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Policy Brief

Developing Biobank Infrastructure in Kazakhstan: Challenges and Policy Directions

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Abstract/Key messages

The development of biobanks in Kazakhstan remains at an early stage, and is characterized by a limited number of operating organizations, an underdeveloped regulatory framework, weak integration with international standards, and low awareness among professionals and the general public. Existing biobanks do not provide sufficient coverage and diversity of biomaterials, thereby limiting opportunities for conducting novel biomedical research and participating in international collaborative projects.

Barriers to the development of biobanks in Kazakhstan:

- A limited number of biobanks and the absence of a centralized national registry.
- Insufficient detail and relevance of the regulatory framework.
- Insufficient funding and low investment attractiveness.
- A lack of educational programs and qualified personnel.
- Low public awareness and participation.
- A lack of accreditation and certification mechanisms.

Policy options:

Option 1. Improving infrastructure and stimulating public and private investment.
Option 2. Developing human resources through professional training.
Option 3. Promoting a culture of donation and increasing public awareness.
Option 4. Improving the regulatory framework for biobank activities.
Option 5. Developing and implementing a national digital platform for biobank management.

Policy Implementation Framework:

The effective implementation of the proposed policy options requires intersectoral coordination, sustained government support, the mobilization of private and international investment, and active engagement of both the professional community and civil society. The integration of digital solutions, harmonization of the regulatory framework, expansion of educational initiatives, and strengthening of international collaboration will support the development of a sustainable and competitive biobanking system capable of advancing national and international research and contributing to the progress of science and healthcare in Kazakhstan.

Keywords: Biobanking, Biobank, Kazakhstan, Regulatory framework, Donor culture, Public awareness, Funding, Human resources, International collaboration, Biomedical research.

1. Introduction

Over the past two decades, biobanking has emerged as one of the key areas of development in the biomedical and healthcare research worldwide. The development of biobanks has been identified as a strategic priority in the European Union (EU), and support for the establishment and operation of biobanks has become an important component of the EU's Seventh Framework Programme (FP7) and, subsequently, in the Horizon 2020 programme [1, 2].

A biobank is a specialized repository of biological materials for scientific and medical purposes [3]. By collecting, processing, and storing diverse biological materials, biobanks provide the essential infrastructure for biomedical research [4].

Centralized storage and standardization of biomaterials enable the formation of large, well-characterized research cohorts, advance personalized medicine, and promote the integration of national research systems into the global scientific ecosystem [5,6].

Kazakhstan remains at an early stage of biobank development. Despite several successful initiatives, the national biobanking system faces challenges, including a limited number of active biobanks, an insufficient legal framework, a shortage of qualified personnel, a lack of integration with international standards, and low awareness among specialists and the general public. These factors significantly limit opportunities to conduct advanced biomedical research and to participate in international scientific projects.

The global expansion of biomedical technologies and the growing demand for high-quality biomaterials highlight the need to strengthen the organization and development of biobanks in Kazakhstan as a key priority.

2. Barriers to the development of biobanks in Kazakhstan

2.1 Limited number of biobanks

Biobanks provide the systematic storage, processing, and controlled access to biological materials required for research in medicine, genetics, and related fields. Consequently, without the strategic development of biobanks, it is difficult to strengthen research infrastructure and enhance scientific capacity in biomedical research.

Global trends show that the biobank network is growing dynamically, with new organizations covering a wide range of scientific fields appearing every year. Europe is a leader in the global market, controlling approximately 36% of global biobanking as of 2024, with a projected compound annual growth rate (CAGR) of 5.6% [7]. According to O'Donoghue et al. (2021), the Biomolecular Resources Research Infrastructure (BBMRI) registered more than 650 biobanks in the EU in 2021, with approximately 95% of them concentrated in the ten countries with the highest GDP per capita, including Norway, Sweden, the Netherlands, the United Kingdom, Austria, Finland, Germany, Belgium, France, and Italy [8]. The authors further report that Canada has 7 biobanks per million inhabitants (up to 350 in total), while the United Kingdom has 4 biobanks per million inhabitants (up to 250 biobanks in total).

In recent years, biobank digitalization has advanced rapidly, serving as a tool for analyzing and identifying correlations between biomaterials and clinical parameters [9]. Examples include highly specialized biobanks, such as the UK Post-Cancer Sample Collection Database, APPRISE Virtual Biobank, and multidisciplinary data integration, such as DxConnect Virtual Biobank and BioIVT, etc.

There are two main biobanks operating in Kazakhstan. In 2017, a biobank of central nervous system tumours was established at the National Centre of Neurosurgery to support conducting research aimed at developing neuroscience and improving the quality and length of life of neurosurgical patients in Kazakhstan [10]. Additionally, since 2023, a biobank focused on socially significant and non-communicable diseases of the population of Kazakhstan has been operating at the Asfendiyarov Kazakh National Medical University [11].

However, the existing biobanks in the country do not yet provide sufficient population coverage and the necessary diversity of biomaterials, which limits opportunities for conducting comprehensive research. According to a foresight study conducted by the National Academy of Sciences of the Republic of Kazakhstan (2023), the establishment of a national biobank was identified as one of the priority areas for grant and program-targeted funding to strengthen research capacity and enhance the international competitiveness of biomedical science in Kazakhstan. [12].

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2.2 Lack of a unified national biobank registry

One of the major challenges in the development of biobanks in the country is the absence of a centralized national registry that documents existing biobanks, their profiles, and available biomaterials. The lack of such a system leads to difficulties in coordination, resource sharing, and the effective use of collected biomaterials. This significantly limits the capacity to conduct large-scale translational research and restricts participation in national and international projects that require large, well-annotated cohorts of biological samples.

The consolidation of biobanks is a global trend that has been observed over the past decade, and the growing need for it has become particularly relevant in the context of large-scale scientific research. A unified network of biobanks under standardized procedures for obtaining informed consent, sample collection, processing, storage, and annotating samples can significantly improve the efficiency of cohort development. This approach contributes to the generation of statistically significant results, ensuring high data quality and comparability, as well as facilitating the exchange of resources among researchers and research institutions. As a result, the consolidation of biobanks is becoming a key factor in the successful implementation of modern biomedical research projects [13].

Regional and national biobank networks have already been established in more than 20 countries. An example of a regional network is the pan-European EuroBioBank (EBB) database, created by the European consortium BBMRI-ERIC, which allows users to search for the necessary biomaterials in European biobanks (25 organizations from 9 EU countries), contributing to the development of the scientific potential of the industry [14, 15]. Biobanks can also be consolidated within a single country or even around a specific scientific mission. For example, in Spain, there is the CNIO – Spanish Biobank Network, which operates as a service platform providing biomedical researchers with access to the biological materials required for their studies, bringing together more than 10 organizations [16].

To overcome the fragmentation of university and clinical biobanks in South Korea, a unified digital platform called the National Biobank of Korea Data Portal was established. The platform integrates the country's national biobank and 17 regional biobanks and enables access to biomaterials from 2008 to 2019 [17]. Similarly, in Finland, biobanks are integrated through the FINBB (Fingenious®) digital platform, which provides unified access to samples and data from Finnish biobanks [18].

Despite the fact that there are only two biobanks operating in Kazakhstan, there is a low level of awareness among healthcare professionals about their existence, capabilities, and potential. These biobanks, created to support specific research projects, are developing in a decentralized manner. The creation of a unified network of biobanks will allow for the centralized management of biological samples, standardize the processes of their collection, storage, and use, and ensure broader and more equitable access to biomaterials for modern research. This is expected to support the development of biomedical research, facilitate the adoption of innovative technologies, and improve the international integration of biomedical science in Kazakhstan.

2.3 Insufficient specificity of standards and procedures

Despite the existence of regulatory norms, the current legal framework does not fully reflect best practices in biobank management and does not cover all stages of working with biological materials. This leads to differences in approaches between organizations, affects the quality of sample storage and use, and limits the integration of Kazakhstan biobanks into international projects.

The ISO 20387 standard (ST RK ISO 20387-2019) applicable in Kazakhstan covers a wide range of biobanks and establishes general requirements for biological material obtained from both multicellular organisms and microorganisms [19]. Despite their common features, these groups of biological material have specific characteristics and requirements for storage and handling.

In addition to ISO 20387, additional standards have been developed and implemented in global practice to regulate the activities of biobanks specializing in materials of animal (ISO/TS 20388:2021) and plant origin (ISO/TS 23105:2021) [20, 21]. Nevertheless, there is no similar comprehensive standard for biobanks working with human materials. Several new standards have been introduced since 2022 that reflect the specifics of working with different types of cells, in particular: ISO 24651:2022 (requirements for human mesenchymal stromal cells derived from bone marrow), ISO 24603:2022 (requirements for mouse pluripotent stem cells), ISO/TS 22859:2022 (requirements for human mesenchymal stromal cells derived from umbilical cord tissue), ISO 18162:2024 (requirements for human neural stem cells derived from human pluripotent stem cells) and others [22,23,24].

Administrative regulation of the processes of establishing and operating biobanks in Kazakhstan is carried out in accordance with Order No. KR DSM-328/2020 requires further refinement [3]. In particular, there is insufficient detail in the procedures for validating and verifying methods, including preparation, preservation, and testing, which makes it

difficult to assess the quality of the obtained results. In addition, there is a lack of metrological traceability of measurements, which negatively affects the reproducibility and reliability of data.

The competencies of biobank personnel are defined narrowly within the current regulatory framework and are primarily limited to possessing relevant education and a Good Clinical Practice (GCP) certificate, which might be insufficient. Analysis of current practices highlights the importance of systematic assessment of personnel technical competence, implementation of a structured skills matrix, and regular training with evaluation of effectiveness (e.g., through testing and certification) in relation to specific biobanking functions.

In Kazakhstan, the conditions for storing biological material (temperature, humidity, lighting) are regulated only in general terms, with an emphasis on preserving 'biological properties.' At the same time, international standards define the key objective as ensuring the suitability of the material for its intended use, which implies not only preservation but also guaranteed quality of the material, allowing reproducible and reliable results to be obtained in specific types of research (e.g., RNA analysis or sequencing).

The harmonisation of internationally agreed guidelines and the adaptation of developed standards help to improve the efficiency of biobanks, as it overcomes these differences and create a common understanding of quality and reliability in the scientific community [25].

2.4 Limited funding for biobanks

The creation and operation of biobanks require significant financial investment, both at the establishment stage and to ensure smooth operation. A lack of financial resources limits the ability to purchase modern equipment, introduce new technologies, and maintain the infrastructure of biobanks at the required level.

Financial support is currently one of the most important factors in ensuring the long-term viability of biobanks. According to the report from the Australian biobank, the median annual total cost of all biobank expenses ranges from 146,000 to 941,000 Australian dollars (excluding cost recovery through paid services), of which 5-49% of expenses are for staff and infrastructure [26]. Forty-five biobanks in France and the Netherlands participated in the survey, and the result showed that an average of US$440,000 (ranging from US$220,000 to US$880,000) is required to cover the operating costs of biobanks; however, excluding research-related costs [27, 28].

Nowadays, the main sources of funding ensuring the stable operation of biobanks are government subsidies (about 1/3 of all revenues), funds from organizations engaged in scientific research (1/3), and grant support, which accounts for approximately 1/4 of the total funding [27, 29]. Many biobanks report a lack of financial resources, which limits the expansion of infrastructure and improvements in biobank operations.

Both biobanks in Kazakhstan, operating based on the National Centre for Neurosurgery and the S.D. Asfendiyarov Kazakh National Medical University was created as part of the implementation of programme-targeted financing projects, and their current maintenance is provided by the own funds of these organizations. Since at this level of development it is difficult to generate income from biobank service and the financial resources of organizations involved in medical science are limited, state support is particularly important, and possibly crucial, for ensuring the sustainable functioning and further development of biobanks.

Expanding the financial capacity of Kazakhstan's biobanks is currently an important requirement, as it will help strengthen their potential, broaden the range of services they offer, and integrate them into the international network of biobanks.

2.5 Lack of qualified personnel and educational programs

In accordance with the requirements of ST RK ISO 20387-2019, a biobank must have personnel with the appropriate competence, education, and skills necessary to carry out its activities. The limited number of specialists with the required qualifications, as well as the lack of relevant educational programs, constrain the development of a biobanking system in the country.

According to Seidler D. et al. (2023) and Samir A.A. et al. (2021), the curricula of medical universities do not adequately address the importance of biobanking, resulting in a low level of awareness among medical students in many countries [30, 31, 32]. Nevertheless, in recent years, countries with a developed biobanking system have introduced specialist training across all levels of education, which has helped raise awareness and develop basic skills in working with biobanks among future medical professionals and researchers.

In a study by Walkowiak D. et al. (2022) among medical students in Kazakhstan, found that only 31.3% of students were informed about the functioning of biobanks and their role in achieving research goals [33]. These findings indicate a substantial knowledge gap in this area and highlight the need to integrate relevant topics into the curricula of medical education programs.

2.6 Low public awareness and participation

As reported by Kamenskikh E.M. et al. (2023), public attitudes towards biobanking are shaped by a range of factors, including cultural traditions, religious

beliefs, ethical norms, national legislation, and the level of public trust in medical professionals and the healthcare system as a whole [4]. Despite the active development of biobanking and the growth in the number of biobanks, as well as the increase in public involvement in the donation of biomaterials for scientific purposes, the level of awareness of biobanking in different countries remains relatively low and varies significantly, ranging from 20 to 80%. For example, according to Bahareva Yu.O. et al. (2024), only about one-third of EU residents are aware of the existence of biobanks and their activities, with the highest levels of awareness observed in Sweden, Finland, and Iceland [34]. At the same time, the level of awareness in Germany has remained low (up to 30%) over the past five years, and in China, it is only 20.7% among urban residents with higher education. In Morocco, the situation is even more pronounced, with 97% of patients having never heard of biobanks. Latvia has shown a negative trend: while public awareness of biobanks decreased from 27.6% in 2010 to 15.9% in 2019 [35].

In Kazakhstan, despite the absence of large-scale studies assessing public awareness of biobanking, the situation is likely comparable to that observed in other countries, where knowledge of biobanking remains limited. The lack of structured educational and informational initiatives may reduce public trust and willingness to participate in donor programs, thereby constraining the collection and diversity of biomaterials.

2.7 Regulatory and Accreditation Framework for Biobanks

The sustainability of biobanks and biobank networks is influenced by multiple factors, among which the level of trust in biobank operations is critical, as it reflects the quality of procedures for the collection and storage of biological samples. In international practice, accreditation and certification programs are widely used as effective instruments to enhance trust by verifying compliance with established standards (e.g., in Australia, Italy, and other countries). The International Laboratory Accreditation Cooperation (ILAC) has recognized ISO 20387:2018 as an appropriate standard for the accreditation of biobanks (ILAC Resolution GA 22.19) [36,37]. Accreditation programs are currently being implemented in several countries across Europe, Southeast Asia, as well as in the United States and China, and their geographic coverage continues to expand. According to Georges Dagher (2022), more than 20 biobanks have already obtained such accreditation [38].

In Kazakhstan, given the current limitations in biobank infrastructure, the implementation of full accreditation or certification systems may be premature. However, for future integration into international biobank networks and the development of a research-supportive ecosystem, the gradual adoption and implementation of relevant standards and procedures will be required.

3. Policy options

3.1 Option 1. Infrastructure modernization and investment stimulation in the biobanking system

A comprehensive assessment of public expenditure requirements for biobank development, including identification of additional costs associated with infrastructure modernization, implementation of digital platforms, and training of qualified personnel, is a necessary condition for establishing a sustainable and competitive biobanking system and ensuring the long-term viability of biobanks in Kazakhstan.

An important strategic step is the development of effective mechanisms to stimulate private investment and attract international grant funding, including participation in joint scientific projects and research initiatives. This approach would diversify funding sources and facilitate the integration of Kazakhstan's biobanks into global research networks, thereby expanding opportunities for transnational exchange of knowledge, technologies, and biomaterials.

3.2 Option 2. Development of workforce capacity in the biobanking sector

Particular attention should be given to strengthening workforce capacity through the development of specialized educational programs in biobanking and bioethics, the organization of academic exchanges and international training placements, and the implementation of continuous professional development systems for biobank personnel. This approach would support the formation of a highly qualified workforce capable of effectively applying modern standards and innovative technologies in biobanking, thereby advancing Kazakhstan's scientific and technological capacity in the international context.

3.3 Option 3. Promotion of donor culture and public awareness

The development of a robust donor culture and the systematic improvement of public awareness of biobanking represent strategic priorities for ensuring the sustainable development of biobanks and strengthening public trust in biomedical research.

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The comprehensive implementation of educational and informational initiatives aimed at promoting biomaterial donation can contribute to expanding the donor base and fostering informed public engagement with issues related to biosafety, ethics, and personalized medicine.

The implementation of targeted information campaigns, integration of biobanking-related topics into educational programs at different levels, and active collaboration with professional and public organizations can enhance knowledge and motivation among potential donors. Strengthening communication with the public, leveraging modern information technologies and social platforms to disseminate reliable information, and engaging civil society and professional communities may support the development of positive attitudes toward biomaterial donation and further expand the donor base.

3.4 Option 4. Strengthening the Regulatory Framework for Biobank Activities

To ensure the effective functioning of biobanks and their integration into the international scientific environment, further development of the national legal and regulatory framework governing all aspects of biobank operations is required. Priority should be given to refining provisions that define the core principles of biobank organization and operation, as well as the rights and responsibilities of all stakeholders, including donors, researchers, and biobank operators.

It is also necessary to establish mechanisms for interagency coordination and collaboration among governmental bodies, medical research institutions, and healthcare organizations to support effective governance of the biobanking system.

Strengthening the regulatory framework will provide a foundation for the sustainable development of biobanks in Kazakhstan, ensure the protection of the rights of all stakeholders, and support the formation of a modern, competitive, and ethically grounded biobanking system.

3.5 Option 5. Development and implementation of a digital platform for biobank management

The implementation of a unified digital platform for biobank management represents a strategic direction for improving the efficiency and transparency of biobank operations in Kazakhstan. Such a platform would enable comprehensive monitoring and analysis of biobank activities, facilitate centralized documentation management, and support the standardization of procedures for sample registration and the assignment of unique identifiers to biological specimens. An important advantage would be the integrated management of information on donor-informed consent and the intended use of biomaterials, thereby supporting compliance with ethical and legal requirements throughout the lifecycle of human biological samples.

A digital platform would also facilitate data exchange between research centers, improve the quality of biomaterial annotation, and simplify access for the scientific community, thereby supporting the formation of large, well-characterized cohorts for advanced biomedical research. Furthermore, alignment with international standards and integration with global biobank networks could enhance scientific collaboration, expand opportunities for participation in international research initiatives, and strengthen the development of biomedical research capacity in Kazakhstan.

3.6 Implementation challenges and opportunities

The main barriers to the implementation of the proposed policy options may include insufficient funding, limited human resources, low levels of awareness, weaknesses in the regulatory and legal framework, and insufficient workforce capacity.

The proposed policy options may contribute to improving research quality, strengthening integration into international research networks, increasing public trust, developing workforce capacity, modernizing infrastructure, and expanding the range of biobank services.

4. Conclusion

The development of biobanks in Kazakhstan provides a foundation for advancing science and healthcare by ensuring the availability of high-quality, standardized biological materials required for biomedical research.

Addressing existing challenges related to the decentralization of biobanks, insufficient funding, the need to strengthen the regulatory framework, and low public awareness will be critical for establishing a sustainable biobanking system capable of supporting both national and international research.

The comprehensive implementation of the proposed policy options could facilitate the development of a sustainable and competitive biobanking system in Kazakhstan, supporting scientific advancement and the continued development of healthcare in the country.

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Қазақстандағы биобанктер инфрақұрылымын дамыту: Сын-қатерлер мен саяси шешімдер

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Түйіндеме/ Түйінді ойлар

Қазақстанда биобанктерді дамыту ерте кезеңде тұр, бұл әрекет ететін ұйымдардың шектеулі санымен, нормативтік-құқықтық реттеудің жеткіліксіздігімен, халықаралық стандарттармен әлсіз интеграциямен және мамандар мен халықтың хабардарлық деңгейінің төмендігімен сипатталады. Қолданыстағы биобанктер биоматериалдардың қажетті қамтылуын және әртүрлілігін қамтамасыз етпейді, бұл заманауи биомедициналық зерттеулер жүргізу және халықаралық ғылыми жобаларға қатысу мүмкіндіктерін шектейді.

Мәселе неде?

- Биобанктердің шектеулі саны және бірыңғай ұлттық тізілімнің болмауы.
- Нормативтік-құқықтық базаның жеткіліксіз нақтылануы және өзектілігінің төмендігі.
- Қаржыландырудың шектеулілігі және инвестициялық тартымдылықтың әлсіздігі.
- Білікті кадрлардың және білім беру бағдарламаларының тапшылығы.
- Халықтың хабардарлығы мен қатысу деңгейінің төмендігі.
- Аккредиттеу және сертификаттау тетіктерінің болмауы.

Саясат нұсқалары

1-нұсқа. Биобанктер жүйесінің инфрақұрылымын жаңғырту және инвестицияларды ынталандыру.

2-нұсқа. Саланың кадрлық әлеуетін дамыту.

3-нұсқа. Донорлық мәдениетті және қоғамның хабардарлығын дамыту.

4-нұсқа. Биобанктер қызметін нормативтік-құқықтық реттеуді жетілдіру.

5-нұсқа. Биобанктерді басқаруға арналған цифрлық платформаны әзірлеу және енгізу.

Саясат нұсқаларын іске асыру жөніндегі көзқарас

Ұсынылған саясаттарды кешенді түрде іске асыру ведомствоаралық өзара іс-қимылды, мемлекеттік қолдауды, жеке және халықаралық инвестицияларды тартуды, сондай-ақ кәсіби және азаматтық қоғамның белсенді қатысуын талап етеді. Цифрлық шешімдерді енгізу, нормативтік базаны үйлестіру, білім беру бастамаларын дамыту және халықаралық ынтымақтастық Қазақстанда ұлттық және халықаралық зерттеулерді қолдай алатын, ғылым мен денсаулық сақтау саласының дамуына ықпал ететін орнықты әрі бәсекеге қабілетті биобанкинг жүйесін құруға мүмкіндік береді.

Түйін сөздер: биобанкинг, биобанк, Қазақстан, нормативтік-құқықтық реттеу, донорлық мәдениет, хабардарлық, қаржыландыру, кадрлық әлеует, халықаралық ынтымақтастық, биомедициналық зерттеулер.

Развитие инфраструктуры биобанков в Казахстане: Барьеры и политические решения

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Резюме/ Ключевые положения

В Казахстане развитие биобанков находится на ранней стадии, что выражается в ограниченном количестве действующих организаций, недостаточном нормативно-правовом регулировании, слабой интеграции с международными стандартами и низком уровне информированности специалистов и населения. Существующие биобанки не обеспечивают необходимого охвата и разнообразия биоматериалов, что ограничивает возможности для проведения современных биомедицинских исследований и участия в международных научных проектах.

В чем заключается проблема?

- Ограниченное количество биобанков и отсутствие единого национального реестра.
- Недостаточная детализация и актуальность нормативно-правовой базы.
- Ограниченное финансирование и слабая инвестиционная привлекательность.
- Дефицит квалифицированных кадров и образовательных программ.
- Низкая информированность и вовлеченность населения.
- Отсутствие аккредитационных и сертификационных механизмов.

Варианты политики

Вариант 1. Модернизация инфраструктуры и стимулирование инвестиций в биобанковскую систему.

Вариант 2. Развитие кадрового потенциала отрасли.

Вариант 3. Развитие донорской культуры и информированности общественности.

Вариант 4. Совершенствование нормативно-правового регулирования деятельности биобанков.

Вариант 5. Разработка и внедрение цифровой платформы для управления биобанкам.

Видение по реализации вариантов политики

Комплексная реализация предложенных политик требует межведомственного взаимодействия, государственной поддержки, привлечения частных и международных инвестиций, а также активного участия профессионального и гражданского общества. Внедрение цифровых решений, гармонизация нормативной базы, развитие образовательных инициатив и международное сотрудничество позволят создать устойчивую, конкурентоспособную систему биобанкинга, способную поддерживать национальные и международные исследования, а также способствовать развитию науки и здравоохранения в Казахстане.

Ключевые слова: биобанкинг, биобанк, Казахстан, нормативно-правовое регулирование, донорская культура, информированность, финансирование, кадровый потенциал, международное сотрудничество, биомедицинские исследования.

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