Biobank: problems of legal regulation

Біобанк: проблеми правового регулювання

Natalia Kvit

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Introduction. The development of medicine and the quality of healthcare directly depends on conducting relevant scientific, including biomedical research, which today can not be imagined without the existence of biobanks created for the purpose of collecting, storing and using human biological materials and related information. Biobanks are not only a source of scientific progress in the field of medicine, but also a central factor in the proper and effective functioning of the health care system, since their creation and use is associated with the development of new diagnostic and therapeutic methods and new medicines. Therefore, it is particularly important to formulate legal and regulatory guarantees for the protection of human rights, which will enable to secure both individual and collective trust of society in the activities in the field of creation and use of biobanks. The basic issue of obtaining citizens' trust is the provision of basic human rights, namely, the rights to honor, individuality and bodily integrity[1].

Unfortunately, both in Ukraine and other EU-countries, the legislator is still working to gain the trust of society in biobanks, unifying all necessary norms and terminology in a single special legal act (law).But at the same time, it is important to take into account the freedom of scientific activity and not to impose such strct requirements that can complicate the work of scientists in the field of biomedicine and lead to a crisis in the development of medicine in general. Due to the fact that relations regarding biobanks balance between the necessity of establishing guarantees of the protection of the rights of a natural person-donor and the freedom of research (scientific) activity, it is therefore necessary to ensure their balance with the help of the rules of special legislation.

1. Biobank evolution and definition

The history of the existence of biobanks in the modern sense is estimated at about 30 years. The first biobanks were repositories of randomly collected biological samples and information. Over time, the amount of data increased, they became significantly more complicated. The appearance of biobanks led to the emergence of new terminology, definitions, requirement sand obligations. Despite the fact that biobanks successfully operate in the EU countries and in many developed and developing countries of the world, including Ukraine, which has caused the necessity to create the appropriate legal and regulatory framework both at the international and national levels, there is no unified terminology in biobanking[2].

The most important is sue that needs to be considered and studied in detail is the definition of the biobank concept and its legal nature, as the central object of the selegal relations hips. Definition of the term "biobank" has a great, not only theoretical, but also practical value, since the clear criteria outlined in the unified definition will make it possible to determine the scope of legislative guarantees of the protection of basic human rights in the field of biomedical research and biomedicine. Instead, the lack of such a definition will undoubtedly create the preconditions for abuses and numerous violations in these socially sensitive relations.

[1] „Biobankgesetz – Augsburg – Münchner – Entwurf", zusammen mit Ulrich Gassner, Jens Kersten, Michael Lindemann, Henning Rosenau, Ulrich Schroth, Ferdinand Wollenschläger, Tübingen : Mohr Siebeck, 2015. – P. 2.

[2] Shaw D.M. What's a biobank? Differing definitions among biobank stakeholders / D.M. Shaw, B.S. Elger, F. Colledge // Clinical genetics. – 2014. – Vol. 85. – Iss.3. – P. 223-227, available at: http://onlinelibrary.wiley.com/dei/10.1111/cge.12268/full Accessed 10 Aug 2017.

Large international organizations, suchas Organisation for Economic Cooperation and Development (OECD), International Society for Biological and Environmental Repositories (ISBER), European Commition (EC) and Biobanking and Biomolecular Resources Research Infrastructure – European Research Infrastructure Consortium (BBMRI–ERIC) etc., developed their own definitions of "biobank".

OECD defines a biobank as a collection of biological material and the associated data and information stored in an organized system, for a population or a large subset of a population[3]. It also provides guidance for the establishment, governance, management, operation, access, use, and discontinuation of human biobanks and genetic research databases, which are structured resources that can be use for the purpose of genetic research, in Recommendation on Human Biobanks and Genetic Research Databases, which include: human biological materials and/or information generated from the analysis of the same; extends it with associated information[4]. Worth noting is also a definition, gave by the UK Biobank Ethics and Governance Council, which defines the biobank as "a large data base and biopsies specially collected for research needs"[5].

Both of the abovementioned definitions are directed at repositories that are used for scientific purposes and accordingly do not apply to biobanks used for diagnostic and/or the rapeutic needs. Also, it should be noted that the second definition, emphasizes the large amount of data and biological specimens, using the estimated term "significant", which, in our opinion, may cause a problem with the outline of the range of subjects whose activities will be subject to special legislation.

International Society for ISBER defines biobank as an entity that receives, stores, processes, and/or disseminates specimen as needed. It encompasses the physical location as well as the full range of activities associated with its operation[6].

The evolution of the biobank definition made by EC must also be taken into consideration. In 2010 EC defined biobanks as organized collections consisting of biological samples and associated data of great significance for research and personalized medicine defined[7].Two years later in Report of an expert group on Dealing with Ethical and Regulatory Challenges of International Biobank Research: Biobanks for Europe, A challenge for governance more comprehensive definition was made. It was supposed, that biobanks typically: collect and store biological materials that are annotated not only with medical, but often also epidemiological data; are not static "projects," since biological materials and data are usually collected on a continuous or long-term basis; are associated with current and/or future research projects at the time of specimen collection; apply coding or anonymization to assure donor privacy but have, under specific conditions, provisions that participant remain re-identifiable in order to provide clinically relevant information back to the donor; include established governance structures and procedures (e.g., consent) that serve to protect donors' rights and stakeholder interests[8].

And finally, the BBMRI–ERIC, defines biobanks as follows: biobanks contain biological samples and associated information that are essential raw materials for the advancement of biotechnology, human health, and research and development in life science[9]. It seems to be the most general and overall definition, which can cover all possible relations in this sphere.

One more general definition covering both of the abovementioned areas of use was given in 2010 by the German Ethic Council (Deutscher Ethikrat). In particular, it identified biobanks as "a collection of samples of

[3] OECD Creation and Governance of Human Genetic Research Databases, OECD. Paris. Glossary of Statistical Terms. 2006, available at:http://stats.oecd.org/glossary/detail.asp?ID=7220Accessed 10 Aug 2017.

[4] OECD Guidelines on Human Biobanks and Genetic Research Databases, available at:www.oecd.org/sti/biotech/44054609.pdf Accessed 10 Aug 2017.

[5] UK Biobank Ethics and Governance Framework, available at: www.ukbiobank,ac.uk/wp-content/uploads/2011/05/EGF20082.pdf Accessed 10 Aug 2017.

[6] 2012 best practices for repositories collection, storage, retrieval, and distribution of biological materials for research international society for biological and environmental repositories // Biopreservation and Biobanking. – 2012. – Vol.10. – Iss.2: - P. 79–161, available at :https://www.ncbi.nlm.nih.gov/pubmed/24844904 Accessed 10 Aug 2017.

[7] Zika E., Paci D., Bäumen S. et al. Biobanks in Europe: prospects for harmonisation and networking / E. Zika, D. Paci, S. Bäumen // JRC Scientific and Technical Reports. – L. : Publications Office of the European Union. – 2010. – P. 10, available at : http://ftp.jrc.es/EURdoc/JRC57831.pdf Accessed 10 Aug 2017.

[8] Report of the Expert Group on Dealing with Ethical and Regulatory : Challenges of International Biobank Research Biobanks for Europe, A challenge for governance 2012, available at : http://www.coe.int/t/dg3/healthbioethic/Activities/10_Biobanks/biobanks_for_Europe.pdf Accessed 10 Aug 2017.

[9] Kinkorová J. Biobanks in the era of personalized medicine: objectives, challenges, and innovation : Overview / J. Kinkorová // The EPMA Journal. – 2015. – Vol. 7. – P. 4, available at : https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4762166/ Accessed 10 Aug 2017.

substances of the human body (tissues, blood, urine, saliva, etc.) that are associated with personal data and socio-demographic information of the donor person"[10]. But the German Biobanks Draft Law, in particular § 3 Nr. 2 AME – Biobank G, provides the following definition of biobank – a collection or functional combination of samples and encoded or uncoded data collected for the purpose of research, regardless of the organizational form of the holder (manager) (public or private institutions)"[11].So, as we see, the definition given by the German Ethics Council is wider, when the draft law narrows it by establishing as one of the characteristic features purpose of the study. Consequently, biobanks created for another purpose (for example, storage of biomaterials or therapeutic purposes) will be excluded from the scope of this law if it becomes legally valid in this wording, which in our opinion narrows the range of relations, governed by this law and can create problems in practice of protecting the rights of the subjects of these relations.

Consequently, the widest legislative definition of the biobank is, in our opinion, the definition given by BBMRI–ERIC, which is the best in order of protecting donor rights, since it covers a wide range of subjects and relation ships with their participation. Al though the definitions contained in different legal systems differ in detail, but most of them essentially establish that biobanks are human biological samples to rages with their accompanying information.

The research of modern tendencies in the definition of biobank was conducted by a scientist from the Swiss Institute of Biomedical Ethics D.M. Shaw, on the basis of the analysis of data definitions of the 36 biobanking stakeholders with international experience currently working in Switzerland. The author emphasizes, that while there is widespread agreement on the broad aspects of what constitutes a biobank, there is much disagreement regarding the precise definition. The results showed that, in addition to the core concepts of biological samples and linked data, the planned use of samples (including sharing) is held to be a key criterion. It also emerges that some researchers avoid the term in order to circumvent certain regulatory guidelines, including informed consent requirements. Developments in the field of biobanking will be complicated if researchers are unaware, or deny that their collection is a biobank. A clear definition of the term is therefore an important step towards fostering collaboration amongst researchers, enabling them to more easily identify potential sources of samples[12]. The authors of another publication believe that biobank is a structure consisting of two parts: 1) biological material that is collected, processed and stored for a long time; 2) a database with demographic and clinical data for each sample that provides sampling, processing, storage, inventory and distribution of biological material[13]. Greek researchers give a fairly broad interpretation of the biobank as a repository that collects, stores and uses samples of human origin and data associated with them[14].

It is also worth stressing the need to differentiate between the different concepts, used in the biobanking, for example: "biological collection" and "biobank". In particular, a biological collection means a systematic repository of biological material derived from different biological species, whereas biobanks are collections of human biological material[15]. However, in the literature, these terms are often used as synonyms[16].Concerning the delineation of related concepts and the definition of the concept of biobank, B. Parodi believes that the terms "biorepository", "Biological resource centre" (BRC) and "biobank" all refer to structured collections of biological samples and associated data, stored for the purposes of present and future research. Both biorepositories

[10] Deutscher Ethikrat, Humanbiobanken für die Forschung, Stellungnahme. – 2010 Available at : http://www.ethikrat.org/dateien/pdf/stellungnahme-humanbiobanken-fuer-die-forschung.pdf Accessed 10 Aug 2017.

[11] „Biobankgesetz – Augsburg – Münchner – Entwurf", zusammen mit Ulrich Gassner, Jens Kersten, Michael Lindemann, Henning Rosenau, Ulrich Schroth, Ferdinand Wollenschläger, Tübingen : Mohr Siebeck, 2015. – P. 3.

[12] Shaw D. What's a biobank? Differing definitions among biobank stakeholders / D. Shaw, B. Elger, F. Colledge // Clinical genetics. – March 2014. – Vol. 85. – Iss. 3. – P. 223–227, available at : http://onlinelibrary.wiley.com/dei/10.1111/cge.12268/full Accessed 10 Aug 2017.

[13] Artene S.-A., Ciurea M., Purcaru S. et al. Biobankingin a constantly developing medical world / S.-A. Artene, M. Ciurea, S. Purcaru // Sci. World J. – 2013. – Vol. 343275, available at : https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3794514/ Accessed 10 Aug 2017.

[14] Arampatzis A., Papagiouvanni I., Anestakis D. et al. A Classification and Comparative Study of European Biobanks : an Analysis of Biobanking Activity and its Contribution to Scientific Progress / A. Arampatzis, I. Papagiouvanni, D. Anestakis // Arch Med. – 2016. – Vol. 8. – P. 3, available at : http://www.archivesofmedicine.com/medicine/a-classification-and-comparative-study-of-european-biobanks-an-analysis-of-biobanking-activity-andits-contribution-to-scientific-p.php?aid=9575 Accessed 10 Aug 2017.

[15] Kamenski P., Sazonov A., Fedyanin A. et al. Biological Collections : Chasing the Ideal / P. Kamenski, A. Sazonov, A. Fedyanin //Acta Naturae. – 2016. – Vol. 8. – Iss. 2. – P. 6–9, available at : https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4947984/ Accessed 10 Aug 2017.

[16] Bragina Y., Buikin S., Puzyryov V. Databases of biological collection : organization of associated information / S. Bragina, Y. Buikin, V. Puzyryov // Med. Genetika. – 2009. –Vol. 3. – P. 20–27. (Брагина Е., Буйкин С., Пузырев В. Биологические банки : проблемы и перспективы их использования в исследованиях генетических аспектов комплексных заболеваний человека / Е. Брагина, С. Буйкин, В. Пузырев //Мед. генетика. – 2009. – №. 3. – 20–27.)

(ISBER 2001) and BRC's (OECD 2007) can include tissues from human, animals, cell and bacterial cultures, and even environmental samples, while a biobank typically handles human biospecimens – such as tissue, blood, urine – and information pertaining to the donors: demography and lifestyle, history of present illness, treatment and clinical outcomes[17].

Consequently, the analysis of foreign literature shows that the concept of "biobank" is interpreted by different authors in different ways, but it is always supposed to contain three main components: 1) human biological material; 2) the information relating to it and the accompanying data; 3) ethical and legal issues, with regard to the consent of donors, the security of personal data and their protection[18].

The developers of the Augsburg-Munich Biobanks Draft Act (2015) extend the action of this law on biobanks at clinics, primarily by university clinics, research institutes in the pharmaceutical industry and biotech enterprises and support this position making no differentiation in the size of the research-collection. There fore the action of the abovementioned law will also spread to the relations with the participation of one or more researchers who collected a small amount of biological materials and data for the purpose of their study. However, developers point out that in practice (primarily in Germany, which can't be said about Ukraine), the study of a small amount of data collected by the researcher (for example, in the course of writing a dissertation study) is very rare, since researchers are increasingly borrowing the materials for their research from big biobanks, and therefore the developers consider that making an exception for such cases is inappropriate taking into consideration the fact that this may create preconditions for circumventing the rules of this law. Also, their point of view against the narrow interpretation of the concept of biobank, the draft law developers are substantiating by the following arguments: the scope of regulation can't be limited to the size of biobank, since this indicator can change rapidly and, based on a small collection of samples and data, a large biobank can quickly develop; the requirements to ensure the protection of the rights of the individual donor must be identical for both small collections of samples and data, and for large biobanks; such subjective features as the planned duration of use of biobank as a demarcation criterion is limited (partially) permissible.

Instead, the German Ethics Council proposes to exclude from the scope of the regulation of a special law research projects that are limited by the achievement of a specific goal or time frame and do not provide for the forward transfer of samples and data to third parties. Because they believe that these cases will be subject to general rules on the protection of personal data and to guarantee the protection of donor rights when sampling. They will also be subject to using rules of medical secrecy, and in the case if the subject is not a health care worker (such as biologists) the possibility of establishing such a duty on a contractual basis.

In our opinion, the extensive, but not limited, approach to the scope of the special law is fully justified in the light of Ukrainian realities. And since Ukraine currently does not have such wide opportunities for individual researchers, unfortunately, there is no such rich database of biological data and a large number of biobanks with free access to samples as in the European Union, and therefore some researchers with their "own" database of biological materials and data are usually a rule and not an exception of it, that is why the legal regulation of such researcher's activities is more than necessary, also taking into consideration, that our scientists have recently faced the problem of inconsistency of their research to the world recognized ethical requirements, which entails problems with promulgation of the results of their researches. There fore, the current rules governing the ethical review of biomedical research in Ukraine should be brought into line with international standards and should be integrated into a new special law that will regulate the human research conducting as well as establishment and using of biobanks.

2. Current Ukrainian biobank regulation and definition problems

Despite the fact that our lawmaker does not pay enough attention to the issue of the legal regulation of relations with the participation of biobanks, there are already the first attempts to define the concept of biobank in Ukrainian science. In particular, it is proposed to consider biobank as a kind of biorepository, in which organized collections of biological samples are received from a person, and also the associated information for

[17] Parodi B. Biobanks : a definition / B. Parodi // Ethics, Law and Governance of Biobanking : National, European and Intenational Approaches/ Maascalzoni D. (Ed.), 2015. – V III. – P. 15.

[18] Budimir D., Polašek O., Marušić A. et al. Ethical aspects of human biobanks : a systematic review / D. Budimir, O. Polašek, A. Marušić // Croatian Medical Journal. – 2011. –Vol. 52. – Iss. 3. – P. 262–279, available at : https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3118708/ Accessed 10 Aug 2017.

research purposes is preserved[19]. The existence of an attempt in Ukrainian science to define the biobank is a very positive phenomenon, but it is not devoid of certain disadvantages. In particular, defining the purposes and limits of the use of samples and information stored in biobank is highly inefficient in the current Ukrainian biobanking, since all currently in Ukraine existing biobanks are mostly private umbilical cord blood banks, which act only to gain profit sand do not pursue any research goals.

Speaking about the legal regulation of the creation and use of umbilical cord blood banks, the situation in Ukraine has recently got worse. Due to the fact that the new, approved by the Resolution of the Cabinet of Ministers of Ukraine (CMU) on 02.03.2016 № 286 "Licensing conditions for the activities of banks of umbilical cord blood, other human tissues and cells in accordance with the list approved by the Ministry of Health"[20] not only excluded the conditions for the minimum area which is necessary to ensure the availability of specialized premises, but also gave the possibility of transfer of laboratory research to third parties. This led to doubling the number of such "banks" in a few months, and, secondly, allowed to engage in this type of activity business entities who are not even specialists in this field, and thus created the basis for abuse.

Moreover, the ad option of this legal act has led to duplication of the current norms. Namely, the abovementioned CMU Resolution № 286 regulates the same is sues as the old not yet repealed Order of the Ministry of Health (MOH) on 10.04.2012 № 251 "On approval of licensing conditions for the conduct of economic activity of umbilical cord blood, other human tissues and cells banking"[21]. This conflict may have been caused by the adoption of the Law of Ukraine "On Licensing Types of Economic Activities"[22], according to which (Art. 9, p. 2) the Cabinet of Ministers of Ukraine should approve the license conditions. In order to comply with this provision, licensing conditions were adopted by the CMU resolution, but the old MOH order was not abolished. In June 2016, a working group was set up in the ministry to bring the ruling in line with European directives. So, the question a rises why the resolution was not immediately brought into line with Europe an directives at the development stage of the project, taking into consideration that any draft resolution of the CMU should be subject to compulsory work on compliance with Ukraine's commitments in the field of Europe an integration[23].

It is necessary to compare the definition of the concept of a bank of umbilical cord blood, other human tissues and cells (as we see the Ukrainian legislator a voids the term "biobank") in the licensed terms of the "old edition" of April 10, 2012, № 251 and "new edition". Consequently, earlier this concept was understood as a separate establishment of a business entity or a structural subdivision of a healthcare institution that independently carries out processing, marking (coding), cryopreservation, testing (checking), storage of umbilical cord blood, other human tissues and cells and products and / or preparations derived there from. Now it is a ***business entity or a structural subdivision of an entity*** that has received an appropriate license and independently ***or with the help of third parties*** conducts business processing, marking (coding), cryopreservation, testing (checking), preservation, p***roviding (realization) and / or clinical application*** of products and / or preparations of cord blood, other human tissues and cells.

Firstly, now it can even bean individual entrepreneur, since there is no longer an attachment to a health care institution that seems completely in compatible with the nature and content of such activities. Secondly, the new norm has allowed the involvement of third parties, in particular concerning the conduct of laboratory research, which may complicate in the future the resolution of liability issues. Also, the legislator was not consistent in resolving this issue, as the new conditions also contain in clause 8 of the requirement that the activities of umbilical cord blood banks are carried out in the presence of premises that ensure the flow of technological processes of the bank, in particular biotechnological laboratories. Therefore, the question arises if the subject,

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[19] Voronina I. Legal backgrounds for founding and functioning biobanks (biorepositories) in Ukraine / I. Voronina // Law and innovative society. – 2014. – Vol. 2. – Iss. 3. – P. 60, pp.59–66 (Вороніна І. Правові засади створення та функціонування біологічних банків (біорепозитаріїв) в Україні / І. Вороніна // Право та інноваційне суспільство. – 2014. – № 2 (3). – P. 60, pp. 59–66), available at: http://apir.org.ua/wp-content/uploads/2014/12/Voronina_I.pdf Accessed 10 Aug 2017.

[20] Resolution of the Cabinet of Ministers of Ukraine (CMU) on 02.03.2016 № 286 "Licensing conditions for the activities of banks of umbilical cord blood, other human tissues and cells in accordance with the list approved by the Ministry of Health", available at : http://zakon2.rada.gov.ua/laws/show/286-2016-%D0%BF/print1497266996621351 Accessed 10 Aug 2017.

[21] Order of the Ministry of Health (MOH) on 10.04.2012 № 251 "On approval of licensing conditions for the conduct of economic activity of umbilical cord blood, other human tissues and cells banking", available at : http://zakon3.rada.gov.ua/laws/show/z0660-12/print1498719116647766 Accessed 10 Aug 2017.

[22] Law of Ukraine on 02.03.2015 № 222 "On Licensing Types of Economic Activities", available at : http://zakon3.rada.gov.ua/laws/show/222-19/print1498719116647766 Accessed 10 Aug 2017.

[23] See Iss. 1 § 35 CMU Regulation 18.07.07. № 950, available at : http://zakon2.rada.gov.ua/laws/show/950-2007-%D0%BF/print1497266996621351 Accessed 10 Aug 2017.

in accordance with the terms of the license, must have his own laboratory, why consolidate the possibility of transfer of samples to third parties? And thirdly, the legislator additionally included to content of the biobank activity the provision (implementation) and / or clinical application of products and/or preparations of the umbilical cord blood, other human tissues and cells, which obviously means their transfer free of charge or sale to third parties. As for the transfer on a royalty-free basis, such innovation is generally positive, since it gives private biobanks the opportunity to share their data and samples, for example, with scholars or other actors who pursue a non-commercial purpose or aim at achieving the so-called social effect. However, in order for this norm to work properly, it should be supplemented, in particular, with the purpose for which samples are transmitted and the conditions for such a transfer, in particular, obtaining permission from the donor and means of control over their observance and liability in case of their violation, should be fixed in special legislation. At the same time it's important to emphasize, that the sale of biological materials clearly goes beyond the principle of prohibiting the commercialization of the human body and its parts, and therefore it is inadmissible from the point of view of protecting basic human rights.

Thus, at a time when legislators from developed countries are discussing the need for more stringent rules and monitoring the process of creating and using biobanks, Ukrainian ones are actively working to streamline the licensing process. Therefore, the question arises: Are we moving in the right direction, or still there is a need to revise the strategy for the development of legal regulation of the creation and use of biobanks in Ukraine.

Another important issue, which has a direct connection with the definition of the concept of biobank is its legal nature. The experience of European countries, shows that the biobank has a dual legal nature. Namely, the German National Ethics Council has emphasized that the biobank is not only a collection of human biological materials but also related personal data and information about donor. Consequently, this is a complex object, which contains biological (anatomical) materials as material objects and information as an immaterial object.

Based on the definition contained in the abovementioned Licensing Terms, the Ukrainian legislator understands the legal nature of the biobank as the subject of legal relationships. While the foreign legislation, interprets the concept of biobank as an object, namely as a collection of human biological materials and related information (personal data). Instead, the manager (holder) of the biobank acts as the subject of the legal relationship, who carries out activities related to verification, collection, storage, processing and transfer to the third parties (users) of the object of these legal relations, namely samples of biomaterials and/or information. Therefore, we can conclude that the approach of the Ukrainian legislator to determining the legal nature of the biobank is incorrect and the definition contained in the License Terms must be changed in the light of this provision. Consequently, the activity of a biobank is not subject to licensing, but the activity of the manager of a biobank. Accordingly, it is also necessary to make changes to the title of the Act, namely, to formulate it as follows: "Licensing conditions for the management of banks for umbilical cord blood, other human tissues and cells (biobanks), in accordance with the list approved by the Ministry of Health", and generally revise the concept of this Legal Actingeneral.

Consequently, we apply the following definition to change the current one: ***Bank of umbilical cord blood, other tissues and human cells (biobank)*** is a collection of human biological materials and associated in formation (object), which can be collected, store dand managed by the business entity or a structural subdivision of an entity that received a corresponding license and independently conducts economic activity for processing, marking (coding), cryopreservation, testing (inspection), storage, provision (realization) and/or clinical use of the product sand/or preparations cord blood and other human tissues and cells for diagnostic, therapeutic, scientific purposes on the basis of free and informed consent of the donor or another authorized person or on the basis of a civil contract with such persons.

There fore, a unified definition of a biobank, which will cover both commercial and non-commercial areas, with a focus on its dual legal nature, should be contained in a special law and determine the scope of its application. Such an approach will be in line with international standards and requirements for the development and use of biobanks, and will be another step towards harmonization of Ukrainian legislation with the European Community law and global trends in the development of legislation in this area.

Summary

In this work the author emphasized the main problem of biobank regulation is the balance between then ecessity of establishing guar an tees of the protection of the rights of a donor and the freedom of scientific activity. There fore she supposed the necessity to ensure this balance in the rules of special legislation. The analyze of "biobank" concept definition led to a conclusion, that it is usually supposed to contain three main components: 1) human biologic al material; 2) the information relating to it and the accompanying data; 3) ethical and legal issues, with regard to the consent of donors, the security of personal data and their protection. The author supposed, that the extensive, but not limited, approach to the scope of the special biobank law is fully just ifiedin the light of Ukrainian realities. The legislative definition in EU-countries supports the dual legal nature of the biobank as on object of relations. The approach of the Ukrainian legislator to determining the legal nature of the biobank as subject is supposed to be incorrect, as the activity of a biobank is not subject to licensing, but the activity of the manager of a biobank there fore the definition contained in the License Terms, as well as the Title of the Act must be changed. The author suggest a new definition, where biobank is defined as an object, which has a dual legal nature, emphasizing the ethical component and the need for free informed consent of the donor or the other authorized person.

Анотація

У цій роботі автор підкреслив, що головною проблемою регулювання біобанку є баланс між необхідністю встановлення гарантій захисту прав донора та свободи наукової діяльності. Аналіз визначення поняття «біобанк» дозволив дійти висновку, що він, зазвичай, містить три основні компоненти: 1) біологічний матеріал людини; 2) супровідну інформацію; 3) етичні та правові питання щодо згоди донорів, гарантування безпеки персональних даних і їх захисту. Автор вважає, що саме широкий підхід до сфери застосування спеціального закону про біобанк цілком виправданий, зважаючи на українські реалії. Законодавче визначення біобанку в країнах Європейського Союзу акцентує увагу на його подвійній правовій природі як об'єкта відносин. Підхід українського законодавця до визначення правової природи біобанку як суб'єкта є хибним, оскільки не діяльність біобанку підлягає ліцензуванню, а діяльність керівника біобанку. Тому визначення, що міститься в чинних ліцензійних умовах, а також їхня назва, необхідно змінити. Автор дає власне визначення, в якому біобанком називає об'єкт, який має подвійну правову природу з акцентом на етичному складнику та необхідності вільної інформованої згоди донора чи іншої уповноваженої особи.

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Natalia Kvit,
Ass. Prof., Doctor of Law,
Docent on Department for civil law and procedure
at Iwan Franko Lviv National University[24]

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