

<https://doi.org/10.15407/scine22.04.036>

DOROSHENKO, O. F. (<https://orcid.org/0000-0002-2542-2328>),
KASHYNTSEVA, O. Yu. (<https://orcid.org/0000-0002-2598-5614>),
OMELCHENKO, O. P. (<https://orcid.org/0000-0002-3265-205X>),
PONOMAROVA, O. O. (<https://orcid.org/0000-0002-8232-3748>),
and CHOMAKHASHVILI, O. Sh. (<https://orcid.org/0000-0002-0546-2138>)

Scientific-Research Institute of Intellectual Property,
 National Academy of Law Sciences of Ukraine,
 11, Kazymyra Malevycha St., Kyiv, 03150, Ukraine,
 +380 44 200 0876, letter@i.kiev.ua

LEGAL REGULATION OF BIOBANKS: REALITIES, CHALLENGES, AND PROSPECTS IN THE CONTEXT OF MILITARY AGGRESSION

Introduction. *The war has highlighted the need to ensure access to medical treatment for the population of Ukraine, including through the removal of legal barriers to the protection of intellectual property rights in medicine and pharmacy, together with their important interdisciplinary component — biotechnologies in the form of biobanking.*

Problem Statement. *Legal gaps are particularly evident in areas where advances in science and technology give rise to complex social relations, including those associated with biobanking.*

Purpose. *The purpose of this study is to examine the specific features of the legal regulation of biobanking in Ukraine and the trends in its development within the European Union, to formulate recommendations for improving Ukrainian legislation in this field, and to draw the attention of the scientific community to the challenges and threats posed by military aggression, under which biobanking has acquired particular relevance.*

Materials and Methods. *The study has been based on an analysis of normative legal acts and scholarly works by Ukrainian and foreign researchers. The research has employed the dialectical method, methods of analysis and generalization, systemic and comparative methods, and the formal-legal method of legal interpretation.*

Results. *The study has identified the following priority and promising tasks for Ukraine in the field of biobank regulation: the adoption of comprehensive legislation governing the establishment, operation,*

Citation: Doroshenko, O. F., Kashyntseva, O. Yu., Omelchenko, O. P., Ponomarova, O. O., and Chomakhashvili, O. Sh. (2026). Legal Regulation of Biobanks: Realities, Challenges, and Prospects in the Context of Military Aggression. *Sci. innov.*, 22(4), 36—46. <https://doi.org/10.15407/scine22.04.036>

© Publisher PH “Akadempriodyka” of the NAS of Ukraine, 2026. This is an open access article under the CC BY-NC-ND license (<https://creativecommons.org/licenses/by-nc-nd/4.0/>)

and termination of biobanks; the regulation of the legal aspects of informed consent, including its forms, types, and specific features depending on the purpose for which biological material is collected; and the determination of the legal regime applicable to data collected and generated by biobanks.

Conclusions. *The growing impact of biotechnology on the fields of defense and security poses a challenge to the international community regarding the proper governance of the further development of such technologies and the lawful and responsible use of their achievements. Further improvement of the legal regulation of biomedical research involving biobank resources remains an important task. Legislation should ensure clarity and legal certainty in the relevant legal relationships in order to safeguard the rights of their participants.*

Keywords: biobank, biomedical research, biomaterial, access to treatment, intellectual property, security, human rights, patient rights.

Accelerated R&D development is often accompanied by a lag in the legal framework required to regulate newly emerging forms of social relations.

The Russian Federation's aggression against Ukraine, accompanied by acts of genocide and ecocide committed on Ukrainian territory, has generated a humanitarian crisis affecting not only Ukraine's healthcare system but also Europe more broadly, creating additional challenges for the values and institutions of Western civilization. As German Federal Minister of Health Karl Lauterbach noted, "It would be unfair to assume that, if we do not prepare for military conflict, it will not occur... Doing nothing is not a solution. A different approach is needed in the healthcare system as well, especially considering that Germany could become a hub for this. Moreover, Germany could serve as a center for providing medical assistance to the wounded and injured from other countries within an alliance" [1].

The Russian Federation's aggression should be considered not only in light of the full-scale invasion of Ukraine but also in the context of potential future threats to other European states, including the Baltic countries and Poland. In blatant disregard of the existing international legal order, the aggressor state has systematically targeted civilian infrastructure in Ukraine, thereby creating serious concerns regarding the possibility of similar actions against other countries bordering the Russian Federation, including the Baltic states [2].

Among the areas most profoundly affected by the war, the healthcare sector warrants particular

attention. Ensuring access to medical treatment for the population of Ukraine requires, inter alia, the removal of legal barriers related to the protection and exercise of intellectual property rights in medicine and pharmacy, including their important interdisciplinary component represented by biotechnology, particularly biobanking.

Deficiencies in legal regulation are especially evident in areas where scientific and technological advances give rise to complex social relations requiring a clear and comprehensive legal framework. Biobanking represents one such area and therefore merits particular scholarly and legislative attention.

Biobanks have become an important element of medical and biological research infrastructure and a component of national security. Biobanks facilitate the expansion of research scope, mobility, and efficiency through repositories of biological samples and data.

The absence of adequate legal regulation for storing biological samples and related information in biobanks in Ukraine not only has a chilling effect on the development of scientific biomedical research but also keeps out of the legal framework the preservation of biological materials that have strategic importance for the state in terms of security. This refers mainly to forming a database of biological materials to preserve as evidence for war crimes investigations and preserving genetic material of the state's biodiversity.

However, while preparing for negotiations with the EU, the Ministry of Health of Ukraine actively

cooperates with various state bodies and the public sector. At the hearing of the European integration subcommittee of the Verkhovna Rada National Health Committee on August 21, 2024, the Ministry of Health of Ukraine presented a roadmap of actions as a part of the negotiation process with the EU on the health of the nation [3]. In the mentioned roadmap of actions, the Deputy Minister of Health of Ukraine for European Integration, Maryna Slobodnychenko, outlined the main directions of healthcare reform:

1. medicines for humans and veterinary use (general directive, regulation of clinical trials, regulation of authorization (registration), others);
2. cosmetic products;
3. medical products;
4. tobacco control;
5. patients' rights in cross-border healthcare;
6. Social and economic determinants of health;
 - 6.1. Health inequalities;
 - 6.2. Healthy lifestyle — prevention of alcohol and drug use;
 0. Blood, tissues, cells, and organs;
 0. Health information (electromagnetic fields);
 0. Infectious diseases:
 - 9.1. Supervision and reporting;
 - 9.2. European Centre for Disease Prevention and Control;
 - 9.3. Health security;
 0. Non-communicable diseases:
 - 10.1. Cancer;
 - 10.2. Mental health;
 - 10.3. Rare diseases;
 0. EHEALTH;
 0. EU4HEALTH program;
 0. Health technology assessment.

The priority block of healthcare reform in Ukraine, pointed out by the Ministry of Health of Ukraine is “Blood, tissues, cells, and organs.”

The research aims to investigate the specific features of legal regulation of biobanking in Ukraine together with the trends in its formation in the EU, to formulate recommendations for improving Ukrainian legislation in this field, and to draw the attention of academics to the challenges

and dangers of military aggression, during which biobanking becomes particularly relevant.

The research was conducted through analysis of normative legal acts and scientific works of Ukrainian and foreign scholars. The authors applied general scientific methods: methods of analysis and generalization, dialectical, systemic and comparative methods, method of formal-legal interpretation.

Academic papers by N. Kvit, I. Senyuta, V. Pashkov, R. Hewitt, W. Watson, V. Argudo-Portal, M. Domènech, and others that are dedicated to the study of legal regulation of biobank activities and various aspects of biomedical research.

Legal regulation of collection, storage, and use of human biological material and related data by biobanks requires a multi-aspect analysis.

Since the term “biobank” was first used in the scientific literature in 1996 [4] and in 2009, *The Times* named biobanks among ten major ideas that are changing the world right now [5], biobanking has developed into an entire infrastructure of relevant institutions that operate with various human biological samples and associated information for research purposes (here we do not cover cord blood banks, gamete banks, etc., which perform personalized storage of biological material).

There is no unified legislation on biobanks at the European Union level, the member countries have somewhat different approaches to the legal regulation of biobank functioning, and some of them lack the necessary legislation altogether. However, the collection and storage of human biological material in biobanks in the EU are regulated by the norms of the following acts:

- ◆ The Convention for the Protection of Human Rights and Dignity of the Human Being about the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (establishes principles and rules for ensuring human dignity in the field of biology and medicine) [6];
- ◆ Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medical products for human

use, and repealing Directive 2001/20/EC (provisions on informed consent and the right to withdraw from the research also apply to the functioning of the biobanks) [7];

- ◆ Recommendation CM/Rec(2016)6 of the Committee of Ministers to member States on research on biological materials of human origin [8],
- ◆ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons about the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC [9].

The procedure for collecting and storing human biological material in biobanks in Ukraine is fragmentarily regulated in several normative legal acts, mostly secondary legislation. Here are some of them. The normative legal acts related to biobanks in general include the Constitution of Ukraine [10], the Civil Code of Ukraine [11], the Law of Ukraine on “The Fundamentals of Ukrainian Legislation on Health Care” [12], the Law of Ukraine on “The Personal Data Protection” [13], the Law of Ukraine on “The Transplantation of Anatomical Materials to Humans” [14], and others. The legislation that regulates the functioning of biobanks specifically includes:

- ◆ The Law of Ukraine on “The Licensing of Economic Activities” [15], in Article 7 mentions the actions of cord blood banks, other human tissues, cells banks, that are subject to licensing according to the list approved by the Ministry of Health of Ukraine;
- ◆ The Licensing Conditions For Conducting Economic Activities of cord blood banks, other human tissues and cells, according to the list approved by the Ministry of Health of Ukraine in the Resolution of the Cabinet of Ministers of Ukraine 02.03.2016 No. 286 [16] (hereinafter — Licensing conditions) (this act defines the requirements and documents, compliance with and submission of which is mandatory for entities intending to conduct economic activities of cord blood banks, other human tissues and cells. The Licensing conditions establish legal defini-

tions of several terms, including the cord blood bank, other human tissues and cells, as the act does not operate with the term “biobank”);

- ◆ The List Of Human Cells And Tissues with which the activity of cord blood banks, other human tissues and cells is allowed, approved by the Order of the Ministry of Health of Ukraine 20.04.2012 No. 276 [17], which lists the following biological material: umbilical (cord) blood and cells isolated from it, umbilical cord and cells isolated from it, placenta and cells isolated from it, hematopoietic stem cells isolated from peripheral blood, connective tissue and cells isolated from it, ovarian/testicular tissue, embryo-fetal material and cells isolated from it, milk teeth and cells isolated from them, eyeball or its components, and their definitions are established.

Special regulatory acts also include: the Procedure of Collection and Temporary Storage of Umbilical (Placental) Blood and/or Placenta, approved by the Order of the Ministry of Health of Ukraine dated 10.07.2014 No. 481 [18]; The Procedure of Collection, Storage, and Use of Bone Marrow approved by the Order of the Ministry of Health of Ukraine dated 04.05.2000 No. 96 [19]; the Criteria For Assessing The Degree Of Risk From The Economic Activities Of Cord Blood Banks, Other Human Tissues, And Cells according to the List approved by the Ministry of Health, determining the frequency of planned state supervision (control) measures carried out by the said Ministry, approved by the Resolution of the Cabinet of Ministers of Ukraine 11.02.2016 No. 69 [20], and others.

Despite the existence of the abovementioned legal acts in Ukraine, many important issues are left outside of legal regulation, accompanied by complicated ethical and legal controversies. The forms and procedures for creating relevant biobanks require regulation in the context of research biobanking, including the types of informed consent and the process of obtaining it, etc.

The lack of harmonized legislation on biobanks within the European Union gives rise to ambiguous legislative approaches of the member states in this field at the national level. For example, a new

law on biobanks came into effect in July 2023 in Sweden, which, in particular, is intended to provide a higher level of protection of the donors' rights and increase confidentiality. The law defines a biobank as one or more collections of samples stored by a principal, where the principal is a company responsible for the biobank [21].

Contrary to this, Spain (The Royal Decree 1716/2011, dated 18 November) provides three legal regimes for the use of biological samples and data in biomedical research: project, collection, and biobank. A biobank for biomedical research purposes is a public or private non-profit institution that contains one or more collections of human biological material, technically organized according to quality criteria and order. A collection of human biological samples is an ordered set of biological material stored outside of a biobank, while a project refers to biological samples of human origin stored outside the framework organized by a biobank, exclusively for use in a specific research project, provided that their preservation does not extend beyond the completion date of such a project and will not be transferred [22]. There are differences in obtaining informed consent for these three regimes; in the case of the biobank, the so-called broad consent is applied, while in the case of a project or collection narrow consent is used.

The V. Argudo-Portal and M. Domènech state that the existence of these three distinct regimes themselves, legally provided for preserving and using biological material in research, creates controversial practices and violations. Since the creation and maintenance of biobanks requires going through a series of bureaucratic procedures and constant funding fulfilling the task of providing high-quality samples and related data for research, biobanks must, among other things, regularly implement ISO standards, undergo audits, etc. Meanwhile, the collection regime allows bypassing these procedures. The need for transformation of the Spanish legislation towards the transition to the biobank regime is simultaneously a need to form a high-level scientific culture regarding sample storage, data processing, and other aspects [23].

The biobank associations, for example, the European Research Infrastructure Consortium — Biobanking and Biomolecular Resources Research Infrastructure (BBMRI-ERIC) which unifies standards and approaches, and sets out recommendations on best practices in this field, are actively developing in European countries [24]. The number of countries joining BBMRI-ERIC is increasing. In 2023, Denmark, Lithuania, and Switzerland were officially accepted as members of the Biobanking and Biomolecular Resources Research Infrastructure Consortium — European Research Infrastructure Consortium (BBMRI-ERIC). Lithuania and Switzerland transitioned from observers to full members, while Denmark joined as an observer [25].

Given the practice of the EU member states that are currently discussing legislation in the field of biobanking, corresponding changes should also be proposed in Ukraine taking into account specific conditions caused by the military aggression that should be considered in two contexts:

- ◆ in the context of providing strategic spheres for treatment, and
- ◆ in the context of storing biological samples to prove war crimes, which have no limitation period.

Even though a discussion on terminology in the context of alternatives to the term “biobank” takes place, thus such terms as biorepository, biotrust, repository, biocollection and even biodistributor appear [26], “biobank” and its derivatives have already become commonly used terms. Additionally, the term “biobank” has been legally introduced into the legislation of several countries, i.e., a culture of understanding and perception of the collection and storage of human biological material through the prism of biobanking has already been formed.

Different approaches to define biobank are proposed by scholars [27—29], however in general they all regard it as a collection or collections of human biological material and related data for research. Thus, in most cases, a biobank is understood as an object of legal relations.

The full-scale invasion by the Russian Federation is slowing down several processes in Ukraine,

contrary to this trend biobanking is undoubtedly among the priorities of the country's defense and contributes hugely to the proof of crimes committed on its territory. On August 21, 2024, the Verkhovna Rada of Ukraine adopted the Law of Ukraine on "The Ratification of the Rome Statute of the International Criminal Court with Amendments thereto" [30].

Taking into account the strategic importance of biobanking, the Cabinet of Ministers of Ukraine on August 30, 2024, approved the procedure for the collection, storage and use of human biological samples for research purposes [31] (hereinafter referred to as the Procedure), defining the mechanism for the collection, storage, and use of human biological samples and related data for the purpose of conducting scientific research and using their results to ensure the development of the healthcare sector for the first time in Ukrainian legislation. For the first time, the biobank is defined by this act as "a company or a separate structural subdivision of a company that carries out biobanking in the form of following types of economic activity: experimental development in the field of biotechnology, healthcare, higher education, data processing, including the provision of data entry services."

The recent news in the area highlights the importance and prospects of biobanks for advancing biomedical research. For example, the UK Biobank project offers scientists access to the complete genetic sequences of almost half of a million people, which is the world's largest database of whole genomes, this indicates good prospects for genetic research [32]. The world's first biobank of living brain tissue was created in Spain, with samples collected from patients with metastatic brain cancer, the use of which for research purposes is expected to provide a more complete picture of the relevant aspects of the disease and/or treatment responses [33]. However, today, for Ukraine and its Western partners, the use of biobanking is no longer a question of scientific research, but rather the question of national security and defense. Thus, in February 2024, the defense ministers of the North Atlantic Alliance officially adopted the NATO Stra-

tegy for Biotechnology and Human Enhancement Technologies [34]. The purpose of this strategy is to establish a common NATO approach to the development and use of biotechnology and human enhancement technologies, to promote their integration into NATO military system, and to identify and protect against threats posed by the hostile use of such technologies [35]. This is the first international strategy for the responsible development and use of biotechnology in defense and security sectors, which indicates a significant potential for further development of biotechnology and its application in defense and security.

The question of preserving the gene pool as a response to the daily destruction of Ukrainians and other nations that are the citizens of the country is crucially important and deserves special attention. Article 16 of the Constitution of Ukraine enshrines the obligation of the state to preserve the gene pool of the Ukrainian people. Although the legislation does not go into detail of how the state should fulfill this obligation, it is clear that favorable conditions should be created for the safe life of the Ukrainian population, which will contribute to a high birth rate. To preserve the gene pool of the Ukrainian people, it is important to resist infectious diseases and provide access to medicines, including innovative ones. However, full-scale armed aggression against Ukraine poses a considerable challenge to Ukraine in fulfilling this obligation by the state. As a response to them, the Ukrainian Parliament, Verkhovna Rada of Ukraine adopted a new act (having still some disadvantages) to ensure the right of military personnel and other persons to biological paternity (motherhood), which, in particular, provides that during the period of martial law, military personnel have the right to receive free medical services related to ensuring the exercise of their right to biological paternity (motherhood), including the collection, cryopreservation, and storage of their reproductive cells in case of loss of reproductive capacity [36].

Studies show that the support for the development of biobanking at the national level is influenced not only by the understanding of the scien-

tific tasks of biobanks, their activities, and importance for biomedical research but also by their development as a strategic component of the health care system [37].

The issue of legal regulation of biobanks exists at the international level within the European Union in terms of harmonized legal norms and common approaches to addressing numerous legal aspects.

The Russian aggression undermines not only the national security of Ukraine but also threatens peace and order in the entire European region. Under such conditions, the storage of human biological samples and the activities of biobanks to develop new methods of treating diseases are gaining strategic importance and have innovative potential.

The adoption of the Procedure by the Cabinet of Ministers of Ukraine is undoubtedly a significant achievement in the development of legal regulation of the collection, storage, and use of human biological samples and related data for scientific research. Sharing N. Kvit's proposals [38] to amend the legislation of Ukraine in the context of cryopreservation of human biological material, we note that the activities of biobanks and the use of human biological material in biomedical research should be regulated at the level of law, and not limited to bylaws. The key tasks for Ukraine in this area include at least the following:

- ◆ to set out the legislation that will comprehensively regulate the procedure for the establishment, operation, and termination of biobanks;
- ◆ to consolidate the legal aspects of giving informed consent: its form, types, and features depending on the purpose for which biological material is collected;
- ◆ defining the legal regime of data collected and generated by biobanks.

According to the international agenda, the improvement of the legislation on the legal regulation of the donation of biological material for use in research in biology, medicine, and pharmacy is up to date. On August 25, 2023, the United Nations General Assembly adopted a resolution proclaiming 2024–2033 as the International Decade of Science for Sustainable Development, emphasizing

that humanity faces complex challenges and that a more effective and inclusive approach is needed to fully implement the 2030 Agenda for Sustainable Development, based on synergetic cooperation in all fields of science — basic and applied, social and humanitarian, including traditional knowledge, allowing the development of technology, innovation and education [39].

The need to ensure access to treatment for the population hugely increased and emerged in response to the full-scale aggression of the Russian Federation to Ukraine. Such access should be ensured by overcoming legal barriers and restrictions in protecting the intellectual property rights of pharmaceutical companies, in particular by removing obstacles to the timely entry of generic drugs and biosimilars onto the market through the proper application of the “Bolar rule.” Therefore, Ukraine needs to use all possible legal instruments for this purpose. We share the opinion of O. Gurgula that Ukraine's obligation under the TRIPS Agreement to protect IP rights may be canceled or limited due to the need to protect other non-trade interests that prevail. This is possible based on Article 73 of the TRIPS Agreement, that provides for the right of the participant country to derogate from its obligations under TRIPS by waiving IP rights to essential medicines and medical devices to protect national security interests [40].

The growing impact of biotechnology on defence and national security requires the international community to develop and adopt appropriate regulatory frameworks for the further advancement of such technologies, ensuring that their achievements are applied in a lawful and responsible manner. The use of biotechnological innovations contributes to the defence and security objectives of Ukraine and other European countries in response to Russia's aggression against Ukraine and serves to mitigate existing and potential future military threats.

The absence of harmonized regulations at the European level, together with ongoing efforts within Ukrainian legislation to regulate biobanks, underscores the broader challenge of establishing

an adequate and coherent legal framework in this field. At the same time, current developments demonstrate both the significance and the considerable potential of biobanking. Many countries have adopted national legislation governing the donation of biological materials, their storage in biobanks, and their subsequent use in biomedical research. Ukraine should carefully examine international experience in order to develop an effective national regulatory framework for biobanking.

Measures aimed at improving the national legal framework for biobanks should include a comprehensive analysis of foreign regulatory practices, consideration of international expertise and recommendations developed by the World Health Organization and the European Union, and the establishment of a dedicated working group involving representatives of the scientific community,

healthcare institutions, patient organizations, and other relevant stakeholders to prepare legislative proposals in this area.

The unprovoked armed aggression of the Russian Federation has posed unprecedented challenges to all spheres of public life in Ukraine. Given the scale of the country's future reconstruction, the further development of biology, medicine, and pharmacy has become particularly important. In this context, improving the legal regulation of biomedical research involving biobank resources is of special relevance. Such legislation should provide clarity and legal certainty in the regulation of the relevant legal relationships, while ensuring effective protection of the rights and interests of all participants. Ukrainian legislation should also adopt appropriate terminology in this field in order to align with generally accepted international standards and practices.

REFERENCES

1. Lauterbach wants to prepare the healthcare system for wars. URL: <https://www.tagesschau.de/inland/lauterbach-militaerkonflikt-gesundheitswesen-100.html> (Last accessed: 24.10.2024).
2. We have no Plan B if Ukraine falls, says Estonia URL: <https://www.bbc.com/news/articles/c722zxj0kyro> (Last accessed: 24.10.2024).
3. The Ministry of Health of Ukraine presented a roadmap of actions on the health of the nation as a part of the negotiation process with the EU. URL: <https://www.kmu.gov.ua/news/moz-predstavylo-dorozhniu-kartu-pidhotovky-systemy-okhorony-zdorovia-do-perehovornoho-protsesu-z-ies> (Last accessed: 24.10.2024).
4. Hewitt, R., Watson, P. (2013). Defining Biobank Biopreservation and Biobanking. *Biopreservation and biobanking*, 11(5), 309—315. <https://doi.org/10.1089/bio.2013.0042>
5. 10 Ideas Changing the World Right Now. URL: https://content.time.com/time/specials/packages/article/0,28804,1884779_1884782_1884766,00.html (Last accessed: 24.10.2024).
6. The Convention for the Protection of Human Rights and Dignity of the Human Being (Council of Europe) April 4, 1997. URL: http://zakon2.rada.gov.ua/laws/show/994_334 (Last accessed: 24.10.2024).
7. Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC. URL: <https://eur-lex.europa.eu/eli/reg/2014/536/2022-12-05> (Last accessed: 24.10.2024).
8. Recommendation CM/Rec(2016)6 of the Committee of Ministers to member States on research on biological materials of human origin. URL: https://search.coe.int/cm/Pages/result_details.aspx?ObjectID=090000168064e8ff (Last accessed: 24.10.2024).
9. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC. URL: <http://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3> (Last accessed: 24.10.2024).
10. The Constitution of Ukraine. URL: <https://zakon.rada.gov.ua/laws/show/254%D0%BA/96-%D0%B2%D1%80> (Last accessed: 24.10.2024).

11. The Civil Code of Ukraine 16.01.2003 p. URL: <http://zakon3.rada.gov.ua/laws/show/435-15/conv?nreg=435-15&find=1&text=%E4%EE%ED%EE%F0&x=0&y=0#w11> (Last accessed: 24.10.2024).
12. The Law of Ukraine on “The Fundamentals of Ukrainian Legislation on Health Care” 19.11.1992. URL: <http://zakon2.rada.gov.ua/laws/show/2801-12> (Last accessed: 24.10.2024).
13. The Law of Ukraine on “The Personal Data Protection” June 1, 2010 No. 2297-VI. URL: <https://zakon.rada.gov.ua/laws/show/2297-17> (Last accessed: 24.10.2024).
14. The Law of Ukraine on “The Transplantation of Anatomical Materials to Humans” May 17, 2018. No. 2427-VIII. URL: <https://zakon.rada.gov.ua/laws/show/2427-19> (Last accessed: 24.10.2024).
15. The Law of Ukraine on “The Licensing of Economic Activities” March 2, 2015 No. 222. URL: <https://zakon.rada.gov.ua/laws/show/222-19> (Last accessed: 24.10.2024).
16. The Licensing Conditions For Conducting Economic Activities of cord blood banks, other human tissues and cells, according to the list approved by the Ministry of Health of Ukraine in the Resolution of the Cabinet of Ministers of Ukraine 02.03.2016 No. 286. URL: <https://zakon.rada.gov.ua/laws/show/286-2016-%D0%BF> (Last accessed: 24.10.2024).
17. The List Of Human Cells And Tissues with which the activity of cord blood banks, other human tissues and cells is allowed, approved by the Order of the Ministry of Health of Ukraine 20.04.2012 No. 276. URL: <https://zakon.rada.gov.ua/la-ws/show/z1124-12> (Last accessed: 24.10.2024).
18. The Procedure of Collection and Temporary Storage of Umbilical (Placental) Blood and/or Placenta, approved by the Order of the Ministry of Health of Ukraine dated 10.07.2014 No. 481. URL: <https://zakon.rada.gov.ua/laws/show/z0869-14> (Last accessed: 24.10.2024).
19. The Procedure of Collection, Storage, and Use of Bone Marrow approved by the Order of the Ministry of Health of Ukraine dated 04.05.2000 No. 96. (Last accessed: 24.10.2024).
20. The List approved by the Ministry of Health, determining the frequency of planned state supervision (control) measures carried out by the said Ministry, approved by the Resolution of the Cabinet of Ministers of Ukraine 11.02.2016 No. 69. URL: <https://zakon.rada.gov.ua/laws/show/69-2016-%D0%BF> (Last accessed: 24.10.2024).
21. The Swedish Biobank Act. URL: <https://biobanksverige.se/en/the-swedish-biobank-act/> (Last accessed: 05.01.2025).
22. Royal Decree 1716 / 2011. URL: <https://www.boe.es/buscar/doc.php?id=BOE-A-2011-18919> (Last accessed: 05.01.2025).
23. Argudo-Portal, V., Domènech, M. (2022). We Came Here to Stay’: Making Biobanks Worth Maintaining in Spain. *Sociology of Health & Illness*, 44(2), 328—344. <https://doi.org/10.1111/1467-9566.13420>
24. BBMRI-ERIC. URL: <https://www.bbmri-eric.eu/> (Last accessed: 24.10.2024).
25. Denmark, Lithuania and Switzerland Strengthen Biobanking Research Infrastructure in Europe. URL: <https://www.biobanking.com/denmark-lithuania-and-switzerland-strengthen-biobanking-research-infrastructure-in-europe/> (Last accessed: 24.10.2024).
26. Watson, P., Hewitt, R., Catchpoole, D., Grizzle, W. (2019). Biobank: What’s in a Name? *Biopreservation and Biobanking*, 17(3), 204—208. <https://doi.org/10.1089/bio.2019.29053.mjb>
27. Beier, K., Lenk, C. (2015). Biobanking strategies and regulative approaches in the EU: recent perspectives. *Journal of Biorepository Science for Applied Medicine*, 3, 69—81. <https://doi.org/10.2147/BSAM.S64578>
28. Henderson, G. E., Cadigan, R. J., Edwards, T. P., Conlon, I., Nelson, A. G., Evans, J. P., Davis, A. M., Zimmer, C., Weiner, B. J. (2013). Characterizing biobank organizations in the U.S.: results from a national survey. *Genome Medicine*, 5(1), 3. <https://doi.org/10.1186/gm407>
29. Hewitt R., Watson W. (2013). Defining Biobank. *Biopreservation and Biobanking*, 11(5), 309—315. <https://doi.org/10.1089/bio.2013.0042>
30. The Law of Ukraine on “The Ratification of the Rome Statute of the International Criminal Court with Amendments thereto” No. 3909-IX, 21.08.2024. URL: <https://zakon.rada.gov.ua/go/3909-20> (Last accessed: 24.10.2024).
31. The procedure for the collection, storage and use of human biological samples for research purposes Resolution of the Cabinet of Ministers of Ukraine. August 30, 2024, No. 999. URL: <https://www.kmu.gov.ua/npas/prozatverdzhennia-poriadku-zboru-zberihannia-ta-vykorystannia-biolohich-a999> (Last accessed: 24.10.2024).

32. UK Biobank releases half a million whole-genome sequences for biomedical research. URL: <https://www.science.org/content/article/uk-biobank-releases-half-million-whole-genome-sequences-biomedical-research> (Last accessed: 24.10.2024).
33. Spanish researchers open first biobank for living human brain samples. URL: <https://newatlas.com/medical/spanish-researchers-open-first-biobank-for-living-human-brain-samples/> (Last accessed: 24.10.2024).
34. Healthier, cleaner, greener: a NATO strategy for the coming bio-revolution. URL: <https://www.nato.int/docu/review/articles/2024/05/30/healthier-cleaner-greener-a-nato-strategy-for-the-coming-bio-revolution/index.html> (Last accessed: 24.10.2024).
35. Summary of NATO's Biotechnology and Human Enhancement Technologies Strategy. URL: https://www.nato.int/cps/en/natohq/official_texts_224669.htm (Last accessed: 24.10.2024).
36. Amendment's act to ensure the right of military personnel and other persons to biological paternity (motherhood). URL: <https://zakon.rada.gov.ua/go/4749-20> (Last accessed: 24.10.2024).
37. Domaradzki, J., Czekańska, J., Walkowiak, D. (2023). To donate or not to donate? Future healthcare professionals' opinions on biobanking of human biological material for research purposes. *BMC Medical Ethics*, 24(1), 88. <https://doi.org/10.1186/s12910-023-00930-z>
38. Kvit, N. M. (2020). The civil forms of creation and use of biobanks in Ukraine. Thesis honorary doctor: 12.00.03. Lviv.
39. An International Decade of Sciences for Sustainable Development. URL: <https://www.iybssd2022.org/en/an-international-decade-of-sciences-for-sustainable-development/> (Last accessed: 24.10.2024).
40. Gurgula, O. (2022). Saving Ukrainian Lives during the Russian War: Ukraine Must Waive IP Rights under Article 73 TRIPS to Provide Access to Essential Medicines. *GRUR International*, 71(8), 719—730. <http://dx.doi.org/10.2139/ssrn.4082247>

Received 25.10.2024

Revised 18.02.2026

Accepted 23.02.2026

О.Ф. Дорошенко (<https://orcid.org/0000-0002-2542-2328>),
О.Ю. Кашинцева (<https://orcid.org/0000-0002-2598-5614>),
О.П. Омелченко (<https://orcid.org/0000-0002-3265-205X>),
О.О. Пономарьова (<https://orcid.org/0000-0002-8232-3748>),
О.Ш. Чомахашвілі (<https://orcid.org/0000-0002-0546-2138>)

Науково-дослідний інститут інтелектуальної власності
Національної академії правових наук України,
вул. Казимира Малевича, 11, Київ, 03150, Україна,
+380 44 200 0876, letter@i.kiev.ua

ПРАВОВЕ РЕГУЛЮВАННЯ ДІЯЛЬНОСТІ БІОБАНКІВ: РЕАЛІЇ, ЗАВДАННЯ, ПЕРСПЕКТИВИ В УМОВАХ НЕБЕЗПЕК ВОЄННОЇ АГРЕСІЇ

Вступ. Війна гостро окреслила потребу забезпечення доступу до лікування населенню України, зокрема й шляхом усунення правових бар'єрів захисту прав інтелектуальної власності у сфері медицини та фармації із їх особливою міждисциплінарною складовою — біотехнологіями у формі біобанкінгу.

Проблематика. Правові прогалини стосуються особливо важливих сфер, у яких досягнення науки та техніки спричиняють появу складних за своєю природою суспільних відносин, зокрема біобанкінг.

Мета. Дослідити особливості правового регулювання біобанкінгу в Україні та тенденції формування в ЄС, сформулювати рекомендації щодо вдосконалення законодавства України, а також звернути увагу наукової спільноти до викликів небезпек воєнної агресії, оскільки біобанкінг набуває особливої актуальності.

Матеріали й методи. Здійснено аналіз нормативно-правових актів, наукових робіт українських та зарубіжних вчених. Застосовано діалектичний метод, метод аналізу, системний та порівняльний методи, метод узагальнення та формально-юридичний метод тлумачення права.

Результати. Визначено необхідними та перспективними завданнями для України у сфері правового регулювання біобанків: прийняття законодавства, яке комплексно регулюватиме порядок створення, провадження діяльності та припинення біобанків; закріплення правових аспектів інформованої згоди: її форми, видів та особливостей залежно від того, з якою метою збирається біологічний матеріал; визначення правового режиму даних, зібраних та згенерованих біобанками.

Висновки. Збільшення впливу біотехнологій на сферу оборони та безпеки кидає виклик міжнародній спільноті щодо належної практики подальшого поступу таких технологій і використання їх здобутків у законний та відповідальний спосіб. Актуальним виглядає удосконалення правового регулювання здійснення медико-біологічних досліджень із використанням ресурсів біобанків. Законодавство має слугувати чіткості та визначеності відповідних правових відносин з метою забезпечення прав їхніх учасників.

Ключові слова: біобанк, медико-біологічні дослідження, біоматеріал, доступ до лікування, інтелектуальна власність, безпека, права людини, права пацієнтів.