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LEGAL AND BIOETHICAL FOUNDATIONS OF HUMAN CELL AND TISSUE CRYOBANKS IN UKRAINE: REGULATORY FRAMEWORK, CHALLENGES AND PROSPECTS

The paper considers the legal and bioethical foundations of the activity of cryobanks of human cells and tissues in Ukraine. The importance of adapting national legislation to international standards in the field of biobanking, transplantology and assisted reproductive technologies is shown. The study provides an analysis of the basics legal regulation of cryobanks, identifies directions for improving the legislation of Ukraine in accordance with European standards. For the analysis, the authors were guided by the laws of Ukraine, directives of the European Union, recommendations of the World Health Organization, documents of the Council of Europe, and used scientific publications in the field of medical law, bioethics, cryobiology, and reproductive medicine. Regulatory, documentary, comparative methods of analysis were applied. It has been established that the current regulatory framework for governing the activities of cryobanks is fragmented, does not determine the legal status of biological material, the procedure for its inheritance and use after the donor's death. The proposed ways to improve the legal field are as follows: adoption of a special law on biobanks, creation of a unified state register of biological samples, adaptation of protocols and procedures to the norms of the European Union. The implementation of the proposed measures will contribute to the transparency, ethics, and efficiency of cryobanks, the protection of the rights of donors and patients, and the development of biomedical research in Ukraine.

Key words: *medical law, bioethics, cryobanks, gametes, embryos, placental blood, stem cells, human tissues.*

Ukraine is within the chain of global, European and national integration processes. In solving the key global issues, the United States, China, and the European Union (EU) are building the scientific, educational, and innovative medical and technological spheres, strengthening the financial and economic system, and actively introducing high-tech production, in particular artificial intelligence, and quantum technologies [1, 3, 15, 24, 42].

As Prof. John Bischof, Director of the Institute of Engineering in Medicine (USA), emphasizes, the research collaboration is aimed at developing innovative engineering solutions for the diagnosis, prevention, and treatment of diseases, as well as at constantly expanding the range of scientific topics [6]. Cryopreservation of biological material holds a special place among innovative biotechnologies.

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Cryobiology, the science that studies the impact of low temperatures on structural and functional properties of biological systems of various levels of organization, has become the foundational science for the creation of cryobanks that provide long-term storage of biological samples for medical, scientific and educational purposes. The storage of human reproductive cells, embryos, placental blood, and human stem cells at low temperatures is an important technological step in reproductive medicine, transplantology, oncohematology, and genetic research [7, 4, 39].

Today, cryotechnology plays a key role in biomedicine, particularly in reproductive medicine, oncohematology, transplantology, and biobanking. They make it possible to store spermatozoa, oocytes, and preimplantation embryos for further use either in infertility treatment programs or to delay parenthood; to accumulate stem cells used to treat leukemias, anemias, autoimmune and other diseases; to preserve tissues and organs for transplantation; to create biobanks of samples for scientific and clinical research.

Cryopreservation technology has become especially relevant in the context of modern hostilities and martial law in Ukraine [59], as it ensures the realization of the right of military personnel and their partners to biological paternity by preserving reproductive cells until the end of service or in case of loss of reproductive function [19, 30].

According to the current legislation of Ukraine, the main areas of activity for cryobanks when working with biological material are as follows [10]:

harvesting;

processing — manufacturing of products/preparations from biological material;

testing (verification) — laboratory control of safety and quality;

cryopreservation — cooling under different modes;

storage at an appropriate temperature regimen that ensures the stability and integrity of samples;

keeping records and documenting technological procedures;

protecting donors' personal data in accordance with the legislation of Ukraine;

transferring biological material for medical, scientific or educational purposes, as well as interacting with third parties during all stages of sample's circulation, testing, or disposal.

Cryobanks perform not only biomedical, but also important regulatory, medical, pharmaceutical, ethical, and socio-economic functions. They ensure the implementation of the constitutional human right to health care, reproductive freedom, respect for human dignity, privacy, and preservation of the gene pool [17, 56].

At the same time, the efficiency and safety of cryobanks depends not only on technological support, but also on the regulatory framework that regulates the circulation, use and protection of biological material. International practice demonstrates that clear standards and unified procedures are the basis for the legal regulation of biobanks' activities [8, 12, 13, 21, 23, 31].

Several reports of Ukrainian researchers (V. Grishchenko, O. Petrenko, M. Petrushko, S. Mazur, N. Volkova, T. Yurchuk and others) on studying the impact of low temperatures on structural and functional properties of biological systems of various levels of organization indicate significant achievements in cryopreservation of biological material [27, 33, 36, 39—41, 43].

The publications of many Ukrainian researchers, including N. Voloshina, O. Weitz, O. Gryzodub, A. Osintseva and others, cover the issues of drug quality control, patient health, medical, pharmaceutical and criminal law risks, the elimination of medical errors within the "doctor-patient-pharmacist-lawyer" legal relationship and the prevention of corruption in the procurement of biological material within the health care sector [14, 28, 37, 38, 44—49].

In Ukraine, the circulation of hematopoietic and mesenchymal stem cells intended for medical use is regulated by the provisions of the State Pharmacopoeia of Ukraine, which defines the requirements for the quality, safety, and storage of such drugs. As for other types of biological materials, the activities of biobanks are regulated by separate regulatory documents depending on the nature and purpose of the samples. For example, the circulation of human anatomical materials is regulated by the Law of Ukraine No. 2427-VIII of May 17, 2018 "On the use of transplantation of anatomical materials to humans" and by-laws to it; the storage and use of biological samples for scientific research are governed by the provisions of bioethics committees and international ethical declarations; the work with microorganisms and biological materials of animal and plant origin is regulated by appropriate sanitary, veterinary and phytosanitary requirements.

The main areas of this research concern legal support for the activities of banks of gametes, pre-

implantation embryos, placental blood, and human stem cells. The activities of other types of biobanks is regulated by specific legal regimes that require additional analysis.

The experience of global public and private umbilical cord blood banks and the activities of international structures indicate that regulatory conflicts and gaps can lead to violations of the rights of donors and patients, complicate international cooperation, and reduce the effective functioning of these structures. Despite the significant development of cryotechnologies, the issues of organization, legal support and ethical aspects of cryobanks have not yet been finally settled.

The regulations of Ukraine governing the activities of banks for gametes, embryos, placental blood and stem cells are partially aligned with European requirements. At the same time, they remain fragmented and do not cover all possible legal situations that may arise in this area. There are no clear provisions on the inheritance and use of biological material, the responsibility of cryobanks in case of their liquidation, as well as the protection of rights for children born through ART.

The relevance of this study is due to the need to improve and adapt Ukrainian legislation to European norms and standards, to guarantee safety, legal certainty and ethical validity of cryobank activities, as well as to protect the rights of patients and donors in modern social and legal conditions, including wartime challenges.

The article aims to justify the legal and bioethical foundations of human cell and tissue cryobanks in Ukraine, identifying regulatory gaps, determining the features of regulating the circulation of human biological material and developing proposals for improving national legislation, taking into account international standards and practice of the European Union.

Laws, regulations of the World Health Organization (WHO), the EU, Ukraine, reports in the National Academy of Sciences of Ukraine, publications of leading scientists — specialists in this field from Ukraine, the USA, and the EU — were used as imperative material.

The source base of the study was made up of the following documents:

laws and by-laws of Ukraine that regulate the activities of banks for human gametes, embryos, placental blood and stem cells;

international agreements and recommendations of the WHO, the Council of Europe, the European Association of Tissue Banks, and other specialized organizations;

protocols, regulations, and recommendations of bioethics committees;

scientific reports of leading Ukrainian and foreign researchers in the field of medical law, bioethics, cryobiology, and reproductive medicine;

materials from the official websites of state bodies: the Ministry of Health of Ukraine, the Committee on Public Health, Medical Assistance and Medical Insurance of the Verkhovna Rada of Ukraine.

A comprehensive interdisciplinary approach was used, combining normative, legal, documentary, comparative methods of analysis. The research was based on the principles of medical law, current regulations of Ukraine, international agreements, scientific publications, and analytical materials on the legal regulation of cryobank activities.

The paper comprehensively assessed the state of legal and regulatory framework, organizational and legal mechanisms for cryobank functioning, as well as the compliance of the national legal framework with international requirements and standards.

INTERNATIONAL LEGAL INSTRUMENTS

The main international documents that regulate activities of cryobanks [18, 25, 62, 63] are shown in Fig. 1.

It is necessary to note a number of international regulatory and recommendatory documents governing certain aspects of activities of cryobanks for gametes, embryos, placental blood, human tissues and cells, in particular: Guidance for Industry: Unique Device Identification for Human Cells, Tissues, and Cellular and Tissue-Based Products, approved by the US Food and Drug Administration; Directive 2004/23/EC of the European Parliament and of the Council and related Commission Directive 2006/17/EC and Commission Directive 2006/86/EC; Regulation (EU) 2017/745 on medical devices; Good Tissue Practice and Good Manufacturing Practice for Human Cells, Tissues, and Cellular and Tissue-Based Products, approved by the Food and Drug Administration; as well as internal regulatory documents of the United States Navy Tissue Bank, which operates within the US Navy system, taking into account the special procedures related to military requirements [20, 22, 23, 26, 51].

Scientists emphasize that the cryobank is a critical infrastructure independent of clinical departments [34]. Its technological base, management

Fig. 1. Main international documents regulating the activities of cryobanks

and quality assurance system, protection of patient personal data, as well as availability of necessary permits play a key role in maintaining the proper quality and scope of clinical cell and tissue transplantation programs. Of particular importance is the quality and safety of special tools for assessing microbiological risk during the collection and processing of cells and tissues. Since 2004, Directive 2004/23/EC of the European Parliament and of the Council "On setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells" [25] has entered into force, which obliged the EU member states to appoint a national competent authority responsible for accreditation, licensing and continuous supervision of cryobank activities. The issue of organizing a biobank at the local, regional and national levels using the example of the Uppsala Biobank was considered by A. Beskow [5], while the basic principles of biobanking (from biological samples to precision medicine for patients) were discussed by L. Annaratone *et al.* [2].

NATIONAL REGULATIONS

It should be noted that Ukraine is not a party to some regulatory acts, but their provisions are often used as a unified (implementation) model for adapting national legislation to international standards for the circulation of cryopreserved biological materials.

A cryobank is a specialized institution or structural unit that provides collection, testing, processing, cryopreservation, long-term storage and transfer of cells, subcellular structures, fragments of tissues and organs, tissue-specific and organotypic cell cultures, as well as other human biological samples. The cryobank activities are focused on medical application, scientific research and educational processes and are carried out in accordance with the requirements of Ukrainian legislation and international standards [10].

The Fig. 2 presents the basic laws and regulations of Ukraine that govern cryobank activities [53, 55—57, 61].

It has been determined that the Law of Ukraine No. 3496-IX of November 22, 2023 "On Amendments to Certain Laws of Ukraine Regarding Ensuring the Right of Military Personnel and Other Persons to Biological Paternity (Maternity)" enshrines legal guarantees for the preservation of biological material after a person's death for a period of three years, and also regulates the procedure for its further use in accordance with the intentions ex-

The Family Code of Ukraine (Article 123) determines the origin of the child in the case of the use of assisted reproductive technologies

The Civil Code of Ukraine (Articles 281, 294) establishes the right of a person to use his or her biological materials and provides general principles regarding medical interventions

The Law of Ukraine "Fundamentals of the Legislation of Ukraine on Healthcare" defines the general principles of providing medical care, in particular regarding reproductive health, voluntary consent, confidentiality and patient information

The Law of Ukraine "On Transplantation of Anatomical Materials to Humans" regulates the circulation of organs, tissues and cells, its provisions partially overlap with the activities of cryobanks

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Fig. 2. Laws of Ukraine regulating the activities of cryobanks

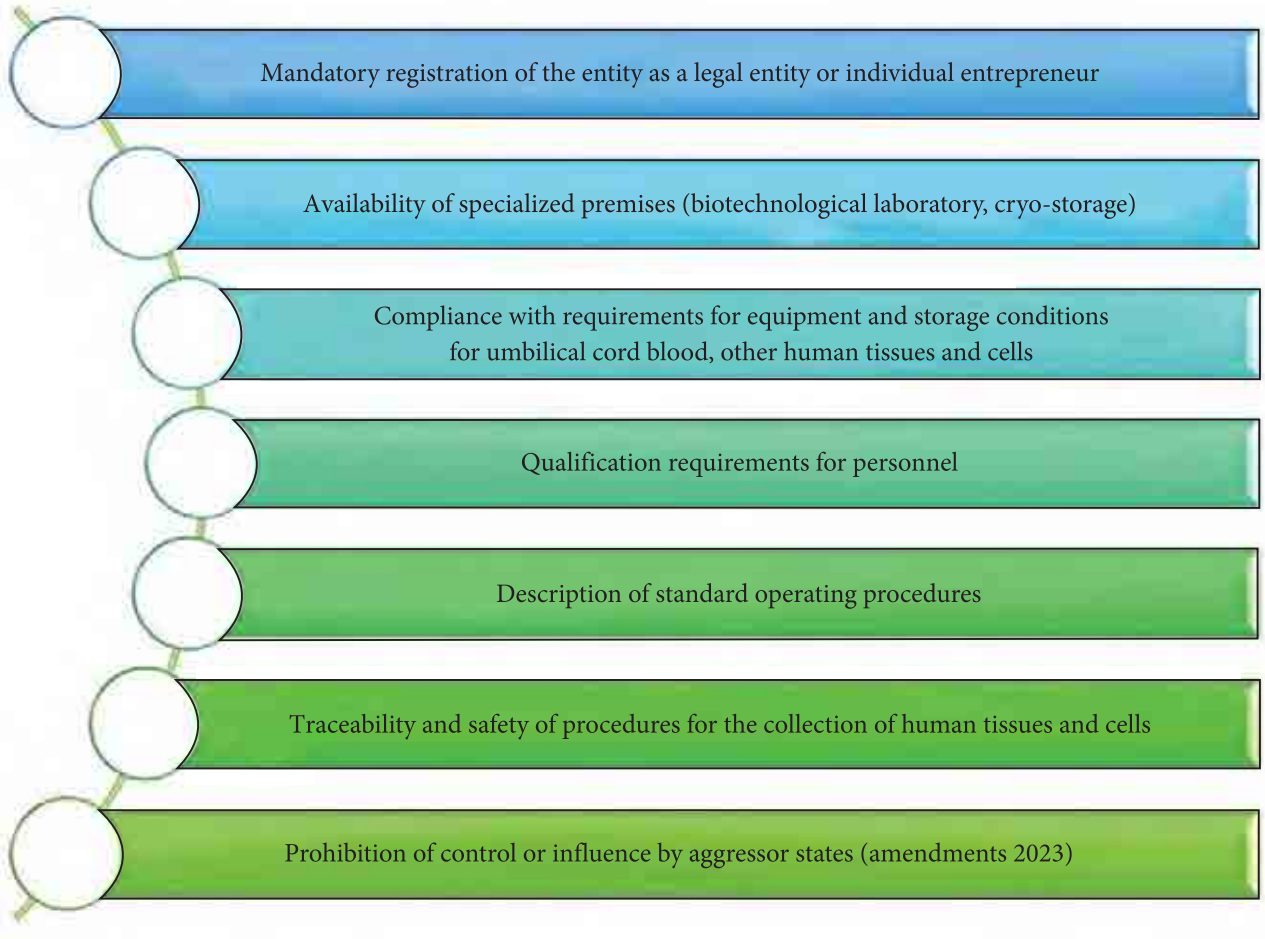

Fig. 3. Requirements of the Licensing Conditions for the economic activities of banks for umbilical cord blood, other human tissues and cells in accordance with the list approved by the Ministry of Health of Ukraine

pressed in the will, or according to the procedure, established by the Cabinet of Ministers of Ukraine [57]. This law is an example of the consolidation in Ukrainian legislation of the principle of priority rights of military personnel to preserve their reproductive material. In addition, the law demonstrates the humanistic orientation of modern medical law, which is based on the principles enshrined in Art. 4 of the Law of Ukraine "Fundamentals of the Legislation of Ukraine on Health Care" [56].

The principles of humanistic orientation of medical law include the following: priority of health care as a social value; observance of human rights in the medical field; accessibility and non-discriminatory nature of medical care; protection of vulnerable groups; orientation to modern standards and technologies; combining national experience with the best world practices; preventive orientation and intersectoral approach; decentralization of management and development of self-government; e-healthcare, barrier-free access and inclusion.

The activities of umbilical cord blood banks, and those dealing with other human tissues and cells are licensed in accordance with the Resolution of the Cabinet of Ministers of Ukraine dated March 2, 2016 No. 286 "On Approval of the Licensing Conditions for Conducting Economic Activities of Banks for Umbilical Cord Blood, Other Human Tissues and Cells in accordance with the List approved by the Ministry of Health" as amended by the Resolution of the Cabinet of Ministers of Ukraine No. 1245 dated November 24, 2023 (hereinafter referred to as — License Conditions) [10]. The Resolution defines the following requirements for the License Conditions, which are shown in Fig. 3.

In addition to licensing, a prerequisite is the certification of laboratories involved in technological process (testing, storage, *etc*.) in accordance with the current legislation.

Thus, Ukraine has established a regulatory framework for cryobank activities, which is being gradually adapted to modern challenges.

LEGAL STATUS OF BIOLOGICAL MATERIAL

The legal status of biological material is one of the most complex and debatable issues in medical law. Ukrainian legislation does not clearly define the ownership rights to biological material, however, certain provisions of the Civil Code of Ukraine (Article 294) provide for the right of individuals to dispose of their body or parts for medical, scientific or donation purposes during their lifetime.

Currently, the Verkhovna Rada of Ukraine is considering amendments to the current Civil Code and discussing the draft law "On the Application of Assisted Reproductive Technologies" (No. 13683 of August 22, 2025) regarding the legal status of human reproductive cells and embryos, postmortem reproduction, and the protection of rights for children born though the use of ART, particularly cryotechnologies.

In a practical sense, from the moment of collecting biological material (sperm, oocytes, stem cells) and storing it in a cryobank, a person acquires *de facto* control and the right to dispose of biological material: to store or terminate storage; to transfer it for use in donation programs, scientific or medical research; to determine its fate (in a will or a separate application after the donor's death).

In accordance with paragraph 3 of Section II of the Law of Ukraine No. 3496-IX, in the event of the death of a citizen or official recognition of his or her death, the storage of reproductive cells is carried out free of charge for three years, and thereafter at the expense of the person specified in the will or determined in another way in accordance with the current legislation [57]. This norm actually certifies the existence of hereditary rights to biological material, although the concept of "ownership" is not directly used in the norm.

LEGAL AND ETHICAL PRINCIPLES OF THE CIRCULATION OF BIOLOGICAL MATERIAL

The key legal and ethical principles of circulation of biological material are voluntariness and informed consent of persons for the collection and storage of biological material. According to the Procedure for ART application [35], it begins with the registration of patient's statement for the use of appropriate clinical protocols. In the case of donation of reproductive material, it is mandatory to sign an informed voluntary consent (Form No. 003-6/o), which includes both medical aspects (conducting examinations, determining the volume and storage period of biological material) and legal provisions (conditions for the use or disposal of biological material, as well as the donor's right to withdraw consent).

The provisions are consistent with international ethical standards, in particular the recommenda-

tions of the WHO, the provisions of the Oviedo Convention (1997) and the Helsinki Declaration of the World Medical Association "Ethical Principles of Medical Research with Human Participation as an Object of Study" (1964), which emphasize that any medical intervention is possible only with the voluntary and informed consent of the person [18, 25, 62, 63].

The right to medical and genetic secrecy is fundamental in health. In Ukraine, this right is guaranteed by Art. 40 of the Law of Ukraine "Fundamentals of Health Care Legislation", as well as Art. 7 of the Law of Ukraine "On Personal Data Protection" [56, 60]. Cryobanks, as entities working with personal data, are required to obtain written consent to the processing of personal data; provide appropriate technical and organizational protection measures; guarantee access to information only to authorized persons, as well as inform donors about the purpose and scope of processing their personal data.

Cryobanks must ensure the traceability of biological material at all stages of its circulation — from the moment of collection to disposal — with the ability to identify the donor (except in cases of anonymous donation). At the same time, ensuring the traceability of biological material should not violate the donor's rights to confidentiality [10].

In the case of storage of reproductive cells by military personnel in accordance with the Law of Ukraine No. 3496-IX [57], the Cabinet of Ministers of Ukraine is obliged to determine a separate procedure for the use of such biological material, taking into account the requirements of the legislation on the protection of personal data, which is of particular importance under martial law [11].

Thus, in Ukraine, the regulatory framework governing the circulation of biological material at the storage stage is based on the principles of inviolability of the body; freedom of expression; privacy; secure access to medical and genetic data.

These principles need further development in law enforcement practice, especially in view of the expansion of the functions of cryobanks and the increase in the volume of stored biological material.

The most developed area of use of cryopreserved biological material in Ukraine is ART. According to the Order of the Ministry of Health of Ukraine No. 787 of September 9, 2013, procedures for extraction of reproductive cells, insemination, cultivation, freezing and thawing of reproductive cells and embryos are integral components of *in vitro* fertilization programs. Various methods of sperm aspiration (TESA, PESA, MESA, TESE) and intracytoplasmic sperm injection (ICSI, IMSI) are considered as assistive technologies that are used in certain stages of ART in the presence of medical indications [35].

Cryopreserved cells can be used in the treatment of male and female infertility; in patients with cancer before the start of chemotherapy or radiation therapy; in delayed parenthood programs, as well as in donor programs.

The Law of Ukraine No. 3496-IX "On Amendments to Certain Laws of Ukraine on Ensuring the Right of Military Personnel and Other Persons to Biological Paternity (Motherhood)" provides for free storage of reproductive cells of military personnel for the period of martial law [57]. In the event of the death of a service member or recognition of him as dead, further storage of biological material can be carried out based on a will or at the expense of a designated person. This approach creates a precedent for the use of biological material of a deceased citizen, which requires further legal regulation in the context of family, inheritance, administrative and medical law.

In view of the above, we consider it appropriate to initiate a public discussion of the introduction of the institute of testament of reproductive material, as well as a discussion of the possible legal and social consequences of this decision. The use of cryopreserved preimplantation embryos in reproductive medicine is also indirectly regulated by the norms of the Family Code of Ukraine, in particular Article 123, which determines the legal status of a child whose conception took place with the help of ART, including the use of donor embryos [55].

Stem cells, particularly those obtained from umbilical cord blood, stored in specialized cryobanks, and are used mainly in transplantology. The Law of Ukraine determine the legal regulation of this activity "On Transplantation of Anatomical Materials to Humans", the legal basis for transplantation, storage and circulation of cells and tissues [61] and the Resolution of the Cabinet of Ministers of Ukraine No. 286 of 02.03.2016 are defined [10].

The legal basis of the relationship between the donor (or parents of the newborn) and the institution that owns the cryobank is a cell storage agreement, which specifies the conditions for storage, access, transfer of biological material for treatment or scientific research.

The transfer of cellular or tissue materials to entities associated with aggressor states is legally restricted, reflecting the priority of national security and control over the international circulation of medicines [10].

Cryopreserved biological material is also used in the research field to study the molecular mechanisms of the development of genetic diseases, to design new methods of cell and gene therapy, and to test pharmacological drugs. The use of biological material is regulated by the following documents:

The Law of Ukraine "On Scientific and Scientific-Technical Activities", which defines the general requirements for conducting research, compliance with ethical principles, expertise, *etc.* [58].

Legislation in the field of bioethics and personal data protection in the case of the use of identifiable cells [16].

The norms of the Procedure for applying ART, approved by the Order of the Ministry of Health of Ukraine No. 787 of September 9, 2013, determine that after the completion of the fertilization cycle, the patient has the right to decide on the further use of unused oocytes or embryos (for her own treatment, in other patients' programs or for storage). Data on the residue and use of biological material are entered into the relevant logs of accounting, storage and use of cryopreserved samples (paragraphs 3.12, 3.13) [35].

An important ethical criterion is the non-personalization of biological material used for scientific purposes, if the donor has not given direct consent to the identified use.

Thus, the use of cryopreserved materials covers a wide range of legal areas: from medical law and bioethics to civil, family and information law. Ukrainian legislation is harmonized with international standards, but several aspects (use of biological material after the death of a donor, commercial use of samples, protection of the rights of a child conceived by the ART method) remain insufficiently regulated.

One of the key legal issues in the activities of cryobanks is the uncertainty of the legal status of cryopreserved biological material after the death of a donor. Currently, neither the Civil Code of Ukraine nor special regulations contain a clear answer to the question of whether reproductive cells (spermatozoa, oocytes) and embryos can be considered an object of inheritance.

LEGAL CONFLICTS IN PRACTICE

In medical practice, situations may arise that require urgent resolution and are associated with complex legal situations:

the absence of a will or specific instructions from the donor;

a dispute between several applicants for access to biological material;

uncertainty of the legal status of a child born after the death of the donor.

To solve the above-mentioned legal dilemmas, it is necessary to amend the Civil and Family Codes of Ukraine.

Another unresolved legal problem is the liquidation or bankruptcy of the cryobank. In case of termination of the bank's activities, the biological material must be transferred to another institution that has the appropriate license [10]. At the same time, the procedure for such transfer, as well as the procedure for notifying donors, the distribution of responsibility for the preservation of biological material and financial settlements between the parties are not detailed by any regulatory act.

The lack of a clear procedure on these issues can lead to several negative consequences, namely:

loss of biological material;

violation of patients' rights;

impossibility of exercising the right to paternity/maternity;

litigation (administrative, *etc.*) between the bank, patients and the new owner;

initiation of criminal proceedings [54].

An additional problem is the lack of a unified State Register of Biological Material, as well as a clearly defined supervisory body that would ensure quality control and reliability of information and the safety of materials in case of transfer from one subject to another.

DIRECTIONS FOR IMPROVING NATIONAL LEGISLATION

Considering the current challenges, promising directions for improving the legislation on the activities of cryobanks have been identified (Fig. 4).

Considering the rapid development of reproductive technologies, medical biotechnology and the need to protect the rights of public health, in general, and of an individual citizen (in particular, in sensitive areas), improving the legislation on cryobanks should be one of the priorities of modern medical and legal policy in Ukraine. Further development of cryobanks,

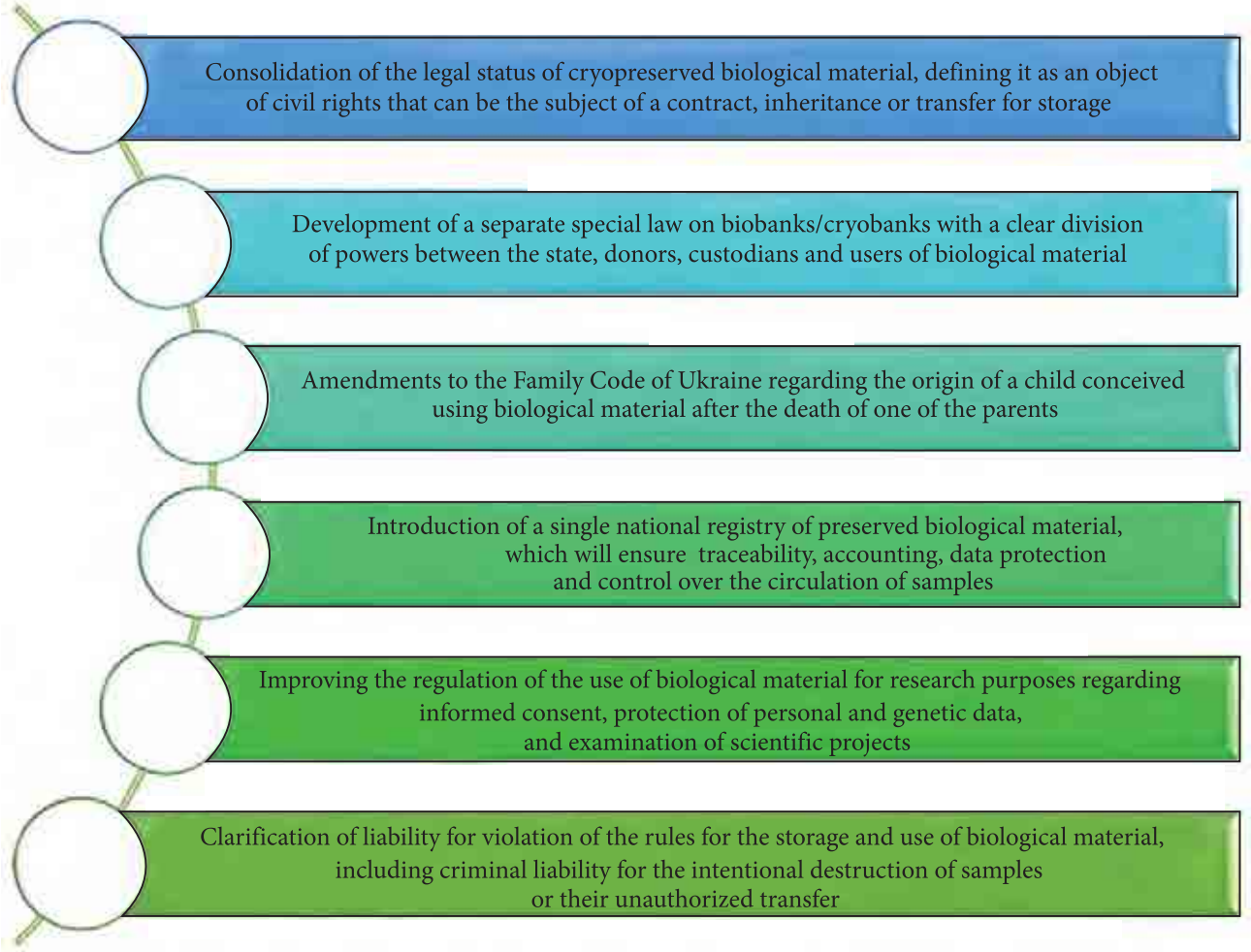

Fig. 4. Promising directions for the development of legislation and regulations on the activities of cryobanks

as a component of research in the field of cryobiology and cryomedicine, depends on modern cryobiological approaches and methods [27]. In addition, the implementation of the results obtained in modern conditions is important for medicine, pharmacy, veterinary medicine, agronomy and fisheries, food and microbiological industry, cosmetology. The results should be based on the principles of evidence-based medicine and evidence-based pharmacy, taking into account COVID-19, post-COVID and long-COVID disorders according to ICD-11 [49, 50].

Therefore, the following issues need to be addressed:

improvement of the legislative and regulatory framework for the receipt, storage, use and transfer of human reproductive cells and embryos, considering the already defined procedures of cryopreservation and accounting;

development of areas of cryobiology and medicine related to cryopreservation of human reproductive cells and embryos;

creation of a national bank of reproductive cells of citizens who belong to high-risk groups (military, police, medical workers, *etc.*) in Ukraine.

The solution of these issues lies in the creation of an interdisciplinary working group on the development of the draft law of Ukraine "On the Activities of Cryobanks" and the creation of a consortium. As noted by N. Sidorenko [52], a consortium in the modern sense is a form of partnership between scientific institutions, enterprises and other organizations that pool resources for the implementation of joint scientific, technical, or social projects. Such associations, such as The Psychiatry Consortium, *etc.*, demonstrate the effectiveness of intersectoral interaction in research [29]. After the abolition of the Commercial Code of Ukraine, the legal regulation of the activities of such associations is carried out on the basis of the Civil Code, special laws and constituent documents that determine the terms of cooperation, financing and distribution of the results of joint activities.

In our opinion, the regulatory framework governing cryobanks in Ukraine is currently fragmented. However, a holistic legislative and regulatory system is gradually being formed, covering the issues of circulation (receipt, quality control, efficiency, safety, storage, transportation, processing, use, management, disposal/destruction, economic availability, protection) of biological material [9—11, 18, 25, 35, 53, 55, 57, 60—62]. At the same time, several important regulatory and legal issues remain unregulated or have a contradictory legal formulation. This concerns the legal status of biological material as an object of civil rights, the procedure for its inheritance, its use after the donor's death, the liability of banks in case of liquidation, the legal status of children conceived using ART from the biological material of a deceased person.

An interesting example of international experience is the practice of the leading American cryobanks, specifically California Cryobank and Fairfax Cryobank, which establish strict criteria for the selection of sperm donors (about one percent of all candidates were selected). This approach is based on medical, genetic, and bioethical requirements aimed at guaranteeing the safety of recipients and the quality of biological material. Considering the increased requirements applied in certain fields of medicine and biotechnology in Ukrainian legislation could strengthen the system of control over donation and contribute to increasing confidence in the activities of cryobanks [32, 50].

Thus, the current stage of reforming the legal field in biomedical technologies opens up an opportunity for Ukraine not only to harmonize legislation with international approaches, but also to form its own model of ethical and legal regulation, taking into account national characteristics, social needs and scientific achievements. The successful implementation of these changes will depend on the dialogue between the scientific community, lawyers, medical professionals and the public, because only interdisciplinary interaction can ensure the sustainable development of cryobanks and increase the effectiveness of legal regulation in biomedicine.

CONCLUSION

The regulatory framework governing the activities of human cell and tissue cryobanks in Ukraine is at the stage of gradual approximation to international standards of medical law, bioethics, and protection of patients' rights, but remains fragmented and needs to be systematically improved. It is advisable to adopt a special law on biobanks; amendments to the Civil and Family Codes regarding the legal status of biological material; creation of a unified state register of biological samples; establishment of rules for the inheritance of biological material and rights to its use; determination of the legal status of children conceived using cryopreserved material of deceased persons; regulation of activities in the event of liquidation or bankruptcy of a cryobank; increasing transparency and control, as well as developing regulations for various types of biological objects; gametes, embryos, placental blood, stem cells and human tissues. Important areas of further adaptation should be the implementation of the ethical principles of the Helsinki Declaration of the World Medical Association; ensuring voluntary informed consent of donors, confidentiality, and transparency of the use of biological material. Comprehensive improvement of legislation should be based on the principles of humanism, reproductive freedom, and scientific integrity, which will contribute to the development of biomedical technologies and strengthen public confidence in the activities of cryobanks in Ukraine.

The study is a fragment of research works of the Private Scientific Institution "Research University of Medical and Pharmaceutical Law" and the State Enterprise "krainian Scientific Pharmacopoeia Center for the Quality of Medicines"on the topic "Interdisciplinary research of the quality system, standardization, validation, certification, safety and accessibility of circulation of medicines" (state registration No. 0125U001529, deadline 2025—2033); Private Scientific Institution "Research University of Medical and Pharmaceutical Law" and Danylo Halytsky Lviv National Medical University on the topic "Diagnosis, treatment, pharmacotherapy of inflammatory, traumatic and onco-thoracic pathologies using instrumental methods" (State registration No. 0125U000071, implementation period 2025—2031). Lviv Medical University on the topic "Improving the system of drug circulation during pharmacotherapy on the basis of evidence-based and forensic pharmacy, organization, technology, biopharmacy and pharmaceutical law" (State registration No. 0120U105348, implementation period 2021—2026); Private Scientific Institution "Research University of Medical and Pharmaceutical Law" and Volodymyr Dahl East Ukrainian National University on the topic "Interdis-

ciplinary Scientific and Methodological Research in the Field of Pharmaceuticals and Veterinary Medicine: Inn" (State Registration No. 0125U000598, implementation period 20252–031.); Private Scientific Institution "Research University of Medical and Pharmaceutical Law" on the topic "Multidisciplinary research of post-traumatic stress disorders during the war among patients (primarily combatants)" (State registration No. 0124U002540, deadline 2024—2028); Private Scientific Institution "Research University of Medical and Pharmaceutical Law" and European Wellness biomedical group on the topic "Multimodal innovative research of digital medical technologies through the use of approaches and methods of evidence-based medicine, quantum medicine, bioquantum medicine, bioquantum therapy, artificial intelligence, bioresonance, proton-plasma, frequency-wave, electron-pulse, bioregenerative, information mathematical methods diagnostics, therapy, evidence-based pharmacy, pharmacotherapy of health disorders according to ICD-11 (oncological, allergic, immunological, infectious, addictive, cardiological, comorbid, covid, post-COVID, long-covid, etc.) on the basis of medical and pharmaceutical law" (state registration No. 0125U002484, implementation period 2025—2033).

REFERENCES

1. Allen C. The Greatest Show on Earth: The US-China competition for technology leadership. Hinrich Foundation. [Internet]. 2025 Mar 25 [cited 2025 May 1]. Available from: https://www.hinrichfoundation.com/research/wp/trade-and-geopolitics/us-china-competition-for-technology-leadership/
2. Annaratone L, De Palma G, Bonizzi G, et al. Basic principles of biobanking: From biological samples to precision medicine for patients. Wirchows Archiv. 2021; 479: 233—46.
3. Anwar F. Two sessions 2025: China's tech revolution redefining the global future. Modern Diplomacy. [Internet]. 2025 Mar 21 [cited 2025 May 1]. Available from: https://moderndiplomacy.eu/2025/03/21/two-sessions-2025-chinas-tech-revolution-redefining-the-global-future/
4. Belous AM, Grischenko VI. [Cryobiology.] Kyiv: Naukova Dumka; 1994. 430 p. Russian.
5. Beskow A. Uppsala Biobank — the development of a biobank organization in a local, regional, and national setting. Uppsala J Med Sci. 2019; 124(1): 6—8.
6. Bischof J. Our research Institute for Engineering in Medicine (IEM), University of Minnesota. [Internet]. 2025 [cited 2025 May 1]. Available from: https://med.umn.edu/iem
7. Britannica Encyclopaedia. Cryogenics. [Internet]. [Cited 2025 Aug 10]. Available from: https://www.britannica.com/science/cryogenics
8. British Cryogenic Council Safety Committee. Cryogenics safety manual: A guide to good practice. British Cryogenic Council; 2018. 75 p.
9. Cabinet of Ministers of Ukraine. [Resolution No. 257 of March 25, 2020: On approval of the Procedure for obtaining and providing hematopoietic stem cells and exchanging information on available human anatomical materials intended for transplantation.] [Internet]. [Cited 2025 May 1]. Available from: https://zakon.rada.gov.ua/laws/show/257-2020-%D0%BF#Text Ukrainian.
10. Cabinet of Ministers of Ukraine. [Resolution No. 286 of September 2, 2016: On approval of the Licensing conditions for business activities of umbilical cord blood banks and other human tissues and cells.] [Internet]. [Cited 2025 May 1]. Available from: https://zakon.rada.gov.ua/laws/show/286-2016-%D0%BF Ukrainian.
11. Cabinet of Ministers of Ukraine. [Resolution No. 78 of January 24, 2025: On approval of the Procedure for collection, cryopreservation and storage of reproductive cells of servicemen and other persons in case of loss of reproductive function.] [Internet]. [Cited 2025 May 1]. Available from: https://zakon.rada.gov.ua/laws/show/78-2025-%D0%BF Ukrainian.
12. Caramia V, Ghirardini A, Di Ciaccio P, et al. From the EU legislation to the application of the single European code: Support to the implementation. Transfus Med Hemother. 2017; 44: 391—4.
13. Carreras E, Dufour C, Mohty M, et al. The EBMT Handbook: Hematopoietic stem cell transplantation and cellular therapies. 7th edition. Cham: Springer; 2019. 700 p.
14. Chernenko M, Nehreba T, Voloshyna N, et al. Modern pulse corticosteroid relevance of impact of non-drug methods on neuroplasticity in system of neurorehabilitation: multilevel neuroplastic effects of electromagnetic fields caused by transcranial magnetic stimulation. SSP Mod Pharm Med. [Internet]. 2025 Jul 21 [cited 2025 Aug 10]; 5(3): 45–62. Available from: https://ssp.sreif.us/index.php/mpm/article/view/7
15. China could win 'the next industrial revolution,' US congressional hearing told The Macao News. [Internet]. 2025 Feb 10 [cited 2025 May 1]. Available from: https://macaonews.org/news/greater-china/china-overtake-us-technology/
16. Committee of the Verkhovna Rada of Ukraine on National Health, Medical Care and Medical Insurance. [Internet]. [Cited 2025 May 1]. Available from: https://komzdrav.rada.gov.ua/ Ukrainian.

17. Council of Europe. Additional Protocol to the Convention of Human Rights and Biomedicine. Transplantation of organs and tissues of human origin. In: Council of Europe guide to safety and quality assurance for human organs, tissues and cells. 1st edition. Strasbourg: Council of Europe Publishing; 2002. p. 79—87.
18. Council of Europe. Convention on Human Rights and Biomedicine: Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Oviedo, 4.IV.1997). [Internet]. [Cited 2025 May 1]. Available from: https://rm.coe.int/168007cf98
19. Denysova K. [The Parliament allowed the storage and use of reproductive cells of deceased servicemen]. NV. [Internet]. 2024 Feb 7 [cited 2025 May 1]. Available from: https://nv.ua/ukr/ukraine/events/shtuchne-zaplidnennya-reproduktivni-klitini-viyskovih-ne-budut-utilizuvati-50390720.html Ukrainian.
20. Distler P, editor. United States consensus guidance for the uniform labelling of cellular therapy products using ISBT 128.Version 1.3.1. Tracking Number IG-003. San Bernardino, CA: ICCBBA. [Internet]. 2015 March. [Cited 2025 Aug 18]. Available from: https://www.isbt128.org/_files/ugd/83d6e1_db6451af6a764387a3c85d0c95957b47.pdf
21. European Commission, Health and Food Directorate–General, Directorate B — Health systems, medical products, and innovation B4. Medical products: quality, safety, innovation (2021) EU Coding Platform Compendia User Manual. REF. ARES (2021) 3506463-27/05/2021. 11 p.
22. European Commission. Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells. Official Journal of the European Union. 2006 Oct 25; (294): 32—50.
23. European Commission. Horizon Europe strategic plan 2025—2027 Publications Office of the European Union. [Internet]. 2024. [Cited 2025 May 1]. Available from: https://data.europa.eu/doi/10.2777/092911
24. European Directorate for the Quality of Medicines & Health Care. Press Release — EDQM releases new edition of the Tissue and Cells Guide, providing state-of-the-art guidance for healthcare professionals — December 2022 [Internet]. [Cited 2025 Aug 18]. Available from: https://www.edqm.eu/en/d/1227077
25. European Parliament, Council of the European Community. Directive 2004/23/EC of March 31, 2004 on Setting Standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. [Internet]. [Cited 2025 May 1]. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02004L0023-20090807
26. Food and Drug Administration, HHS. Current good tissue practice for human cell, tissue, and cellular and tissue-based product establishments; Inspection and enforcement. Final rule, 24 Nov 2004. Fed Regist. 69(226): 68611–88.
27. Grischenko V, Petrushko M, Gerodes A, et al. Pregnancy and labour after transplantation of frozen-thawed human embryos. Problems of Cryobiology. 2003; 13(3): 99—102.
28. Gryzodub O, Shapovalov V. Quality Systems in Pharmacy: Multidisciplinary Context of the State Pharmacopoeia of Ukraine. SSP Mod Law Pract. [Internet]. 2023 Mar 14 [cited 2025 Aug 10]; 3(1): 1—23. Available from: https://archive.sreif.us/index.php/mlp/article/view/81
29. International Consortium for Advanced Medicines Manufacturing. 4th Symposium of the International Consortium for Advanced Medicines Manufacturing: Celebrating Success and Advancing Adoption. (2023 Apr 27—28, Royal Sonesta, Cambridge, USA). [Internet]. [Cited 2025 Aug 10]. Available from: https://icamm.mit.edu/
30. Kikhtenko V. The law obliged cryobanks to dispose of frozen biomaterial of deceased servicemen (updated). [Internet]. 2024 Jan 26 [cited 2025 May 1]. Available from: https://www.village.com.ua/village/city/city-news/347207-zakon-zobov-yazav-kriobanki-utilizuvati-zamorozheniy-biomaterial-zagiblih-viyskovih Ukrainian.
31. Kröger N, Gribben J, Chabannon C, et al. The EBMT/EHA CAR-T cell handbook. Cham: Springer; 2020. 237 p.
32. Lewin T. 10 things to know about being a sperm donor. The New York Times. [Internet]. 2016 Nov 3 [Cited 2025 Aug 10]. Available from: https://www.nytimes.com/2016/11/08/health/sperm-donor-facts.html
33. Mazur S, Rogulska O, Revenko O, et al. Isolation of human third molar dental pulp stem cells and their characteristics before and after cryopreservation. Probl Cryobiol Cryomed. 2021; 31(1): 58—69.
34. Měřička P, Janoušek L, Benda A, et al. Cell viability assessment using fluorescence vital dyes and confocal microscopy in evaluating freezing and thawing protocols used in cryopreservation of allogeneic vascular grafts. Int J Mol Sci. [Internet]. 2021 Sep 30 [cited 2025 Aug 20]; 22(19): 10653. Available from: https://www.mdpi.com/1422-0067/22/19/10653
35. Ministry of Health of Ukraine. [Order No. 787 of September 9, 2013: On approval of the Procedure for the application of assisted reproductive technologies in Ukraine]. [Internet]. [Cited 2025 May 1]. Available from: https://zakon.rada.gov.ua/laws/show/z1697-13#Text Ukrainian.
36. Mutsenko V, Anastassopoulos E, Zaragotas D, et al. Monitoring of freezing patterns within 3D collagen-hydroxyapatite scaffolds using infrared thermography. Cryobiology. 2023; 111: 57—69.
37. Nevzghoda O, Osyntseva A, Shapovalova V, et al. Optimization of pharmacotherapy for chronic pancreatitis: use of ABC/VED analysis in marketing and pharmacoeconomic studies. Proc Shevchenko Sci Soc Med Sci. 2025; 77(1): 1—14.

38. Nevzghoda OA, Shapovalov VV, Shapovalova VO, et al. Optimisation of antibiotic selection: ABC and VED analysis of medicines against intracellular microorganisms. Tuberc Pulm Dis HIV-infect. [Internet]. 2025 Jul 29 [cited 2025 Aug 10]; (3): 68–79. Available from: http://tubvil.com.ua/article/view/336295
39. Petrenko OYu. [Current state and prospects for the development of cryobiology and cryomedicine: transcript of the report at the meeting of the Presidium of the National Academy of Sciences of Ukraine, December 14, 2022.] Visnyk of the National Academy of Sciences of Ukraine. 2023; (2): 75—8. Ukrainian.
40. Petrushko M, Piniaiev V, Yurchuk T. The history of cryotechnologies in reproductive medicine: From randomness to stability. Hist Sci Technol. 2024; 14(2): 401—18.
41. Petrushko M, Yurchuk T, Piniaiev V. Oolemma invagination degree during ICSI as a prognostic criterion for cryopreserved oocyte fertilization. Cryobiology. 2020; 97: 296.
42. Putman M. Revitalizing America's industrial might: harnessing AI to lead the next industrial revolution. Forbes. [Internet]. 2025 Jan 24 [cited 2025 May 1]. Available from: https://www.forbes.com/councils/forbestechcouncil/2025/01/24/revitalizing-americas-industrial-might-harnessing-ai-to-lead-the-next-industrial-revolution/
43. Rogulska OY, Trufanova NA, Petrenko YA, et al. Generation of bone grafts using cryopreserved mesenchymal stromal cells and macroporous collagen-nanohydroxyapatite cryogels. J Biomed Mater Res B Appl Biomater. 2022; 110(2): 489—99.
44. Shapovalov V, Osyntseva A, Shapovalov V. Organization of pharmaceutical business, drug technology, forensic and clinical pharmacy: multidisciplinary innovative nanotechnologies in the development and implementation of new medical products to medical and pharmaceutical practice. SSP Mod Pharm Med. [Internet]. 2022 Aug 31 [cited 2025 Aug 20]; 2(3): 1—18. Available from: https://archive.sreif.us/index.php/mpm/article/view/61
45. Shapovalov V, Shapovalova V, Titarenko I, et al. Quantum medicine and pharmacotherapy of chronic pancreatitis: analysis of drugs and international experience of microwave resonance therapy. Revista Colombiana de Ciencias Químico-Farmacéuticas. [Internet]. 2025 Jul 8 [cited 2025 Aug 20]; 54(2): 220—44. Available from: https://revistas.unal.edu.co/index.php/rccquifa/article/view/117235
46. Shapovalov V, Veits O. Forensic and pharmaceutical, criminal and legal, social and economic study of the conditions, that cause bribery corruption in the system of legal relations "doctor-patient-investigator-lawyer". SSP Mod Law Pract. [Internet]. 2022 Jul 22 [cited 2025 Aug 20]; 2(3): 1—16. Available from: https://archive.sreif.us/index.php/mlp/article/view/57
47. Shapovalov V. Medical errors in health care institutions: an interdisciplinary study of the competences of specialists based on medical and pharmaceutical law. SSP Mod Law Pract. [Internet]. 2023 Dec 14 [cited 2025 Aug 20]; 3(4): 1—14. Available from: https://archive.sreif.us/index.php/mlp/article/view/121
48. Shapovalov VO Jr, Zbrozhek SI, Shapovalova VO, et al. Organizational and Legal evaluation of availability of medicines' circulation for cancer patients. Pharmacia. 2018; 65(2): 17—22.
49. Shapovalova V. Forensic and pharmaceutical risks in the organization of pharmacotherapy of covid, post-covid and long-covid disorders. COVID-19 and vaccination practice standards. SSP Mod Pharm Med. [Internet]. 2022 Oct 19 [cited 2025 Aug 20]; 2(4): 1—24. Available from: https://archive.sreif.us/index.php/mpm/article/view/69
50. Shapovalova V. The ICD-11 for the twenty-first century: the first view from the organizational, legal, clinical and pharmacological aspects. SSP Mod Pharm Med. [Internet]. 2022 Jan 18 [cited 2025 Aug 20]; 2(1): 1—13. Available from: https://archive.sreif.us/index.php/mpm/article/view/37
51. Strong DM. The US Navy Tissue Bank: 50 years on the cutting edge. Cell Tissue Bank. 2000; 1: 1—19.
52. Sydorenko M. [Creating a Consortium: Is It Necessary to Apply to the Antimonopoly Committee?] Yurydychna Hazeta-online. [Internet]. 2023 Jan 20 [cited 2025 May 1]. Available from: https://yur-gazeta.com/publications/practice/inshe/stvorennya-konsorciumu-chi-potribno-zvertatisya-do-amku.html Ukrainian.
53. Verkhovna Rada of Ukraine. [Civil Code of Ukraine: Law No. 435-IV of January 16, 2003.] [Internet]. [Cited 2025 May 1]. Available from: https://zakon.rada.gov.ua/laws/show/435-15#Text Ukrainian.
54. Verkhovna Rada of Ukraine. [Criminal Code of Ukraine: Law No. 2341-III of April 5, 2001.] Vedomosti Verkhovnoi Rady Ukrainy. [Internet]. 2001; (25—26): 131. [Cited 2025 May 1]. Available from: https://zakon.rada.gov.ua/laws/show/2341-14#Text Ukrainian.
55. Verkhovna Rada of Ukraine. [Family Code of Ukraine: Law No. 2947-III of January 10, 2002.] [Internet]. [Cited 2025 May 1]. Available from: https://zakon.rada.gov.ua/laws/show/2947-14#Text Ukrainian.
56. Verkhovna Rada of Ukraine. [Fundamentals of Ukrainian Legislation on Health Care: Law No. 2801-XII of November 19, 1992.] Vedomosti Verkhovnoi Rady Ukrainy. [Internet]. 1993; (4): 19. [cited 2025 May 1]. Available from: https://zakon.rada.gov.ua/laws/show/2801-12#Text Ukrainian.
57. Verkhovna Rada of Ukraine. [On amendments to certain Laws of Ukraine to ensure the right of servicemen and other persons to biological parenthood (maternity): Law No. 3496-IX of November 22, 2023.] [Internet]. [Cited 2025 May 1]. Available from: https://zakon.rada.gov.ua/laws/show/3496-20 Ukrainian.
58. Verkhovna Rada of Ukraine. [On scientific and scientific-technical activity: Law No. 848-VIII of November 26, 2015]. [Internet]. [Cited 2025 May 1]. Available from: https://zakon.rada.gov.ua/laws/show/848-19#Text Ukrainian.

59. Verkhovna Rada of Ukraine. [On the Legal Regime of Martial Law: Law No. 389-VIII of June 24, 2015.] Vedomosti Verkhovnoi Rady Ukrainy. [Internet]. 2015; (28): 250. [Cited 2025 May 1]. Available from: https://zakon.rada.gov.ua/laws/show/389-19#Text Ukrainian.
60. Verkhovna Rada of Ukraine. [On the Protection of Personal Data: Law No. 2297-VI of June 1, 2010]. Vedomosti Verkhovnoi Rady Ukrainy. [Internet]. 2010; (34): 481. [Cited 2025 May 1]. Available from: https://zakon.rada.gov.ua/laws/show/2297-17#Text Ukrainian.
61. Verkhovna Rada of Ukraine. [On transplantation of human anatomical material: Law No. 2427-VIII of June 17, 2018.] Vedomosti Verkhovnoi Rady Ukrainy. [Internet]. 2018; (28): 232. [Cited 2025 May 1]. Available from: https://zakon.rada.gov.ua/laws/show/2427-19#Text Ukrainian.
62. World Health Organization. Quality Rights: Self-help tool for recovery-oriented mental health and well-being planning. [Internet]. 2019 Aug 2 [cited 2025 Aug 20]. Available from: https://www.who.int/ukraine/uk/publications/9789241516822
63. World Medical Association. Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects. JAMA. 2013; 310(20): 2191–4.

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ПРАВОВІ ТА БІОЕТИЧНІ ЗАСАДИ ДІЯЛЬНОСТІ КРІОБАНКІВ КЛІТИН І ТКАНИН ЛЮДИНИ В УКРАЇНІ: НОРМАТИВНЕ РЕГУЛЮВАННЯ, ВИКЛИКИ ТА ПЕРСПЕКТИВИ

У роботі розглянуто правові та біоетичні засади діяльності кріобанків клітин і тканин людини в Україні. Показано важливість адаптації національного законодавства до міжнародних норм у сфері біобанкінгу, трансплантології та допоміжних репродуктивних технологій. У дослідженні подано аналіз основ нормативно-правового регулювання діяльності кріобанків, визначено напрями вдосконалення законодавства України відповідно до європейських стандартів. Для аналізу автори керувались законами України, директивами Європейського Союзу, рекомендаціями Всесвітньої організації охорони здоров'я, документами Ради Європи, а також використовували наукові публікації у сфері медичного права, біоетики, кріобіології та репродуктивної медицини. Застосовано нормативно-правовий, документальний, порівняльний методи аналізу. Встановлено, що чинна нормативна база регулювання діяльності кріобанків є фрагментарною, не визначає правового статусу біологічного матеріалу, порядку його спадкування та використання після смерті донора. Запропоновано напрями вдосконалення правового поля: ухвалення спеціального закону про біобанки, створення єдиного державного реєстру біологічних зразків, адаптація протоколів і процедур до норм Європейського Союзу. Реалізація запропонованих заходів сприятиме прозорості, етичності та ефективності діяльності кріобанків, захисту прав донорів і пацієнтів, розвитку біомедичних досліджень в Україні.

***Ключові слова*:** медичне право, біоетика, кріобанки, гамети, ембріони, плацентарна кров, стовбурові клітини. тканини людини.