethical review is

conducted and the extent to which participant interests are protected.

Standardized algorithms describing the stages of submission, processing, discussion, and decision-making have been developed and applied internationally. These approaches significantly reduce administrative burdens, increase transparency, and shorten application review times.

Application Submission Algorithms and Digitalization

Digitalization of application submission for ethical review is one of the most effective tools to enhance transparency and accelerate processes. In developed countries such as Canada and Germany, eLBCtronic systems allow not only the structuring of the entire document package but also reduce the administrative burden on both committees and applicants.

For example, Canada uses the CTO Stream system, where each application is tracked online, automatically checked for completeness, and the applicant receives notifications at every stage [2]. In Germany, universities and clinics have implemented the EthikPool system, through which researchers submit applications eLBCtronically. The system also includes form templates and built-in reference materials (FU Berlin, 2024) [7].

In Kazakhstan, most Local Bioethics Committees still operate offline or rely on postal and email correspondence. This creates difficulties for researchers and slows down the review process. Some universities are attempting to implement online forms (e.g., via internal portals), but such systems are not centralized and often have limited functionality.

The introduction of a unified eLBCtronic platform with the capability to track application status, automatic field validation, and integration with the Ministry of Health databases (e.g., clinical trials registry) could significantly improve the efficiency and transparency of ethical review in Kazakhstan.

Standardization of Review Timelines

Globally, setting clear standards for review timelines is a mandatory element of effective LBC operation. This allows researchers to plan project initiation and committees to enhance operational transparency.

In the European Union, Regulation EU 536/2014 requires that decisions on clinical trials be made within 60 calendar days from the submission of a complete application package (European Medicines Agency, 2022) [4].

Similar timelines are established in Canada: according to CTO Stream regulations, 85% of applications receive decisions within 30–45 days (Clinical Trials Ontario, 2021) [9].

In Kazakhstan, regulatory acts contain approximate timelines, but their adherence largely depends on the workload of LBCs and the qualifications of the applicant. In practice, review periods may reach up to 30 days.

The Role of GCP Training for Researchers and LBC Members

Completion of training on Good Clinical Practice (GCP) standards is a mandatory requirement in many countries for all participants in the research process.

In the United States, for example, the National Institutes of Health (NIH) requires a verified GCP certificate for researchers involved in all federally funded clinical trials [12].

The role of GCP training goes beyond basic knowledge: modern programs include modules on informed consent, protection of vulnerable populations, participant safety monitoring, and risk analysis.

In Kazakhstan, holding a GCP certificate is a formal requirement for researchers; however, systematic training for members of Local Bioethics Committees (LBCs) is often insufficient. The lack of mandatory continuing education programs for committee members leads to inconsistent interpretations of ethical standards, which in turn increases the number of protocol submissions returned for revision.

To optimize LBC operations, it is advisable to consider implementing mandatory GCP training programs for all new LBC members, followed by regular recertification at least every three years, as practiced in the United Kingdom [15].

Feedback System and Interaction with Applicants

An effective feedback system between LBCs and applicants not only improves the quality of research protocols but also strengthens trust in the ethical review process itself.

For instance, in Canada (Clinical Trials Ontario), after protocol review, applicants receive not only a list of comments but also recommendations for corrections, with mandatory references to specific regulatory documents or ethical principles [2]. In the UK, under the Health Research Authority (HRA), standards require LBCs to provide detailed written feedback on each rejected point within 10 working days following the meeting [15].

Effectiveness of Local Bioethics Committees (The "Outcome" Component)

The "outcome" component in Donabedian's model reflects the effectiveness and final results of LBCs in protecting research participants. This aspect includes both qualitative and quantitative performance indicators such as the soundness and timeliness of decisions, the proportion of approved, rejected, or revised protocols, researcher satisfaction with the review process, and the presence of quality improvement mechanisms (KPIs, reporting, accreditation, etc.).

Despite the recognized importance of evaluating ethical review effectiveness, this area has historically been underexplored. As early as the 2010s, Abbott and Grady (2011) noted a lack of publications directly assessing IRB/LBC

performance [1]. Empirical studies highlighted inconsistencies and inefficiencies across committees, prompting calls for regular monitoring and standardization of practices.

Metrics of LBC Performance

Quantitative indicators are widely used to measure LBC outcomes. A key metric is the distribution of decisions on applications: percentages of approvals, rejections, or requests for revision. Data show that the vast majority of submissions are eventually approved, with outright rejections being relatively rare. This may indicate both high initial application quality and a committee practice of collaborating with researchers to improve protocols rather than outright forbidding studies.

For example, a 10-year analysis (2008–2017) of the Ethics Committee in Qassim, Saudi Arabia, showed that out of 389 reviewed protocols, 85.4% were approved, 11.4% returned for revision, and only 1.1% rejected outright [14].

Review Timeliness

Another important outcome indicator is the timeliness of ethical review. Excessive delays hinder research progress, so many jurisdictions set target review periods.

In the multinational APHINITY trial, median time from submission to ethics approval was approximately 56–67 days in European countries and about 73 days in North America. In Asian countries, times varied more widely, with some cases exceeding 400 days [6].

Researcher Satisfaction with Ethical Review

Researcher trust and satisfaction are critical qualitative outcomes of LBC performance. International surveys indicate high satisfaction levels when committees adhere to transparency and efficiency principles.

A recent study in Kuwait found that 98% of respondents regarded the existence of an ethics committee as essential for research, and 92.7% expressed satisfaction with the comments and evaluations received from LBCs. Most respondents (89%) considered the committee feedback constructive and aligned with ethical principles [13].

KPIs and Reporting in Ethics Committees

Key Performance Indicators (KPIs) and regular reporting are widely used to manage LBC quality. Common KPIs include

- Average review time
- Percentage of applications returned for revision
- Percentage of protocols rejected outright
- Percentage of applications reviewed within target timelines

A study by Liu *et al.* (2022) in China demonstrated that systematic performance assessment of IRBs (equivalent to LBCs) helps identify weaknesses and improve researcher satisfaction. Surveying over 750 respondents, the study revealed significant gaps between ideal and actual IRB characteristics in fairness, timeliness, transparency, and applicant interaction, underscoring the need for regular self-assessment and KPI use as internal audit tools [11].

Benefits of KPI Implementation

KPI monitoring contributes to:

- Improved application review processes through tracking average review times, revision rates, and comment types
- Increased transparency and researcher trust by publishing feedback and satisfaction data

- Enhanced committee member qualifications by monitoring regular GCP training and participation in workshops
- Cultivating a culture of continuous improvement based on data rather than subjective judgment

Experience from China shows that committees implementing internal audits and KPI tracking receive significantly higher researcher satisfaction ratings. Although Liu et al. do not provide exact numerical improvements (e.g., +18% satisfaction), they clearly demonstrate a strong correlation between quality management and perception of IRBs as reliable, professional, and applicant-focused bodies [11].

Problems in Monitoring Effectiveness in Kazakhstan

In the Republic of Kazakhstan, the development of a system for assessing the effectiveness of Local Bioethics Committees (LBCs) is at an early stage, and several obstacles currently hinder comprehensive performance monitoring. A recent study on the functioning of 16 LBCs in Kazakhstan showed that, on average, committees operate satisfactorily (an average cumulative score of approximately 71.9% of the ideal level); however, there are significant discrepancies and shortcomings. For instance, 38.5% of LBCs were not registered in the national registry maintained by the Ministry of Health of the Republic of Kazakhstan, indicating gaps in external oversight. Weaknesses were identified in the thoroughness of protocol reviews and the resource availability of committees: the average score for completeness in reviewing key ethical aspects was only 33.7% of the maximum, and for resource provision (funding, premises, staff) - 56.2%. Only 62.5% of Kazakhstani LBCs implemented quality improvement (QA/QI) programs, i.e., conducted regular performance evaluations. Moreover, only 25% of the committees had their own budgets and dedicated staff responsible for ethical review, while the remainder operated without specialized resources. These issues result in fragmented and inconsistent performance monitoring. The lack of standardized reporting and incomplete compliance with several international standards hinder comparability among LBCs within the country. Overall, this analysis highlights the need for strengthened national oversight and methodological support. Measures are required to standardize the quality of ethical review across all research institutions in Kazakhstan. [5]

Comparison with International Practices and Ways Forward

In leading research institutions worldwide, LBCs operate based on principles of standardization, transparency, and continuous quality improvement, which directly impact the effectiveness of their activities. In Kazakhstan, the establishment of the Central Commission on Bioethics under the Ministry of Health, which achieved FERCAP/SIDCER international accreditation in 2017, was an important milestone, confirming the country's commitment to global ethical review standards. The next step should be the extension of these practices to the local committee level. Experts recommend implementing a national LBC accreditation system with regular external audits, requiring all active committees to register and comply with unified standard operating procedures. Targeted measures have also been proposed to enhance effectiveness: increasing funding and resources, expanding training programs for LBC members, and facilitating international knowledge exchange. Implementing these steps would improve LBC performance in Kazakhstan. Anticipated benefits include

reduced protocol review times without compromising ethical rigor, more consistent and well-substantiated committee decisions, and increased trust from researchers. Ultimately, strengthening LBC effectiveness will enhance participant rights protection in clinical research and bring national ethics practices in line with international standards. [5]

Conclusion

This review confirms the critical role of Local Bioethics Committees (LBCs) as key institutions for protecting the rights and safety of participants in biomedical research. International experience demonstrates the maturity of ethical review systems in countries with developed research infrastructures. Key features of these systems include well-regulated committee structures, standardized application review procedures, mandatory training programs for LBC members, digital platforms for protocol submission and tracking, and performance monitoring mechanisms such as key performance indicators (KPIs).

At the same time, the analysis of the current state of LBCs in the Republic of Kazakhstan revealed several systemic limitations. These include the lack of unified operational standards, weak process digitalization, insufficient resources, irregular training of LBC members, and limited mechanisms for internal audits and performance assessment. Despite the existence of a regulatory framework and a central coordinating body - the Bioethics Commission under the Ministry of Health - the practical implementation of proper ethical review principles remains fragmented and inconsistent across institutions.

To enhance the effectiveness and credibility of the ethical review system in Kazakhstan, it is advisable to implement comprehensive reforms, including the development of national standard operating procedures, mandatory accreditation and registration of LBCs, a centralized digital application platform, regular GCP training programs, and KPI-based performance reporting systems. Adapting international best practices to the local context will ensure a consistent level of ethical review quality, strengthen Kazakhstan's reputation in the global research community, and reliably safeguard the rights of clinical research participants.

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